International Trade Centre
UNCTAD/WTO

INDIA

SUPPORT TO SUSTAINABLE EXPORT DEVELOPMENT OF INDIAN NATURAL MEDICINAL PRODUCTS: A NEEDS ASSESSMENT STUDY

August 2008

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ADMA	Ayurvedic Drug Manufacturers Association
AMAM	Association of Manufacturers of Ayurvedic Medicines
APEDA	Agricultural & Processed Food Products Export Development Authority
API	Ayurvedic Pharmacopoeia of India
ASSOCHAM	The Associated Chambers of Commerce and Industry of India
AYUSH	Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy, Ministry of Health and Family Welfare, Government of India
CCRAS	Central Council for Research in Ayurveda & Siddha
CCRUM	Central Council for Research in Unani
CCRYN	Central Council for Research in Yoga & Naturopathy
CERPA	Centre for Research, Planning and Action
CHAMF	Central Herbal Agro Marketing Federation
CHEMEXCIL	Basic Chemicals, Pharmaceuticals & Cosmetics Export Promotion Council
CIMAP	Central Institute of Medicinal and Aromatic Plants
CITES	Convention on International Trade of Endangered Species of Wild Flora and Fauna
CSIR	Council of Scientific & Industrial Research
DGFT	Directorate General of Foreign Trade
EPRP	Export-Led Poverty Reduction Programme
EXIM Bank	Export-Import Bank of India
FIHI	Federation of Indian Herbal Industry
FRLHT	Foundation for the Revitalisation of Local Health Traditions
GACP	Good Agricultural and Collection Practice
GMP	Good Manufacturing Practice
HADSA	Health Foods and Dietary Supplements Association of India
HEPAI	Herbs and Herbal Export Promotion Association of India
IDMA	Indian Drug Manufacturers Association
ISO	Indian Standards Organisation
ITC (HS)	Indian Trade Classification Harmonized System
ITC	International Trade Centre / UNCTAD / WTO
ITPO	Indian Trade Promotion Organisation
Kg	Kilogram
MAI	Market Access Initiative Scheme
MAP	Medicinal and Aromatic Plants

MAPSCON	Medicinal, Aromatic & Dye Plants Stakeholders' Consortium
MT	Metric Tons
NMPB	National Medicinal Plants Board
NTFP	Non-Timber Forest Produce
NWFP	Non-Wood Forest Products
PHARMEXCIL	Pharmaceuticals Export Promotion Council
PLIM	Pharmacopoeial Laboratory for Indian Medicine
SHEFEXCIL	Shellac and Forest Products Export Promotion Council
SME	Small and Medium Enterprise
SPI	Siddha Pharmacopoeia of India
TKDL	Traditional Knowledge Digital Library
TRIPS	Trade Related Intellectual Property Rights
TRTA	Trade Related Technical Assistance
UNCTAD	United Nations Conference on Trade and Development
UNIDO	United Nations Industrial Development Organisation
UNDP	United Nations Development Programme
UPI	Unani Pharmacopoeia of India
WHO	World Health Organisation
WTO	World Trade Organisation

CHAPTER 1 – INTRODUCTION

A. Background

In December of 2006, the Permanent Representative / Ambassador of India to the United Nations Offices in Geneva, Shri Swashpawan Singh, requested that the International Trade Centre (ITC) formulate a Country Cooperation Strategy for India. To initiate this process, it was agreed to first start with a specific intervention at sector level and later move on to a long term strategic perspective on what technical assistance could be provided by ITC to improve export performance particularly at the grass roots level.

In this context, the His Excellency Ambassador of India presented the Concept Paper "Proposal to Seek Support from ITC for Development of International Trade of Indian Natural Medicinal Products" as a formal request from the Government of India, Department of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homoeopathy) for assistance from ITC. In addition, and based on the good results achieved by ITC in the spices sector it was felt that additional assistance should be provided to this sector focusing on its link with the Natural Medicinal Products sector and the promotion of community based tourism. The Concept Paper in enclosed as Appendix 1.

This was followed-up with a visit to India, in October 2007, by the ITC Executive Director, Ms. Patricia Francis, where she met representatives of the Department of AYUSH (Ministry of Health), the Spices Board (Ministry of Commerce), and the Ministry of Tourism in Kerala, among others. Two Frameworks for Cooperation were signed by the ITC Executive Director during this mission; one with Department of AYUSH and one with the Spices Board. These frameworks of cooperation provide a platform for initiating and mobilizing resources for new TRTA programmes in India focusing specifically on the following sectors: spices and medicinal plants, and Ayurvedic medicine products, starting with undertaking a market assessment study for Ayurvedic products. The Framework for Cooperation concerning this study is enclosed as Appendix II.

During the project mission in April 2008, the ITC consultant worked closely with representatives of the Department of AYUSH and the National Medicinal Plants Board (NMPB), as well as with Central Council for Research in Ayurveda and Siddha Medicine (CCRAS), Central Council for Research in Unani Medicine (CCRUM), Ayurvedic Drug Manufacturers' Association (ADMA), and Foundation for the Revitalisation of Local Health Traditions (FRLHT), among others.

B. Products Coverage

In the initial Concept Paper and subsequent Framework for Cooperation, the question was raised as to whether India's HS coding system needs to have separate categories for "Dietary Supplement Products," "Health Food Products," and/or "Herbal Medicinal Products."

The Ayurvedic Product Manufacturers' Association (ADMA), after reviewing the project report of an HS Codes Study that had been co-sponsored by NMPB and Ministry of Commerce, submitted to NMPB that the HS Code chapters of greatest significance to the Ayurvedic products industry and relevant to current commerce (exports and imports) are chapters 30, 12, 13, and 21, respectively. And after studying the Indian Trade Classification (ITC) HS Codes that have been assigned thus far by the Directorate General of Foreign Trade (DGFT), ADMA identified several unassigned codes that could be utilized. ADMA prepared and submitted a proposed revision of HS Codes which included recommended codes and commodity descriptions thereof for a range of important Ayurvedic botanicals and extracts in chapters 12 and 13, herbal dietary supplement products in chapter 21, and herbal pharmaceutical products in chapter 30. It should be noted however that many

botanicals that are used as active medicinal ingredients in Ayurvedic products also appear in other chapters, particularly in HS Code Chapter 09.

NMPB has since been informed that the addition of any currently unassigned HS Codes requires that the product must meet a minimum export value threshold of Rs Crore 200. This is a rather steep minimum level that if enforced would exclude many important botanical raw materials, extracts and/or finished products from gaining a unique HS Code identifier.

The International Trade Centre (ITC) has also been asked to prepare an expert opinion on the best categorization(s) and grouping(s) of Indian medicinal herbal products for purposes of trade analysis. The Indian Trade Classification (ITC) Harmonized System (HS) already differentiates by the system of medicine. For example HS 3003 includes separate subsets for Medicants of Ayurvedic System (not put up in measured doses), Unani System, Siddha System, Homoeopathic System, and Bio-chemic System (See Table 1). Correspondingly HS 3004 includes separate subsets for Medicaments of Ayurvedic System (put up in measured doses), as well as Unani System), Siddha System, Homoeopathic System, and Bio-chemic System (See Table 2).

During the project mission however it was made clear by representatives of Department of AYUSH that the scope of this study should not be limited only to products in these chapters. It has been suggested that the products of India cannot be exported successfully outside of the context of Indian Systems of Medicine. Therefore the Indian Systems themselves along with Ayurvedic education curriculum, clinical practice and treatment centres must accompany the marketing of the products.

Table 1: ITC HS Codes for Medicants of Indian Systems of Medicine

Chapter No	**Chapter Title**	**HS CODE**	**HS CODE**	**ITC HS CODE**	**ITC HS CODE**
		Sub heading	Description	(DGFT)	Item Description
		(WCO)	*(WCO)*		*(DGFT)*
30	Pharmaceutical Products	3004	Medicaments (excluding goods of heading 3002,3005 or 3006) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings **not for retail sale**	300490	Ayurvedic, Unani, Siddha, Homoeopathic or bio-chemic systems medicaments :
				30049011	Of Ayurvedic System
				30049012	Of Unani System
				30049013	Of Siddha Systems
				30049014	Of Homeopathic Systems
				30049015	Of Bio-Chemic Systems

SOURCE: Ayurvedic Drug Manufacturers' Association.

Table 2: ITC HS Codes for Medicaments of Indian Systems of Medicine

Chapter No	Chapter Title	HS CODE	HS CODE	ITC HS CODE	ITC HS CODE
		Sub heading	Description	(DGFT)	Item Description
		(WCO)	*(WCO)*		*(DGFT)*
30	Pharmaceutical Products	3003	Medicaments (excluding goods of heading 3002,3005 or 3006) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings **for retail sale**	300390	Ayurvedic, Unani, Siddha, Homoeopathic or bio-chemic systems medicaments :
				30039011	Of Ayurvedic System
				30039012	Of Unani System
				30039013	Of Siddha Systems
				30039014	Of Homeopathic Systems
				30039015	Of Bio-Chemic Systems

SOURCE: Ayurvedic Drug Manufacturers' Association.

It should be clearly noted however that the codes that are used by the importing countries may not identify these products as ASU products. For example, in the Harmonized Tariff Schedule of the United States,[1] HS 300490 medicaments (put up in measured doses or in forms for retail sale) are described only as "other" pharmaceutical products with numerous 8- and 10- digit codes assigned according to the therapeutic indications for use of the product. In the USA, other pharmaceutical products for veterinary use are listed under HS 3004.9010, sedative medicaments are coded under HS 3004.909135, dermatological agents and local anesthetics fall under HS 3004.909145, laxatives (e.g. psyllium or senna products) under 3004.909150, and cough and cold preparations under HS 3004.909176, among others.

C. Objectives

The specific objectives of this project included:

- Mission to India to conduct a Needs Assessment Study with cooperation of the Government of India, Department of AYUSH.
- Identify a national consultant to assist with programme development in second phase.
- Based on the outcome of the Needs Assessment Study, formulate a sector development programme with emphasis on international competition.
- Carry out a second mission in India to present the results of the Needs Assessment Study to the Department of AYUSH.
- Based on the outcome of second mission in India, prepare a programme document outlining the specific programme that is recommended for India to undertake to promote the export of

[1] United States International Trade Commission. *Harmonized Tariff Schedule of the United States (2008) Revision 2.* Washington, DC: United States International Trade Commission 2008.

Ayurvedic, Siddha, and Unani (ASU) medicinal products and other Indian natural health products and services.

D. Methodology

The methodology used for this study is based on ITC's "Needs Assessment and Programme Design: A Methodological Approach and Road Map."

The specific methods used by the ITC International Consultant included:

- Discussions with Government Agencies and Trade Associations: The Department of AYUSH, PHARMEXCIL, ASSOCHAM, and ADMA, respectively, organized various focused meetings during the mission in India, some of which were luncheons or dinners with government officials and industry stakeholders, including representatives from several of the leading producers and exporters of Indian natural medicinal products. Additionally there was a full day of presentations made at the Research Councils Complex. The ITC Consultant met with representatives of the Central Council for Research in Ayurveda and Siddha (CCRAS), Central Council for Research in Unani Medicine (CCRUM), and Central Council for Research in Yoga and Naturopathy (CCRYN).

- Participation as a Speaker and Panelist at the 2008 Hi-MAPS Herbal International Summit and Expo on Medicinal, Aromatic Products and Spices: The ITC Consultant was an invited speaker at the ASSOCHAM conference and made a presentation on the topic: "Understanding the USA Natural Products Market: Data, Opportunity, Approach, Strategy and Regulatory. Implications of U.S. GMPs for Indian Exports of ASU Natural Ingredients and Finished Natural Products." At the Conference, the ITC Consultant served as a panelist, took questions from stakeholders in attendance, was introduced to a large number of industry stakeholders by representatives of ASSOCHAM and ADMA, held discussions with enterprises exhibiting at the concurrent trade exhibition, and also met with representatives of PHARMEXCIL. List of stakeholders met on mission in India is enclosed as Appendix III.

- Site visits and Interviews with Selected Enterprises: Site visits took place at Arya Vaidya Sala Kottakkal (Delhi), Maharishi Ayurveda Products Pvt. Ltd. (New Delhi), and Natural Remedies (Bangalore). A fourth site visit was scheduled with The Himalaya Drug Company (Bangalore), but this company canceled the appointment at the last minute.

- Meetings with other Consultants: Meetings were held with various consultants. A full-day meeting was held with Drs. D.K.Ved and G.S. Goraya, of the Foundation for Revitalisation of Local Health Traditions (FRLHT) in Bangalore, and authors of the NMPB study "Demand and Supply of Medicinal Plants in India 2008"[2] These consultants have offered to play a role in the assessment of sustainability and conservation status for key ingredients of targeted products for export. Other consultants met included Anant P Singh, CEO, and Uma Shukla, Technical Advisor, of Apex Cluster Development Service Pvt. Ltd., Don Greenberg, Team Leader of DAI SME Financing and Development Project on behalf of GTZ, Janak Raj Rawal, Managing Director of Rawal Medherb Consultants Pvt. Ltd., and Pushp Jain, CEO of Nature & People Research and Support Group.

- Questionnaire Design and Distribution: The Enterprise Survey was designed by the ITC International Consultant based on input from the mission to India and followed the framework defined in Annex I The Export Enterprise Survey: Check List of ITC's Needs

[2] Ved DK, Goraya GS. *Demand and Supply of Medicinal Plants in India*. Dehra Dun, India: Bishen Singh Mahendra Pal Singh. 2008. Also available at website of NMPB: http://nmpb.nic.in/DS_study.htm

Assessment and Programme Deign technical paper (March 2000). The draft survey was reviewed and commented upon by the ITC Consultant's direct supervisor, the Market News Service (MNS) Coordinator, and by representatives from both Department of AYUSH and ADMA. The review comments were used to create the final version which was disseminated by ADMA and PHARMEXCIL to their respective memberships. The Enterprise Survey is enclosed as Appendix IV. The List of Survey Respondents is enclosed as Appendix V.

- Secondary Research: Sources used to collect and analyze other relevant data included various existing reports and studies such as:

    - Consultancy Development Center (CDC). ***Technology Status on Isabgol Based Industry***. New Delhi: Department of Scientific and Industrial Research, Government of India. July 2005.

    - Government of India Planning Commission. ***Annexure 3: Report of the Steering Committee on AYUSH for the Eleventh Five-Year Plan (2007-2012).*** New Delhi: Government of India Planning Commission. December 2006.

    - ITC South-South Trade Promotion Programme. ***India: Supply and Demand Survey on Pharmaceuticals and Natural Product*s**. December 2007.

    - Lohar DR. ***Legal Status of Ayurvedic, Siddha & Unani Medicines***. Ghaziabad: Pharmacopoeial Laboratory for Indian Medicine.

    - Subrat N, Iyer M, Prasad R. ***The Ayurvedic Medicine Industry: Current status and sustainability***. New Delhi: Ecotech Services (India) Pvt. Ltd. 2002.

    - Technopak Advisors Pvt. Ltd. ***Study on Medicinal and Aromatic Plants***. New Delhi: Agricultural and Processed Food Products Export Development Authority (APEDA), Ministry of Commerce & Industry, Government of India. October 2007.

    - Ved DK, Goraya GS. ***Demand and Supply of Medicinal Plants in India***. New Delhi: National Medicinal Plants Board. 2008.

    - Wight P. ***Integrated Community-Based Export Development Project in Kerala, India***. Geneva: International Trade Centre / UNCTAD/WTO. November 2007.

- Data Analysis and Report Writing

CHAPTER 2 – TRADE ENVIRONMENT

A. Natural Medicinal Products Market and Demand:

a. Botanical Raw Materials

The National Medicinal Plants Board (NMPB), Ministry of Health & Family Welfare, Department of AYUSH, initiated a study "Demand and Supply of Medicinal Plants in India 2008,"[3] which was carried out by Drs. D.K.Ved and G.S. Goraya, of the Foundation for Revitalisation of Local Health Traditions (FRLHT). This study provides an estimation of the annual demand of botanical raw drugs, the annual trade value of botanical raw drugs, the annual domestic turnover of herbal industry in India, and an estimation of annual production and supply of botanical raw drugs, among other important data points for trade analysis. FRLHT estimated the annual demand of botanical raw drugs at 319,500 MT for the year 2005-06. This estimate reflects a synthesis of data related to estimates of consumption of botanicals by the domestic herbal industry, the rural households and the volume of botanicals recorded in the export database during the year 2004-05.

Estimated Annual Demand of Botanical Raw Drugs* (Dry Wt. in MT) for 2005-06			
Herbal Industry	**Rural Households**	**Exports****	**Total**
177,000	**86,000**	**56,500**	**319,500**

* The demand estimates pertain to botanical entities that are exclusively traded as 'herbal raw drugs' and do not include demand on account of entities that have their major usage as spices, fruits, vegetables and cereals.
** Data pertains to the year 2004-05.
SOURCE: Ved DK, Goraya GS. *Demand and Supply of Medicinal Plants in India*. Dehra Dun, India: Bishen Singh Mahendra Pal Singh. 2008. Also available at website of NMPB: http://nmpb.nic.in/DS_study.htm

Explanatory notes: The demand estimates in respect of the domestic herbal industry were prepared based on the compilation and analysis of data on 'consumption' of botanical raw drugs provided by 188 herbal manufacturing units. The demand estimates in respect of rural households of the country were prepared based on analysis of sample survey of 1,223 rural households located in 5 states.

The FRLHT researchers also noted that while amla fruit (*Phyllanthus emblica*) is the highest consumed botanical raw drug by the domestic herbal industry, 70% of total botanical raw material exports (by volume) are made up just a few species, namely psyllium husk (*Plantago ovata*), senna leaf and pod (*Cassia angustifolia*), henna leaf & powder (*Lawsonia inermis*), and the three myrobalans: amla fruit (*Phyllanthus emblica*), belleric myrobalan fruit (*Terminalia bellerica*), and chebulic myrobalan fruit (*Terminalia chebula*).

FRLHT estimated an annual trade value of Rs. 1,069 crores based on their estimated annual demand of 319,500 MT calculated as a synthesis of trade values worked out separately for each of the three consumption sectors.

Estimated Annual Trade Value of Botanical Raw Drugs (Rs. in Crores) for 2005-06			
Herbal Industry[1]	**Rural Households[2]**	**Exports[3]**	**Total**
627.90	**86.00**	**354.80**	**1,068.70**

1. The aggregated procurement costs reported by four major manufacturing units (Dabur, Charak, Sami and Zandu) have been utilized for estimating the procurement value of 177,000 MT of raw drugs.
2. Trade value of material consumed by the rural households has been estimated using a notional rate of Rs.10 per kg of dry material.
3. Actual value as per DGCIS data.

[3] Ved DK, Goraya GS. *Demand and Supply of Medicinal Plants in India*. Dehra Dun, India: Bishen Singh Mahendra Pal Singh. 2008. Also available at website of NMPB: http://nmpb.nic.in/DS_study.htm

It should be noted that many supply and demand surveys, including the FRLHT study, limit the inclusion criteria for natural ingredients mainly to those listed in HS Chapter 1211, and selectively adding certain botanical exudates and gums listed in HS Chapter 1301, certain saps and extracts in HS Chapter 1302, some botanicals in HS Chapter 1404, and only a few medicinal and aromatic plants that are listed in HS Chapter 09.

Table 3 shows the reported export values (Rs. Lacs) for four main general categories of natural raw materials, Chapter 0902 through 0910 (spices and tea leaf), Chapter 1211 (plants used in pharmacy and perfumery), Chapter 1301 (exudates, gums and resins), Chapter 1302 (saps & extracts and mucilages), and Chapter 1404 (vegetable products NESOI; includes henna leaf, myrobalan fruits and soapnut).

Table 4 shows the total quantities of selected herbal materials of various HS Chapters exported by India during the agricultural seasons of April through March, 2003 through 2007. .

TABLE 3: Natural Raw Material Exports / HS 4-Digit Code Chapter / Apr-Mar 2005-2007 / Value: Rs. Lacs / % Growth

Chapter	HS CODE	Apr-Mar 2005-2006 Rs. Lacs	Apr-Mar 2006-2007 Rs. Lacs	% Growth
SPICES & TEA LEAF (= Chapter 09 excluding Coffee)	0902 - 0910	**288248.59**	**396686.03**	**+37.62**
PLANTS & PARTS OF PLANTS INCLD SEEDS & FRUITS USED FOR PERFUMERY & PHARMACY	1211	**35103.20**	**38977.56**	**+11.04**
LAC; NATURL GUMS, RESINS,GUM-RESINS & OLEORESINS	1301	**42557.97**	**23776.40**	**-44.13**
VEG SAPS & EXTRACTS; PECTIC SUBSTANCES; AGAR-AGAR & OTHER MUCILAGES	1302	**134042.29**	**151589.99**	**+13.09**
VEG PRODUCTS N.E.S. OR INCLUDED	1404	**8283.39**	**10195.83**	**+23.09**
Total Value (Rs. Lacs):		**508235.44**	**621225.81**	**+22.23**

SOURCE: Government of India Ministry of Commerce & Industry, Department of Commerce, Export Import Data Bank: http://commerce.nic.in.

TABLE 4: Selected Botanical Exports: Herb Name / HS 8-Digit Code / Apr-Mar 2002-2007 / Quantities: kilograms (kg) / % Growth

HERB NAME	HS CODE	Apr-Mar 2003-2004 kg	Apr-Mar 2004-2005 kg	Apr-Mar 2005-2006 kg	Apr-Mar 2006-2007 kg	% Growth
Amla fruit (*Phyllanthus emblica*)	14041061	303,210	160,160	196,880	89,360	**-54.61**
Asafetida gum resin (*Ferula assa-foetida*)	13019013	744,210	731,640	723,200	491,070	**-32.10**
Belleric & Chebulic myrobalan fruits (*Terminalia bellerica* & *T. chebula*)	14041069	2,377,870	3,849,700	973,900	414,160	**-58.19**
Chicory root, roasted (*Cichorium intybus*)	21013010	798,000	1,029,290	2,233,020	2,672,740	**+19.69**
Chirata whole plant (*Swertia chirayita*)	12119091	35,350	415,570	34,030	19,230	**-43.48**
Ginger rhizome (*Zingiber officinale*)	091010	4,602,570	14,908,130	10,890,430	9,661,340	**-11.29**
Coriander fruit (*Coriandrum sativum*)	090920	18,344,220	30,632,290	26,398,730	27,321,880	**+3.50**
Garcinia extract (*Garcinia cambogia*)	13021918	920,160	541,690	672,650	946,880	**+40.77**
Green tea leaf (*Camellia sinensis*)	090210 090220	1,384,920	1,860,680	2,061,630	7,446,490	**+361.19**
Guar gum (*Cyamopsis tetragonoloba*)	13023220 13023230	115,869,900	126,593,960	183,571,850	189,111,860	**+3.02**
Gymnema leaf (*Gymnema sylvestre*)	12119024	88,180	118,530	59,224	53,140	**-10.27**
Henna leaf (*Lawsonia inermis*)	14041011	209,700	488,300	217,240	264,670	**+21.83**
Henna powder (*Lawsonia inermis*)	14041019	2,913,680	3,601,130	4,320,640	3,767,700	**-12.80**
Indian frankincense gum (*Boswellia serrata*)	13019032	7,990	12,080	28,400	17,670	**-37.79**
Karaya gum (*Sterculia urens*)	13019016	429,690	832,100	1,269,420	932,220	**-26.56**
Long pepper fruit (*Piper longum*)	09041110	940,430	812,770	718,570	320,750	**-55.36**
Neem leaf (*Azadirachta indica*)	12119023	42,690	155,650	373,970	245,190	**-34.44**
Opium exudate (*Papaver somniferum*)	13021100	258,010	216,280	71,070	66,510	**-6.41**
Psyllium husk (*Plantago ovata*)	12119032	7,235,620	19,387,380	24,959,900	19,926,060	**-20.17**
Psyllium seed (*Plantago ovata*)	12119013	3,520,040	1,191,210	760,510	1,122,560	**+47.61**
Senna leaf / pod (*Cassia angustifolia*)	12119022	10,973,690	10,924,050	11,430,180	9,398,890	**-17.77**
Sickle-pod senna seed (*Cassia tora*)	09109915	1,881,090	1,572,450	2,083,280	6,496,230	**+211.83**

SOURCE: Government of India Ministry of Commerce & Industry, Department of Commerce, Export Import Data Bank: http://commerce.nic.in.

b. Extracts, Oils and Oleoresins

Table 5 shows, in terms of reported value (Rs. Lacs), Indian exports of other saps and extracts listed und HS Code 130219, castor oil listed under HS Code 151530, essential oils and oleoresins listed under HS Chapter 3301, and mixtures of odoriferous substances listed under HS Chapter 3302. This chapter includes a wide range of botanical alcoholic extract solutions (prepared from minor forest products) that are grouped under HS 33029020 as part of the *Vishesh Krishi Upaj Yojana* (Special Agricultural Produce Scheme.

TABLE 5: Selected Extracts and Oils Exports: Herb HS 4-Digit Code Chapter / Apr-Mar 2005-2007 / Value: Rs. Lacs / % Growth

HERB NAME	HS CODE	Apr-Mar 2005-2006 Rs. Lacs	Apr-Mar 2006-2007 Rs. Lacs	% Growth
OTHER VEGETABLE SAP & EXTRACTS	130219	**24824.44**	**32599.44**	**+31.32**
Castor oil (*Ricinus communis*)	151530	**84502.87**	**98690.24**	**+16.79**
ESSENTIAL OILS (CNCRTS/ABSLTS);RSNDS,EXTRTD OLORGN,CNCNTRTS IN FATS ETC	3301	**73454.59**	**100538.68**	**+36.87**
MXTR/SLTN OF ODORFRS SBSTNS OF A KIND USD AS RAW MTRL IN INDSTRY	3302	**25673.71**	**27417.20**	**+6.79**
Total (Rs. Lacs):		**208455.61**	**259245.56**	**+24.36**

SOURCE: Government of India Ministry of Commerce & Industry, Department of Commerce, Export Import Data Bank: http://commerce.nic.in.

c. Finished Natural Health Products

The "Report of the Sub Group on Research & Industry" of the Steering Committee on AYUSH for the Eleventh Five-Year Plan (2007-2012),[4] in its proposed export-oriented scheme "Schemes for Development of New Formulations, Technologies, Tools and Practices with Validation of Existing Products and Procedures," states that one of the measurable outputs for this scheme in the 11th plan would be a rise in exports of products put up for retail sales from the AYUSH sector to Rs 3000 Crore by 2012 from Rs 120 Crore in 2005.

Another proposed scheme in the Report of the Sub Group on Research and Industry is the "Scheme to Identify, Promote and Develop "Star product(s) for the International market" and Brand Promotion for the ASU sector – domestically and internationally," for which one of the measurable outputs for the 11th plan would be an increase of exports of value added from the sector to Rs 10,000 Crore from the current Rs 1200 Crore.

Table 6 shows export values (in Rs. Lacs) for Indian medicinal natural products (both medicants & medicaments) for the 12-month period of April 2006 through March 2007, and the subsequent 3-month period of April 2007 through June 2007, as reported by the Government of India, Department of Commerce Export Import Data Bank. This table is limited in scope to only those medicinal natural products that are classified under HS Code Chapters 3003 and 3004. There may be finished products being exported under other codes for example as natural cosmetics or dietary supplements, among other possibilities. The total export value for these medicinal natural products is reported at Rs. Lacs 28,128.36. For all medicants and medicaments listed, the Ayurvedic products coded under HS 30039011 and HS 30049011, respectively, make up 92.3% of the total export value.

[4] Government of India Planning Commission. Annexure 3: *Report of the Steering Committee on AYUSH for the Eleventh Five-Year Plan (2007-1012).* New Delhi: Government of India. December 2006.

Table 6: Exports of Indian Finished Medicinal Natural Products / Value: Rs. Lacs / % Share of Total Indian Exports

HS Code	Commodity	2006-2007	%Share	2007-2008 (Apr-Jun)	%Share
30039011	MEDICANTS OF AYURVEDIC SYSTEM	9036.09	0.0158	1785.93	0.0124
30049011	MEDICAMENTS OF AYURVEDIC SYSTEM	16917.80	0.0296	4461.30	0.0309
30039012	MEDICANTS OF UNANI SYSTEM	5.00	0.0000	2.52	0.0000
30049012	MEDICAMENTS OF UNANI SYSTEM	65.05	0.0001	67.65	0.0005
30039013	MEDICANTS OF SIDDHA SYSTEM	1.11	0.0000	0.00	
30049013	MEDICAMENTS OF SIDDHA SYSTEM	0.96	0.0000	9.19	0.0001
30039014	MEDICANTS OF HOMOEOPATHIC SYSTEM	135.65	0.0002	5.61	0.0000
30049014	HOMEOPATHIC MEDICINE	138.11	0.0002	33.26	0.0002
30039015	MEDICANTS OF BIO-CHEMIC SYSTEM	1494.35	0.0026	614.32	0.0043
30049015	MEDICAMENTS OF BIO-CHEMIC SYSTEM	334.24	0.0006	75.07	0.0005
	TOTAL VALUE in Rs Lacs	28128.36		7054.85	

SOURCE: Government of India, Department of Commerce Export Import Data Bank.

B. Indian Standards:

***Quality Standards for Indian Natural Ingredients*:**

- *AGMARK Quality Grading and Certification*:[5] Grade standards for several botanical raw materials, oils and other natural ingredients have been prescribed under the Agricultural Produce (Grading and Marking) Act. Quality grading and certification at farm level are available for export and domestic trade. The AGMARK quality certification mark acts as third party guarantee to quality certified. Table 7 lists the standards are available on-line for selected Indian natural ingredients.

Table 7: Indian Natural Ingredients with AGMARK Standards

Common Name of Botanical	Download Standard At:
Agar Agar	http://www.agmarknet.nic.in/agaragargmr.pdf
Ajowan Seed	http://www.agmarknet.nic.in/spices.pdf
Betel Nut	http://www.agmarknet.nic.in/arecanutsgmr.pdf
Caraway and Black Caraway	http://www.agmarknet.nic.in/Caraway.pdf
Castor Seed	http://www.agmarknet.nic.in/oilseeds1.htm#CASTOR
Catechu (extractive of heartwood)	http://www.agmarknet.nic.in/catechugmr.pdf
Cloves	http://www.agmarknet.nic.in/Cloves.pdf
Compounded Asafoetida	http://www.agmarknet.nic.in/CompoundedAsafotied.pdf
Essential Oils	http://www.agmarknet.nic.in/Essential_Oils.pdf
Ghee	http://www.agmarknet.nic.in/gheegmr.pdf
Guar Gum	http://www.agmarknet.nic.in/guargumgmr.pdf

[5] Directorate of Marketing and Inspection, Department of Agriculture and Cooperation. *List of Commodities for which Grade Standards have been prescribed under the Agricultural Produce (Grading and Marking) Act, 1937* (as on 31-3-08). Faridabad (Haryana): Ministry of Agriculture. 31 March 2008. Available at: http://www.agmarknet.nic.in/lstcm1937.pdf

Honey	http://www.agmarknet.nic.in/honeygmr.pdf
Indian Cassia Leaf	http://www.agmarknet.nic.in/tejpat.pdf
Jaggery	http://www.agmarknet.nic.in/sugarcanegurgmr.pdf
Kangra Tea	http://www.agmarknet.nic.in/kangrateagmr.pdf
Karaya Gum	http://www.agmarknet.nic.in/gumkarayagmr.pdf
Linseed	http://www.agmarknet.nic.in/oilseeds1.htm#LINSEEDS
Mace	http://www.agmarknet.nic.in/mace.pdf
Myrobalan Fruit	http://www.agmarknet.nic.in/myrobalangmr.pdf
Nutmeg	http://www.agmarknet.nic.in/Nutmeggrading.pdf
Papain	http://www.agmarknet.nic.in/papaingmr.pdf
Psyllium Husk	http://www.agmarknet.nic.in/isubgoalhusk.pdf
Saffron	http://www.agmarknet.nic.in/Saffron.pdf
Senna Leaves and Pods	http://www.agmarknet.nic.in/sennaleavesgmr.pdf
Sheekakai Pods and Powder	http://www.agmarknet.nic.in/sheekakaigmr.pdf
Spices (capsicum, cardamom, celery seed, coriander, cumin, fennel, fenugreek, ginger, pepper, turmeric):	http://www.agmarknet.nic.in/spices.pdf
Tendu Leaf	http://www.agmarknet.nic.in/tenduleafgmr.pdf

- *Ayurvedic Pharmacopoeia of India (API) Standards*:[6] The Ayurvedic Pharmacopoeia of India is a legal document of standards for the quality of Ayurvedic drugs and substances included therein (under the Drugs and Cosmetic Act, 1940). There are 418 quality standards monographs published thus far in the API. See Appendix VI for list of monographs published in the API (as excerpted from "Legal Status of Ayurvedic, Siddha & Unani Medicines")[7]:
    - Part I, Volume I contains 80 monographs
    - Part I, Volume II contains 78 monographs
    - Part I, Volume III contains 100 monographs
    - Part I, Volume IV contains 68 monographs
    - Part I, Volume V contains 92 monographs

  The monographs deal with Pharmacognostical, Chemical and Ayurvedic standards of the plant drugs used in Ayurveda. Each monograph describes macroscopic, microscopic characters along with the permissible limit of foreign matter. Chemical standards of identity, purity and strength have been developed on the basis of parameters like Total ash, Acid insoluble ash. Alcohol soluble extractives. Water soluble extractives, etc. with the references of important constituents present in it. The work on various monographs on all parameters have been carried out at Pharmacopoeial Laboratory for Indian Medicine (PLIM) and approved by the Ayurvedic Pharmacopoeia Committee.

- *Bureau of Indian Standards (BIS)*: The Bureau of Indian Standards Act of 1986 provided for the establishment of a Bureau for the harmonious development of the activities of standardization, marking and quality certification of goods. BIS standards exist for the following natural ingredients, among others: capsicum (chilli) fruit, cardamom capsules & seeds, celery fruit, coriander fruit, cumin fruit, fennel fruit, fenugreek seed, garlic bulb (dehydrated), ginger rhizome, and turmeric rhizome.

[6] Ayurvedic Pharmacopoeia Committee. *The Ayurvedic Pharmacopoeia of India*, Part I, Volumes I-V. New Delhi: Government of India, Ministry of Health & Family Welfare, Department of AYUSH.

[7] Lohar DR. *Legal Status of Ayurvedic, Siddha & Unani Medicines*. Ghaziabad: Pharmacopoeial Laboratory for Indian Medicine. Available at: http://plimism.nic.in/Legal_Status.pdf.

- *Indian Pharmacopoeia Standards*:[8] The Indian Pharmacopoeia Commission (IPC) is an autonomous institution under the Ministry of Health & Family Welfare, Govt. of India dedicated for setting of standards for drugs, pharmaceuticals and healthcare devices/ technologies, besides providing reference substances and training. While the various other official pharmacopoeias for the Indian Systems of Medicine already provide hundreds of quality standards monographs for the test and release of botanical raw materials (Ayurvedic Pharmacopoeia of India [API], Siddha Pharmacopoeia of India [SPI], and Unani Pharmacopoeia of India [UPI]), the Indian Pharmacopoeia [IP] also provides official standards for many natural medicinal ingredients. However quality standards monographs for newer extracted forms of herbal drugs have yet to be established. The Crude Drugs and Herbal Products Committee of the Indian Pharmacopoeia Commission (IPC) plans to develop quality standards monographs for herbal extract ingredients that are largely exported by Indian extract manufacturers. In the coming two years, supplements to the IP 2007 will begin to include several herbal extract monographs. In addition to Indian medicinal botanicals that already appear in the IP (e.g. licorice root, psyllium husk, senna leaf and pod), several new herbal monographs have been entered into the IP 2007 (See Table 8).

Table 8: New Botanical Monographs added to the IP 2007

Common Name	Description	Also in API
Amalaki	fresh fruit pulp of *Emblica officinalis* Gaertn.	also in API Vol I
Amra	dried seed of *Mangifera indica* Linn.	also in API Vol III
Arjuna	stem bark of *Terminalia arjuna* W.& A.	also in API Vol II
Artemisia	dried aerial part of *Artemisia annua* L.	not in API
Bhibhitaki	dried ripe fruits of *Terminalia belerica* Roxb.	also in API Vol I
Bhringraj	whole plant of *Eclipta alba* Hassk.	also in API Vol II
Coleus	dried mature root of *Coleus forskohlii* Briq.	also in API Vol V
Gokhru	root of *Tribulus terrestris* Linn.	also in API Vol I
Gudmar	dried leaf of *Gymnema sylvestre* R.Br.	also in API Vol V
Guduchi	dried matured stem pieces of *Tinospora cordifolia* (Willd.) Miers.	also in API Vol I
Haritaki	pericarp of mature fruits of *Terminalia chebula* Retz.	also in API Vol I
Kunduru	exudate of *Boswellia serrata* Roxb.	also in API Vol IV
Kutki	dried rhizome with root of *Picrorhiza kurroa* Royle ex Benth.	also in API Vol II
Lasuna	bulb of *Allium sativum* Linn.	also in API Vol III
Manjistha	dried stem of *Rubia cordifolia* Linn.	also in API Vol III
Maricha	fully mature dried fruit of *Piper nigrum* Linn.	also in API Vol III
Pippali	dried immature, catkin-like fruits with bracts of *Piper longum* L.	also in API Vol IV
Punarnava	dried, matured whole plant of *Boerhaavia diffusa* Linn.	also in API Vol I
Sarpagandha	air dried root of *Rauwolfia serpentina* (Linn.) Benth. Ex Kurz	also in API Vol V
Shatavari	tuberous roots of *Asparagus racemosus* Willd.	also in API Vol IV
Shati	sliced, dried rhizomes of *Hedychium spicatum* Ham. ex Smith	also in API Vol I
Tulasi	dried whole plant of *Ocimum sanctum* Linn.	also in API Vol II

- *Siddha Pharmacopoeia of India (SPI) Standards*:[9] The Siddha Pharmacopoeia of India is a legal document of standards for the quality of Siddha drugs and substances included therein (under the Drugs and Cosmetic Act, 1940). There are 73 quality standards monographs published thus far in the new SPI Volume I 2008:
    - Part I, Volume I contains 73 monographs.

[8] Indian Pharmacopoeia Commission, Central Indian Pharmacopoeial Laboratory. *Indian Pharmacopoeia 2007*, Volume I. New Delhi: Government of India, Ministry of Health and Family Welfare. 2007

[9] Siddha Pharmacopoeia Committee. *The Siddha Pharmacopoeia of India*, Part I, Volume I. New Delhi: Government of India, Ministry of Health & Family Welfare, Department of AYUSH.

- *Unani Pharmacopoeia of India (UPI) Standards*:[10] The Unani Pharmacopoeia of India is a legal document of standards for the quality of Unani drugs and substances included therein (under the Drugs and Cosmetic Act, 1940). There are 250 quality standards monographs published thus far in the UPI:
    - Part I, Volume I contains 45 monographs
    - Part I, Volume II contains 50 monographs
    - Part I, Volume III contains 53 monographs
    - Part I, Volume IV contains 50 monographs
    - Part I, Volume V contains 52 monographs.

***Quality Systems for Indian Natural Products*:**

- *Bureau of Indian Standards (BIS) Code for Hygienic Conditions for Spices and Condiments Processing Units*:[11] This code of hygienic practices applies to spices and condiments, whole, broken or ground, spice blends or processed spice products. It also covers the minimum requirements of hygiene for post harvest technology (curing, bleaching, drying, cleaning, grading, packing, transportation and storage including microbial and insect disinfestation), processing establishment, processing technology (grinding, blending, extraction of essential oils and oleoresins, frozen and freeze dried or dehydrated, etc), packaging and storage of processed products; available at: http://www.bis.org.in/bis/html/14216.html

- *National Medicinal Plants Board (NMPB) Good Agriculture Practices (GAPs) for Medicinal Plants*:[12] The NMPB has formulated (draft) GAPs under a project financed by World Health Organisation (WHO). These guidelines have been drafted on the model guidelines developed and published by WHO. These guidelines seek to disseminate GAPs for ensuring quality and safety of the AYUSH medicines. The guidelines have been drafted by NMPB through a consultative process involving agronomists, practitioners of traditional medicine, industry, R&D institutions and the concerned subject matter departments; available at: http://nmpb.nic.in/Draft%20GAPs.pdf

- *Ministry of Health & Family Welfare (MOHFW) Good Manufacturing Practices (GMPs) for Ayurveda, Siddha and Unani Medicines*:[13] The GMPs are published in Schedule T of the Drugs and Cosmetic Act and Rules. The certificate of GMP to manufacturers of Ayurveda, Siddha or Unani drugs shall be issued to licensees who comply with the requirements of GMP of Ayurveda, Siddha and Unani drugs as laid down in Schedule T; available at: http://cdsco.nic.in/html/Drugs&CosmeticAct.pdf

C. Main Export Markets

The top four destinations for Ayurvedic products in 2006-2007 for both HS 30039011 and HS 30049011, respectively, in terms of reported value (Rs. Lacs), were Russian Federation, Nepal, United Arab Emirates, and United States of America, albeit not in the same order for each code. For HS 30039011, the top ten destinations represented 73.5% of the total reported export value. For HS 30049011, the top ten destinations represented 63.4% of total reported export value. The current

[10] Unani Pharmacopoeia Committee. *The Unani Pharmacopoeia of India*, Part I, Volumes I-V. New Delhi: Government of India, Ministry of Health & Family Welfare, Department of AYUSH.

[11] Bureau of Indian Standards. IS 14216-1994: *Code for Hygienic Conditions for Spices and Condiments Processing Units*. New Delhi: Bureau of Indian Standards. 2005.

[12] National Medicinal Plants Board. *Good Agriculture Practices (GAPs) for Medicinal Plants.* New Delhi: National Medicinal Plants Board. 2007. Available at: http://nmpb.nic.in/Draft%20GAPs.pdf.

[13] Government of India Ministry of Health & Family Welfare. Schedule T: *Good Manufacturing Practices (GMPs) for Ayurveda, Siddha and Unani Medicines.* In: *The Drugs and Cosmetics Act and Rules* (as amended up through 30th June 2005. New Delhi: Department of Health. 2005. Available at: http://cdsco.nic.in/html/Drugs&CosmeticAct.pdf.

situation is important information to consider for the prioritization of selected export markets to focus on for program development. Table 9 shows the top ten destinations for Ayurvedic exports with their respective reported values in Rs. Lacs.

Table 9: Top ten export destinations for Ayurvedic Products / Value: Rs. Lacs

HS Code	Commodity		2006-2007
30039011	**MEDICANTS OF AYURVEDIC SYSTEM**		**9036.09**
1	United States of America	1696.49	
2	Nepal	1260.91	
3	Russian Federation	1186.62	
4	United Arab Emirates	1201.34	
5	Kenya	314.58	
6	Germany	278.82	
7	The Netherlands	209.49	
8	South Africa	190.22	
9	Ukraine	151.82	
10	United Kingdom	148.68	
	Top Ten Total (Rs. Lacs):	**6638.97**	**(73.5%)**
30049011	**MEDICAMENTS OF AYURVEDIC SYSTEM**		**16917.80**
1	Russian Federation	2745.00	
2	United Arab Emirates	1789.54	
3	Nepal	1261.39	
4	United States of America	1069.62	
4	Ukraine	844.50	
5	Sri Lanka	822.45	
6	Kenya	538.68	
7	Burundi	475.25	
8	Australia	421.10	
9	Malaysia	415.52	
10	Kazakhstan	346.89	
	Top Ten Total (Rs. Lacs):	**10729.94**	**(63.4%)**

SOURCE: Government of India, Department of Commerce Export Import Data Bank.

For Indian exports of botanical raw materials and extracts, the top ten destinations for natural ingredients classified under Chapters 09, 1211, 1301, and 1302, respectively are listed below.

Chapter 09 Destinations: In terms of reported values, the top ten destinations for natural raw materials listed under HS Chapter 09 are the USA, Italy, Malaysia, UK, Russia, Germany, UAE, Sri Lanka, Bangladesh, and Australia.

Chapter 1211 Destinations: The top ten destinations for HS Chapter 1211 exports are the USA (accounting for about 35% of total), followed by Pakistan, Germany, Japan, Indonesia, UAE, Spain, UAE, Australia, and the PRC.

Chapter 1301 Destinations: The top ten destinations for HS Chapter 1301 exports are the USA, Indonesia, Pakistan, Germany, Egypt, UAE, Bangladesh, Mexico, UK, and Spain.

Chapter 1302 Destinations: The top ten destinations for HS Chapter 1302 exports are the USA (accounting for 40.6% of total), followed by PRC, Germany, Japan, Italy, South Africa, Belgium, Australia, Netherlands, and UAE.

CHEMEXCIL, which represents natural product categories including agarbattis (herbal incense sticks), castor oil & derivatives, herbal cosmetics & toiletries, dyes & dye intermediates, chemicals (menthol), maintains a record of the top countries, the top-five being the USA, the PRC, Indonesia, Germany, and the UK. Table 10 Shows the Top 25 Countries of Exports of Chemexcil's Items 2002 through 2005 in terms of value (Rs. in million).

Table 10: Top 25 Countries of Export of Chemexcil's Items (Rs. in millions)

Countries	2004-05	2003-04	2002-03
U.S.A.	38487	32821	30427
CHINA P.RP.	17590	11651	9286
INDONESIA	14985	8178	4438
GERMANY	10501	15108	12145
U.K.	9996	8803	7847
PAKISTAN	9977	3187	2187
NETHERLAND	8829	6372	6654
SINGAPORE	8619	1570	4324
U.A.E.	7832	6571	5958
RUSSIA	7601	7145	5778
JAPAN	6788	6566	5348
MALAYSIA	6465	1791	3420
SPAIN	6092	4307	4320
ITALY	6045	5957	5450
THAILAND	5155	3003	4457
FRANCE	4456	2855	4796
BANGALADESH	4421	1647	3109
KOREA REP.	4258	1436	3490
TURKEY	4188	4000	2126
IRAN	4171	4404	2480
BELGIUM	3924	2713	3192
SRILANKA	3760	3582	3832
SWITZERLAND	3680	3400	3212
SOUTH AFRICA	3267	2153	2887
KENYA	1643	1704	1730
TOTAL	**202730**	**150924**	**142893**

SOURCE: CHEMEXCIL: http://www.chemexcil.gov.in/stats/documents/12_doc.doc

D. Market Access Barriers

a. Negative and Positive Lists of Substances

Many countries publish their own negative and positive lists of substances for use in various classes of goods (cosmetics, dietary supplements, foods, medicines). There is however no comprehensive global listing or database and therefore one must check each individual list for each targeted export market. The following are a few examples of negative and positive lists from selected countries of relevance to exporters of Indian natural medicinal products.

***Australia*:** The Therapeutic Goods Administration (TGA) annually updates a list of "Substances that may be used in Listed Medicines in Australia," which is available on-line at: http://www.tga.gov.au/cm/listsubs.pdf.[14] These substances are eligible for use in medicines Listed on the Australian Register of Therapeutic Goods for supply in Australia. The list includes the approved role of the substance (i.e. active, excipient, and/or component), and any restrictions and conditions that apply to the substance when used in Listed medicines. Some substances are permitted as food excipients only. These substances (e.g. apple, pear) refer only to edible substances fit for human consumption as a food. Only certain preparations are permitted for most food excipients: fresh dry or powdered plant material and fresh, dried or concentrated juices. Juice preparations may only be named where the fresh plant part has a high water content.

Further details are provided in the "Herbal Substances Australian Approved Names (AAN) List" in the TGA Approved Terminology for Medicines, which is available on-line at: http://www.tga.gov.au/docs/pdf/aan/aanherb3.pdf.[15] The list does not include substances that may be used as homoeopathic preparations. The Office of Complementary Medicines is currently conducting a review of homoeopathic substance permitted in listed medicines. The Australian TGA also maintains a list of proprietary ingredients which have been used in Listed Medicines but which are not usable in ELF3 (Electronic Listing Facility) until further information regarding proprietary ingredient purpose, restricted ingredients and quantities of restricted ingredients have been supplied to the TGA; available on-line at: http://www.tga.gov.au/cm/elf3pring.pdf.[16]

***Belgium*:** The Belgian Federal Public Service (FÖD) for Health, Food Safety and Environment Food regulates dietary supplement products and food products that contain botanicals as defined in a royal decree 1997, which is available on-line (in Dutch, French, and German).[17] The appendix to this decree covers 3 lists: List 1: Botanicals that may not be used in foods or dietary supplement products; List 2, Part 1: Cultivated edible mushrooms that may be used; List 2, Part 2: Wild mushrooms which may be used so long as they are not threatened species; List 3: Botanicals that may be used but only with pre-marketing authorization and with specified upper dosage limits. The FÖD also regulates medicinal herbal products which require pre-marketing authorization either as new drugs, traditional herbal medicinal products (THMP), or well-established use (WEU) herbal medicinal products.

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[14] Therapeutic Goods Administration. *Substances that may be used in Listed Medicines in Australia*. Woden: Australian Government, Department of Health and Ageing, Therapeutic Goods Administration. 12 December 2007. Available at: http://www.tga.gov.au/cm/listsubs.pdf

[15] Therapeutic Goods Administration. *Herbal Substances AAN List*. In: *TGA Approved Terminology for Medicines*. Woden: Australian Government, Department of Health and Ageing, Therapeutic Goods Administration. July 1999. Available at: http://www.tga.gov.au/docs/pdf/aan/aanherb3.pdf

[16] Therapeutic Goods Administration. *Proprietary ingredients which have been used in Listed Medicines but which are not usable in ELF3 until further information is provided*. Woden: Australian Government, Department of Health and Ageing, Therapeutic Goods Administration. 15 July 2004. Available at: http://www.tga.gov.au/cm/elf3pring.pdf

[17] Albert II, King of Belgium. Königlicher Erlaß über die Herstellung von und den Handel mit Lebensmitteln, die Pflanzen oder Pflanzenpräparate enthalten oder daraus bestehen. Brüssel: Föderaler Öffentlicher Dienst (FÖD) Volksgesundheit, Sicherheit der Lebensmittelkette und Umwelt. 29 August 1997. Available at: https://portal.health.fgov.be/portal/page?_pageid=56,513211&_dad=portal&_schema=PORTAL

***Canada*:** The Health Canada Natural Health Products Directorate (NHPD) maintains several lists of natural ingredients that may occur in natural health products (NHPs) either as medicinal ingredients or as non-medicinal ingredients. These lists are available on-line.

- **List of single ingredient monographs for natural health products (NHPs).** These monographs may be used to help speed up the evaluation of the safety and efficacy of medicinal ingredients commonly used in NHPs sold in Canada. They can also serve as reliable sources of product information for consumers. Available at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/mono_list_e.html

- **List of product monographs for natural health products (NHPs)**. Available at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/product_mono_produit_e.html

- **List of acceptable non-medicinal ingredients for natural health products (NHPs).** Available at:[18] http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/nmi-imn_list1_e.html

- **Summary of NHP/DRUG Classification of Therapeutic Products Directorate (TPD) Category IV Labelling Standards Ingredients.**[19] Available at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/list_mono4_e.html

- **The Natural Health Products Ingredients Database (NHPID)** is being developed to provide information on acceptable medicinal and non-medicinal ingredients used in NHPs in order to assist applicants with the submission of their application. The database contains the medicinal and non-medicinal ingredient information which the Natural Health Products Directorate (NHPD) has developed for ingredients that are considered to be acceptable when used under the conditions of use outlined in this database. A medicinal ingredient is any substance that has been classified as an NHPD as per Schedule 1 of the NHP Regulations. A non-medicinal ingredient is any substance such as a binder, coloring agent or flavor added to an NHP that is necessary for the formulation of the dosage. Non-medicinal ingredients should not exhibit any pharmacological effects of their own, and, where applicable, should not exceed the maximum concentration allowed. Information on ingredients for homeopathic applications is not yet part of the NHPID, but will be available in a subsequent release. The proper name and common name of all medicinal ingredients as well as the common name and purpose of all non-medicinal ingredients must be provided on the Product License Application. The NHPID includes non-medicinal ingredients that are generally regarded to be of minimal toxicological concern. Where appropriate, certain limitations regarding quantity, dosage form and route of administration are listed. Respecting any specified limitations, non-medicinal ingredients found in the NHPID require no further assessment. For any non-medicinal ingredient not contained in the NHPID or used outside of the stated limitations, NHPD may require safety assessment. If there is a particular safety concern with a non-medicinal ingredient, the NHPD may request additional information. The applicant should provide information supporting its non-medicinal use for all proposed non-medicinal ingredients when submitting an application for a product license. The latest release of the NHPID is available (as of May 2008) at http://205.193.93.55/IngredientDatabaseV1_4. The USER ID and PASSWORD are "nhpdemo" and "nhpd1," respectively.

[18] Natural Health Products Directorate. List of Acceptable Non-medicinal Ingredients. Ottawa: Natural Health Products Directorate. 2004. Available at: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/nmi-imn_list_e.pdf

[19] Natural Health Products Directorate. *A Summary of NHP/DRUG Classification of Therapeutic Products Directorate (TPD) Category IV Labelling Standards Ingredients*. Ottawa: Natural Health Products Directorate. 2006. Available at: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/list_mono4_e.pdf

- **Food ingredients and food additive ingredients** are listed in the Food and Drug Regulations. Available at: http://laws.justice.gc.ca/en/ShowTdm/cr/C.R.C.-c.870///en

- **Novel foods and/or novel food ingredients** require pre-marketing notification and authorization by the Directorate. Available at: http://laws.justice.gc.ca/en/showdoc/cr/C.R.C.-c.870/bo-ga:l_B-gb:l_28//en#anchorbo-ga:l_B-gb:l_28

***Denmark*:** Denmark's National Food Institute (Fødevareinstituttet**)** maintains a "*Drogelisten,*"[20] which is a safety assessment of medicinal and aromatic plants and mushrooms for use in foods, food supplements and herbal teas. The *Drogelisten* lists botanicals by their Latin botanical name, Danish common name and plant part, with an estimated safe maximum daily dosage level if the botanical is permitted in Danish commerce. If the botanical is not permitted or has any restrictions for use these are noted. The document is available only in the Danish language.

- ***Drogelisten: Vurdering af planter, svampe og dele heraf anvendt i kosttilskud og urtete:*** http://www.dfvf.dk/Admin/Public/Download.aspx?file=files/filer/publikationer/drogeliste/rapport.pdf.

***European Union*:** The European Medicines Agency (EMEA) is developing Community Herbal Monographs and a Community List of Herbal Substances for the registration, marketing authorization and labeling of traditional herbal medicinal products (THMPs) as well as well established use (WEU) medicinal products. These lists and monographs are available on-line.

- **Community Herbal Monographs**. These monographs provide a harmonized approach to the scientific assessment of herbal medicinal products in the EU, and the Member States shall take them into account when they examine an application relating to a product for which a Community monograph has been established. Available at: http://www.emea.europa.eu/htms/human/hmpc/hmpcmonographsdraft.htm

- **Community List of Herbal Substances, preparations and combinations thereof for use in traditional herbal medicinal products (THMPs)**. This list is established by the Committee on Herbal Medicinal Products (HMPC), in accordance with Directive 2001/83/EC as amended. The list is being gradually developed through entries of structured information relating to individual herbal substances or preparations. Available at: http://www.emea.europa.eu/htms/human/hmpc/hmpclist.htm. The principle underlying the development of the positive list is to remove the need for many companies each to have to produce similar evidence of traditional use and safety where this has already been clearly accepted. There will be an agreed list of herbal substances accompanied by the therapeutic indication, specified strength, route of administration and any relevant safety information. An applicant seeking to register a product containing a substance on the list in the form and for the indications as specified on the list could then refer to this list rather than have to demonstrate traditional use and safety. The applicant would still need to demonstrate quality.[21]

- **Inventory of Herbal Substances for Assessment**.[22] This list shows the status (as of January 2008) of all herbal substances that have been prioritized for the development of a

[20] Gry J, Hallas-Møller T, Pedersen E, Pilegaard K, Strube M. *Rubus fruticosus* L. In: *Drogelisten: Vurdering af planter, svampe og dele heraf anvendt i kosttilskud og urtete*. København: Fødevaredirektoratet. 2000. Available at: http://www.dfvf.dk/Admin/Public/Download.aspx?file=files/filer/publikationer/drogeliste/rapport.pdf.

[21] Medicines and Healthcare products Regulatory Agency (MHRA). Frequently asked questions: What is the role of the positive list? London: MHRA. 2008.

[22] European Medicines Agency (EMEA) Committee on Herbal Medicinal Products (HMPC). *Inventory of Herbal Substances for Assessment.* London: European Medicines Agency HMPC. 10 January 2008. Available at: http://www.emea.europa.eu/pdfs/human/hmpc/49407907en.pdf

Community Herbal (therapeutic) Monograph. Available at: http://www.emea.europa.eu/pdfs/human/hmpc/49407907en.pdf

***United Kingdom*:** The Medicines and Healthcare products Regulatory Agency (MHRA) maintains several lists which are available on-line.

- **List A:**[23] Consolidated List of Substances which are present in Prescription Only Medicines (POM), with exemptions for Pharmacy Sale or Supply (P). Available at: http://www.mhra.gov.uk/home/groups/pl-a/documents/websiteresources/con009484.pdf

- **List B:**[24] Consolidated List of Substances which are present in Authorized Medicines for General Sale (General Sales List (GSL) Medicines). Available at: http://www.mhra.gov.uk/home/groups/pl-a/documents/websiteresources/con009485.pdf

- **List of Herbal Ingredients and their Reported Uses.**[25] This is a listing of botanical ingredients which are present in aromatherapy products, cosmetics, foods, and medicines in the United Kingdom. Available at: http://www.mhra.gov.uk/home/groups/is-pol/documents/websiteresources/con009277.pdf

- **List of Herbal Ingredients which are Prohibited or Restricted in Medicines** in the United Kingdom.[26] Available at: http://www.mhra.gov.uk/home/groups/es-herbal/documents/websiteresources/con009294.pdf

***United States of America*:** Whether a natural ingredient may be present in a product is dependent on the regulatory framework for the finished product, i.e. cosmetic, dietary supplement, drug or food product. Some information is available on-line to help determine the status and framework for natural.

- **Cosmetic ingredients:** For natural ingredients used in cosmetic products, the FDA provides guidance on basic requirements for color additives and cosmetics at: http://www.cfsan.fda.gov/~dms/cos-col.html. The list of ingredients that are prohibited and restricted for use in cosmetics is available at: http://www.cfsan.fda.gov/~dms/cos-210.html.

- **Dietary Supplement ingredients:** For a natural ingredient to be permitted for use in a dietary supplement product there must be documentary evidence that such species was marketed in the United States prior to 15 October 1994. It is also the responsibility of finished product manufacturers and distributors to ensure that the particular natural ingredients that they use as components of dietary supplement products are safe for human consumption, do not contain contaminants, are properly identified on the label, are legally marketed, and conform to all governing regulations. Although the FDA does not endorse the American Herbal Products Associations' (AHPA) publication "*Herbs of Commerce*," 2nd

[23] Medicines and Healthcare Products Regulatory Agency (MHRA). List A: *Consolidated List of Substances which are present in Prescription Only Medicines (POM), with exemptions for Pharmacy Sale or Supply (P).* London: MHRA. March 2008. Available at: http://www.mhra.gov.uk/home/groups/pl-a/documents/websiteresources/con009484.pdf

[24] Medicines and Healthcare Products Regulatory Agency (MHRA). *List B: Consolidated List of Substances which are present in Authorized Medicines for General Sale*. London: MHRA. December 2007. Available at: http://www.mhra.gov.uk/home/groups/pl-a/documents/websiteresources/con009485.pdf

[25] Medicines and Healthcare Products Regulatory Agency (MHRA). *List of Herbal Ingredients and their Reported Uses*. London: MHRA. 31 March 2005. Available at: http://www.mhra.gov.uk/home/groups/is-pol/documents/websiteresources/con009277.pdf

[26] Medicines and Healthcare Products Regulatory Agency (MHRA). *List of Herbal Ingredients which are Prohibited or Restricted in Medicines*. London: MHRA. 28 October 2005. Available at: http://www.mhra.gov.uk/home/groups/es-herbal/documents/websiteresources/con009294.pdf

Edition (2000),[27] for the purpose of determining whether a botanical was in U.S. commerce prior to 1994, the Herbs of Commerce does provide a very good indication that the ingredient was likely in commerce prior to 1994. If a natural ingredient was not marketed in the USA prior to 1994, it is classified as New Dietary Ingredient (NDI) and is subject to the 1997 regulation "Premarket Notification for a New Dietary Ingredient": http://www.cfsan.fda.gov/~lrd/fr97923e.html.[28]

- **Drug ingredients:** For a natural ingredient to be permitted for use in an over-the-counter (OTC) or prescription drug product, the ingredient, if the active pharmaceutical ingredient, must be classified by the FDA as Generally Recognized as Safe and Effective (GRASE) and included in a positive therapeutic monograph published in Title 21 of the Code of Federal Regulations (21 CFR) which are available on-line.[29] Some ingredients, however, are not yet entered in the current edition of the CFR and can be found listed in a tentative final monograph. These monographs are posted on-line at the "Rulemaking History for Non-prescription Products: Drug Category List," available at: http://www.fda.gov/cder/otcmonographs/rulemaking_index.htm. Natural ingredients that are classified as GRASE active ingredients in the CFR monographs (e.g. Castor Oil, Karaya Gum, Psyllium Husk, Senna Extract, among others) have corresponding quality standards monographs published in the United States Pharmacopeia (USP).[30]

- **Food ingredients:** For a natural ingredient to be permitted for use in a food product in the United States it must be classified by the U.S. Food and Drug Administration (FDA) as Generally Recognized as Safe (GRAS) for use in foods. The FDA Center for Food Safety and Applied Nutrition (CFSAN) maintains a food additive database known as the "*Everything Added to Food in the United States* (EAFUS)," available on-line at: http://vm.cfsan.fda.gov/~dms/eafus.html. The EAFUS list of substances contains ingredients added directly to food that FDA has either approved as food additives or listed or affirmed as GRAS. Nevertheless, it contains only a partial list of all food ingredients that may in fact be lawfully added to food, because under federal law some ingredients may be added to food under a GRAS determination made independently from the FDA. The list contains many, but not all, of the substances subject to independent GRAS determinations. For information about the GRAS notification program please consult the Inventory of GRAS Notifications at: http://www.cfsan.fda.gov/~rdb/opa-gras.html. Additional information on the status of Food and Color Additives can be obtained from the Food Additive Status List at: http://www.cfsan.fda.gov/~dms/opa-appa.html or the Color Additive Status List (formerly called Appendix A of the Investigations Operations Manual), available at: http://www.cfsan.fda.gov/~dms/opa-appc.html.

b. Quality Standards & Limits in Selected Destination Markets

Australia / New Zealand

Australia and New Zealand had proposed to establish an Australia New Zealand Therapeutic Products Authority (ANZTPA) and joint regulatory scheme. As of 16 July 2007, the project has been postponed but may resume in the future. Until such time as there is agreement to resume the

[27] McGuffin M, Kartesz JT, Leung AY, Tucker AO (eds.). *American Herbal Products Association's Herbs of Commerce*, 2nd Edition. Silver Spring MD: American Herbal Products Association. 2000.

[28] Food and Drug Administration. Premarket Notification for a New Dietary Ingredient. Final Rule. *Federal Register*. 23 September 1997;62(184)49886-49892. Available at: http://www.cfsan.fda.gov/~lrd/fr97923e.html.

[29] Food and Drug Administration. Title 21 Food and Drugs. In: *Code of Federal Regulations*. Washington, DC: National Archives and Records Administration. 2008. Available at: http://www.gpoaccess.gov/cfr/index.html

[30] United States Pharmacopeia Convention. *United States Pharmacopeia – National Formulary* (USP 31-NF 26). Rockville, MD: United States Pharmacopeia Convention. 2008.

process to establish ANZTPA and the joint regulatory scheme, stakeholders are advised to refer instead to the separate national authorities, the Australian Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

The Australian Regulatory Guidelines for Complementary Medicines (ARGCM),[31] which are available on-line at http://www.tga.gov.au/docs/html/argcm.htm have been developed to:

- provide information to help sponsors of complementary medicines to meet their obligations under therapeutic goods legislation;
- help ensure that applications to the Therapeutic Goods Administration (TGA) relating to complementary medicines uniformly meet all essential regulatory requirements so that applications may be processed successfully within minimum timeframes; and
- enhance clarity and transparency of processes leading to the Registration and Listing of complementary medicines in the Australian Register of Therapeutic Goods (ARTG).

The *British Pharmacopoeia* (BP) is the official standard for regulatory purposes in Australia. It establishes a number of general standards for medicines and specific standards for some active ingredients and finished products. The BP has regulatory force in Australia, unless there is a specific Therapeutic Goods Order (TGO) that overrides BP requirements. For natural medicinal products (that are regulated as complementary medicines in Australia), manufacturers should refer to the specific herbal material monographs in the current BP for the range of tests usually employed. The BP 2008 contains many new and revised monographs (including herbal monographs), which set out the mandatory standards for active substances, excipients and formulated preparations, together with General Notices, Appendices (test methods, reagents, etc) and Reference Spectra. The complete BP 2008 Index is available at: http://www.pharmacopoeia.co.uk/2007/pdfs/BP%202008%20Index.pdf. BP 2008 Veterinary Index is available at: http://www.pharmacopoeia.co.uk/2007/pdfs/BP%202008%20Vet%20Index.pdf.

Where there is a BP monograph, this must be followed for the active ingredients quality standards testing. All identification tests in the monograph must be complied with. In this case an authenticated voucher specimen is not essential. If there is no BP monograph, manufacturers should use the scientific literature (including current editions of other National Pharmacopoeias. National Pharmacopoeias such as the European (PhEur), United States of America (USP), Chinese (PPRC), German (DAB), Indian (IP) and Japanese (JP) etc. The pharmacopoeias must be issued by or endorsed by the relevant government authority. (Note that the word 'pharmacopoeia' in the title of a text does not mean it is a government-endorsed text). Sponsors should contact the Australian Office of Complementary Medicines (OCM) if they are unsure as to the suitability of a pharmacopoeia.

The British Pharmacopoeia Commission is presently directing resources towards the development of monographs for some Ayurvedic and Homoeopathic medicines. Ayurvedic monographs targeted for inclusion in the BP 2009 include *Terminalia arjuna*, *Terminalia chebula*, *Terminalia belerica* and *Withania somnifera.*[32]

Canada

[31] Australian Government Therapeutic Goods Administration (TGA). Australian Regulatory Guidelines for Complementary Medicines (ARGCM). Woden: Australia. 2006. Available at: http://www.tga.gov.au/docs/html/argcm.htm

[32] British Pharmacopoeial Commission. Summary Minutes: Expert Advisory Group: Herbal and Complementary Medicines. London: BPC. 5 June 2007. Available at: http://www.mhra.gov.uk/home/groups/is-bp/documents/committeedocument/con2033239.pdf

The Health Canada Natural Health Products Directorate (NHPD) guidance document "*Evidence for Quality of Finished Natural Health Prod*uct,"[33] available on-line at: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/eq-paq-eng.pdf, provides applicants (manufacturers, packagers, labelers, importers, distributors) with the details necessary to comply with the *Natural Health Products Regulations* at the time of submitting the product license application (PLA) with respect to the manufacture and quality requirements of natural health products (NHPs).

The procedures outlined in the NHPD guidance document apply to the quality assessment of all types of pre-market submissions of NHPs that fall under the purview of the Regulations. This document should be read in conjunction with other NHPD guidance documents such as the *Product Licensing Guidance Document*, *Good Manufacturing Practices Guidance Document*, *Evidence for Safety and Efficacy of Finished Natural Health Products Guidance Document* and *Evidence for Homeopathic Medicines Guidance Document* to ensure the product requirements are comprehensively applied and documented in a product license application. Further, reference has also been made to a number of national and international standards, such as the *United States Pharmacopoeia* (USP), *European Pharmacopoeia* (PhEur), and *Therapeutic Goods Administration of Australia* (TGA) where it is recommended that these standards be applied. This guidance is intended for use by applicants, as well as by scientific reviewers/assessment officers and submission coordinators within NHPD and other stakeholders.

The NHPs available in Canada can be broadly classified into: (1) Single ingredient products; and (2) Multi-ingredient products. The general quality requirements are outlined in Section 2 of the NHPD guidance document. Specific quality requirements of products containing particular items from Schedule 1 of the Regulations have also been included where they differ from the general requirements. A multi-ingredient product is defined as a finished product containing more than one item from Schedule 1 of the Regulations (Appendix 2). Section 3 of the NHPD guidance document outlines specific test requirements for the finished natural health product in various dosage forms. Section 4 of the guidance document outlines the quality requirements for homeopathic medicines.

Table 11 shows a list of all NHPD guidance documents that are available on-line and may relate to legislative quality requirements

Table 11: NHPD Guidance Documents on Quality Requirements

Quality	
Product Licensing Guidance Document	http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/license-licence_guide-eng.pdf
Evidence for Quality of Finished Natural Health Products Guidance Document	http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/eq-paq-eng.pdf
Evidence for Homeopathic Medicines Guidance Document	http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/ehmg-nprh-eng.pdf
Master File Procedures Guidance Document	http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/eq-paq-eng.pdf
Post-Licensing Guidance Document	http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/plgd_psdldr_V1.0-eng.pdf
Site Licensing Guidance Document	http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/slgd-drle-eng.pdf
Good Manufacturing Practices Guidance Document	http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/gmp-bpf-eng.pdf

[33] Health Canada Natural Health Products Directorate. *Evidence for Quality of Finished Natural Health Products*, Version 2. Ottawa, Ontario: Health Canada Natural Health Products Directorate. June 2007. Available at: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/eq-paq-eng.pdf

European Union Member States

For natural medicinal products exported to the EU, it is essential to understand the EMEA's "*Guideline on Specifications: Test Procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations, and Herbal Medicinal Products / Traditional Herbal Medicinal Products*," which is available on-line at: http://www.emea.europa.eu/pdfs/human/qwp/282000en.pdf.[34]

EMEA quality guidance documents relevant for herbal medicinal products are listed below in Table 12 and are also available on-line at: http://www.emea.europa.eu/htms/human/hmpc/hmpcguide.htm.

Table 12: EMEA Guidance Documents on Quality Requirements

Quality	
EMEA/HMPC/253629/07	Reflection paper on Markers used for quantitative and qualitative analysis of Herbal Medicinal Products and traditional Herbal Medicinal Products
EMEA/HMPC/CHMP/CVMP/287539/05	Guideline on Declaration of Herbal Substances and Herbal Preparations in Herbal Medicinal Products/Traditional Herbal Medicinal Products in the SPC
EMEA/HMPC/230249/2006	Overview of comments received during the consultation period for Guideline on Declaration of Herbal Substances and Herbal Preparations in Herbal Medicinal Products/Traditional Herbal Medicinal Products in the SPC
EMEA/HMPC/CHMP/CVMP/214869/06	Guideline on Quality of Combination Herbal Medicinal Products / Traditional Herbal Medicinal Products (Deadline for comments 31 Oct 2007)
EMEA/HMPC/125562/06	Reflection Paper on the use of Fumigants (Adopted October 2006)
EMEA/HMPC/CHMP/CVMP/58222/06	Concept Paper on Quality of Combination Herbal Medicinal Products/Traditional Herbal Medicinal Products (Released for consultation June 2006)
EMEA/HMPC/CHMP/CVMP/287539/05	Draft Guideline on Declaration of Herbal Substances and Herbal Preparations in Herbal Medicinal Products/Traditional Herbal Medicinal Products in the SPC (Released for consultation June 2006)
EMEA/HMPC/246816/05	Guideline on Good Agricultural and Collection Practice for starting materials of Herbal Origin (Adopted January 2006)
EMEA/HMPC/11138/06	Overview of comments on the GACP Guideline
CPMP/QWP/2819/00 *Rev 1*	Guideline on Quality of Herbal Medicinal Products/Traditional Herbal Medicinal Products
EMEA/CHMP/CVMP/QWP/40683/06	Overview of comments on the Draft Guideline Quality of Herbal Medicinal Products/Traditional Herbal Medicinal Products
CPMP/QWP/2820/00 *Rev 1*	Guideline on specifications: Test procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Products / Traditional Herbal Medicinal Products
EMEA/CHMP/CVMP/QWP/40728/06	Overview of comments on the Draft Guideline on Test procedures and Acceptance

Medicinal ingredients used in herbal medicinal products need to have written specifications for test and release that are in conformance with an official pharmacopoeial quality control monograph. The European Pharmacopoeia (PhEur) contains quality standards monograph for these natural ingredients. Additionally, there are natural ingredients quality standards monographs still official in the various national pharmacopoeias of EU Member States. After each monograph is harmonized between the pharmacopoeial commissions of the various EU Member States, the monograph is

[34]European Medicines Agency (EMEA) Committee for Medicinal Products for Human Use (CHMP) Committee for Medicinal Products for Veterinary Use (CVMP). *Guideline on Specifications: Test Procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations, and Herbal Medicinal Products / Traditional Herbal Medicinal Products*. London, UK: EMEA CHMP CVMP. March 2006. Available at: http://www.emea.europa.eu/pdfs/human/qwp/282000en.pdf.

retired from the national pharmacopoeias as the new harmonized monograph is entered into the PhEur. Therefore, not all relevant monographs for natural ingredients are found in the PhEur and in some cases the required quality standards for an imported natural ingredient will be based on a monograph published in one of the national pharmacopoeias, for example the British Pharmacopoeia (BP), French Pharmacopoeia (PhFr), or German Pharmacopoeia (DAB), among many others.

See Appendix VII for a list of natural ingredients with quality standards monographs published in the PhEur.

United States of America

The quality standards that are applied to natural ingredients and finished products in the United States of America (USA) are dependent on the regulatory framework for the product, i.e. whether it is a botanical drug product, herbal dietary supplement product, natural cosmetic product, or natural food product. Official monographs published in *The United States Pharmacopeia – National Formulary* (USP-NF)[35] designate that the article has an FDA-approved or USP-accepted use. USP-NF botanical monographs are FDA-enforceable and include descriptions, requirements, tests, analytical procedures, and acceptance criteria. The USP-NF includes three sections:

1. USP monographs provide standards for drug substances including certain medicinal herbs and extracts;
2. USP-DS monographs provide standards for dietary supplement ingredients; and
3. USP-NF monographs provide standards for excipient ingredients.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines the term "official compendium" as the official *USP*, the official *NF*, the official *Homeopathic Pharmacopeia of the United States*, or any supplement to them. FDA may enforce compliance with official standards in *USP–NF* under the adulteration and misbranding provisions of the FD&C Act. These provisions extend broad authority to FDA to prevent entry to or remove designated products from the United States market based on standards in the *USP–NF*. The identity of an official article, as expressed by its name, is established if it conforms in all respects to the requirements of its monograph and other relevant portions of the compendia. The FD&C Act stipulates that an article may differ in strength, quality, or purity if the difference is stated on the article's label. Official preparations (a drug product, a dietary supplement including nutritional supplements, or a finished device) may contain additional suitable ingredients.[36]

Dietary Supplements—The Dietary Supplement Health and Education Act of 1994 (DSHEA) amendments to the FD&C Act name *USP* and *NF* as the official compendia for dietary supplements. The amendments also provide that a dietary supplement may be deemed misbranded if it is covered by a monograph in an official compendium, is represented as conforming to this monograph, but fails to conform. The dietary supplement must be represented as conforming to a *USP–NF* dietary supplement monograph in order for the compendial standards to apply. This contrasts with pharmaceutical products, wherein conformance to the monograph is mandatory whether or not the product claims to conform.[37]

[35] United States Pharmacopeial Convention. *The United States Pharmacopeia – The National Formulary* (USP-NF). Twinbrook Parkway, MD: United States Pharmacopeial Convention. 2008.
[36] United States Pharmacopeial Convention. *The United States Pharmacopeia – The National Formulary* (USP-NF). Twinbrook Parkway, MD: United States Pharmacopeial Convention. 2008.
[37] United States Pharmacopeial Convention. *The United States Pharmacopeia – The National Formulary* (USP-NF). Twinbrook Parkway, MD: United States Pharmacopeial Convention. 2008.

Additionally, the FDA has clarified in its "*Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements*,"[38] that dietary supplements need not conform to pharmaceutical quality standards but can be composed of food-grade ingredients. And for the purpose of setting specifications including maximum allowable limits for contaminants, certain food ingredient monographs can be incorporated by industry. FDA states: "We do not have a ``zero tolerance" policy for such unavoidable contaminants but we have issued some regulations and guidance to address certain common contaminants. We also have issued a booklet entitled ``*Action Levels For Poisonous or Deleterious Substances in Human Food and Animal Feed.*"[39] The booklet is a useful resource for manufacturers who seek information about common contaminants that may adulterate a dietary supplement product or lead to adulteration. Another resource is the Foods Chemical Codex (FCC), which includes monographs on many substances, such as salts that are used as sources of minerals used in both dietary supplements and conventional food. These monographs include limits on common contaminants, such as lead or other heavy metals. In addition, the regulations in 21 CFR Part 109 provide information about certain contaminants." The Food Chemicals Codex (FCC)[40] is a compendium of internationally recognized standards for purity and identity of food–grade substances. Published since 1966, FCC allows manufacturers of food, food chemicals, and food additives to comply with standards that have been created and vetted by a highly rigorous and transparent scientific process. The United States Pharmacopeia (USP) acquired FCC from the Institute of Medicine in 2006, with the goal of providing full support for the continuing revision and update of the compendium.

Drugs—USP's goal is to have substance and preparation (product) monographs in *USP–NF* for all FDA-approved drugs. USP also develops monographs for therapeutic products not approved by FDA, e.g., pre-1938 drugs, dietary supplements, and compounded preparations. Although submission of information needed to develop a monograph by the Council of Experts is voluntary, compliance with a *USP–NF* monograph, if available, is mandatory.[41]

Quality requirements in the USA are described in the GMPs for each product group (cosmetics, dietary supplement, foods, or drugs). Table 13 provides the links to the various GMPs where quality requirements can be viewed. See also Appendix VII for a list of natural ingredients that have quality standards monographs published in the USP-NF.

Table 13: FDA Guidance and Regulations on Quality Requirements

Quality	
Cosmetic GMP Guidelines	http://www.cfsan.fda.gov/~dms/cos-gmp.html
21 CFR 110: Current GMP in Manufacturing, Packing, or Holding Human Food	http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr110_07.html
21 CFR Part 111: Current GMP in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements	http://www.cfsan.fda.gov/~lrd/fr07625a.html
21 CFR 210: Current GMP for Finished Pharmaceuticals	http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr211_07.html

[38] United States Food and Drug Administration. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements. *Federal Register*. 25 June 2007;72(121):34751-34958. Available at: http://www.cfsan.fda.gov/~lrd/fr07625a.html

[39] United States Food and Drug Administration. Action Levels For Poisonous Or Deleterious Substances In Human Food And Animal Feed. Washington, DC: Industry Activities Staff, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration. August 2000. Available at: http://www.cfsan.fda.gov/~lrd/fdaact.html

[40] *Food Chemicals Codex*, 6th edition. Twinbrook Parkway, MD: United States Pharmacopeial Convention. 2008.

[41] United States Pharmacopeial Convention. *The United States Pharmacopeia – The National Formulary* (USP-NF). Twinbrook Parkway, MD: United States Pharmacopeial Convention. 2008.

c. Legislative Marketing Authorization Requirements

Different regulations and requirements are in place cosmetics, dietary supplements, foods, and pharmaceuticals. It is conceivable that a single natural ingredient could be utilized in all four of these product categories, therefore an awareness of legislative requirements for each is useful for the Indian exporter of natural medicinal products. As an example, Table 14 provides a comparison of the basic pre-marketing submission (or notification) requirements for typical (oral-ingestion) natural medicinal products in four different foreign markets; Australia, Canada, EU, and USA.

Table 14: Market Access: Comparison of basic pre-marketing submission requirements for registration of herbal products in Australia, Canada, EU, and USA

Submission Packet Contents	AUSTRALIA Complementary Medicine Product (CMP)	CANADA Natural Health Product (NHP)	EU Traditional Herbal Medicinal Product (THMP)	USA (Herbal) Dietary Supplement Product (DSP)
Application Forms	CMP registration application form & administration info	NHP license application form	THMP registration application form	DSP notification letter within 30 days
Index	Index of contents	Index of contents	Index of contents	No
Overview	Overview report	No	No	Substantiation file should contain an interpretative summary
Fees	Application fee; Processing fee; Annual charge; Evaluation fee for assessing information or documentation relating to the safety; GMP audit fee; Manufacturer license fee	No	THMP registration fee; THMPD registration fee; Manufacturer license fee; Inspection fee Annual fee	No
Labeling	Artwork ready for printing or draft labeling examples and Consumer Medicine Information (CIM) document	Proposed label text in WORD document or mock-up of label	Mock-up of outer label and the Patient Information Leaflet (PIL)	Notification letter should include the text of the claim statement that is being made; product name & ingredients
Readability Test	No	No	PIL readability test results	No
Braille Labeling	No	No	Yes	No
Summary of Product Characteristics	No	No	Yes	No
Efficacy Evidence	Evidence of efficacy expert report CTD format not required but encouraged	Evidence Summary Report NHP format	Evidence of traditional use expert report CTD format	Substantiation File must contain expert evidence report
Safety Evidence	Evidence of safety expert report CTD format not required but encouraged	Safety Summary Report NHP format	Evidence of safety expert report CTD format	Substantiation File must contain product safety evidence
References	Full copies of all relevant references (no abstracts)	Full copies of all relevant references (no abstracts)	Bibliography of Traditional Use Evidence Sources	Substantiation File should include list of references
Quality Evidence	Evidence of quality expert report	Quality Summary Report	Quality dossier CTD format	Substantiation file must include an

	CTD format not required by encouraged	NHP format		assurance of GMP compliance
Quality Standards	Pharmacopoeial Grade (BP)	Pharmacopoeial Grade (BP, PhEur or USP)	Pharmacopoeial Grade (PhEur)	Food Grade (FCC)
GMP	Products manufactured under Australian GMPs for medicinal products	Products manufactured under NHP GMPs in licensed site(s)	Products manufactured under pharmaceutical GMPs in licensed site(s)	Products manufactured under DSP GMPs in registered sites
Site Licenses	Manufacturer site license, GMP license	Manufacturer, Packager, Labeler, Importer, Distributor, Contract Laboratory	Manufacturer's and Importer Authorization Wholesale dealer's license; Contract Laboratory	No site license required
Qualifications	Expert reports must be prepared by a person with appropriate qualifications and experience	Expert reports must be prepared by a person with appropriate qualifications and experience	CVs of experts who prepared the evidence reports; CVs of Qualified Person (QP) and Qualified Pharmacovigilance Person (QPPV)	Qualifications of the experts who prepare and review the substantiation file should be included in the file
Other Claim Evidence	N/A	Copies of certifications (FairTrade, Kosher, Organic)	Ecological and Social Certification claims not permitted on medicine labels	Not required with FDA notification letter

The specific product licensing or registration requirements for each country are generally available on-line. For example, Table 15 shows the Canadian NHPD product license application requirements sorted by application type.

Table 15: NHPD Product License Application Requirements

Requirements	**Application Type**								
	Compendial	**Traditional Claim**		**Non-traditional Claim**	**Homeopathic**		**TPD Category IV/**	**Homeopathic DIN**	**Transitional DIN**
	(NHPD Monograph)	**Regular stream**	**Pharmacopoeial stream**		**Specific Recommended use**	**Non-specific Recommended Use**	**Labelling Standard**		
Product License Application form	✓	✓	✓	✓	✓	✓	✓	✓	✓
NHPD Label text	✓	✓	✓	✓	✓	✓	✓	✓A	✓A
Evidence Summary Report	Not applicable	✓	Not applicable	✓	Not applicable	Not applicable	Not Applicable	Not Applicable	Not applicable
References	B	C	H	D	E, F	F	G	Not applicable	Not applicable
Safety Summary Report	Not applicable	✓	✓	✓	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Animal Tissue form (if applicable)	✓	✓	✓	✓	✓	✓	✓	✓	✓
Quality Summary Report (including finished product specifications)	Not applicable	✓	✓	✓	✓	✓	✓	✓	✓

A - Also a copy of the most recent version of the label approved by the Therapeutic Products Directorate.
B - Attest to NHPD Monograph from the *Compendium of Monographs*.
C - Minimum of two traditional references (e.g. text books). Photocopy the relevant pages, including cover page

D - Minimum of two pieces of evidence to support product (e.g. full text journal article). Note that abstracts will not be accepted as key references; however they may be included in addition.
E - Photocopied and underlined evidence from at least one homeopathic reference to support the recommended use or purpose of each medicinal ingredient.
F - For each medicinal ingredient, a photocopy of the monograph from the pharmacopoeia to which the applicant attests.
G - Reference to the TPD Labelling Standard or Category IV monograph in cover letter
H - Only one approved pharmacopoeial reference (e.g. *Pharmacopoeia of the People's Republic of China*, or *State Drug Standard*) is required. Reference must meet criteria outlined in Appendix 7 of the *Evidence for Safety and Efficacy of Finished Natural Health Products* guidance document

A summary of the basic differences in legislative market access requirements for foreign manufacturers of natural products marketed in the USA is provided in Table 16 sorted by the category of product (dietary supplement product, food product, and OTC drug product).

Table 16: Market Access: Comparison of basic requirements in the USA for natural products that are foods, supplements, or drugs

DIETARY SUPPLEMENT PRODUCT	FOOD PRODUCT	OTC DRUG PROUDCT
GMP: must be manufactured under DS GMP in a registered food facility	GMP: must be manufactured under food GMP in a registered food facility	GMP: manufactured under pharmaceutical GMP in a registered drug establishment
Foreign dietary supplement facilities must be registered as per the Bioterrorism Act	Foreign food facilities must be registered as per the Bioterrorism Act	Foreign drug establishments must submit Form FDA-2656 (Registration of Drug Establishment) to FDA
Ingredients must have been in U.S. commerce prior to 1994 (otherwise New Dietary Ingredient Notification); can be food-grade quality	Ingredients must be classified by FDA as Generally Recognized as Safe (GRAS) (otherwise GRAS petition); can be food-grade quality	Active ingredients must be classified as GRASE in a current CFR monograph; must be pharmaceutical-grade quality
Notification Letter must be mailed to FDA within 30 days of marketing	No product notification or registration required	Drug Product Listing (Form FDA-2657) must be mailed to FDA; FDA assigns NDC number for each drug
Substantiation File (evidence of quality, safety and efficacy) must be prepared in advance of marketing	No substantiation file required	No substantiation file required

CHAPTER 3 – TRADE PATTERNS AND EXPORT POTENTIAL

A. Export Channels

During interviews on first mission in India, some enterprises provided typical export flows for their exported medicinal natural products. For example, one Indian enterprise operating in a Special Export Zone (SEZ) provided an example of their U.S. trade channels. They export to a single exclusive master distributor who in turn re-distributes into four different channels:

Manufacturing Facility in SEZ ► Exclusive / Master Distributor in the USA ►

1) Wholesale Distribution Companies servicing retail stores ► Retail Stores
2) Wholesale Distribution Companies servicing practitioners ► Practitioners (Doctors of Chiropractic, Naturopathy, and Osteopathy, among others)
3) Mail Order Companies servicing consumers
4) Own Company Outlets (health stores, nutritional consultants (Vaidyas) and spas);

Another interviewee stated that they do not export directly at this time but their authorized dealers are exporting their products to countries including Malaysia, UAE, and USA. This product manufacturer desires to eventually export and market its products directly to selected foreign markets. They are also aware that there may be some risks involved with the present situation of products being exported only via secondary distributors. In the current scenario the manufacturer is selling to about 2,000 franchised retail pharmacies in India. Some of these franchises are exporting products directly to clinics and doctors in foreign markets including the UK. The manufacturer may not even know how many Indian retail pharmacies are exporting its products and under what conditions. It is also possible that some pharmacies may have notified or registered the manufacturer's products in certain foreign countries without the manufacturer's knowledge. In any case, neither the Indian retail pharmacy exporter nor the foreign clinic or physician importer will have the capacity or resources for proper legal notification and registration of these medicinal products. Therefore, the product manufacturer is considering how to take control over its current export business which is presently occurring outside of their control.

B. Indian Export Promotion Structure

Presentations made at the Hi-MAPs Conference 2008, organized by ASSOCHAM and NMPB, clarified the India export promotion structure for natural medicinal products under three separate export promotion organizations as shown in Table 17:

Table 17: Indian Export Promotion Organizations and Product Groups

Name of Council	Product Categories
CHEMEXCIL Basic Chemicals, Pharmaceuticals & Cosmetics Export Promotion Council	agarbattis (herbal incense sticks), castor oil & derivatives, herbal cosmetics & toiletries, dyes & dye intermediates, chemicals (menthol)
PHARMEXCIL Pharmaceuticals Export Promotion Council	bulk drugs and intermediates, formulations, herbal medicinal products, Ayurvedic, Unani and Homoeopathic medicines, nutraceutical products, biotech and biological products
SHEFEXCIL Shellac and Forest Products Export Promotion Council	dyeing substances (myrobalans), gum resins, lacs, mixtures of odoriferous substances, mucilages, oil cakes, oleoresins and other resins, vegetable saps and herbal extracts

The list of items covered under Minor Forest Produce which are under the purview of SHEFEXCIL and included under the Vishesh Krishi Upaj Yojana scheme is available on-line at: http://www.shellacepc.com/products.html.

C. Indian Export Strategy for Natural Medicinal Products

The "Report of the Sub Group on Research & Industry" of the Steering Committee on AYUSH for the Eleventh Five-Year Plan (2007-2012)[42] have proposed two export-oriented schemes: "Schemes for Development of New Formulations, Technologies, Tools and Practices with Validation of Existing Products and Procedures," and "Scheme to Identify, Promote and Develop "Star product(s) for the International market" and Brand Promotion for the ASU sector – domestically and internationally."

The central objectives of the Schemes for Development of New Formulations, etc, would be to (1) Provide funding for AYUSH Industry / entrepreneurs who are desirous of launching new products and aiding their technical development and validation as per GLP, GCP, GMP and other norms for a world class product dossier; (2) Provide funding for research & development of new products that fall within the classification of nutritional and dietary supplements; and (3) Promote development of technologies, tools, practices and implements to aid the growth of AYUSH/THS practices. The measurable outputs for this Scheme in the 11th plan would be the (1) Development of globally acceptable standardized AYUSH formulations catering to immense global demand for natural products through PPP model; (2) Acceptance of AYUSH products for foreign drug control and food regulatory authorities for marketing and distribution; (3) Rise in exports of products put up for retail sales from the AYUSH sector to Rs 3000 Crore by 2012 from Rs 120 Crore in 2005; and (4) Diagnostic tools and implements for a minimum standard of AYUSH practices in the country. The total outlay for this Scheme for the 11th plan (5 years) is estimated at 50 Crore.

The central objectives of the "Scheme to Identify, Promote and Develop "Star product" are as follows:

1. To identify " star product(s)" from India to the world on the lines of ginseng and develop it for the international market;
2. Establishment of a Export Certification mechanism for accrediting individual Product Dossiers for ease in Registration in foreign countries and guarantee of pre-shipment Quality Assurance;
3. Establishment of a market penetration and assistance fund for promotion of brands in the export market
4. Establishment of a National Fund for creating brand equity in AYUSH mark and TQS for domestic and foreign markets
5. Participation as "AYUSH AROGYA" pavilions in every major health care and natural products expositions in the world
6. To promote bilateral discussions between Health Ministries of foreign countries and India, for automatic acceptance of AYUSH registered products and AYUSH practitioners
7. Promotion of value added exports of medicinal plant portions and herbal extracts

The measurable outputs for this scheme for the 11th plan would be:

1. Emergence of AYUSH products having international standing;
2. Prevention of adverse reports regarding Quality of Ayurvedic formulations in foreign markets;

[42] Government of India Planning Commission. Annexure 3: *Report of the Steering Committee on AYUSH for the Eleventh Five-Year Plan (2007-1012).* New Delhi: Government of India. December 2006.

3. Establishment of a bilateral dialogue between India and health authorities for acceptance of AYUSH products;
4. Promotion of AYUSH brand through awareness campaigns undertaken in major markets for natural products;
5. Facilitation for AYUSH Industry to participate in global trade fairs, expositions and gain insight on global benchmark;
6. Establishment of a network of laboratories as essential technological infrastructures to aid and assist TQS and scientific work in our country;
7. Increase of exports of value added from the sector to Rs 10,000 Crore from the current Rs 1200 Crore;
8. Establishment of an ASU Brand promotion agency and programme in interest of AYUSH sector in India and internationally.

The total outlay for this Scheme for the 11th plan (5 years) is estimated at 300 Crores (260 Crore Govt. + 40 Crores Industry). The specific details of this proposed budget are found on page 50 of Annexure 3 of the Report.

The "Report of the Sub-Group on Medicinal Plants" of the Steering Committee on AYUSH for the Eleventh Five-Year Plan (2007-2012)[43] has identified three export-oriented areas of priority concern that need to be addressed over the 11th Five Year Plan period:

- ***Quality Control and Certification***: That accredited quality assurance and certification mechanism to further the cause of export of botanicals needs to be developed and put in place; "*Lack of quality control, standardization and non-availability of accredited certification mechanism form one of the major reasons for India's meager share in global trade of botanicals. Even for the national trade, the same very factors keep many a potential clients away from the classical formulations. The need for putting in place a quality assurance regime and a certification mechanism need no emphasis. It assumes greater significance in view of the WTO guidelines. Quality assurance and certification mechanisms will be studied and an appropriate system put in place*."
- ***Enabling Legal and Administrative Measures*:** That enabling legal and administrative provisions for cultivation and export of medicinal plants needs to be put in place; "*The medicinal plant sector at present is governed under a multiplicity of rules and guidelines. No wonder that these legal and administrative provisions have failed to regulate the collection, cultivation and marketing medicinal plants. Issues like price harmonization between cultivated and collected medicinal plants and putting in place a cultivation friendly regulatory regime in place for medicinal plants on the restricted list of exports are some of the major areas requiring attention. There is thus a felt need to study all these provisions and evolve national guidelines to promote this sector. Nation-wise policy studies will be initiated and representatives of various stakeholder groups involved in formulating policy guidelines for development of this sector*."
- **Special Medicinal Plant Processing Zones: "***The herbal sector has remained neglected over a long period and needs a kick start to give it developmental push. It is proposed to set up agro-climatic region-wise medicinal plant processing zones (MPPZs) to promote organized collection from wild and cultivation of priority species. These MPPZs will also be provided with facilities for post harvest management, storage, semi-processing, quality checks, packaging and trade. It is intended to gradually reduce the exploitation of the gatherer and the farmer engaged in medicinal plant collection and cultivation and to ensure better returns to him. The MPPZs will, in future, become centres for production and procurement of quality botanicals. With the setting up of the processing facilities it is aimed*

[43] Government of India Planning Commission. Annexure 3: *Report of the Steering Committee on AYUSH for the Eleventh Five-Year Plan (2007-1012).* New Delhi: Government of India. December 2006.

to reverse the present ratio of exports of raw to finished product from 70:30 to 30:70 if not completely eliminate export of raw herbs by the end of 11th plan."

It is also noted that part of the Terms of Reference for the Sub Group on Medicinal Plants was (1) To suggest a plan in collaboration with EXIM Bank and reputed scientific institutes for the preparation of monographs on prioritized medicinal plants to help India to register selected Indian medicinal plants with Food and Drug Administration authorities in importing countries, thus assisting Indian industry to enhance its export and promoting via backward linkages, income and employment for farmers in rural areas; (2) To outline the composition of a representative Task Force and designate effective nodal agencies to take responsibility for implementation of the program; and (3) To advise on budget outlay for this program.

D. Export Markets with Supportive Structure for ASU Products & Services

In a 2004 article from the South Asia Institute,[44] Georg Berkemer asks an important question relevant to identifying export markets with a supportive structure for ASU products and services: "*How does Ayurveda perform in a global environment dominated by economic interests, scientific biomedicine and in which consumers can shop around for treatments? What have the cures advertised in lifestyle magazines in common with Caraka, Susruta and the elder Vagbhata?*" Furthermore, he writes that a new project is being planned under the directorship of Prof. G. Dharampal-Frick in co-operation with Prof. W. Eckart (History of Medicine) that aims to look at how Ayurveda constituent elements have been adapted to the new challenges from a global world. "*It plans to analyze this on the fundamental level of its categories of causality, healing methods, agents and rituals, and spiritual discipline. A comparison with the development of western medical history is necessary in order to understand how Ayurveda is being perceived through the eyes of its western patients, few of whom are familiar with its roots*."

In addition to the specific examples shown below of export markets with a supportive structure for ASU products and services, the Department of AYUSH also maintains a database of active NGOs in foreign countries working for AYUSH Systems, which is available on-line at: http://indianmedicine.nic.in/NGOs_working_abroad_for_propagation_of_AYUSH_Systems.htm

a. Ayurvedic & Naturopathic Physicians Licensure and Regulation:

Australia / New Zealand

According to a 2003 report by the Expert Committee on Complementary Medicines in the Health System,[45] the number and type of healthcare practitioners who supply or provide advice to consumers on complementary medicines is large and varied. The group ranges from complementary healthcare practitioners such as naturopaths, traditional Chinese medicine (TCM) practitioners, and herbalists, to medical practitioners who may or may not provide complementary medicines to patients but need to be aware of the complementary medicines that patients may be using. There are only rough estimates of the size of the complementary healthcare workforce.

In 2003, a workforce survey was undertaken of Western herbalists and naturopaths. It is estimated that there are approximately 1,750 individuals practicing these professions, who account for 1.9 million consultations per year. The Committee has not been able to obtain any other reliable information on the numbers of practitioners in complementary healthcare disciplines. There are

[44] Berkemer G. Ayurveda in a global environment: Proposal for a new project. South Asia Institute Report 2004. 2004. Available at: http://www.sai.uni-heidelberg.de/saireport/2004/pdf/sai_report2004_low_res.pdf.

[45] Expert Committee on Complementary Medicines in the Health System. *Complementary Medicines in the Australian Health System: Report to the Parliamentary Secretary to the Minister for Health and Ageing*. Canberra, ACT: Australian Government. September 2003. Available at: http://www.tga.gov.au/docs/pdf/cmreport.pdf.

essentially two approaches to the regulation of healthcare practitioners: statutory regulation and self-regulation. Co-regulation is a hybrid of these approaches and is on the continuum between statutory regulation and self-regulation. The primary objective of statutory regulation is to ensure that the practice of any form of health care is safe to the public. When mutual recognition legislation was introduced across all States and Territories in the early 1990s, the policy rationale for occupational regulation of the health professions was clarified.

Canada

In Canada, Ayurveda is still an unregulated modality. There are schools for practitioner training and practitioners do work as health consultants but no licensure to practice medicine is available. It is conceivable that Ayurveda could become incorporated into the curriculum of naturopathic schools and therefore it could be within the legal scope of practice for a Naturopathic Doctor (ND) or Doctor of Natural Medicine (DNM) to practice Indian Systems of Medicine in their clinical practice in Canada in the future.

Board of Natural Medicine Doctors and Practitioners North America & Natural Medicine Certification Council: http://www.boardofnaturalmedicine.org

Federation of Naturopathic Physician Licensing Authorities: http://www.fnpla.org

North American Board of Naturopathic Examiners: http://www.nabne.org

European Union

The practice of Ayurvedic medicine is recognized only in some member states of the European Union. For example in Hungary as per governmental decree 40/1997, available at (in Hungarian): http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700040.KOR.

According to the Hungarian Ayurveda Medical Foundation PUO, in 2007 the Foundation accepted an assignment of the Government of India to create the Ayurveda Coordination Center of Europe (ACCE), a web database (at www.ayurveda.hu) to enhance the cooperation and daily contact between the Ayurveda organizations, companies and practitioners working in Europe. The Letter of Assignment to the Hungarian Ayurveda Medical Foundation PUO issued by H.E. Mr. Ranjit Rae, Ambassador of India to Hungary to establish the Ayurveda Coordination Centre of Europe (ACCE) is enclosed as Appendix X. One of the aims and tasks of the ACCE is to establish a central database on the status of Ayurveda in the countries of Europe. This database is in development and available on-line at: http://www.ayurveda.hu/eu.html.

In Britain, practitioners must undertake a three-year BSc, followed by a 1,000-hour internship under an Ayurvedic doctor, in order to be registered with the British Association of Accredited Ayurvedic Practitioners (BAAAP, 47 Nottingham Place London, W1M 3FE Tel 0207 7224 6070).

Malaysia

Five main groups of Traditional and Complementary Medicine (T/CM) are recognized and approved by the Government of Malaysia Traditional and Complementary Medicine Division, Ministry of Health (MoH). The various practices that are being adopted by the local and foreign practitioners can be categorized into 5 main groups, namely:

1. *Traditional Malay Medicine*: Perubatan Herba Tradisional Tempatan, Urutan Tradisional Melayu, Rawatan Patah Tulang, Rawatan Perbidanan, Rawatan Tenaga Batin, Rawatan Sakit Puan, Rawatan Resdung, Rawatan Penyakit Kayap, and Rawatan Pawang.

2. *Traditional Chinese Medicine*: Chinese Physician Practice, Chinese Herbal Medicine, Acupuncture and Moxibustion, Tuinalogy, Acupressure, Chinese Foot Massage, and Cosmetology.
3. *Traditional Indian Medicine*: Ayurveda, Siddha, and Unani.
4. *Complementary Therapies*: Aromatherapy, Chiropractic, Colour Therapy, Colon Hydrotherapy, Crystal Healing, Naturopathy, Psychotherapy, Qigong, Reflexology, Reiki, and Thai Traditional Massage.
5. *Homoeopathy*.

The practitioner body that is recognized by the Government of Malaysia T/CM Division, MoH, that is responsible for Indian Systems of Medicine practitioners is called the *Pertubuhan Perubatan Traditional India Malaysia*.[46]

The Government of Malaysia T/CM Division, MoH, maintains a list of practitioner approvals including practitioners of Indian Systems of Medicine, available on-line at: http://tcm.moh.gov.my/uploads/list_of_practitioners_approved_in_2007.htm.

South Africa

Allied Health Professions Council of South Africa (AHPCSA) is a statutory health body established in terms of the Allied Health Professions Act, 63 of 1982 in order to control all allied health professions, which includes Ayurveda, Chinese Medicine and Acupuncture, Chiropractic, Homoeopathy, Naturopathy, Osteopathy, Phytotherapy, Therapeutic Aromatherapy, Therapeutic Massage Therapy, Therapeutic Reflexology and Unani-Tibb. The AHPCSA includes a Professional Board for Ayurveda, Chinese Medicine and Unani-Tibb (PBACMU) and a Professional Board for Homoeopathy, Naturopathy and Phytotherapy (PBHNP): http://www.ahpcsa.co.za

The AHPCSA maintains a list of practitioners of Ayurvedic medicine including Ayurvedic Practitioners, Ayurvedic Primary Health Care Advisors, Ayurveda Yoga Therapists, Panchakarma Technicians, and Maharishi Practitioners, available at: http://www.ahpcsa.co.za/practitioners.htm

United States of America

The United States of America has no national standard for certifying or training Ayurvedic practitioners, although a few States have approved Ayurvedic schools. Some Ayurvedic professional organizations are collaborating to develop licensing requirements.[47] The licensure of practitioners of naturopathic medicine is possible in several States. It is conceivable that schools of Naturopathic Medicine could incorporate an Ayurvedic curriculum in the future.

California Bureau of Naturopathic Medicine: http://www.naturopathic.ca.gov

Federation of Naturopathic Physician Licensing Authorities: http://www.fnpla.org

North American Board of Naturopathic Examiners: http://www.nabne.org

Oregon Board of Naturopathic Examiners: http://www.obne.state.or.us

[46] Government of Malaysia Traditional and Complementary Medicine Division Ministry of Health. List of Practitioner Bodies Recognized by T/CM Division. In: *Foreign Practitioner Application Guidelines*. Kuala Lumpur, Malaysia: Traditional and Complementary Medicine Division Ministry of Health. May 2006. Available at: http://tcm.moh.gov.my/uploads/list_practitioner_edit.pdf

[47] National Center for Complementary and Alternative Medicine (NCCAM). What is Ayurvedic medicine? June 2007. Available at: http://nccam.nih.gov/health/ayurveda/ayurveda.pdf.

b. Ayurvedic & Naturopathic Physicians Associations:

Australia / New Zealand: Table 18 shows the traditional and complementary medicine practitioner associations that are listed in Schedule 1 of the Australian Therapeutic Goods Regulations.

Table 18: Practitioner Associations Listed in Schedule 1 of Therapeutic Goods Regulations

Column 1 - Item No.	Column 2 - Body
1	Acupuncture Association of Australia
2	Acupuncture Ethics and Standards Organisation
2A	Association of Natural Health Practitioners Limited
3	Association of Traditional Health Practitioners Incorporated
3A	Aust-China Acupuncture and Chinese Medicine Association Inc.
3B	Australasian Federation of Natural Therapists Inc.
4	Australian Acupuncture Association Ltd.
5	Australasian Association of Ayurveda Incorporated
5A	Australian Association of Exercise and Sports Scientists
6	Australian Association of Professional Homoeopaths
7	Australian Committee of Natural Therapies Inc. (SA)
9	Australian Federation of Homoeopaths
9A	Australian Federation of Homoeopaths (Qld.) Inc.
9B	Australian Federation of Homoeopaths (WA) Inc.
10	Australian Natural Therapists Association Ltd
11	Australian Naturopathic Practitioners and Chiropractors Association
11A	Australian Society of Homeopaths Inc
12	Australian Traditional Chinese Herbalists Association (Qld)
13	Australian Traditional Chinese Medicine Association Inc.
14	Australian Traditional Medicine Society
14A	Australian Unani Medicines Society Inc.
15	Chinese Medicine Association Pty Ltd
15A	Chinese Medicine Association of Australia Inc.
16	Complementary Medicine Association
16A	Federation of Chinese Medicine and Acupuncture Societies of Australia
17	Homoeopathic Education and Research Association
17A	International Association of Trichologists
17B	International Christian Association of Natural Therapists Ltd (ICANT)
18	National Herbalists Association of Australia
18A	Naturopathic Physicians Association of Australia Inc.
19	Queensland Naturopathic Association
20	Register of Acupuncture and Traditional Chinese Medicine
21	Society of Natural Therapists and Researchers [SNTR] Inc.
22	Society of Classical Homoeopathy Ltd
23	Traditional Medicine of China Society Australia
24	Society of Chinese Medicine and Acupuncture (Vic) Inc.
25	Naturopathic Practitioners Association Inc.
26	The Acupuncture Association of Australia, New Zealand and Asia
26A	The Alumni Association of Natural Medicine Practitioners Inc.
26AA	The Australian Association of Homotoxicology Incorporated
26B	The Australian Podiatry Association (NSW)

26BA	The Homoeopathic Medicines Associations Inc.
27	The New South Wales Research Association of Traditional Chinese Medicine

There are two Ayurvedic organizations registered as incorporated societies with the Government of New Zealand Companies Office, a business unit of the Ministry of Economic Development. In New Zealand, an incorporated society is a group of at least 15 people who have applied for registration as an incorporated society under the Incorporated Societies Act 1908.

Once registered the incorporated society becomes a separate legal entity distinct from its members. This means that the members are not personally liable for the society's debts, contracts or other obligations. Likewise, members do not have any personal interest in any property or assets owned by the society. An incorporated society will continue in existence as long as it files certain documents with the Registrar of Incorporated Societies, or until its members, or a creditor, decide to bring the society to an end.

The following Ayurvedic organizations are registered with Government of New Zealand with listings and incorporation documents maintained at the Societies and Trusts Online website: http://www.societies.govt.nz/pls/web/dbssiten.main:

- *Australasian Ayurvedic Practitioners Association (New Zealand and Australia) Incorporated*
- *The New Zealand Ayurvedic Association Incorporated*

One Ayurvedic organization was struck from the registry in February 2008:

- *International Council of Ayurvedic Medicine Incorporated*.

The *New Zealand Ayurvedic Association Inc.*, was formed in 2003 to support Ayurveda and Yoga students, schools, suppliers, practitioners and enthusiasts. The emphasis was a democratic structure that gave equal voice to all members, and that recognized training from all backgrounds. The association has since been involved in raising awareness about educational standards that suit the New Zealand and international environment. Some of the main activities of the NZAA include working to further the interests of natural health practitioners and working closely with the *Natural Health Council* to establish standards of education and practice, which will encourage acceptance of Ayurvedic Medicine within the proposed Integrated Medicine model of national health. Website: http://www.ayurveda.org.nz

Both the *Australasian Ayurvedic Practitioners Association* Inc and the *New Zealand Ayurvedic Association Inc* are affiliates of the *New Zealand Charter of Health Practitioners Inc (NZCHP)*. The NZCHP was formed in October 1993 to represent the varied modalities involved in the natural healthcare profession of New Zealand including practitioners of Ayurvedic Medicine. Among other activities, the NZCHP makes submissions and representations to NZ Government Bodies on behalf of all members regarding the Health Practitioners Competence Assurance Bill (HPCA), Proposed Regulations to Create a New Zealand Register of Medical Devices, Inquiry into the proposal to establish a Trans-Tasman agency to regulate therapeutic products. Representation to the Health Select Committee, and Representation to meetings of the Codex Alimentarius Commission. Website: http://www.healthcharter.org.nz

Canada

Ayurvedic Medical Association of Canada: althealth@followme.com

British Columbia Naturopathic Association: http://www.bcna.ca

Canadian Association of Naturopathic Doctors: http://www.naturopathicassoc.ca

Canadian Order of Practitioners of Naturopathy and Naturotherapy: http://www.ocpnn.ca

International Council of Ayurvedic Physicians: http://www.herbalists.on.ca

National Association of Naturopaths: http://www.naturopathie.ca

Ontario Herbalists Association: http://www.herbalists.on.ca

European Union

Association of European Ayurveda Practitioners and Therapists e.V. (VEAT) is made up of qualified medical doctors, traditional healers, and therapists, specialized in Ayurvedic Medicine. Website: http://www.ayurveda-verband.eu

Ayurvéda en France: http://www.ayurveda-france.org

Ayurvedic Practitioners Association (APA) has been established to achieve the following key aims and objectives: (1) To establish Ayurveda as a distinct, credible and relevant system of traditional medicine in the UK; (2**)** To help create a regulatory environment in which the full range of Ayurvedic healthcare modalities can be authentically, safely and effectively practiced; and (3) To empower Ayurvedic practitioners to deliver best practice solutions via a continuous programme of professional development. Website: http://www.apa.uk.com

British Association of Accredited Ayurvedic Practitioners (BAAAP): 47 Nottingham Place London, W1M 3FE Tel 0207 7224 6070).

British Ayurvedic Medical Council: No contact details available.

European Ayurveda Association (EuAA), Website: http://www.euroayurveda.com, has been established to: (1) promote Ayurveda as a traditional holistic medicine system in terms of the WHO definition; (2) develop Educational standards recognized by medical associations, associations for non-medical practitioners, other health organizations (e.g. physiotherapists, masseurs) and government health services; (3) establish quality standards for Ayurvedic products to ensure public safety and lobby for these standards to be accepted by EU regulatory authorities; and (4) support National Ayurveda organizations in Europe.[48]

For the realization of its Purposes, the EuAA supports and promotes the following and takes other measures consistent with the intention of the statutes taking into account European Union law and the national laws of European member states:

- Directives and laws in Europe are being implemented in Member States and at the European Union parliamentary level without sufficient consideration of or communication with the Ayurvedic community. The EuAA will lobby on behalf of the Ayurvedic community and in case of any restrictions imposed upon it.

[48] European Ayurveda Association (EuAA). EuAA Statutes. Bell, Germany: European Ayurveda Association. 12 February 2008. Available at: http://euroayurveda.com/Downloads/Satzung%20EUAA_12.11.07.pdf

- The EuAA supports the fundamental right of free choice of therapy and promotes Ayurveda as a natural, traditional, diagnostic and therapeutic system for the improvement of health and well-being of the individual and of society.
- The EuAA supports the application of Ayurveda in its completeness thus contributing to an optimization of the health systems in the European countries and relieving their health budgets.
- The EuAA recognizes the need to create education standards for Ayurvedic practitioners and therapists to practice safely and competently and will develop curriculum suitable to safeguard the public.
- The EuAA is an umbrella for National Organizations, Institutes, NGO's, NPO´s and other Associations connected to Ayurveda.

European Herbal & Traditional Medicine Practitioners Association **(**EHTPA) was set up in 1994 as an umbrella body for professional associations across Europe wanting to benefit from joint working and strengthening a role of the herbal profession. The EHTPA currently represents practitioners from Ayurveda, Chinese Herbal Medicine, Tibetan Herbal Medicine, Traditional Chinese Medicine and Western Herbal Medicine. Website: http://www.ehpa.eu

General Council and Register of Naturopaths, United Kingdom: http://www.naturopathy.org.uk

Hungarian Ayurveda Medical Foundation PUO, founded in 1996, Budapest, Hungary, coordinator of the Government of India sanctioned project Ayurveda Coordination Centre of Europe (ACCE). Website: http://www.ayurveda.hu. The ACCE database should be utilized to find links to many other relevant European Ayurveda organization, available at: http://www.ayurveda.hu/eu.html,

Unified Register of Herbal Practitioners (URHP), United Kingdom, includes practitioners of Ayurvedic, Western Traditional, Unani Tibb, Traditional Chinese Medicine: http://www.urhp.org

Malaysia

The Malaysia Ministry of Health has classified the practices and cultures of Traditional & Complementary Medicine (T&CM) into 5 main groups, hence the formation of 5 practitioner bodies; Malay, Chinese, Indian, Complementary and Homeopathy in 1999. As a result, representatives from each of these practitioner bodies were elected to assist the Traditional and Complementary Medicine Division, Ministry of Health, and contribute towards the development of T&CM activities. The primary functions of these bodies are to develop criteria and standards of practice and to self-regulate their respective practices and practitioners in accordance with the guidelines set by MOH.

Table 19 shows the list of practitioner bodies recognized by the Government of Malaysia Traditional and Complementary Medicine Division, Ministry of Health.[49] The practitioner body responsible for Indian Systems of Medicine is Pertubuhan Perubatan Traditional India Malaysia.

[49] Government of Malaysia Traditional and Complementary Medicine Division Ministry of Health. List of Practitioner Bodies Recognized by T/CM Division. In: *Foreign Practitioner Application Guidelines*. Kuala Lumpur, Malaysia: Traditional and Complementary Medicine Division Ministry of Health. May 2006. Available at: http://tcm.moh.gov.my/uploads/list_practitioner_edit.pdf

Table 19: List of Practitioner Bodies Recognized by Government of Malaysia T/CM Division

Traditional & /Complementary Medicine Practice	Practitioner bodies and their respective representative	Address / Contact Number
1. Traditional Malay Medicine	Persekutuan Perubatan Tradisional Melayu Malaysia (PUTRAMAS) • Tuan Haji Hamzah Abu • Tabib Syed Mohsin Baroqbah	No ; 25 – 2, Jalan PJU 5/10, PJU 5 Dataran Sunway, Kota Damansara 47810 Petaling Jaya, Selangor Tel : 03-6140 9777 Fax: 03-6140 9778
2. Traditional Chinese Medicine (Choose to register with either one)	Federation of Chinese Physicians and Medicine-Dealers Associations of Malaysia (FCPMDAM) • Mr Tan Kee Huat	106-2 & 107-2, Jalan 1, Pusat Niaga Batu Caves, 68100 Batu Caves. Selangor Darul Ehsan. Tel : 03-6189 5188 Fax: 03-6189 5199 www.fcpmdam.org
	Federation of Chinese Physicians & Acupuncturists Association of Malaysia (FCPAAM) • Mr Ng Poh Kok	780A, Jalan Sentul, 51000 Kuala Lumpur. Tel/ Fax : 03- 4041 8027
	Chinese Physician's Association of Malaysia (MCPA) • Mr Liow Tuck Soon	2, Jalan Hang Jebat, 50150 Kuala Lumpur. Tel : 03-2078 0636 03-2070 3848 Fax: 03-2031 2118
3. Traditional India Medicine	Pertubuhan Perubatan Traditional India Malaysia (PEPTIM) • Dato' Dr. Dorai Raja	d/a Darshan Ayurvedic Centre, No 32, Queen Street, 10200 Penang. Tel: 04-2625875 Fax: 04-2633194
4. Complementary Medicine	The Malaysian Society for Complementary Therapies (MSCT) • Dr Mohamad Ishak Syed Ahmad	Room No 1, 5th Floor, Bangunan Sultan Salahuddin Abdul Aziz Shah, 16, Jalan Utara, 46200 Petaling Jaya. Selangor Darul Ehsan. Tel : 03-7954 4521 Fax: 03-7955 7541 Malacca Office: Tel: 06-2835878 Fax:06-2815344
5. Homeopathy Medicine	Majlis Perubatan Homeopathy Malaysia (MPHM) • Tuan Haji Mohamed Bin Mohd Noor	No 4, Jalan Kemajuan, Desa Rahmat 81200 Tampoi, Johor Bharu. Johor Darul Takzim. Tel: 07-2350251 Fax: 07-2345478

South Africa

National Ayurveda Medical Association of South Africa: rdh@icon.co.za

South African Naturopathy Association: http://www.naturopathy.org.za

South African Registered Yoga Therapy Teachers Association (SARYTA): tulsi@mweb.co.za

South African Tibb Association: Contact details not available.

United States of America

American Association of Naturopathic Physicians: http://www.naturopathic.org

California Association of Ayurvedic Medicine (CAAM) supports the establishment and growth of Ayurveda as an independent healing profession in the state of California. As a non-profit professional organization, CAAM aims to safeguard the quality and integrity of Ayurvedic practice. Furthermore, CAAM serves to bring this ancient healing science into our communities through education. CAAM goals include professional peer support and review and public and legislative education about Ayurveda. The Association's founding members are professional Ayurvedic practitioners, teachers, and students who have joined to work toward these goals. Website: http://www.ayurveda-caam.org

California Naturopathic Doctors Association: http://www.calnd.org

National Ayurvedic Medical Association (NAMA) is a national organization representing the Ayurvedic profession in The United States of America. Its mission is to preserve, protect, improve and promote the philosophy, knowledge, science and practice of Ayurveda for the benefit of humanity. The purpose of the Association is to provide leadership within the Ayurvedic profession and to promote a positive vision for Ayurveda and its holistic approach to health and wellness. We will carry out our mission by creating and implementing a dynamic strategic plan to ensure the professional growth and success of Ayurveda. Website: http://www.ayurveda-nama.org

Oregon Association of Naturopathic Physicians: http://www.oanp.org

c. Schools of Indian Systems of Medicine:

Australia / New Zealand:

Australasian Institute of Ayurvedic Studies (AIAS) was founded in 1999 in Auckland, New Zealand, and offers same Ayurvedic courses both in New Zealand & Australia. AIAS is a Registered Training Organisation delivering nationally recognized qualifications in Australia under the HLT02 Health Training Package and in New Zealand the New Zealand Qualifications Authority (NZQA) approved Courses. Website: http://www.aiasinstitute.com. The NZQA has posted a "*Quality Audit Summary on the Australasian Institute of Ayurvedic Studies*"[50] which concludes the following: "Australasian Institute of Ayurvedic Studies is providing a learning experience that supports high quality learning outcomes. Students are appropriately supported throughout their studies and there is a body of evidence to confirm that students are satisfied with the courses that are offered and that there are appropriate resources available. Despite the requirements of QA Standard One for goals and objectives and their achievement not being met, the organisation is substantially meeting the requirements of QA Standard One."

Equals Institute of Integrated Therapies (EIIT), established in 1991, is an internationally recognized and Registered Training Organisation (registered with the Australian Quality Training Framework). EIIIT offers nationally recognized and industry accredited Ayurvedic training at the Certificate IV

[50] New Zealand Qualifications Authority. *Quality Audit Summary on the Australasian Institute of Ayurvedic Studies*. Wellington, New Zealand: New Zealand Qualifications Authority. November 2007. Available at: http://www.nzqa.govt.nz/nqfdocs/provider-reports/7624.pdf

and Advanced Diploma level. EIIT programs cover: Ayurvedic Nutrition, Ayurvedic Cooking, Kitchen Pharmacy, Herbal Therapy, Pulse Diagnosis, Yoga & Pranayama, Ayurvedic Massage & Aromatherapy, Meditation & Mantra therapy, Chakra and Gem therapy, Vastu Shastra (pre-cursor of Feng Shui), Lifestyle Counseling, Astrology, and Vedic Psychology. Website: http://www.equals.net.au/ayurveda

The College of Natural Therapies (SA) was established in 1976 to set up educational programs and to provide natural therapy and traditional medicine components of Government accredited vocational courses. Post-Graduate and Cograduate Educational programs include acupuncture, Chinese Herbal Medicine, Unani Medicine (Graeco-Arabic Medicine), Naturopathic Science, and Western Herbal Medicine. Website: http://www.traditionalmedicine.net.au/college.htm

Wellpark College of Natural Therapies is a New Zealand Qualifications Authority (NZQA) registered private training establishment. It offers tertiary education in Naturopathy, Herbal Medicine, Massage, Aromatherapy, Ayurvedic Medicine, Yoga and Medical Sciences. The NZQA has conducted a "*Quality Audit Summary on the Wellpark College of Natural Therapies*"[51] but the report is not publically available because the Wellpark College of Natural Therapies has not consented to the publication of this information. Wellpark College Ayurvedic programmes are formally recognized by the NZ government. The Diploma of Ayurvedic Lifestyle Management (1 year) and the Diploma of Ayurvedic Medicine (3 years) are recognized qualifications with the *New Zealand Ayurvedic Association* and the *Australasian Ayurvedic Association*. From 2008, the curriculum will include two pre-eminent teachers from India every year providing an opportunity to develop a relationship with them leading to internships in India. An integral part of the program will be assisting on a Panchakarma retreat each year. There will also be an optional annual internship in India to experience Ayurveda in action in hospitals and teaching centres. The focus of the three-year Diploma will continue on the academic aspect of Ayurveda but students will at the same time be exposed to the lifestyle of successful Ayurveda practitioners. Website: http://www.wellpark.co.nz

Canada

Association of Accredited Naturopathic Medicine Colleges: http://www.aanmc.org

Canadian College of Naturopathic Medicine: http://www.ccnm.edu

Centre for Ayurveda & Indian Systems of Healing (CAISH) Educational & Wellness Centre, Toronto, Ontario, is accredited by: The Examining Board of Natural Medicine Practitioners (EBNMP), The International College of Alternative Medicine (ICAM), and Westbrook University in New Mexico. Website: http://www.caish.ca

European Union

The database of the Ayurveda Coordination Centre of Europe (ACCE) can be utilized for links to Ayurvedic educational institutions throughout European countries. Some of the schools of Ayurveda are listed here below. The database is available at: http://www.ayurveda.hu/eu.html.

College of Ayurveda Middlesex University, United Kingdom, offers a unique programme, delivered jointly by Middlesex University and the College of Ayurveda that provides students who already

[51] New Zealand Qualifications Authority. *Quality Audit Summary on the Wellpark College of Natural Therapies*. Wellington, New Zealand: New Zealand Qualifications Authority. July 2007. Available at: http://www.nzqa.govt.nz/nqfdocs/provider-reports/8341.pdf

have a degree-level qualification in Ayurveda with the advanced knowledge and skills to enable them to practice professionally and independently as practitioners of Ayurvedic medicine. Website: http://www.mdx.ac.uk/PIPupload/PG/PG-Complementary%20Health/MSc%20Ayurvedic%20Medicine/011B390.asp

European Institute of Vedic Studies, United Kingdom: http://www.atreya.com/uk/about/institute

Manipal Ayurvedic University of Europe offers accredited university degree programmes: BSc (Hons) in Ayurveda, BSc (Hons) in Yoga and MBA in Humanistic Management. Website: http://www.ayurvedagb.com/ayurvediccollege/home.htm

Mayur The Ayurvedic University of Europe offers a Bsc (Hons) Ayurveda programme, which provides students with the opportunity to acquire health assessment and diagnostic skills, knowledge of treatments and an ability to appraise their effectiveness in maintaining the health and well being of the individual. MAYUR envisages this degree to be a platform for further education and practice, which would eventually lead to registration as a practitioner of Ayurvedic Medicine by the statutory regulatory body for Herbal Medicine in the UK. Website: http://www.theayurvedicuniversity.co.uk

Malaysia

Malaysia has a *National Policy on Traditional and Complementary Medicine*[52] which includes recommendations for education and training for the clinical practice of Indian Systems of Medicine (Ayurveda, Siddha, and Unani). The Traditional and Complementary Medicine (T/CM) Division of Ministry of Health Malaysia has established T/CM Umbrella Bodies which are national bodies that are registered with the Registrar of Societies, and appointed by the Ministry of Health (MOH) to accredit the curriculum and training institutions, register and self-regulate T/CM practitioners through the compliance of standard codes of practice and conduct of identified modalities. There are five umbrella bodies at present, namely, the Malay, Chinese, Indian, Complementary and Homoeopathy T/CM groups. One of the specific objectives of the National Policy is education and training of practitioners to:

- Ensure all T/CM practitioners undergo a formalized system of education and training.
- Put in place a process for accreditation.
- Ensure modern medicine providers have adequate awareness and knowledge of T/CM to allow for healthy co-existence and mutual understanding with T/CM practitioners.
- Ensure the general public has appropriate and adequate knowledge of T/CM to make informed decisions and choices of T/CM modalities.

To support the objectives of education and training, the following strategy is outlined in the National Policy:

Presently there is no system for formal education and training locally (in Malaysia) and no standardization and accreditation of overseas training programmes resulting in a lack of confidence on T/CM by the general public, especially by modern medicine providers. To ensure quality of education and training in T/CM, the following strategies are suggested:

- Establishment of formalized government and private T/CM training institutions locally by the Ministry of Education, Corporate Bodies, NGOs or T/CM Associations.

[52] Ministry of Health Malaysia Traditional and Complementary Medicine Division. *National Policy on Traditional / Complementary Medicine*. Kuala Lumpur, Malaysia: Ministry of Health Malaysia. 2001. Available at: http://tcm.moh.gov.my/uploads/national_policy_latest.pdf

- Recognition, accreditation and credentialing of T/CM Institutions and practitioners, trained locally and overseas by the National Accreditation Board.
- Encouragement of T/CM twinning training programmes between local and overseas institutions.
- Introduction of Continuing Professional Development as a requirement for practitioners.

There is currently a lack of confidence by medical doctors on T/CM due to the paucity of information on T/CM and inadequate access to scientific evidence in T/CM practices. In order to instill confidence and enhance cooperation and smart partnerships, modern medicine providers should have adequate knowledge of T/CM through:

- Incorporation of relevant T/CM modules into the undergraduate and post-graduate modern medicine medical curriculum and allied health science training programmes in the local training institutions.
- Introduction of T/CM in the Continuous Medical Education programmes of modern medicine practitioners.
- Exchange of visits of model premises of both practices.
- Provision of sponsorships of T/CM training programs with participation from NGOs, T/CM Associations and corporate bodies.
- Creation of incentives for training for sub-specialties with scholarships or special financial education packages.

The increasing utilization of T/CM products and practices by the public are due to the extensive promotion of T/CM products, the holistic nature of many T/CM modalities and the increasing demands for alternatives in healthcare. To enable the public to make informed decisions the following are suggested:

- Greater efforts being made to improve awareness through dissemination of accurate information to the general public on the appropriate use of T/CM.
- Incorporation of information on T/CM as an essential component of the Mass Customized and Personalized Health Information and Education of Telehealth (MCPHIE).

South Africa

Ibn Sina Institute of Tibb founded by the Bhikha Family Trust in 1997, is a non-profit organization, supported academically by both Hamdard University (Pakistan) and Jamia Hamdard University (India). Website: http://www.tibb.co.za

University of the Western Cape School of Natural Medicine is a Government approved provider of education and training in Allied Health Professions including Phytotherapy (Western Herbal Medicine) (B Phyt), Unani - Tibb Medicine (BUTM), Chinese Medicine and Acupuncture (BCMA), and Naturopathy (B Nat). The Degree of Bachelor of Science in Complementary Medicine i.e. BSc CHS is awarded after 3 years. Thereafter the School provides full-time training for Professional Practitioner Status leading to the award of a professional Two Year Bachelors Degree in Phytotherapy, Naturopathy and Unani - Tibb Medicine. Website: http://olduwc.uwc.ac.za/faculty_school/school_natural_medicine/index.htm

United States of America:

American Institute of Unani Medicine: http://www.unani.com

Association of Accredited Naturopathic Medicine Colleges: http://www.aanmc.org

Ayurvedic Healing Arts Institute of the Medicine Buddha Healing Centre, a non-profit 501(c)3 religious organization offers both Ayurvedic Correspondence Course (Herbal Distance Learning) and in-person Classroom-based Ayurvedic college training in Berkeley, California. Website: http://www.ayurveda-california.com

Ayurveda Institute of America was founded in 1996 in Dallas Texas with one branch in Houston, TX. AIA moved its main campus to Foster City California in 2000. With a California state approval, AIA started the training program in Foster City. To fulfill the requirements of the National Ayurvedic Medical Association, the AIA Diploma program was upgraded to 500 credit hours instead of 350. Two years ago, AIA started the Diploma Program at branches in Los Angeles and in Hawaii. Website: http://www.ayurvedainstitute.com

California College of Ayurveda (CCA), Nevada City, California, is a state-approved school offering one, two and three year programs leading to certification as a Clinical Ayurvedic Specialist (CAS). Website: http://www.ayurvedacollege.com

Dhyana Center of Health Sciences, Sebastopol, California, offers an Ayurvedic Certification Programme. Website: http://www.dhyanacenter.com/ayurvedic-certification/index.html

Kerala Ayurveda Academy, with five centres in the USA (Los Angeles, California; San Diego, California; San Francisco, California; Santa Cruz, California; and Seattle, Washington), offers a Level 1 Certified Ayurvedic Wellness Counselor (AWC) programme (500 hours) and a Level 2 Certified Ayurvedic Wellness Practitioner (AWP) programme (1,000 hours). Website: http://www.ayurvedaacademy.com

Kripalu School of Ayurveda (KPA), Stockbridge, Massachusetts, offers two levels of certification: Ayurvedic Consultant and Ayurvedic Yoga Specialist. The curriculum for the Ayurvedic Consultant certification program provides a comprehensive foundation in the principles and practices of Ayurveda. Weekend coursework emphasizes both theoretical understanding and experiential work. Home-study assignments require students to integrate their developing knowledge of Ayurvedic principles by applying them to a wide variety of situations. Website: http://www.kripalu.org/article/351

Mount Madonna Institute College of Ayurveda, Watsonville, California, offers three programs leading to Ayurvedic Lifestyle Counselor Diploma, Ayurvedic Practitioner Certificate, or Master of Arts in Ayurveda. The Diploma Program prepares the student for a career as an Ayurvedic Lifestyle Counselor, integrating body/mind assessment, nutrition, use of herbs, and lifestyle counseling. Graduates of the Diploma Program may practice independently as Ayurvedic Lifestyle Counselors under the provisions and conditions of the California Health Freedom Act, join the staffs of Yoga studios or spas, or become licensed as massage therapists and work in health resorts. The Certificate Program prepares the student for a career as an Ayurvedic Practitioner, integrating body/mind assessment, nutrition, herbal medicine and lifestyle counseling. Graduates of the Certificate Program may practice independently as Ayurvedic Practitioners under the California Health Freedom Act, join the staffs of some hospitals offering complementary modalities, or become licensed as massage therapists and work in upscale health resorts. The Certificate program offers on-site, supervised clinical internship in Ayurvedic Medicine in the Kaya Kalpa Wellness Center as well as externships offsite. The Master of Arts Program offers comprehensive education and training in Ayurveda. It combines classroom education and clinical training with an emphasis on creating a skilled Ayurvedic Practitioner. The Master's program provides education and training in Ayurvedic medical theory, diagnosis, philosophy and treatment modalities. Students learn herbal medicine, constitutional analysis, nutrition, Yoga, and rejuvenation therapies in the clinic and

classroom. The Master of Arts – Ayurveda program offers clinical internship in Ayurvedic Medicine, externships offsite and a required Masters' Thesis. Website: http://www.mountmadonnainstitute.org/index.html

National College of Natural Medicine, Portland, Oregon: http://www.ncnm.edu

National Institute of Ayurvedic Medicine (NIAM) was established in 1982 by Scott Gerson, M.D., Ph.D. (Ayurveda). Dr. Gerson has worked principally as a physician specializing in combining Ayurveda and conventional medicine for the past more than twenty years. Website: http://niam.com/corp-web/index.htm

Southwest College of Naturopathic Medicine, Tempe, Arizona: http://www.scnm.edu

The Ayurvedic Institute was founded in 1984 in Santa Fe, New Mexico, as a 501(c)(3) educational, non-profit corporation with a purpose to provide authentic education in a supportive environment that encourages the integration of Ayurveda by individuals into their daily living and by health care professionals into their clinical practices. Website: http://www.ayurveda.com

University of Bridgeport College of Naturopathic Medicine: http://www.bridgeport.edu

d. Treatment Centres and Clinics of Indian Systems of Medicine:

Australia / New Zealand

As an example, here is a non-exhaustive list of links to some treatment centres:

Ananda Clinic & Spa, Christchurch, New Zealand: http://www.panchakarma.co.nz

ChaMunda Ayurvedic Clinic, Christchurch, New Zealand: http://www.ayurveda.net.nz

Prema Clinic of Wellpark College of Natural Therapies, Grey Lynn, New Zealand: http://www.wellpark.co.nz/srv_premaclinic.asp

Shree Ayurvedic Rejuvenation Centre, Auckland, New Zealand: http://www.shreeayurveda.co.nz

Canada

As an example, here are links to some treatment centres Canada:

Centre for Ayurveda & Indian Systems of Healing Wellness Centre provides complete health & wellness care through Ayurveda & Yoga therapies and Pancha Karma treatment. Website: http://www.caish.ca/wellness.html

Salt Springs Spa Resort, British Columbia. Website: http://www.saltspringspa.com/ayurveda.html

European Union

The database of the Ayurveda Coordination Centre of Europe (ACCE) can be utilized for links to Ayurvedic treatment centres throughout European countries. The database is available at: http://www.ayurveda.hu/eu.html.

Malaysia

According to information provided in the Government of Malaysia *'Global Information Hub on Integrated Medicine*' (*Globin*Med),[53] Traditional Malay medicine (TMM), traditional Chinese medicine (TCM), traditional Indian medicine (TIM), homeopathy and other complementary systems are among the biggest modalities being practiced in Malaysia. In 2004, the Malaysian Ministry of Health conducted a study on the utilization of traditional and complementary medicine (T/CM) in local population. The survey showed that 55.6% of Malaysians have never used any kind of T/CM in the past 12 months prior to the study. Table 20 shows that a big percentage of the population surveyed was using biologically-based therapy for health problems.

Table 20: Utilization of T/CM by the Malaysian population based on categories[54]

T/CM Categories	% of sample population citing usage of T/CM for health problems
Biologically-based therapy (e.g. herbs, vitamins supplement)	88.9
Manipulative & body-based (e.g. massage, reflexology, chiropractic)	27.0
Mind-body medicine (e.g. hypnosis, prayer, meditation, yoga, taichi)	11.1
Whole medical system (e.g. acupuncture, Ayurveda, homeopathy, Chinese medicine)	1.9

South Africa

As an example, here are links to some treatment centres in South Africa:

SanAquam Retreat: The AQ Group (Pty) Ltd has partnered with this leading Ayurvedic company to bring qualified and experienced Ayurvedic doctors, therapists and technologists to SanAquam. Through this partnership, SanAquam can serve a spectrum of clients who are seeking leisure, rejuvenation, de-stressing, detoxification, health maintenance, disease prevention or disease reversal and lifestyle and anti-ageing therapies. Website: http://www.sanaquam.com

United States of America

The first national data to answer the question of how common is the use of Ayurveda in the USA came from a survey released in May 2004 by the National Center for Health Statistics and the National Center for Complementary and Alternative Medicine (NCCAM). More than 31,000 adult Americans were surveyed about their use of CAM, including specific CAM therapies such as Ayurveda. Among the respondents, four-tenths of 1 percent had ever used Ayurveda, and one-tenth of 1 percent had used it in the past 12 months. When these percentages are adjusted to nationally representative numbers, about 751,000 people in the United States had ever used Ayurveda, and 154,000 people had used it within the past 12 months.[55]

As an example, here are links to some treatment centres in the USA:

California College of Ayurveda Healthcare Center, Grass Valley, California, uses diet, herbs, aromas, sound (mantra), Pancha Karma, lifestyle counseling, yoga and meditation. Website: http://www.ayurvedacollege.com/clinic/index.htm

[53] Institute for Medical Research Ministry of Health Malaysia. Traditional and Complementary Medicine. In: *Global Information Hub on Integrated Medicine*' (*Globin*Med). Kuala Lumpur, Malaysia: Institute of Medical Research. 2007. Available at: http://www.globinmed.com/IMRContent/tcm.aspx?contentid=CTN00812

[54] Siti Zuraidah Mahmud, Ami Fazlin Syed Mohamed, Tahir Aris et al. Pattern of Traditional and Complementary Medicine Utilization by the Malaysian Public. 21st Annual Seminar of Malaysian Natural Products Society. 22-23 Nov. 2005.

[55] National Center for Complementary and Alternative Medicine (NCCAM). What is Ayurvedic medicine? June 2007. Available at: http://nccam.nih.gov/health/ayurveda/ayurveda.pdf

Dhyana Center of Health Sciences, Sebastopol, California, offers Pancha Karma retreats. Website: http://www.dhyanacenter.com

Himalayan Institute Total Health Center, Honesdale, Pennsylvania, offers Pancha Karma services. Website: http://www.himalayaninstitute.org

Kaya Kalpa Wellness Center, Watsonville, California, offers Swedana, Shirodhara, and Abhyanga treatments. Website: http://www.mountmadonna.org/projects/kayakalpa/index.html

Kerala Ayurvedic Clinic and Wellness Centre, with three locations in the USA (Aptos, California; Foster City, California; and Seattle, Washington) provides a range of comprehensive Ayurveda-based natural healing programs that include customized nutrition & lifestyle guidelines, healing herbs, gentle detoxification with Panchakarma cleansing, appropriate exercise & yoga postures, special daily and seasonal health routines, rejuvenative Rasayana therapy, aroma therapy, music therapy, Pranayama and Meditation. Typical Ayurvedic treatments include: Pulse Diagnosis & Consultations, Herbal & Nutritional Prescriptions, Panchakarma Cleansing & Rejuvenation, Panchakarma Detox Cleansing, and Weight Management Programs. Website: http://www.keralaayurveda.biz

Medicine Buddha Healing Centre, Berkeley and San Francisco, California, offers East Indian and Tibetan Ayurvedic Medicine, Traditional Chinese Medicine and Acupuncture. Website: http://www.ayurveda-berkeley.com

National Institute of Ayurvedic Medicine, New York City, offers Pancha Karma retreats and day spa services. Website: http://niam.com/corp-web/index.htm

The Ayurvedic Institute, Albuquerque, New Mexico, offers Pancha Karma treatments. Website: http://www.ayurveda.com/panchakarma/index.html

e. Indian Medicinal Natural Products already in Market:

Australia / New Zealand

- *Ayurvedic International Pty Ltd*: Life Science Rejuvenate Tribulus 9000; Australian Register of Therapeutic Goods (ARTG) Number: 142089.
- *Catalent Australia Pty Ltd*: RPS Prune and Senna Capsules; Australian Register of Therapeutic Goods (ARTG) Number: 26353. Website: http://www.catalent.com
- *Dabur International Limited* (food products (honey, sauces, spice extracts, syrups), hair care products, oral care and skin care products, herbal formulations). Website: http://www.dabur.com/en/exports/Network/Australia.asp
- *Keen Health Pty Ltd*: KEENMIND Bacopa monnieri 4g Tablet - film coated; Australian Register of Therapeutic Goods (ARTG) Number: 80931. The standardized brahmi extract used in Keenmind products was developed by the CSIR/Central Drug Research Institute of India in Lucknow and licensed exclusively to Keen Mind Pty Ltd. Website: http://www.keenmind.com.au/baccdrix.htm
- *Kerala Ayurveda Ltd*: A small amount of traditional Ayurvedic medicine products and proprietary Ayurvedic medicines are sold directly to small Australian importers.
- *Maharishi Ayurvedic Product Ltd*, Victoria, Australia. E-mail: mapaustralia@yahoo.com; Auckland, New Zealand. E-mail: ayurveda@ihug.co.nz
- *Mediherb Pty Ltd*: Mediherb Bacopa Complex (N/F); Australian Register of Therapeutic Goods (ARTG) Number: 104361. Mediherb co-founder and Director of Research and

Development Kerry Bone is author of "*Clinical Applications of Ayurvedic and Chinese Herbs For the Western Herbal Practitioner."* Website: http://www.mediherb.com.au

- *Natural Remedies*: Australia and New Zealand represent about 33% of Natural Remedies botanical extracts business.
- *Procter & Gamble Australia Pty Limited*: Metamucil psyllium husk powder; Australian Register of Therapeutic Goods (ARTG) 113016, as well as several other registrations for different forms of this Indian medicinal plant.

Canada

The Natural Health Products Directorate (NHPD) is working to complete its Licensed Natural Health Products Database (LNHPD). Once available, the LNHPD will enable users to quickly and easily search for information on natural health products (NHPs) that have been issued a product license (i.e. NPN or DIN-HM), including any Indian ASU products or Canadian NHPs that are composed of Indian medicinal natural ingredients.

The LNHPD will include information on: authorized health claims, medicinal and non-medicinal ingredients and risk information. Furthermore, the LNHPD will provide stakeholders more accurate and up-to-date information as it will be updated on a daily basis as opposed to monthly. Health Canada anticipates launching the LNHPD in summer 2008.

Here are examples of two Canadian licensed products that are composed of Indian medicinal natural ingredients:

- *Procter & Gamble Inc*.: Metamucil® (ispaghula) Fiber Wafers; Drug Identification Number (DIN) 02241614 (cinnamon) and DIN 02241615 (apple).
- *Traditional Medicinals Inc*.: Organic Smooth Move® (senna) Herbal Laxative; Natural Product Number (NPN) 02243711. The senna leaf in this product is cultivated in Rajasthan.

European Union

The database of the Ayurveda Coordination Centre of Europe (ACCE) can be utilized for links to companies throughout Europe who are marketing Ayurvedic products. The database is available at: http://www.ayurveda.hu/eu.html.

Malaysia

- *Dabur International Limited* (food products (honey, sauces, spice extracts, syrups, hair care products, oral care and skin care products, herbal formulations): http://www.dabur.com/en/exports/Network/Asia.asp
- *Himalaya Drug Company* has a strong presence in Malaysia in department stores and retail outlets: http://www.himalayahealthcare.com/globalnetwork/global_presence.htm#malaysia
- *Vasu Healthcare Pvt Ltd* (traditional ASU medicines, patent & proprietary ASU medicines, natural body care and cosmetic products); South Asian nations, including Malaysia and Myanmar, represent about 7% of business for Vasu. One product is licensed in Malaysia, Kumkumadi Tailam, Product License No. MAL07020144K.

South Africa

- *Dabur International Limited* (food products (honey, sauces, spice extracts, syrups, hair care products, oral care and skin care products, herbal formulations): http://www.dabur.com/en/exports/Network/Africa.asp

- *Himalaya Drug Company* is present department stores across South Africa: http://www.himalayahealthcare.com/globalnetwork/global_presence.htm#southafrica
- *Maharishi Aryuved Products* (herbal formulations, body & bath, books, aromatherapy products, foods, organic cotton). South Africa represents about 1% of business. Maharishi Ayurved is in the process of registration of products under the MCC Regulations.

United States of America

A good range of Indian natural products companies as well as U.S. companies marketing Indian formulations or natural products have a presence in the U.S. market. The most visible product brands containing Indian herbs or herbal formulations in the U.S. are (in alphabetical order):

- *Arya Vaidya Sala* (traditional ASU products; patent and proprietary ASU medicines); sold only to patients through practitioner clinic dispensaries.
- *Auromère* (skin & body care and spa products): http://www.auromere.com
- *Ayurceutics®* (standardized single herb extracts in capsules): http://www.ayurceutics.com
- *Ayush Herbs Inc*. (herbal formulations, massage oils, herbs and spices, teas, veterinary care products, bulk botanical raw materials, extracts and oils): http://www.ayush.com
- *Bindi Ayurvedic Skin Care* (aromatherapy products, herbal formulations, massage oils, skin & body care, books): http://www.bindi.com
- *Chandrika Ayurvedic Soap* (herbal soaps): http://www.chandrikasoaps.com
- *Dabur International Limited* (food products (honey, sauces, spice extracts, syrups), hair care products, oral care and skin care products, herbal formulations): http://www.dabur.com/en/exports/Network/America.asp
- *Garry & Son USA* (herbal formulations, aromatherapy products, massage oils): http://www.garrysun.com
- *Himalaya Herbal Healthcare USA* (herbal formulations, single herb products, body care products): http://www.himalayausa.com
- *Himalayan Institute® Varcho Veda®* (herbal formulations, neti pots, books, DVDs): http://www.organixsouth.com
- *Kerala Ayurveda Ltd*: A small amount of traditional Ayurvedic medicine products and proprietary Ayurvedic medicines are exported to small importers in the USA.
- *Maharishi Aryuved Products* International (herbal formulations, body & bath, books, aromatherapy products, foods, organic cotton): http://www.mapi.com
- *Nature's Formulary LLC* (herbal formulations and body care, massage oil, and Indu® spa products): http://www.naturesformulary.com
- *Organic India®* (organic supplement formulations, organic foods, organic herbs and spices); http://www.organicindia.com
- *Organix South Inc. TheraVeda®* (herbal formulations, body care and oral care products, pet products, garden products): http://www.organixsouth.com
- *Procter & Gamble Metamucil®* (psyllium husk over-the-counter (OTC) drug products and dietary supplement products): http://www.metamucil.com
- *Shree Dhootapapeshwar Ltd* (traditional Ayurvedic medicines and patent & proprietary ASU medicines); the USA represents about 16% of export business.
- *Traditional Medicinals® Organic Smooth Move®* (senna-based laxative products): http://www.traditionalmedicinals.com
- *Yogi Tea®* (herbal dietary supplement teas and food beverage teas): http://www.yogitea.com

E. Prospects and constraints for development of Ayurveda, Siddha and Unani

At the moment the Indian Systems of Medicine (ISM) and the natural medicinal products that are utilized in their clinical practice (Ayurveda, Siddha and Unani (ASU) products) are well known primarily in the countries of Bangladesh, India, Malaysia, Nepal, Pakistan and Sri Lanka, and possibly others. Outside of Southern and Southeastern Asian countries, the Indian Systems of Medicine are not yet well known by consumers and patients interested in natural health care. As awareness grows outside of Asia, the development of infrastructure that can support ISM in educational institutions, practitioner licensing, and clinical practice will likely evolve in more countries. There is evidence of growing consumer and patient interest in ISM in other countries including, in particular, Australia, Canada, South Africa, and United Kingdom, among others. In fact, a number of Commonwealth Member Nations do have regulatory frameworks that provide a suitable pathway for Traditional Medicines such as ASU products.

The development and effective promotion of ISM and corresponding ASU products to other countries will require a legal framework for clinical practice in conjunction with a supportive infrastructure for the provision of higher education with clinical practicum, practitioner licensure, and market authorization and availability of the requisite ASU medicinal natural products. The most likely countries for the ISM and ASU products to gain acceptance and popularity include the UK Commonwealth Member countries because in many of these countries the regulatory framework already exists or is evolving in ways to allow for the licensing of Traditional Medicine products and the clinical practice of various systems of Traditional Medicine. This is the case in Commonwealth countries like Australia, Canada, Malaysia, New Zealand, South Africa, and United Kingdom.

Countries like the USA will take much longer, if ever, for legal recognition and licensing of Traditional Medicine. For example in the USA, there is no existing framework or infrastructure for the practice of any of the Indian Systems of Medicine. There are colleges and institutes of Unani Medicine as well as Ayurvedic Medicine but these are non-accredited and therefore the graduates cannot enter into clinical practice unless they have some other State recognized practitioner license such as doctor of chiropractic (DC), doctor of osteopathy (DO), naturopathic doctor (ND), or medical doctor (MD). Practitioners of ISM in the United States are generally operating under one of these aforementioned practitioner credentials because there is no licensing for practitioners of Ayurveda, Siddha or Unani in the USA. On the other hand, practitioners of Traditional Chinese Medicine (TCM) may practice in certain States of the USA under the credential of licensed acupuncturist (LAc). In some cases an L.Ac. may also have training in other systems of Traditional Medicine and therefore may incorporate these other systems into their practice including ISM as well as traditional European systems like Anthroposophical Medicine or Homoeopathic Medicine, among others.

Prospects

Promoting ISM practice to support export development: One prospect to consider would be the introduction of ISM studies into the curriculum of naturopathic colleges and universities. In some countries, for example North American countries, it could be within the scope of practice for a licensed ND to practice Ayurvedic or Unani Medicine and to stock the necessary medications in their clinic dispensaries. Many North American NDs, in addition to a standard naturopathic medicine approach, will also specialize in specific systems of traditional medicine, for example Homoeopathic Medicine or TCM. Some NDs already have training and experience in Ayurveda.

At the same time, schools of Ayurvedic medicine are emerging in American and European countries but graduates receive certificate or diplomas that do not necessarily lead to practitioner licensing for legal clinical practice. These fledgling colleges and universities of Ayurveda must be

supported towards a goal of regulatory changes that will permit graduates to be licensed for primary health care clinical practice.

An approach for the Government of India to consider would be the development of an exportable programme whereby a ready-made curriculum for ISM could be offered to western medical schools as a way to integrate the different systems. This would also require the export or offer of qualified professors and practitioners willing to relocate from India to join the faculty of western educational institutions in order to teach ISM in the classroom and in the clinical practicum. Qualified examiners would also be needed to service on ISM Boards of Examiners responsible for the licensure and regulation of ISM practitioners in each country.

Promoting condition-specific star products: Other prospects to consider would be to approach export markets via market segmentation as opposed to the export of ASU products couched within their holistic context of the Indian Systems of Medicine, philosophy and theory. This prospect would require expert assessments in each target country of the potential opportunities for selected star Indian natural products that could stand on their own as condition-specific products in competition with allopathic drugs and/or other natural medicinal products that share the same indications for use. The star product selection may likely vary from country to country due to cultural differences and varying health concerns among the targets groups of consumers, as well as regulatory differences concerning the allowable indications for use for this class of products.

Constraints

Non-medicinal natural products: According to a presentation by the Health Foods and Dietary Supplement Association (HADSA) of India, the two main growth barriers for its membership are:

- Problems in imports and exports due to lack of clarity on product classification (food supplement or medicine?), and
- Severe competition, too many products in the market and increasing regulatory hurdles through increasing legislative controls has further affected the market growth.

Constraints:

Medicinal *natural products*: For acceptance and legality of ISM practice and ASU products in western countries, particularly those of North America and Western Europe, there are serious constraints that are presently prohibitive for development. It cannot be overemphasized that significant differences in perception of safety, efficacy and quality exist between the health authorities of India and their regulatory counterparts in Europe and North America, which must be clarified and harmonized. For example, it is not yet possible for western health professionals and health regulatory agencies to accept or understand that the intentional use of metals in medicinal products (bhasmas) could be safe and/or effective, regardless of the levels of evidence provided. Therefore safety, quality and efficacy for metallic medicines must be proven using the same laboratory and clinical study methodologies of western evidence-based medical science. This point can be illustrated by referring to the "Lead Poisoning Prevention Program" webpage of the "New York City Department of Mental Health & Hygiene," which features a section entitled "Indian Herbal Medicine Products Containing Lead and Mercury."[56] The New York health officials have also posted a letter to health care providers entitled "Imported Herbal Medicine Products known to contain Lead, Mercury, or Arsenic."[57] Other practices that will require exceptionally strong

[56] New York City Department of Mental Health & Hygiene. Indian Herbal Medicine Products Containing Lead and Mercury. Available at: http://home2.nyc.gov/html/doh/html/lead/lead-herbalmed-in.shtml

[57] New York City Department of Mental Health & Hygiene. Imported Herbal Medicine Products known to contain Lead, Mercury, or Arsenic. Available at: http://home2.nyc.gov/html/doh/downloads/pdf/lead/lead-herbalmed.pdf

arguments for western acceptance include the intentional use of animal urine in certain preparations and therapies. Until safety, quality and efficacy are conclusively proven according to western criteria for levels of evidence, these practices will not be accepted.

Other relevant examples of regulatory hurdles for certain Indian medicinal natural products include:

- In Australia, the Therapeutic Goods Administration (TGA) posts information on the topic of "*The Safety of Ayurvedic Medicines in Australia*," as well as Adverse Drug Reaction Bulletins on the topic of "*Traditional Indian (Ayurvedic) and Chinese medicines associated with Heavy Metal Poisoning*."[58]
- In Canada, Health Canada has posted warnings in English and Hindi Language entitled "Health Canada Reminds Consumers That Some Ayurvedic Medicinal Products Contain High Levels of Heavy Metals."[59]
- In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) posts consumer warnings on the topic of "*Heavy Metals in Ayurvedic Herbal Medicines*."

CHAPTER 4 – ENTERPRISES' NEEDS

A. Findings from Enterprise Interviews of Mission in India

During the first mission in India there were opportunities to interview enterprises at their own offices as well as at a trade exhibition and conference. The following sub-headings are main points made by interviewees concerning the needs of the Indian manufacturers and marketers of medicinal natural products.

Education: One enterprise indicated that they believe that the introduction of Ayurvedic medicine in the curriculum of foreign naturopathic colleges and/or as an elective at conventional medical schools could help the export promotion of Indian Ayurvedic medicinal products. They would like to see a comprehensive list of colleges and universities in the target export markets that already offer some Complementary or Traditional Medicine coursework, as well as a list of schools that could conceivably integrate an ASU curriculum in the future. This list of schools would help the exporters to assess the climate in target countries for the acceptance of Ayurvedic medicine and philosophy by the population.

Importable Botanical and Natural Substances: One enterprise emphasized the need to have a comprehensive handbook that lists the importable substances (positive lists) and non-importable substances (negative lists) for each of the targeted export market countries. This enterprise believes that Department of AYUSH should engage a consultant to compile and cross-reference all of the existing lists from various countries into an easy-to-use handbook for exporters. The handbook should also provide guidance on the preparation of new or novel ingredient petitions or submissions to get certain Indian ingredients removed from negative lists and/or added to positive lists.

In this regard, another company mentioned that their medicated ghee products have been rejected in some foreign markets due to ghee being classified as a dairy food product rather than as a medicinal product.

[58] Australian Drug Reactions Advisory Committee. Traditional Indian (Ayurvedic) and Chinese medicines associated with Heavy Metal Poisoning. Australian Adverse Drug Reactions Bulletin. February 2007;26(1):2. Available at: http://www.tga.gov.au/adr/aadrb/aadr0702.pdf

[59] Health Canada. Health Canada Reminds Consumers That Some Ayurvedic Medicinal Products Contain High Levels of Heavy Metals. 2008. Available at: http://www.hc-sc.gc.ca/ahc-asc/alt_formats/cmcd-dcmc/pdf/media/advisories-avis/2008/2008-73-Hindi.pdf.

A third enterprise made similar points and suggested that the Department of AYUSH should proactively contact their counterparts at each of the targeted foreign governments in order to provide evidence reports of trade and human safety for all commonly use ASU ingredients which presently appear on any negative lists.

Modernization: One enterprise discussed the problem of exporting Traditional ASU products because they may not meet the legal requirements in destination countries, for example shelf-life stability testing and expiry dating. This enterprise suggested that the use of certain preservative substances or other manufacturing techniques that are not traditional per se might be necessary in order to satisfy foreign market expectations and/or legal requirements.

Other enterprises also mentioned the well-known problem of differing purity standards that exclude whole classes of Indian medicinal natural products such as bhasmas. The legal definitions of what constitutes adulteration, contamination, acceptable purity, and maximum allowable limits for heavy metals, pesticide residues, and microbiological quality, etc, are very real problems for the Indian industry to contend with. For example, while on the one hand the Department of AYUSH Office Order of June 2007[60] to permit the use of gamma irradiation for microbial decontamination of ASU herbs, drug and formulations could seem like a solution for exporters, in fact certain methods of sterilization, including irradiation and ethylene oxide, are illegal in many of the target export markets for use on ingredients of medicinal herbal products and/or herbal dietary supplement products. An understanding of the legal method of microbial reduction in each of the target export markets should be clarified for the exporters in order to avoid product recalls and related bad publicity if finished products are tested and found to contain ingredients that have been irradiated or treated with ethylene oxide.

Regulatory Affairs: One enterprise suggested that AYUSH should provide access to a list of pre-qualified international regulatory affairs consultants (who reside in India) for trainings and to handhold during the product licensing processes with the various foreign regulatory authorities. The idea here is for AYUSH to develop and publish a directory of qualified consultants who can be contacted by industry.

Another enterprise suggested that exporter-only enterprises, for example those operating with Special Export Zones (SEZ), should not need Ayurvedic drug registrations with Department of AYUSH if none of the products will be sold in the Indian local market. It would appear that the regulatory requirements of the destination countries for product registration, labeling, GMPs, etc., would be enough for export-only products.

One enterprise suggested that the "South African Regulations for Grading of Ayurveda" is a good model from which AYUSH could prepare a similar standard reference for each target export market. For example, such a document could provide information on what labeling standards are required in each of the targeted foreign markets relevant to Indian natural products.

Table 21 provides an illustration of how a botanical ingredient entry could be presented in a export market labeling standards handbook for industry.

[60] Basant S. Office Order: Permission for use of Gamma Irradiation for Microbial De-contamination of Ayurvedic, Siddha & Unani (ASU) herbs, drugs and formulations – reg. New Delhi, India: Government of India, Ministry of Health & Family Welfare, Department of AYUSH. June 2007.

Table 21: Example Entry for ASU Ingredient Labeling Standards in Selected Foreign Market

ASU Ingredient Botanical Name

Country	Standard Common Name	Positive or Negative List?	Regulatory Framework	Quality Standard	Maximum Dose	Indications for Use	Cautions & Contra-indications
Australia			Complementary Medicine	BP			
Canada			Natural Health Product	PhEur or USP-NF			
EU			Traditional Herbal Medicinal Product	PhEur			
USA			Dietary Supplement	USP-NF			

Research Collaborations: One larger enterprise strongly indicated that success for Indian natural medicinal products in the European and American markets will be depending on solid laboratory and clinical research that is published in peer-reviewed international bio-medical journals and contributes to scientific literature on the topic of quality, safety and efficacy of Indian medicines. To this end, this enterprise believes that the Department of AYUSH should include support for research in the context of Public-Private-Partnerships (PPPs) (e.g. studies that are co-funded between the enterprise and CCRAS), whereby the enterprise has a temporary exclusive right to manufacture and market the researched product. After an agreed number of years, the formulation becomes available in the public domain similar to the patent system.

Another enterprise stated that they already have a research arm (Centre for Medicinal Plant Research) working in collaboration with the Indian Council for Medical Research (ICMR) and the Council for Scientific and Industrial Research (CSIR).

A third enterprise mentioned that they are participating in a CCRAS Golden Triangle Project Scheme to prove the safety of metal-based bhasma preparation and also to standardize bhasmas.

Risk analysis for export scale up: A reoccurring theme expressed by many stakeholders was the lack of comprehensive legal-, market-, and supply chain intelligence in the context of understanding the potential risks of scale up for export development. Knowledge gaps include, among others:

- Conservation status of all ingredients in selected finished products for export. Is there a sustainable supply of quality raw materials?
- Legal status of all ingredients in selected finished products for export. Do any of the ingredients appear on the negative lists of any destination countries? Would any of the ingredients require the filing of new or novel ingredient submissions to the food or drug safety regulatory agencies of any countries prior to marketing authorization?
- Legal status of finished products. What regulatory frameworks do the Indian medicinal natural products fall under in each destination country (cosmetic, dietary supplement, food, or medicine)? What are the legislative market access requirements in each case?
- Market intelligence: What are the relative sizes of the markets in the destination countries?; for medicinal natural products in general as well as for specific product categories. What is the competition?

Concerning conservation status of natural ingredients used in ASU products, the experts at the Foundation for the Revitalisation of Local Health Traditions (FRLHT), Bangalore, are able to

conduct such analysis. It will be recommended for phase 2 of this project to engage the services of FRLHT to help industry determine which products are sustainable for scale up and export development based on conservation status. In an interview at FRLHT it was stated that the reasons to support export promotion are within the context of supporting sustainable wild collection & community benefits from better income if there is enough of the natural resource available beyond the local need for food and/or medicine. What exactly FRLHT can do is to assess the ingredients of each company's top five products for export in order to evaluate whether a product (1) is ready for export marketing; (2) requires any actions and planning before it is ready for sustainable scale up for export marketing; (3) has any ingredients with a conservation status problem and therefore should not be prioritized for export promotion.

Concerning the legal status of natural ingredients used in ASU products, some countries have published guidance as well as negative and positive lists. However, a comprehensive international database of ingredient status is not known to exist. Therefore each exporting enterprise must research the lists from each destination country before determining whether market access will be feasible. For phase 2 of this project it will be recommended that the development of a database should be commissioned in order to enable industry the ability to carry out rapid assessments of international ingredient status.

Concerning the legal status of Indian finished products, each destination country has different legislative market access requirements for pre-marketing authorization and product licensing, listing, notification or registration. In most cases, Indian ASU products will be regulated as medicinal or therapeutic products with the notable exception of the USA where there is not yet a legal framework for Traditional Medicines. Therefore, the USA is an anomaly where orally ingested medicinal natural products are presently regulated as dietary supplement products with significant limitations on allowable indications for use. Topically applied medicinal natural products are regulated as cosmetics in the USA. For phase 2 of this project it will be recommended that the development of an exporter's handbook should be commissioned that would provide the Indian industry with summaries of the legislative market access requirements for selected export market destinations.

Spiritually based businesses: One enterprise pointed out the interesting fact that many Indian manufacturers and marketers of medicinal natural products have been founded around a spiritual base and reason for being. This is a unique feature of Indian business that is unusual in the American and European markets and therefore could conceivably be leveraged as a very positive image for branding and marketing of Indian natural products. In the western countries, natural products companies are just beginning to codify, define and measure their own "corporate social responsibility" practices, in part, because the consumers of natural products are demanding evidence of social responsibility and sustainability (ecological, economical, and social). In would seem that many Indian enterprises are already in a good position to effectively demonstrate their social responsibility practices in the context of their religious or spiritual based business practices.

This enterprise gave examples of Indian natural product companies with a spiritual foundation which could enable the ability to market Indian products within a context of a whole system of living involving healthy lifestyle, meditation, pancha karma, yoga, etc. Examples of some spiritually based companies mentioned during this interview included:

- *Maharishi Ayurveda*: Maharishi Mahesh Yogi is the guiding light of Maharishi Ayurveda: http://www.maharishiayurvedaindia.com
- *Organic India*: Sri H.W.L. Poonja, Papaji, and Sri Ramana Maharshi are the guiding lights of Organic India: http://www.organicindia.com/organic-india-dedication.php
- *Yogi Tea*: Yogi Bhajan is the guiding light of Yogi Tea: http://www.yogitea.com/Pages/AboutUs/AU-History.html

Also mentioned were ashrams that offer Indian medicinal natural products in their own retail outlets or healing centers, for example Swaminarayan ashrams in the USA as well as ashrams of Guru Baba Ramdev Patanjali. Other examples are spiritual institutes in the USA that also have retail stores offering Indian natural products. For example, the Himalayan Institute Store, which markets herbal and other natural products under the Varcho Veda® brand name: http://www.himalayaninstitute.org/store/catalog/fa0a2b8c-4cf2-475c-83eb-f9fa41bf6b23.aspx

B. Findings from the Enterprise Survey

The Enterprise Survey was disseminated electronically by ADMA and PHARMEXCIL to their respective memberships. ADMA sent the survey to 203 members. During the five week period that was designated for response, a total of 13 survey responses were received by the consultant. The memberships were encouraged and reminded to respond on several occasions over the five week period by ADMA and PHARMEXCIL, respectively.

In some cases, supplementary information about an enterprise, if the information were not provided clearly or completely in this survey, may have been confirmed by cross-referencing the same company profile form that was submitted to ITC for the AsiaHealthCare 2008, Malaysia, March 2008.[61] Many Indian companies solicited for this Enterprise Survey also submitted a Company Profile Form to ITC as participants of the AsiaHealthCare event.

Question 1 Name and Address: Four of the respondents to the Enterprise Survey are based in the State of Maharashtra, three in Kerala, two in Karnataka, two in Uttar Pradesh, one in Madhya Pradesh, and one company in Gujarat.

Question 2 Size of Enterprise: Six of the respondents are large (more than Rs. 20 Crs.), four medium sized (5 Crs < 20 Crs), one small (1 Cr. < 5 Crs.) and two respondents were micro-sized enterprises (less than Rs. 1 Cr.). Thus about 46% of the respondents represented the views of large enterprises.

Question 3 Year Established: The dates of establishment and longevity are quite impressive, ranging from 1872 to 2007:

- 100% of the respondents have been in business for at least 1 year.
- 92.3% of the respondents have been in business for at least 10 years.
- 69.2% of the respondents have been in business for at least 20 years.
- 53.8% of the respondents have been in business for at least 30 years.
- 45.2% of the respondents have been in business for at least 50 years.
- 38.5% of the respondents have been in business for at least 70 years.
- 30.8% of the respondents have been in business for at least 90 years.
- 23.1% of the respondents have been in business for at least 100 years.
- 15.4% of the respondents have been in business for at least 120 years.
- 7.7% of the respondents have been in business for at least 130 years.

Question 4 Type of Business: Seven of the respondents are Private Limited Companies and three are Public Limited Companies. There are one respondent each in the categories of Partnership, Proprietary Firm, and Trust, respectively.

[61] ITC South-South Trade Promotion Programme. Annex XI: Enterprise/product profile forms "AsiaHealthCare 2008", Malaysia, March 2008. In: *India: Supply and Demand Survey on Pharmaceuticals and Natural Products.* Geneva: International Trade Centre / UNCTAD / WTO. December 2007.

Question 5 Number of Employees: Most of the respondents (9 enterprises) have more than 100 employees. Two enterprises have 10 to 50 employees and two enterprises have 1 to 10 employees.

Question 6 Names of other Group Companies: Most of the respondents reported no relationship to other group companies. One company also belongs to a group of companies including a biotech company, hotels and resorts, and backwater cruises, among other enterprises. One company has a contract research organization and another company is part of a group with an Ayurvedic products exporting company as well as an Ayurvedic products marketing company. One company belongs to a group of companies along with a chemicals manufacturer and an investments company, and one company is affiliated with another Ayurvedic product manufacturer.

Question 7 Range of Products Offered: Of the 13 respondents, most (69.2%) are primarily offering Patent & Proprietary ASU products and/or Traditional ASU Products. Of these, most are focused mainly on Patent & Proprietary ASU Products. Only one enterprise reported 100% Traditional ASU Products for their list of offerings. Two respondents offer some amount of Natural Body Care and Cosmetic Products and three respondents offer non-traditional finished natural health products. For one of these, the non-traditional natural products comprise 80% of turnover. Other than finished products, two respondents offer botanical extracts and oils, one offers agricultural bioinputs, and one respondent offers some botanical raw materials.

Table 22 shows the range of products offered by the 13 survey respondents with the percentage (%) of turnover that each product category represents for them.

Table 22: Range of Products of Respondents / Percentage (%) of Turnover Represented

	Agricultural Bioinputs	Botanical Raw Materials	Botanical Extracts and Oils	Traditional ASU products	Patent & Proprietary ASU products	Non-traditional natural health products	Natural Body Care and Cosmetic products
1	—	—	—	2%	98%	—	—
2	—	—	—	? %	? %	—	—
3	—	—	—	2%	92%	5%	1%
4	—	—	—	7.6%	69.4%	—	—
5	60%	5%	30%	—	—	5%	—
6	—	—	—	—	100%	—	—
7	—	—	—	72%	38%	—	—
8	—	—	—	—	100%	—	—
9	—	—	20%	—	—	80%	—
10	—	—	—	5%	8%	—	—
11	—	—	—	66.5%	33.5%	—	—
12	—	—	—	? %	? %	—	? %
13	—	—	—	100%	—	—	—

***Question 8 Plans to Increase Exports in next Three Years*:** 100% of the respondents expect to increase their export business in the coming three years. One enterprise plans to "significantly" increase its export business in the next three to five years.

Question 9 Markets: % Domestic vs. Export by Destination: This question was problematic because some enterprises did not respond at all, some respondents reported little or no domestic business which appears not to be correct, and the percentages provided by some companies exceeded 100%. Therefore this data is difficult to evaluate.

The responses do provide some useful information however. None of the 13 survey respondents reported any export business to the Democratic People's Republic of Korea (North Korea), People's Republic of China (PRC), Republic of Korea (South Korea), or in the Republic of China (Taiwan). One enterprise reported that 2% of their export business was to the Hong Kong Special Administrative Region of the PRC. Another reported about 2% of their export business to Japan.

The EU Member States and the United States of America (USA) appear to be the most important export destinations for most of these respondents, followed by exports to South Asian countries (Bangladesh, Bhutan, Malaysia, Myanmar, Nepal, Pakistan, Singapore, Sri Lanka), then Australia / New Zealand. One company reported that 37% of their export business is to Russian Federation, nearly as much as their exports to the EU-27 Member States. African countries and South American countries appear to be minor export markets for some of the respondents at this time. Table 23 shows the relative percentages of domestic vs foreign business for the respondents to this survey

Table 23: ***Markets: % Domestic vs. Export by Destination***

	Domestic	Africa	AUST NZ	Canada	EU	Russia	South Asia	South America	USA	Other
1	100%	—	—	—	—	—	—	—	—	—
2	95%	—	—	—	—	—	—	—	0.25%	4.7%
3	—	—	2%	—	30%	—	63%	—	5%	—
4	—	—	0.12%	—	0.24%	0.06%	0.25%	0.05%	0.38%	0.68%[62]
5	—	—	—	—	—	—	—	—	—	—
6	—	—	—	—	—	—	—	—	—	—
7	4.9%	—	0.9%	—	0.83%	—	0.75%	—	0.36%	2.06%[63]
8	20%	1%	2%	—	48%	—	—	—	24%	3%
9	94%	—	33%	11%	14.5%	—	2.5%	—	25%	—
10	100%	—	—	—	—	—	—	—	—	—
11	—	—	—	—	40%	37%	7%	—	16%	—
12	—	13%	—	—	4%	—	7%	4%	—	72%[64]
13	—	—	—	—	—	—	—	—	—	—

***Question 10: Describe any need your enterprise has for increasing exports in areas of production technology, product quality, packaging, inventory control, staffing, etc..*:** Four of the thirteen respondents did not report any needs in these areas. Four respondents reported that assistance with quality assurance and quality control would help increase imports. For example, there is a need for manufacturers to have access to higher quality, tested and certified botanical raw materials. Industry also needs to know the acceptable maximum allowable limits for all contaminants (purity standards) in the export destination countries. Three enterprises reported that assistance with modernizing production technologies would help to increase exports. Funding was mentioned by two enterprises; (1) funding for R&D to develop clinically-proven value-added extracts; and (2) bridge financing (to maintain liquidity while awaiting cash inflow).

Table 24 shows products and production needs of respondents.

[62] UAE (0.53%), Egypt (0.05%), Others (0.1%)
[63] Japan
[64] Gulf Countries (65%), Hong Kong (2%), Merchant Exporter (5%)

Table 24: Products and Production Needs for Increasing Exports

	Needs reported by Respondents
1	None needed
2	None needed
3	None needed
4	Need support from Government bodies specifically in areas of regulatory updates, production technology and product quality to improve exports.
5	Funding for R&D to develop value added botanical extracts which are clinically proven. Quicker licensing approval for importing herbal raw materials.
6	Bridge financing services to industry.
7	Production technology and packing technology.
8	In terms of product quality the important issue that needs to be addressed is finalization of acceptable limits of various parameters like trace heavy metals, residual organo-chlorine / organo-phosphorous pesticides, microbiological counts and aflatoxins. Currently they are varying in different countries making it difficult for exporters to adhere to such standards.
9	Use of new production technology using ultra sound assisted continuous extraction avoids high temperatures and can result in enhanced component extraction at lower temperatures and in a shorter time. Thermal degradation of the actives is thus significantly minimized in this process. It is believed that the cost of production can be reduced by as much as 30%. A reduction of 30% can make a substantial difference in the market share. Similarly use of other extraction technologies like supercritical, microwave extraction and pressurized solvent extraction also increase the export market share.
10	Technology: Fully automated equipment (capsule filling, blister packing, etc…)
11	Suppliers conforming to global standards in packaging for all formats is a prime requirement. Product quality certification & pre-shipment inspection agencies within reach too are needed on basis on bi-lateral agreements with various importing countries.
12	None needed (we have best qualify of products, packaging, production technology, etc)
13	Our need is to get good quality botanical raw materials.

Question 11 Documentary Evidence of Compliance with GACP and/or GMP: All but two of the respondents reported having a GMP Certificate (e.g. for the manufacture of ASU drugs in compliance with *Schedule T: Good Manufacturing Practices (GMPs) for Ayurveda, Siddha and Unani Medicines* of the Drug and Cosmetics Act)[65] issued by the Drugs Controller of their respective State Government or by the Department of AYUSH. Three respondents also reported being ISO 9001:2000 Certified.[66] ISO 9001:2000 specifies requirements for a quality management system where an organization needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

GACP compliance was only mentioned by two respondents. One respondent stated that they have an agro biotech set up which takes care of GACP compliance for certain important botanical raw materials. Another stated that currently there is no methodology or documentary evidence available for GACP compliance for the raw materials that are procured from the open market. However this company follows the European GACPs for their farms in India. There was no

[65] Government of India Ministry of Health & Family Welfare. Schedule T: *Good Manufacturing Practices (GMPs) for Ayurveda, Siddha and Unani Medicines.* In: *The Drugs and Cosmetics Act and Rules* (as amended up through 30th June 2005. New Delhi: Department of Health. 2005. Available at: http://cdsco.nic.in/html/Drugs&CosmeticAct.pdf.

[66] International Organisation for Standardisation (ISO). ISO 9001:2000 Quality Management Systems – Requirements. Geneva, Switzerland: ISO. 2000.

mention by any respondents of the *National Medicinal Plants Board (NMPB) Good Agriculture Practices (GAPs) for Medicinal Plants*.[67]

Question 12 Do you Operate your own In-house Quality Control Laboratory or do you make use of Governmental or Independent Contract Laboratories for the Testing and Release of your Ingredients and Finished Products?: All but two of the respondents have their own in-house Quality Control laboratories. One respondent reported the exclusive use of governmental and independent laboratories. Most respondents also use governmental or independent contract laboratories for certain tests for which their in-house laboratories do not have the apparatus or capabilities (e.g. aflatoxins, heavy metals, pesticide residues). Table 25 provides the respondents answers to this question.

Table 25: Quality Control Laboratory: In-house or Independent

1	We have our own Analytical Laboratory under Schedule T and for most of the products and ingredients we carry out necessary tests and are taking help of independent contract Laboratories approved by Food and Drug Administration for whatever tests we could not be able to carry out.
2	In-house.
3	No response.
4	Full-fledged In-house Quality Control laboratory. Most of the tests are performed in In-house laboratory, for few tests like Pesticides, Aflatoxins; we get these sourced from outside laboratories.
5	In-house Quality Control Laboratory for TLC.
6	Both.
7	We have our own in-house Quality Control Laboratory for the testing and examination of Ingredients and finished products. Sometimes we make use of governmental or independent contract laboratories.
8	We have in house laboratory to carry out all the testing required for herbal products. Our lab is also a government certified lab for testing Ayurvedic products. Heavy metal testing is only outsourced from an ISO 17025 accredited lab.
9	Yes we have in-house Q.C. Laboratory, and if some advance tests are required we get it done from Govt. approved laboratory.
10	We rely on in-house QA laboratory as well as well as Public Testing laboratories for our needs.
11	Yes, we have our own in-house Q.C. Lab as well as we make use of governmental or independent contract laboratories.
12	Make use of governmental or independent contract laboratories.
13	All the manufacturing plants are with approved Quality Control Laboratories. As and when required, help of External Labs are taken.

Question 13 Are your Natural Ingredients tested and released in conformance to established Pharmacopoeial Quality Standards? All but one respondent reported specifications for test and release according to pharmacopoeial quality standards. Four companies specifically stated that their botanical raw material specifications are written according to the monographs of the Ayurvedic Pharmacopoeia of India (API). One company also uses the Indian Pharmacopoeia (IP) standards for some ingredients. Most companies also reported that when no pharmacopoeial monograph exists, in-house standards are developed which are either based on pharmacopoeial guidelines for specifications or based on experience (past data from several batches). One company reported using the Pharmacopoeial Standards of Ayurvedic Formulations for the testing

[67] National Medicinal Plants Board. *Good Agriculture Practices (GAPs) for Medicinal Plants.* New Delhi: National Medicinal Plants Board. 2007. Available at: http://nmpb.nic.in/Draft%20GAPs.pdf.

of complex mixtures. One company reported that for non-pharmacopoeial botanical extracts are standardized as per in-house specifications and as per Standardized Information on Dietary Ingredients (SIDI). One company reported that their specifications for excipients and additives are based on official monographs of the IP, BP, or USP.

Question 14 Please list the Specific Tests that are performed on your Exported Finished Products, the Specifications and Limits, and the Costs if Carried out by Outside Laboratories: The responses to this question are difficult to analyze and it may be possible that some of the respondents misunderstood the intent of the question. About half of the companies report that they subject their finished products (or extracts) to complete testing for conformance to written specifications that are specific to the dosage form and composition. The other half of companies report only minimal testing for release of finished products, for example mainly an identity test (TLC) or tests for contaminants (heavy metals and microbiological quality). Table 26 shows examples of the tests that are carried out by the survey respondents.

Table 26: List of Tests Carried Out on Finished Products

1	CAPSULES: LOD capsules powder, Average weight of 10 capsules, Percentage of deviation, DT, Weight of filled capsules, Weight of empty capsules, Average weight. SYRUP: Weight per ml at 27 degree Celsius, Description of syrup, Acidity, pH, Total solid. TABLETS: (uncoated/Coated) LOD of granules, Average weight of 10 tabs, DT, Hardness, Diameter, Thickness, LOD of tablets.
2	Pharmacopoeial standards + Heavy metal testing cost: Rs.3000/- per batch.
3	No response.
4	CHYAWANPRASH: Organoleptic evaluation, Identification test, pH, LOD, Total sugar content, Heavy metals, Pesticide residues, Microbiological. HAIR OIL: Description, Insoluble matter, TBHQ, Acid value, Peroxide value, Iodine value, Water, Colour reading PSYLLIUM PRODUCT: Description (organoleptic and visual), Loss on drying, pH, Swelling index, Bulk density, Sieve analysis, Identification by TLC, Microbiological. PUDIN HARA (liquid): Description (color and odor), Identification test, pH, Filled volume, Volume variation. SHILAJIT CAPSULES: Appearance, Identification, Average full weight, Uniformity of weight, Disintegration time, Fulvic acid content, Microbiological.
5	TYPICAL TESTS PERFORMED: Organoleptic evaluation, Solubility test by IP (in water and alcohol), Assay, Heavy metals, Microbial profile.
6	Mainly TLC is done.
7	Heavy metals, Microbiological analysis, as per WHO & FDA norms = Rs. 1500 per sample.
8	EXAMPLE: Organoleptic evaluation, Physico-chemical (average weight, loss on drying, punch size, hardness, disintegration time, friability, total ash, acid insoluble ash, pH of aqueous extract), Trace metals, Residual pesticides, Microbiological examination.
9	EXAMPLE: Organoleptic evaluation, Identification by TLC, Physico-chemical analysis (loss on drying, ash content, acid insoluble ash, pH), physical (bulk density and particle size), Heavy metals, Microbiological analysis, Test for specific pathogen, Mycotoxin analysis, Residual solvent analysis, Pesticide residues, Phytochemical analysis.
10	No exported products. The following tests are carried out for herbal materials: Total ash, Acid insoluble ash, Water soluble extractives, TLC, Loss on drying, Heavy metals, Microbial estimation.
11	EXAMPLE: Description/Macroscopic examination, Physical test (hardness, friability, disintegration time), Ash, Acid insoluble ash, Foreign matter, Water soluble extractive, Ethanol soluble extractive, Ethyl acetate soluble extractive, Loss on drying, Assay by HPLC/HPTLC, Heavy metals, Microbiological tests, Pesticide residues, Aflatoxins. NOTE: Most testing is done in-house but if carried out at an approved Public Testing Laboratory, the cost for this

	range of tests amounts to Rs. 17267.00
12	Heavy metals only.
13	Heavy metals and Microbiological tests only.

Question 15: Which are your top five products? The purpose for asking this question was so that a risk analysis can be carried out that looks at two major risk areas when considering scale-up for increased export promotion. The first risk concerns the conservation status of all of the product's ingredients which necessitates an analysis for the determination as to whether a sustainable supply of cultivated and/or wild collected raw materials are available to accommodate increased production and export over the long haul. It is not wise to invest in the costs of scale-up and marketing in foreign countries only to find that the raw material supply is non-sustainable at with increased demand.

The second risk related to this question concerns the legal status in the target export destination markets for the product's ingredients and for the finished products themselves. It is wise to know which specific countries have an existing regulatory framework for Indian medicinal natural products and what the market access requirements are. It is also important to know up front which countries have significant legislative and/or non-legislative market access barriers for Indian natural medicinal products. A preliminary analysis of the top products that the survey respondents have targeted for export development will be a useful exercise that provides valuable data for the entire Indian natural products industry.

In the second phase of this project, certain experts in the requisite disciplines will be asked to carry out the aforementioned analysis for the Indian trade. For example, the FRLHT, Bangalore, has expressed interest in carrying out the conservation status analysis for the ingredients of the selected top products.

Table 27 shows the list of top products targeted for export promotion as identified by the survey respondents. Please note that wherever possible the English standard common names (SCN) have been used along with the Latin binomials. Where no English SCN exists, the Indian common name has been retained.

Table 27: Selected Top Products for Determination of Conservation Status in India and Legal Status in Foreign Markets

Product Name	Natural Ingredients List
Actiflexan® Tablets	Acacia gum (*Acacia* spp.), Chinese smilax (*Smilax china*), Ext. Dashamool Quath (multi-herb formula), Ext. Maharasnadhi Quath (contains *Vanda roxburghii*, among others), guggal (*Boswellia glabra*).
Actilivforte® Tablets/Syrup/Drops	Acacia gum (*Acacia* spp.), black nightshade (*Solanum nigrum*), eclipta (*Eclipta prostrata*), Himalayan gentian (*Gentiana kurroo*), kukadvel (*Luffa echinata*), phyllanthus (*Phyllanthus niruri*).
Alsaid	Ingredients not provided.
Amlapitta Mishran Suspension	Amla fruit (*Phyllanthus emblica*), belleric myrobalan fruit (*Terminalia bellerica*), chebulic myrobalan fruit (*Terminalia chebula*), chirata whole plant (*Swertia chirayita*), eclipta whole plant (*Eclipta prostrata*), Indian fumitory whole plant (*Fumaria parviflora*), Indian tinospora stem (*Tinospora cordifolia*), licorice root (*Glycyrrhiza glabra*), Malabar nut tree (*Justicia adhatoda*), neem (*Azadirachta indica*), pointed gourd (*Trichosanthes dioica*), and Shouktik Bhasma. NOTE: Each bhasma is a

	complex formulation. For the composition of each bhasma see The Ayurvedic Formulary of India.
Betazen Capsules	Amla fruit (*Phyllanthus emblica*), belleric myrobalan fruit (*Terminalia bellerica*), bitter melon fresh fruit (*Momordica charantia*), chebulic myrobalan fruit (*Terminalia chebula*), fenugreek seed (*Trigonella foenum-graecum*), flame-of-the-forest (*Butea monosperma*), ginger rhizome (*Zingiber officinale*), gymnema leaf (*Gymnema sylvestre*), Indian kino tree (*Pterocarpus marsupium*), Indian tinospora stem (*Tinospora cordifolia*), long pepper fruit (*Piper longum*), neem (*Azadirachta indica*), pepper fruit (*Piper nigrum*), picrorhiza rhizome (*Picrorhiza kurrooa*), turmeric rhizome (*Curcuma longa*)
Biogest	Amla fruit (*Phyllanthus emblica*), belleric myrobalan fruit (*Terminalia bellerica*), boerhavia whole plant (*Boerhavia diffusa*), chebulic myrobalan fruit (*Terminalia chebula*), guggul oleo-gum-resin (*Commiphora mukul*), kokilaksha (*Asteracantha longifolia*), processed cinnabar, sveta sariva root (*Hemidesmus indicus*).
Brihatvat Chintamani	Abhrak bhasma, Loha bhasma, Mauktik bhasma, Parad bhasma, Praval bhasma, Raupya bhasma, Suwarna bhasma. NOTE: Each bhasma is a complex formulation. For the composition of each bhasma see The Ayurvedic Formulary of India.
Chyavanaprasam	Amla fruit (*Phyllanthus emblica*), Arani root (*Premna integrifolia*), air potato tuber (*Dioscorea bulbifera*), ashwagandha root (*Withania somnifera*), bael tree root (*Aegle marmelos*), bamboo silicious concentration (*Bambusa arundinacea*), blue wiss whole plant (*Teramnus labialis*), boerhavia whole plant (*Boerhavia diffusa*), bribati root (*Solanum indicum*), cardamom fruit (*Elettaria cardamomum*), Chinese pistachio galls (*Pistacia integerrima*), cinnamon bark (*Cinnamomum zeylanicum*), clove flower bud (*Syzygium aromaticum*), crystal sugar, cyperus rhizome (*Cyperus rotundus*), finger-leaf morning glory tuber (*Ipomoea digitata*), fragrant padre tree root (*Stereospermum chelonoides*), ghrit (clarified butter), grape fruit (*Vitis vinifera*), heart-leaf sida whole plant (*Sida cordifolia*), honey, Indian cassia leaf (*Cinnamomum tamala*), Indian elecampane root (*Inula racemosa*), Indian tinospora stem (*Tinospora cordifolia*), kakanasa fruit (*Martynia diandra*), leptadenia whole plant (*Leptadenia reticulata*), licorice root (*Glycyrrhiza glabra*), long pepper fruit (*Piper longum*), Malabar nut tree leaf (*Justicia adhatoda*), Malay bush beech root (*Gmelina arborea*), mesua flower (*Mesua ferrea*), oroxylum root (*Oroxylum indicum*), phyllanthus whole plant (*Phyllanthus niruri*), prishniparni root (*Uraria picta*), sandalwood heart wood (*Santalum album*), sarivan root (*Desmodium gangeticum*), sesame seed oil (*Sesamum indicum*), shatavari root (*Asparagus racemosus*), three-lobe-leaf cowpea whole plant (*Vigna trilobata*), tribulus root (*Tribulus terrestris*), waterlily flower (*Nymphoea stellata*), yellow-fruit nightshade root (*Solanum xanthocarpum*), zedoary rhizome (*Curcuma zedoaria*).
Dasamularishtam	Contains over 70 ingredients. See monograph: *Das Amularista*. In: The Ayurvedic Formulary of India, Part I, 2nd Edition, 2003; pages 13-14.

Dhanwantharam Thailam	Contains nearly 50 ingredients. See monograph: *Chanvantara Taila*. In: The Ayurvedic Pharmacopoeia of India Formulations, Part II, Volume I, First Edition, 2007; pages 117-119.
Galactozen Capsules	Fenugreek seed (*Trigonella foenum-graecum*), Indian kudzu tuber (*Pueraria tuberosa*), licorice root (*Glycyrrhiza glabra*), shatavari root (*Asparagus racemosus*).
Glymin® Tablets	Amla fruit (*Phyllanthus emblica*), gymnema leaf (*Gymnema sylvestre*), Indian kino tree (*Pterocarpus marsupium*), Indian tinospora stem (*Tinospora cordifolia*), jambolan (*Syzygium cumini*), salacia (*Salacia oblonga*), turmeric rhizome (*Curcuma longa*), processed white bitumen.
HeezOn®	Ingredients not provided.
Involon Bolus (animal health)	Ceylon leadwort root (*Plumbago zeylanica*), flamelily root tuber (*Gloriosa superba*), garden cress (*Lepidium sativum*), Levant cotton seed (*Gossypium herbaceum*), Malabar nut tree (*Justicia adhatoda*), Syrian rue (*Peganum harmala*).
Isova Powder	Amla fruit (*Phyllanthus emblica*), belleric myrobalan fruit (*Terminalia bellerica*), black salt, Chebulic myrobalan fruit (*Terminalia chebula*), fennel fruit (*Foeniculum vulgare*), fenugreek seed (*Trigonella foenum-graecum*), ginger rhizome (*Zingiber officinale*), Indian jalap root (*Operculina turpethum*), Indian laburnum (*Cassia fistula*), kankphal (?), Lemon peel (*Citrus* × *limon*), licorice root (*Glycyrrhiza glabra*), long pepper fruit (*Piper longum*), psyllium husk (*Plantago ovata*), senna leaf (Cassia angustifolia), turmeric rhizome (*Curcuma longa*), wild celery fruit (*Apium graveolens*).
Jio 99	Ingredients not provided.
Kultab Tablet	Camphor (*Cinnamomum camphora*), elephant yam corm (*Amorphophallus campanulatus*), Indian barberry (*Berberis aristata*), Licorice root (*Glycyrrhiza glabra*), neem (*Azadirachta indica*), senna leaf (*Cassia angustifolia*).
Liposem® Tablets	Arjuna (*Terminalia arjuna*), banana (*Musa paradisiaca*), bombax (*Bombax ceiba*), celastrus (*Celastrus paniculatus*), garcinia (*Garcinia cambogia*), guggul oleo-gum-resin (*Commiphora mukul*), Indian leadwort (*Plumbago indica*), licorice root (*Glycyrrhiza glabra*), moa tree (*Madhuca indica*), salacia (*Salacia oblonga*), strobilanthus (*Strobilanthus* spp.), thatch screwpine (*Pandanus tectorius*), tribulus (*Tribulus terrestris*).
MAK-4 Nectar	Amla fruit (*Phyllanthus emblica*), bacopa whole plant (*Bacopa monnieri*), cane sugar (*Saccharum officinarum*), cardamom (*Elettaria cardamomum*), chebulic myrobalan fruit (*Terminalia chebula*), cinnamon bark (*Cinnamomum verum*), clarified butter, cyperus rhizome (*Cyperus rotundus*), cyperus (*Cyperus scariosus*), dwarf morning glory (*Evolvulus alsinoides*), honey, licorice root (*Glycyrrhiza glabra*), long pepper fruit (*Piper longum*), mesua flower (*Mesua ferrea*), sandalwood heart wood (*Santalum album*), turmeric rhizome (*Curcuma longa*),

	vidanga fruit (*Embelia ribes*). NOTE: These herbs are processed in the extracts of another 25 herb formulation.
MAK-5 Tablets	Amla fruit (*Phyllanthus emblica*), ashwagandha (*Withania somnifera*), curculigo rhizome (*Curculigo orchioides*), dwarf morning glory (*Evolvulus alsinoides*), elephant vine (*Argyreia nervosa*), finger-leaf morning glory tuber (*Ipomoea digitata*), Indian gum arabic tree (*Acacia nilotica*), Indian tinospora (*Tinospora cordifolia*), karira (*Capparis decidua*), licorice root (*Glycyrrhiza glabra*), shatavari (*Asparagus racemosus*), shveta mushali (*Asparagus adscendens*), simple-leaf chaste tree (*Vitex trifolia*).
MAK 7 Sugar Free Tablets	Amla fruit (*Phyllanthus emblica*), bacopa whole plant (*Bacopa monnieri*), cardamom (*Elettaria cardamomum*), chebulic myrobalan fruit (*Terminalia chebula*), cinnamon bark (*Cinnamomum verum*), cyperus rhizome (*Cyperus rotundus*), cyperus (*Cyperus scariosus*), dwarf morning glory (*Evolvulus alsinoides*), licorice root (*Glycyrrhiza glabra*), long pepper fruit (*Piper longum*), mesua flower (*Mesua ferrea*), sandalwood heart wood (*Santalum album*), turmeric rhizome (*Curcuma longa*), vidanga fruit (*Embelia ribes*). NOTE: These herbs are processed in the extracts of another 25 herb formulation.
Myaxyl® Oil	Deodor cedar (*Cedrus deodora*), Eve's apple tree (*Tabernaemontana dichotoma*), greater galangal (*Alpinia galanga*), kokilaksha (*Asteracantha longifolia*), nux-vomica (*Strychnos nux-vomica*), sandalwood heart wood (*Santalum album*), sesame seed oil (*Sesamum indicum*), west Indian lemongrass leaf (*Cymbopogon citratus*).
Nature Care	Amla fruit (*Phyllanthus emblica*), psyllium seed husk (*Plantago ovata*).
Nervono Capsules	Ashwagandha (*Withania somnifera*), gotu kola whole plant (*Centella asiatica*), jatamansi (*Nardostachys jatamansi*), sankha pushpin whole plant (*Convolvulus pluricaulis*).
Nityam Churna	Ginger rhizome (*Zingiber officinale*), senna leaf (*Cassia angustifolia*) and other herbs (full list not provided).
Nilibhringadi Kerathailam	Prepared from (1) juices of amla fresh fruit pulp (*Phyllanthus emblica*), colocynth whole plant (*Citrullus colocynthis*), eclipta whole plant (*Eclipta prostrata*), indigo leaf (*Indigofera tinctoria*), (2) buffalo's milk, coconut oil (*Cocos nucifera*), cow's milk, goat's milk, sesame oil (*Sesamum indicum*), (3) kalka dravyas, daruharidra (*Asteracantha longifolia*), licorice root (*Glycyrrhiza glabra*), precatory root (*Abrus precatorius*).
Pancharishta	Ingredients not provided.
Pep-Up Tablet	Calamus (*Acorus calamus*), Ceylon leadwort root (*Plumbago zeylanica*), eclipta whole plant (*Eclipta prostrata*), long pepper fruit (*Piper longum*), nagar (?), pepper fruit (*Piper nigrum*), phyllanthus (*Phyllanthus niruri*), tephrosia (*Tephrosia purpurea*), wild celery fruit (*Apium graveolens*).
Phytocal	Calcium, phosphorous, vitamin B12, vitamin D3; fortified with herbal

	extracts. *Note*: herbal formulation not provided.
Plasonil® Tablets	Acacia gum (*Acacia* spp.), aconite (*Aconitum napellus*), dita bark tree (*Alstonia scholaris*), ginger rhizome (*Zingiber officinale*), godanti bhasma (hydrated calcium sulphate), holy basil (*Ocimum tenuiflorum*), Indian tinospora (*Tinospora cordifolia*), kajjali (sulphide of mercury), long pepper fruit (*Piper longum*), pepper fruit (*Piper nigrum*), sodium borate (*Sodii biboras*), sudarshan (*Crinum asiaticum*), turmeric rhizome (*Curcuma longa*). NOTE: Each bhasma is a complex formulation. For the composition of each bhasma see The Ayurvedic Formulary of India.
Progen DA Capsules	Bombax stem bark (*Bombax ceiba*), purified extract of horseradish tree (*Moringa oleifera*).
Psoriacare	Ingredients not provided.
Pudin® Hara	Peppermint essential oil (*Mentha × piperita*), shilajit extract (*Asphaltum*), spearmint essential oil (*Mentha spicata*).
Pyocare	Ingredients not provided.
Rasanagugul Tablets	Ashwagandha (*Withania somnifera*), castor (*Ricinus communis*), Chinese chaste tree (*Vitex negundo*), deodor cedar (*Cedrus deodora*), ginger rhizome (*Zingiber officinale*), greater galangal (*Alpinia galangal*), Indian frankincense oleo-gum-resin (*Boswellia serrata*), kokilaksha (*Asteracantha longifolia*), rasanaerandadi kwath (formulation), yogarajagulgulu (formulation). *Note*: For composition of the formulations see Ayurvedic Formulary of India.
Rasnairandadi Kashayam	Ingredients not provided.
Revil	Ingredients not provided.
Rumaflex® Capsules	Ashwagandha (*Withania somnifera*), Chinese smilax (*Smilax china*), hygrophila (*Hygrophila auriculata*), Maharasnadhi Quath (contains *Vanda roxburghii*), Mahayograj guggal (*Commiphora wightii*), shilajit (Asphaltum).
Rumaflex® Liniment	Aconite (*Aconitum napellus*), ajowan (*Trachyspermum ammi*), black mustard (*Brassica nigra*), calamus (*Acorus calamus*), camphor (*Cinnamomum camphora*), ginger rhizome (*Zingiber officinale*), Jimson weed leaf (*Datura stramonium*), menda lakdi stem bark (*Litsea sebifera*), nux-vomica (*Strychnos nux-vomica*), sesame seed oil (*Sesamum indicum*), sindhalun (*Sodi chloridum*).
Shilajit Capsules	Purified extract of raw shilajit (*Asphaltum*).
Shilapravang Mouktik Tablets	Bamboo silicious concentration (*Bambusa arundinacea*), bhimsen kapur, Indian tinospora extract (*Tinospora cordifolia*). mouktik pisti, pravala pisti [cabbage rose (*Rosa centifolia*) and pravala-suddha], shuddha shilajit (*Asphaltum*), suvarna makshik bhasma, tribulus fruit (*Tribulus terrestris*), vanga bhasma (tin bhasma), velachi (?). NOTE:

	Each bhasma is a complex formulation. For the composition of each bhasma see The Ayurvedic Formulary of India.
Shilapravang Special Tablets	Ambrette (*Abelmoschus moschatus*), amla fruit (*Phyllanthus emblica*), ashwagandha (*Withania somnifera*), camphor (*Cinnamomum camphora*), heart-leaf sida (*Sida cordifolia*), Indian tinospora starch (*Tinospora cordifolia*). mouktik pisti (pearl pishti), nutmeg seed (*Myristica fragrans*), praval bhasma (coral bhasma), shatavari root (*Asparagus racemosus*), shuddha shilajit (*Asphaltum*), Spanish pellitory (*Anacyclus pyrethrum*), suvarnamakshik bhasma (iron pyrite bhasma), suvarna bhasma (gold bhasma), tribulus fruit (*Tribulus terrestris*), vanga bhasma (tin bhasma), velvet bean seed (*Mucuna pruriens*), and *Makaradhwaja* [*prepared by shuddha Swarna (Gold), Astasamskarita Parada (Mercury) and shuddha Gandhaka (Sulphur)*]. NOTE: Each bhasma is a complex formulation. For the composition of each bhasma see The Ayurvedic Formulary of India.
Spycus-D	Ingredients not provided.
Sudarshan Churna	Contains chirata whole plant (*Swertia chirayita*) plus 52 other bitter ingredients. See monograph *Sudarsana Curna*. In: The Ayurvedic Formulary of India, Part I, 2nd Edition, 2003, pages 116-117.
Swamala Compound	Abhrak bhasma, chyavanprash (a complex herbal mixture; see separate listing above for example), kantaloha bhasma, pravala pisti [cabbage rose (*Rosa centifolia*) and pravala-suddha], raupya bhasma, suvarna bhasma, and *Makaradhwaja [prepared by shuddha Swarna (Gold), Astasamskarita Parada (Mercury) and shuddha Gandhaka (Sulphur)*]. NOTE: Each bhasma is a complex formulation. For the composition of each bhasma see The Ayurvedic Formulary of India.
Topicure Spray & Gel (animal health)	Chir pine (*Pinus roxburghii*), deodar cedar heart wood (*Cedrus deodora*), eucalyptus leaf (*Eucalyptus globulus*).
Trichup Oil	Amla fruit (*Phyllanthus emblica*), bruhati laxmana (*Solanum indicum*), coconut oil (*Cocos nucifera*), colocynth (*Citrullus colocynthis*), cyperus rhizome (*Cyperus rotundus*), eclipta whole plant (*Eclipta prostrata*), gotu kola whole plant (Centella *asiatica*), horn-of-plenty (*Datura metel*), indigo (*Indigofera tinctoria*), jasmine (*Jasminum officinale*), karum tree (*Derris indica*), licorice root (*Glycyrrhiza glabra*), neem leaf (*Azadirachta indica*), precatory (*Abrus precatorius*), sesame seed oil (*Sesamum indicum*), three-leaf caper (*Crateva nurvala*).
Triphala Tablets	Amla fruit (*Phyllanthus emblica*), belleric myrobalan fruit (*Terminalia bellerica*), chebulic myrobalan fruit (*Terminalia chebula*).
Triphala Plus Tablets	Amla fruit (*Phyllanthus emblica*), belleric myrobalan fruit (*Terminalia bellerica*), cabbage rose (*Rosa centifolia*), chebulic myrobalan fruit (*Terminalia chebula*).
Triver® Capsules	Andrographis (*Andrographis paniculata*), bonduc (*Caesalpinia bonduc*), godanti bhasma (hydrated calcium sulphate), sodium borate (*Sodii biboras*), Sudarsana churna (*Tinospora tomentosa*). NOTE: Each

	bhasma is a complex formulation. For the composition of each bhasma see The Ayurvedic Formulary of India.
Vasant Kusumakar	Abhrak bhasma, kantaloha bhasma, mauktik bhasma, nag bhasma, praval bhasma, rasasindoor (purified mercury preparation), raupya bhasma, suwarna bhasma, wang bhasma. NOTE: Each bhasma is a complex formulation. For the composition of each bhasma see The Ayurvedic Formulary of India.
Vatika Hair Oil	Amla fruit (*Phyllanthus emblica*), belleric myrobalan fruit (*Terminalia bellerica*), chebulic myrobalan fruit (*Terminalia chebula*), coconut oil (*Cocos nucifera*), gotu kola whole plant (*Centella asiatica*), henna leaf (*Lawsonia inermis*), lemon peel essential oil (*Citrus × limon*), milk, neem leaf (*Azadirachta indica*), rosemary leaf essential oil (*Rosmarinus officinalis*), soy bean lecithin phosphatides, (*Glycine max*), spiked ginger lily rhizome (*Hedychium spicatum*), sugandhit dravyas (essential oils of various aromatic drugs).
Ventoluft Capsules	Ashwagandha (*Withania somnifera*), boerhavia whole plant (*Boerhavia diffusa*), castor (*Ricinus communis*), guggul oleo-gum-resin (*Commiphora mukul*), Indian tinospora stem (*Tinospora cordifolia*).
Wisprec Spray (animal health)	Holy basil (*Ocimum tenuiflorum*), lemongrass leaf (*Cymbopogon* spp.), turmeric rhizome (*Curcuma longa*).
Worry Free Tablets	Ashwagandha (*Withania somnifera*), bacopa whole plant (*Bacopa monnieri*), dwarf morning glory (*Evolvulus alsinoides*), greater galangal rhizome (*Alpinia galanga*), Indian tinospora stem (*Tinospora cordifolia*), jatamansi (*Nardostachys jatamansi*), licorice root (*Glycyrrhiza glabra*), Pearl.
X-Pain	Ingredients not provided.
Zeal Plus Lozenges	Amla fruit (*Phyllanthus emblica*), ginger rhizome (*Zingiber officinale*), licorice root (*Glycyrrhiza glabra*), peppermint leaf (*Mentha × piperita*).
Zef's Cough Syrup	Ginger rhizome (*Zingiber officinale*), licorice root (*Glycyrrhiza glabra*), Malabar nut tree (*Justicia adhatoda*), plus 14 other herbs (list not provided).
Zigbo Bolus	Andrographis (*Andrographis paniculata*), boerhavia whole plant (*Boerhavia diffusa*), chebulic myrobalan fruit (*Terminalia chebula*), eclipta whole plant (*Eclipta prostrata*), heart-leaf sida (*Sida cordifolia*), Indian fumitory whole plant (*Fumaria parviflora*), neem (*Azadirachta indica*), phyllanthus root, stem and leaf (*Phyllanthus fraternus*), purple tephrosia (*Tephrosia purpurea*), prickly chaff flower (*Achyranthes aspera*).

For those survey respondents also trading in natural ingredients, Table 28 shows the top medicinal natural ingredients prioritized by the survey respondents for export development.

Table 28: Top Medicinal Natural Ingredients Prioritized for Export Development

Common Name	Plant Part	Botanical Name	Form
Andrographis	Herb	*Andrographis paniculata*	Powdered extract
Ashwagandha	Root	*Withania somnifera*	Powdered extract
Bacopa	Whole plant	*Bacopa monnieri*	Powdered extract
Forskohlii	Root	*Plectranthus barbatus*	Powdered extract
Neem	Seed	*Azadirachta indica*	Extract
Neem	Seed	*Azadirachta indica*	Oil
Psyllium	Seed husk	*Plantago ovata*	Dried husk
Shatavari	Root	*Asparagus racemosus*	
Tribulus	Root	*Tribulus terrestris*	Powdered extract
Triphala	Fruits	*Phyllanthus emblica, Terminalia bellerica, Terminalia chebula*	Powder
Turmeric	Rhizome	*Curcuma longa*	Powdered extract
Velvet bean	Seed	*Mucuna pruriens*	Powder

Question 16: For your top five products only what is the Annual Turnover by Value (Rs) in the Indian Domestic Market. Ten of the thirteen survey respondents provided an answer to this question.

- One respondent reported no domestic business. 100% exports;
- Two of the respondents reported negligible domestic turnover;
- Three of the respondents reported domestic turnover value for their top-five products at Rs 24.62 lacs, Rs. 26.00 lacs, and Rs. 40.30 lacs, respectively (= USD $574,332, $606,414, and $939,942);
- Four of the respondents reported relatively high turnover value for their top-five products at Rs. 21.47 crore, Rs. 56.90 crore, Rs. 60.15 crore, and Rs. 757 crore, respectively (= USD $5,007,580, $13,271,138, $14,029,622, and $176,559,773).

Question 17: Which Harmonized System (HS) Tariff Codes are you using for your top five exported products? Table 29 Shows the HS Codes that the survey respondents are using for their main exports.

In some cases it appears that there are discrepancies between the HS Codes being used by some of the enterprises verses the description of the HS Codes of the Indian Trade Classification (ITC) system. Also, it is worth noting that Chyawanprash is exported as both “put up for retail sale” (HS 3003.9011) and “not put up for retail sale” (HS 3004.9011).

Table 29: HS Codes used by Survey Respondents

HS Codes	Product(s)	Notes from ITC HS Codes
1211.9013	Psyllium Husk	1211.9013 is psyllium seed but 1211.9032 is psyllium husk
1302.1919	Standardized herbal extracts	All "other" extracts
2309.9020	Veterinary feed supplements	Concentrated for compound animal feed
3003.9011	Ayurvedic medicines put up for retail sale, Ayurvedic veterinary medicines, Amrit Kalash Tablet, Amrit Kalash Nectar, Chyawanprash, Nature Care, Shilajit Capsules, Triphala Plus, Worry Free Tablet	
3003.3900	Vatika Hair Oil	Other medicaments containing hormones or other products of heading 2937 excluding antibiotics
3004.9011	Ayurvedic medicines not put up for retail sale, Chyavanaprasam, Dasamularishtam, Dhanwantharam Thailam, Isova Powder, Kultab Tablet, Nilibhringadi Kerathailam, Pep-up Tablet, Rasnairandadi Kashayam, Zeal Plus Ayurvedic Lozenges	
3006.1020	Personal Care Products	Sterile Laminaria & Laminaria tents & Sterile Absorbable Surgical Dental Haemostatics
3305.30	Trichup Oil	Hair lacquers

Question 18: Identify current support received from technology extension centres, standards bureaus, public sector institutions, technology consulting firms, business training institutions. Ten of the thirteen respondents (76.9%) reported that they receive no support at all from any of these types of institutions. However one enterprise reported that collaborative works are being undertaken with institutions like CCRAS, ICMR, and CSIR.

One company reported that they have received a loan from the Technology Development Board. Another company reported that they receive occasional support in the form of one-day seminars and small exhibitions. And one company reported that they do receive good support from technology consulting firms, business training institutions and technology extension centres.

Question 19: Describe any needs your Enterprise has for Transport, Warehousing, Freight Forwarding, Telecommunications, Customs, Freight Insurance, Distribution and Logistics Staffing. Six of the thirteen respondents reported no needs in this area. The remaining seven respondents provided some interesting comments. One in particular made an important remark with regard to the need for warehousing the destination countries in order to provide better and faster service to customers as well as serve just-in-time buyers who cannot wait for the long lead-time of sea freight. Here are the various short responses to this question:

- Need warehousing facility in destination country (e.g. USA) for quicker delivery.
- Transportation time to long distance countries like USA, Canada, Scandinavian countries-Norway, Denmark and to other European countries, due to lack of immediate connections from the respective hub points, time taken to reach the destination is more than 6 days. It should be reduced to 48 hrs to 72 hrs maximum. Customs – Being EOU, permission needs to be taken for DTA and Third party shipments. File movement for permission in the Customs Dept., should be improved. Permission should be granted within 48 hrs of submission as against prevailing minimum 1 week.

- No separate needs other than speedy movements of papers in Customs.
- Interfacing with Customs Dept, Airlifting of consignment.
- With increase in exports the need for all of these support services would go up. The critical among them would be telecommunication, tracking of shipments & secure warehousing. Most critical would be market data regarding procurement of input materials.
- We are managing transportation, forwarding etc at our own. Warehousing at the port whenever required.
- No export is done from our company, but we would like to export if demand for our products, and for the same we definitely in need of export support from concerned agencies.

Question 20: Please list any current facility registration that your enterprise maintains any foreign food and/or drug regulatory agency. Seven of the thirteen respondents reported that their facility is not registered at this time with any foreign regulatory agency. Four of the respondents are registered with the U.S. Food and Drug Administration (FDA) as food facilities under the Bioterrorism Act of 2002, which is a legal requirement for any exports of food or dietary supplement products into the United States. One of these four companies is also in process of obtaining an Australian Government Therapeutic Goods Administration (TGA) GMP certificate. One company has their facility registered with the UAE and another Indian facility is registered with both the Ministry of Health Malaysia and the Ministry of Health Oman.

Question 21: Identify current support and limits thereof received from transport carriers, freight-forwarding industry, telecommunications, customs, and business training institutions. Nine (69.2%) of the thirteen respondents reported no support and/or limitations in this area of distribution and logistics. The remaining four respondents made the following varied comments:

- Need competitive freight charges and need faster approvals for import licenses.
- We are facing problems from freight-forwarding industry.
- Congestion at the port and shutdown / omitting of vessels at the calling ports are the problems being faced by the exporters these days, leading to delays in shipment. Government / Shipping lines are required to take appropriate action for improving infrastructure at ports and vessel availability.
- In an increasing global scenario 24X7 working is a reality. All of the above support services have to align themselves to delivery of products to the global market uninterrupted. Flexi hour workings, skeletal services, out sourcing etc are some of the suggested remedies to overcome bottlenecks caused by public holidays & unforeseen circumstances. The country ethics as such would have to change and only commerce brings about such revolutions, overnight.

Question 22: Describe any needs for export promotion, market access conditions, sales and marketing staffing. Eleven (84.6%) of the thirteen survey respondents provided very insightful and detailed responses to the question of needs in this area of marketing and promotion. The responses are separated below by subheadings of Financial needs, Market intelligence needs, Regulatory affairs needs, and Sales & Marketing needs.

Financial needs

- One of the primary needs for us and any exporting company is that the Financial Institutions in India should provide funding for business development / Market Access and Business Promotions.

Market intelligence needs

- Market estimates, demands for various product categories.
- Exploration of overseas market and overseas market channels.
- Need of market survey report of our competitor.
- Non availability of competent ORG / market survey bodies to understand the upcoming needs of the Nutraceutical / food industry.

Regulatory affairs needs

- Interface with regulatory domains of importing countries.
- Regulatory knowhow for different countries.
- With the changing regulatory scenario and compliance norms / guidelines being framed and implemented, the company needs to be updated and actively supported for export promotion.
- Novel Food Registration at EU regulation should be made easier with a reasonable / affordable cost.
- Non availability of list of medicinal plants those are registered / non-registered as Novel Food neither at EU regulation nor with any other competent body. Same fate with FDA / NDI registration at US FDA.
- License to companies for manufacturing exportable products should be given only if they meet the international standards in all respect, i.e., manufacturing facilities, R&D service, Analytical labs, etc. This encourages export of GMP produced products from the sub-standard products being exported.
- Legalization of documents for exports should be made more time and cost saving. There is no competent State Govt. Body to provide for legalization, it should be sent to Ministry of Commerce, Delhi. Govt. can at least have Ministry of Commerce offices at metro / major cities.

Sales and Marketing needs

- Participation in trade shows, building awareness of Ayurved & capabilities of India in this field are some of the vehicles that can be deployed. Establishment of 'India Distribution Hubs' and 'Contract Sales Force' would also be of help. The point is to have a 'concrete effort to build and sustain an "India Ayurved" Brand.
- Proper arrangements (facilities) and higher grants (50 to 75% of total cost – including accessories) for participation in international expos.
- Providing promotional materials in local languages.
- Appointment of Country manager.
- Market staffing for ethical promotion of our products and marketing agencies for our single herb products.
- Warehouse in export country.

Question 23: In the export markets where your products already have a presence, how are your product sold and marketed? In response, the most common method of sales and marketing for the Indian companies who responded to this survey is marketing products under own brand name through the assignment of an exclusive wholesale distribution company in the destination country. In order of predominance, the methods applied are as follows (Note: some companies are using multiple methods):

- 69.2% of respondents market products under their own brand (or plan to soon) through an exclusive wholesale distribution company in the foreign markets.
- 30.8% of the respondents market their branded products through their own sales and marketing personnel and assigned brokerage networks in the foreign markets.

- 30.8% of the respondents license their products to an established foreign company that markets the products under their brand name.
- 30.8% of the respondents sell their products direct to consumers in the foreign markets by internet or catalogue sales.
- 23.1% of the respondents sell their products to patients through practitioner clinic dispensaries in the foreign markets.
- 7.7% of the respondents sell their products directly to small importers, presumably small retail outlets.

Question 24: Do you already have pre-marketing authorization and product licenses in any countries? If yes, please list which of your products are licensed, notified, or registered, in which countries, and what are the product license numbers? Seven of the thirteen respondents (53.8%) do not have any of their products licensed, notified, or registered in any foreign countries. As could be predicted, the larger Indian companies who responded to this survey are already going down the path of product registrations for the marketing authorization of certain of their important medicinal natural products.

It is also no surprise that the results show that the highest level of success thus far for Indian companies obtaining governmental issued product marketing authorizations has occurred in nearby South Asian countries such as Malaysia, Myanmar, Nepal, and Sri Lanka, as well as in certain Arab States (Kuwait, Morocco, and UAE), and in certain of the Eastern European countries such as Hungary, Romania, Russian Federation, Turkey, and Ukraine. Compared to the very highly regulated markets for licensed or registered over-the-counter (OTC) medicinal products (e.g. Australia, Canada, Western European countries and the USA), legal market access should be, for the time being, relatively easier to attain in the South Asian countries, Arab States, and Eastern European countries.

One surprise in the results is that one Indian company reports having some of their traditional herbal medicinal products registered in Germany which is possibly one of the most highly regulated and most difficult countries in the world for a foreign enterprise to achieve governmental issued marketing authorization. Companies who can achieve marketing authorization for their medicinal natural products in Germany should be capable of accomplishing the same in other less complex and less costly regulatory environments.

One other point to consider is that some companies are registering their medicinal herbal products as food supplements in some European countries which can only be a temporary market access position. The compliance date for the registration of all medicinal herbal products in the EU Member States – as medicines and not as food supplements – is fast approaching in the year 2011. The current safe harbor offered by the dietary supplement grey area is expected to disappear at that time because herbal products offered in therapeutic single dosages cannot be classified as food supplements under the new European directives. The supplement registrations may be limited to vitamin, mineral, enzyme products that may contain only minor amounts of botanicals as aromas or flavors but not as therapeutically active ingredients.

Table 30 shows the countries where product registrations have been obtained (or are in process) by the survey respondents as well as the corresponding number of companies and products licensed thus far.

Table 30: Examples of Indian Products with Product Registrations in Foreign Markets

COUNTRY	COMPANY	PRODUCTS REGISTERED
Brazil	Natural Remedies	Zigbir: PR – 58013
Germany	Shree Dhootapapeshwar	Chyavanprash & some other single/poly-herbal preparations in tablet or powder form
Hungary	Dabur India	Ashwagandha, Chyawanprash, Herbal Toothpastes, Nature Care, Shilajit, Triphala
Italy	Dabur India	Ashwagandha, Chyawanprash, Herbal Toothpastes, Nature Care, Shilajit, Triphala
"	Maharishi Ayurveda	All products
Kuwait	Vasu Healthcare	Trichup Oil: M.D. NC 280-6/03
Malaysia	Vasu Healthcare	Kumkumadi Tailam: MAL07020144K
Morocco	Natural Remedies	Zistliquid: 706/DE/DSA/LNCMV Naturaliv: 704/DE/DSA/LNCMV Zigbir: 707/DE/DSA/LNCMV Zistpowder:708/DE/DSA/LNCMV Natchol: 709/DE/DSA/LNCMV Stodi: 710/DE/DSA/LNCMV
Myanmar	Vasu Healthcare	Zeal Cough Syrup: 1209A9996
Nepal	Shree Dhootapapeshwar	Entire domestic range of products are authorized
"	Zandu Pharmaceutical	Entire domestic range of products are authorized
Romania	Natural Remedies	Topicure Spray: 1063 /2006 Wisprec: 1068/2006 Zist Liquid: 209/2007 Zist powder: 210/2007
Russian Federation	Shree Dhootapapeshwar	Chyavanprash, Triphala Tablets
South Africa	Maharishi Ayurveda	In process of registering all products
South Korea	Natural Remedies	Zist Liquid: 6321 – 4069
Sri Lanka	Shree Dhootapapeshwar	Entire domestic range of products are authorized
Tanzania	Vasu Healthcare	Kumkumadi Tailam: N/C 2006 Trichup Herbal Shampoo: N/C 2007 Shyamla Herbal Shampoo: N/C 2008 Trichup Oil: N/C 2009
Turkey	Natural Remedies	Natchol : 805-246 Stodi: 805- 247 Zigbir: 805- 248
Ukraine	Shree Dhootapapeshwar	Vimliv and a clutch of products
United Arab Emirates	Dabur India	Ashwagandha, Chyawanprash, Herbal Toothpastes, Nature Care, Shilajit, Triphala

Question 25: Have you had any product license applications rejected by a foreign regulatory agency? If yes, by which countries and what were the main reasons for rejection? None of the survey respondents (100%) have ever had a product license application rejected by a foreign regulatory agency which is truly remarkable. This success rate suggests that the companies responding to this survey have excellent regulatory affairs staff and legal counsel, well experienced with the legal requirements for market access under varying regulatory frameworks. Another possible explanation for the lack of failures thus far is that none of these companies have yet applied for product licenses or registrations for their OTC medicinal products in any of the more highly regulated markets such as Australia, Canada, (western) EU Member States, and USA.

However, some Indian companies do have certain of their products existing in the USA market albeit as dietary supplement products which only require notification and not registration. OTC botanical drugs in the US market (e.g. psyllium- or senna- based laxative drug products) do require product registration (annually) and compliance with pharmaceutical GMP requirements.

Question 26: Are any of your products or product ingredients non-importable in target countries due to negative or positive lists or other regulatory issues? If yes, which ingredients in your products have been restricted from access, by which specific countries, and under which regulatory framework (e.g. cosmetic, dietary supplement, food, medicine)? Six of the thirteen survey respondents provided very useful answers to this question. The results show that certain important Indian Ayurvedic finished products are in fact problematic for legal export to certain target countries. There are a number of reasons for this including (1) various national negative lists for ingredients of drugs or foods and these lists have not been harmonized between the different EU Member States and/or the United States; (2) endangered or threatened species status of certain Indian ingredients (e.g. CITES listings); and (3) maximum allowable limits for heavy metals which excludes many traditional Indian medicinal products, in particular bhasmas.

The answers to this question clearly illustrate the complexities of product registration for traditional complex herbal mixtures with multiple processing steps and processing agents that may or may not be permitted in American or European commerce. A flagship Indian natural product such as Chyawanprash can even meet very complicated challenges for market authorization depending on whether the destination country views Chyawanprash as a dietary supplement product, a drug product, or as a food product. In any case, the human safety evidence for all of the Chyawanprash components as the recommended daily dosage levels must satisfy the regulatory agencies of each target country and detailed safety dossiers may need to be submitted to the national authorities for each ingredient that appears on a negative list. Here below are the specific responses to Question 26 from the respondents:

- One company reports that 19 of its ingredients are negative listed in the appendices of the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).
- Neem (*Azadirachta indica*) is non-importable in Russian Federation.
- One company reports that they have bigger problems with the Novel Foods regulation and restrictions in the EU and restrictions in Japan than with the dietary supplement regulations in the USA.
- There are many product ingredients that are non-importable in countries due to negative or positive lists or other regulatory issues. It is difficult to list all the ingredients here but it would be pertained to mention that European countries like Norway and Italy, among others, have various negative/restricted lists for foods or medicines based on the Novel Food Act and other regulatory issues such as CITES, etc.
- Some of the herbal ingredients are not acceptable in certain countries like Singapore or Malaysia in certain quantities in the products. Each country has its own list of 'negative'

herbs which would be too exhaustive to publish here or even provided as Annexure. We generally avoid exporting products containing heavy metals used as per Ayurveda.

- With the growing regulatory needs coming into place in various countries specifically so in the EU where some of the member states continue to follow national standards as well there are restrictions and individual lists (both negative and permitted) created by member states. Under the circumstances a number of products have been scrutinized and have a restricted entry. For example, the important formulation CHYAWANPRASH, which is (presently) sold as an unlicensed medicine in the UK. Some EU countries (Italy and Spain) have some restrictions imposed on the use of the ingredients boerhavia (*Boeharrvia diffusa*) and Indian tinospora (*Tinospora cordifolia*). Also Italy presently authorizes these products to be sold under food category only. Besides these regulatory barriers there are duty issues and product distribution limitations in various countries.
- Many of the popular Indian medicinal plants are not allowed for import in EU, USA, Japan and other developed countries. There is a need to compile a list of such plants which are not allowed for import in different countries. Since we deal with standardized herbal extracts and animal health products, we can only share few plants with our marketing experience. However this list is better prepared by the companies who are manufacturing and exporting human products. Examples: Only few are given below, if needed a complete list may be prepared:
    - *Terminalia bellerica* and *C. mukul* both are not approved in Australia;
    - *Salacia oblonga* is not approved in USA;
    - *Terminalia chebula* is not allowed as food/dietary ingredient in Japan but it is allowed as a medicine.

Question 27: Are your "company name", "finished product brand names," and/or "branded ingredient names" registered trademarks in each export country? If so, in which countries do you own and maintain trademarks? Are your trademarks also registered with World Intellectual Property Organization (WIPO)? Most of the survey respondents do not generally have registered trademarks in foreign countries for their company names and/or product brand names, respectively. None of the companies reported having WIPO registrations at all.

One company reported that their company name and finished product brand names are registered trademarks only in The Netherlands. Another company responded that in some key markets their company name and finished product brand names are registered trademarks. One company responded that they have one brand name registered in Australia, Canada, New Zealand, and the USA, and another brand name is registered only in Canada and USA. The following useful observation was made by another company in this regard: "We do not have any registered trademarks in any country other than India. This is an area that ITC can sensitize, educate and facilitate Indian industry. In the past there have been barriers encountered by fellow industry members having to buy out their own brands from persons with malafide intentions.

Question 28: Do you hold any patents for any products or processes? If so, please list patent numbers and countries where your patents are registered? Ten of the thirteen respondents (76.9%) do not have any process or product patents. One company has applied for one patent with the Indian Patent Office which has not yet been granted. As could be predicted, three of the larger companies are quite advance in this area. One company has 10 Indian patents and another has 35 Indian patents. A third company has 7 process patents and 14 product patents that have been granted by Indian Patent Office. This company also has a an international patent for an "improved anti-allergic herbal composition and a process for the preparation thereof," which has been granted in Australia, Mexico, Russia, Singapore, South Africa, Sri Lanka, and the USA[68] and is pending in

[68] Agarwal RK, Agarwal A. United States Patent 6,730,332: Herbal composition having antiallergic properties and a process for the preparation thereof. Washington, DC: United States Patent and Trademark Office. 04 May 2004.

Brazil, Canada, and India as well as in 19 European countries through the European Patent Office (EPO). This invention comprises a synergistic mixture of extracts from the fruits of *Terminalia chebula*, bark of *Albizia lebbeck*, *Terminalia bellerica* and *Emblica officinalis*, and also contains the fruits of *Piper longum*, *Piper nigrum* and of rhizomes of *Zingiber officinale*, thoroughly mixed to get the final composition which has potent antiallergic activity. The invention also relates to a process for the preparation of such composition. The composition is particularly useful for the treatment of allergic conditions.

Question 29: What levels of evidence do you already have compiled in support of the safety, efficacy, and quality of your top 5 products (e.g. product license application dossiers or substantiation files)? Levels of evidence compiled by the responding companies generally appear to be quite high as most have gone through medicinal product registration and licensing and have also conducted safety and efficacy trials for their top products. A summary of the responses is shown in Table 31.

Table 31: Levels of Evidence compiled in support of Safety, Efficacy and Quality of Products

1	The formulas of the five top products listed in this survey have been approved by Food and Drug Administration, Government of Maharashtra, Wagle Estate, Dist: Thane.
2	Classic textbook references as for Drugs and Cosmetic Act of India.
3	No response.
4	Quality evidence: Raw material specifications; Finished product specifications; and adherence to Good Manufacturing Practices. Safety and Efficacy evidence: For their top products, this company has carried out toxicity studies, clinical studies, and experimental studies. One product also has a post-marketing surveillance study on efficacy and safety.
5	This company has completed safety, animal and clinical efficacy studies for top products.
6	This company responded that compilation of evidence was non-applicable.
7	Evidence exists in the form of the product license application dossiers.
8	This company has product license application dossiers and/or substantiation files prepared for their top five products as well as for many other products that are being exported.
9	This company has compiled product dossiers covering pre-clinical, clinical, quality and manufacturing aspects.
10	This company responded that they have carried out Phase II Clinical Studies.
11	This company has complete product registration dossiers for their products.
12	This company reports having product registration dossiers and clinical trial reports.
13	Evidence exists in the form of product license application dossiers.

Question 30: Are there any published studies in which the investigational product was supplied by your company? If so, please list citations of published studies. Six of the thirteen respondents are actively involved in research and provided information on studies wherein certain of their products were supplied as the investigational product.

For example, Anuja Pharmaceuticals Pvt Ltd provided a copy of a study on their Actiflexan Tablets.[69] The company Arya Vaidya Sala reported one clinical study carried out on their product Misrakasneham.[70] Arya Vaidya Sala Kottakkal also publishes their own Quarterly Journal

[69] Bhatt JB. Clinical trial of anti-arthritic product Actiflexan Tablets. *Journal of the National Integrated Medicine Association*. December 1995.

[70] Ramesh PR, Kumar KS, Rajagopal MR, et al. Managing morphine-induced constipation—A controlled comparison of an Ayurvedic formulation and Senna. *Journal of Pain and Symptom Management*. 1998;16(4):240–244.

"*Aryavaidyan*,"[71] which is intended to encourage scientific writing and intellectual interactions among scholars, academicians, practitioners and students of Ayurveda and allied subjects like Siddha, Unani, and modern medicine. Arya Vaidya Sala Kottakkal has also published a catalogue of their publications from 1903 to present.[72]

Dabur India reported that a few studies have been carried out and published involving their Chyawanprash product, the details of which are available in a published book entitled "*Chyawanprash: From Vedic to Genomic Era*"[73] written by J.K. Ojha. In particular, Dabur India mentions two studies, a clinical study of Chyawanprash as an adjunct in the treatment of Pulmonary tuberculosis,[74] and a study on the preventive effect of Chyawanprash against steroid induced cataract in the developing chick embryo.[75] Maharishi Ayur-Ved Products has published a book which provides abstracts for numerous in vitro, in vivo, and human clinical trials involving their products, in particular many of the studies involve their products MAK-4 and MAK-5.[76]

Natural Remedies reported that more than 100 papers have been published involving their products. Shree Dhootapapeshwar Ltd reported that all of their product have clinical trials and practitioner's opinion reports. In particular, they cited a published paper involving their product "Ashotone," for dysfunctional uterine bleeding.[77]

Question 31: Do any of your products carry any "value-adding" ecological-, quality-, social-, or religious- certifications that may be important market access expectations by consumers in certain export markets? The value-adding certifications reported by most of the respondents (11 of 13) were limited to the category of quality certifications (e.g. GMP, HACCP and ISO).

Only one of the survey respondents has ecological certifications for some of their products exported to the EU (e.g. EU organic certified and BDIH Certified Natural Cosmetics). And only two survey respondents have religious certifications for their products. One company has Halal Certified products and another company has Kosher Certified products for their exports to the U.S. For the U.S. market, Kosher certification can be a market access expectation or requirement of certain natural product wholesale distributors, retailers and consumers. None of the survey respondents reported having any products carrying social certifications (e.g. Fair Trade Certified), although one company reported being the recipient of a TERI Corporate Award for Corporate Social Responsibility (CSR) for 2005/2006.

Here below is a summary of the various value-adding certification marks reported by the survey respondents:

- *<u>Ecological Certifications</u>: (e.g. Biodynamic Certified (Demeter), Certified Organic (EU or USDA), Rainforest Alliance Certified (Sustainable Agriculture Network), or conformance with the International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants (ISSC-MAP)):*

[71] Aryavaidyan: A Quarterly Journal of the Arya Vaidya Sala - Kottakkal. Kerala, India: Department of Publications, Arya Vaidya Sala.

[72] Chief Editor (Publications) Arya Vaidya Sala Kottakkal. *Catalogue (Publications).* Kerala, India: Department of Publications, Arya Vaidya Sala. September 2002.

[73] Ojha JK. *Chyawanprash: From Vedic to Genomic Era.* Delhi, Chaukhamba Sanskrit Pratishthan. 2003.

[74] Ojha JK, Khanna MN, Bajpai HS, Sharma PV, Sharma TN. Clinical study of Chyawanprash as an adjunct in the treatment of pulmonary tuberculosis. Banaras Hindu University. 1976.

[75] Velpandian T, Mathur P, Sengupta S, Gupta SK. Preventive effect of Chyavanprash against steroid induced cataract in the developing chick embryo. *Phytotherapy Research*. 1998;12(5):320-323.

[76] Sharma H (ed.). *Maharish Ayur-Ved Summary of Research Findings.* Colorado Springs, CO: Maharishi Ayur-Ved Products International, Inc. 2002.

[77] Therapeutic profile of an Ayurvedic formulation Ashotone in dysfunctional uterine bleeding (DUB). *Indian Practitioner*. 2003l53(3):193-198.

  - Maharishi Ayurveda Products: Some products carry EU organic certification and some also carry Certified Natural Cosmetics (CNC) – BDIH Certificates.[78] BDIH is the Federation of German Industries and Trading Firms for pharmaceuticals, health care goods, dietary supplements and personal hygiene products. The makers of the products marked with the "Certified Natural Cosmetics" seal use natural raw material such as plant oils, fats and waxes, herbal extracts and essential oils and aromatic materials from certified organic or wild harvested plants. In addition to the careful selection of raw materials, the ecological impact of each product plays an important role.
- *Quality Certifications: (e.g. GACP, GMP, HACCP, ISO, USP):*
  - Anuja Pharmaceuticals: GMP Certificate and ISO 9001:2000 Certificate.
  - Dabur India: GMP Certificate.
  - Exotic Naturals: ISO 9001:2000 Certificate.
  - Jhawar Chemicals: GMP Certificate.
  - Kerala Ayurveda: GMP Certificate.
  - Maharishi Ayurveda Products: GLP, GMP, HACCP, and ISO certifications.
  - Natural Remedies: GMP Certificate, ISO 9001-200 and ISO 22000 certifications.
  - Progen Research Lab: GMP Certificate.
  - Shree Dhootapapeshwar Ltd: GMP Certificate.
  - Vasu Healthcare: GMP Certificate, HACCCP and ISO certifications.
  - Zandu Pharmaceutical: GMP and ISO certificates.
- *Religious Certifications: (e.g. Halal Certified or Kosher Certified):*
  - Maharishi Ayurveda Products: Kosher Certificate for products that are exported to the USA.
  - Vasu Healthcare: Halal Certificate.
- *Social Certifications: (e.g. Fair Trade Certified; Fair Wild Certified; IMO Social & Fair Trade Certified):*
  - Arya Aidya Sala Kottakkal: Recipient of 6th TERI Corporate Award for Corporate Social Responsibility (CSR), 2nd Place in Category II for 2005/2006.[79] The TERI Corporate Awards for CSR are in recognition of corporate leadership for social responsibility and sustainable development initiatives. The objectives are to assess the extent of CSR in corporate functioning and the development of innovative partnership models for fulfilling social responsibilities.

Question 32: What specific problems or market access barriers do you believe are most in the way of reaching the export sales goals? Many of the respondents cited the high complexities and high costs of gaining marketing authorizations from various foreign governmental agencies responsible for medicinal product registration. This is due in part to the dossier submission requirements (safety, efficacy, quality) that are more applicable to single-entity allopathic drugs than to complex traditional herbo-mineral preparations such as Ayurvedic medicinal products. And as discussed in other parts of this study, the intentional use of metals in certain Ayurvedic preparations is completely unacceptable in certain foreign regulatory frameworks. This excludes a good range of traditional Ayurvedic medicinal herbo-mineral products from export potential. Additionally, some enterprises cite the problem of non-harmonized requirements of the various export markets. The latter is not likely to change as it is highly unlikely, for example, that the regulatory agencies of the EU Member States and of the United States of America will ever harmonize their legislative market access requirements. Table 32 lists the specific problems or barriers as reported by the thirteen survey respondents.

[78] BDIH Guidelines and Criteria for Certification of Products. Mannheim, Germany: Bundesverband deutscher Industrie- und Handelsunternehmen für Arzneimittel, Reformwaren, Nahrungsergänzungsmittel und Körperpflegemittel e.V.Available at: http://www.kontrollierte-naturkosmetik.de/en/the_guidelines.htm

[79] TERI. Winners: TERI Corporate Awards for Corporate Social Responsibility. New Delhi, TERI. Available at: http://www.teriin.org/awards/winner_social.htm

Table 32: Problems or Market Access Barriers hindering Export Sales Goals.

1	No problems cited.
2	1) Regulatory provisions of importing countries; 2) Market character study; 3) Regulations of exporting country.
3	No problems cited.
4	1) Application of standards and parameters for conventional drugs blindly; 2) Unclear guidelines, high registration and renewal charges; 3) Different strategies that have to be tuned for each category, each route and each market.
5	Regulations in various export markets; 2) Identifying trade partners.
6	Getting government approvals (marketing authorizations) of importing countries.
7	Regulatory, technical and non-tariff trade restrictions. Drugs & Cosmetics Laws, GMP-QC-QA-Safety-Efficacy, lack of uniform policies, procedures, standards, common pharmacopoeia, and high cost of registration and renewal charges.
8	The major problem in exports is the lack of clarity in terms of categorizing traditional Ayurvedic products as traditional Herbal medicine, Dietary supplement, Food supplement, OTC product, etc. Apart from this, the differing process of registration in different countries makes it difficult for any exporter to prepare documents to meet all the requirements. 2) Similarly there are no acceptable limits of trace heavy metals, residual organo chlorine/ organo phosphorous pesticides, microbiological contamination and aflatoxins applicable to Ayurvedic/Herbal products.
9	1) Regulatory clearance; 2) Non-availability of specific grades of raw materials. Govt (of India) should encourage cultivators by providing cost benefit schemes. 3) See also the responses provided for Question 22.
10	No assessment has been done.
11	Delayed registration process, steep import tariffs, insistence on WHO GMP manufacturing facilities (when WHO has no guidelines in place for Ayurvedic manufacturing units), incomplete knowledge on formalities and consultants to facilitate processes are some of the hurdles faced by this industry.
12	Regulations; 2) Factory inspections.
13	1) Traditional Medicines (Ayurvedic Products) are treated like Allopathic Medicines and data requested to submit; 2) Myths regarding Minerals and Mercury. Products are not accepted; 3) Clinical Data requirements or Bio equivalence data requirements; 4) Not sufficient Government Support.

Question 33: Is your company a member of any trade associations? Eleven of the thirteen survey respondents (84.6%) are members of the Ayurvedic Drug Manufacturers Association (ADMA) and eight respondents (61.5%) are members of the Pharmaceutical Export Promotion Council (PHARMEXCIL).

Each of the following three trade associations were listed by two respondents (15.4%): Association of Manufacturers of Ayurvedic Medicines (AMA), Indian Drug Manufacturers Association (IDMA), and The Associated Chambers of Commerce and Industry of India (ASSOCHAM).

Each of the following nine trade associations were listed by only one respondent (7.7%): Central Herbal Agro Marketing Federation of India (CHAMF), Confederation of Indian Industry (CII), Federation of Gujarat Industries (FGI), Federation of Indian Herbal Industry (FIHI), Karnataka Indian Medicine Manufacturers Association (KIMMA), Medicinal, Aromatic and Dye Plants Stakeholders' Consortium (MAPSCON), Shellac and Forest Products Export Promotion Council (SHEFEXCIL), Veerasandra Industrial Association Bangalore, and AMOI (definition of acronym not provided.

From these results it is clear that the trade associations representing the largest range of enterprises are the ADMA and PHARMEXCIL.

Question 34: Please describe the levels of support that you receive through your trade organization membership(s)? In general, respondents rely on their trade associations for up-to-date news on regulatory issues affecting the industry, market intelligence, and for information on relevant seminars and trade shows. Table 33 lists the levels of support from trade association memberships as reported by the thirteen survey respondents.

Table 33: Levels of Support from Trade Association Memberships

1	Good support.
2	Communication channels.
3	No response to this question.
4	Very active support.
5	We are not dissatisfied with the treatment we have received. We generally think that trade association and export council policies need to undergo major changes.
6	Up-to-date information and trade enquiries and industry representation at government level.
7	Good directives are passed on to members. Representations are made on common issues. Seminars and exhibitions are conducted. Trade enquiries are passed on to members.
8	We have become member very recently and still need to assess the support that we would get from this association in times to come.
9	Government notifications related to policy decisions. Trade show and exhibition details. Training, seminar, and workshop details related to pharmacy / IPR / QC, etc. Reduction in cost of registration fee, etc.
10	Updates of new things in field.
11	We receive first hand news regarding developments in regulatory sphere concerning exports as well as barriers encountered by fellow industry colleagues.
12	Meetings with foreign buyers / importers. Organizing seminars and events.
13	We get trade circulars, reviews and information through their publications.

Question 35: Please describe any technical support programs that your enterprise has participated in through governmental organizations (GOs), international governmental organizations (IGOs), and/or non-governmental organizations (NGOs). Most of the survey respondents (76.9%) have not participated in any of the technical supports programs listed in the questionnaire that are offered by GOs, IGOs, and/or NGOs. One company reported participation in a project financed by Government of India National Medicinal Plants Board (NMPB) for the promotion of sodium tolerance in 3 medicinal plants, namely Ceylon leadwort (*Plumbago zeylanica*), prishniparni (*Uraria picta*), and sarivan (*Desmodium gangeticum*). The NMPB grant was made available to the enterprise from February 2008.

Another company reported that they are presently carrying out a number of collaborative projects with the Department of AYUSH and the Department of Science and Technology. And a third company reported that they have participated as faculty for various programs of FRLHT, GTZ, NMPB, and PHARMEXCIL, respectively.

Question 36: Are you aware of the public–private–partnership opportunities available for the branding and marketing of ASU products that have been developed and researched by GOs such as CCRAS and CCRUM respectively? Seven of the thirteen survey respondents reported that they are aware of that there are opportunities to brand and market products that have been developed by governmental research organizations such as CCRAS and CCRUM. One respondent qualified their answer by stating that while they are aware of these opportunities, they are not aware of the specific

modalities, terms and conditions. One respondent reported that they had applied from some grants but there was too much of a delay which cause them to stop following up.

Question 37: What type of other technical assistance, training or capacity building, or public-private-partnership (PPP) activities do you believe the Government of India should focus on in ways that could help the overall Indian natural products industry become more successful in the export markets? Most respondents provided insightful and detailed responses to this question. The response given by Enterprise #9 is extensive but included in its entirely because it articulates key points that are briefly mentioned by the other respondents.

It appears that many enterprises would like Government of India to operate at a very high level with their counterpart regulatory authorities in the export destination countries in order to facilitate acceptance and streamlined marketing authorizations for Indian medicinal products, and to lobby for a rationale legal framework appropriate for the placement of ASU products in these countries. Interesting ideas on how to go about these interventions are provided by several companies. For example, two companies have suggested that Common Technical Documents should be developed in a way that will be accepted by multiple destination countries and in a way that could be utilized by multiple Indian companies for their foreign product license submissions. There is also a clear interest in harmonization of quality standards between India, EU and USA, among others. Table 34 describes other marketing and export promotion activities that the survey respondents believe the Government of India should focus on.

Table 34: Other Market and Export Promotion Activities that Respondents believe Government of India should focus on

1	Help to promote the export of herbal products, patent and proprietary medicines for small scale units to develop the markets with assistance towards giving necessary concessions in respect of al needs.
2	Enlarging the medicinal plant resources base; support of regulatory domain; helping to get product registrations overseas.
3	No response to this question.
4	Help exporters to understand regulatory issues, registration processes and formalities in the overseas countries. Information should be made available by Government and Semi Government organizations to the exports in order to facilitate registration formalities.
5	Build common infrastructure, support private initiatives in scientific development of products, and provide financial support towards world class manufacturing capacities, but nor for marketing. Presently AYUSH and PHARMEXCIL are primarily focused on helping trade delegations and participation in trade shows. (However) our industry is not yet ready to market.
6	Experts' opinion should prevail which must be in favor of AYUSH industry.
7	1. Create awareness of the peculiarity of Indian system of medicine; 2. Legal restriction to import to be liberalized through Government level discussions. Registration and renewal charges and formalities to be reduced and simplified.
8	The primary focus of the Government of India should be to develop the Ayurvedic Pharmacopoeia of India in order to be in line with the requirements of the EU and other regulatory authorizes. Government of India should also spearhead the initiative along with the industry leaders to get Ayurveda, Siddha and Unani Systems of Medicine recognized worldwide (similar to Homeopathic and Chinese Systems of Medicine) and develop Common Technical Documents (CTD) to facilitate registration of products in various countries.
9	**PROGRAM INITIATIVES:** One of the major hindrances in export of herbal extracts is the lack of inclusion of several important Indian plants in the positive list (importable list) of substances of the importing countries. For example Terminalia belerica is not listed in ARTG (Australian Register for Therapeutic Goods) of TGA (Therapeutic Goods Administration) in Australia. It is not cost effective for individual exporters to attempt to register the individual

herbs in ARTG. We request the Government of India to initiate a major documentation program under which all the available information on safety and efficacy of an herb is compiled systematically. It would be very helpful to simultaneously create a database which can serve as a basis for initiating the global inclusion of Indian plants in the positive lists. Perhaps a parallel activity on similar lines by the national laboratories having competencies in the required areas can speed up the work. Once the database / compiled information is ready, it could also be used in creating international newsletters which can cover comprehensive reviews on safety and efficacy, plant by plant on a regular basis, publishing books, meta-analysis of published clinical trials, etc.

There is also a need to compile the format of a "Common Technical Document" (CTD). This exercise will help in understanding the different regulatory requirements of different importing countries apart from identifying the missing information (gaps) which need to be filled by conducting research. It would be very helpful to simultaneously create a database which can serve as a basis for initiating the global inclusion of Indian plants in the positive lists.

To make some of the Indian medicinal plants big in the international arena there is a need to initiate a specific research program under which elaborate safety studies are conducted apart from establishing the known use (s) and identifying new uses. For this purpose we suggest that an expert committee identifies the top 10 plants of the country which are preferably cultivated already / can be cultivated easily and similarly identifies top 5 stake holders (exporters of herbal extracts having DSIR recognized in-house research laboratories). These stakeholders should then be allotted / asked to choose any two plants of their interest (preferably those in which the concerned exporter holds some kind of existing competence). These stake holders should then submit an elaborate project proposal to establish known uses, generate safety data and explore new uses. The total cost of the project per plant is expected to be around Rs.100 lakhs, out of which the stake holders can be asked to contribute 10 or 20% and the remaining should be a grant by the Government of India. The concerned stake holders shall have exclusive access to the research data generated, for a period of 5 years, thereafter it could be declared as public property / information in public domain. This way only the genuine and bonafide exporters would have the opportunity to create science based standardized herbal extracts which can serve as ingredients to dietary supplement, cosmetic, phytomedicine and food and beverage industries.

POLICY INITIATIVES: Initiate a scheme under which companies can seek soft loan for establishing / upgrading their manufacturing units to international standards like those of US-FDA, TGA of Australia, MCA of UK etc. The loan amount should be up to a ceiling limit of Rs. 10 crores / unit at a reducing interest rate of 2% or less with convenient repayment terms spread over ten years. The units may be allowed to spend a part of this loan for achieving the international certifications also.

Initiate another scheme for encouraging research aimed at brand building to convert existing, commodities into brand products by identifying / incorporating unique features. This scheme can be similar to the scheme of DBT under their Phase I programme of SIBRI.

Initiate a new scheme for brand building of Indian products, similar to MAI/MDI scheme of Pharmexcil, but which allows independent participation in trade fairs, payment to patent / trademark attorneys and consultancy charges of marketing / registration experts overseas. Alternatively the existing MAI /MDI scheme may be altered suitably to accommodate all the above aspects. If required the Government of India can identify some common marketing consultants, IPR attorneys, other experts in various countries having big market potential, who could be approached by Indian exporters. The fees of these experts can be borne by Government of India or at least subsidized to help the small and medium scale exporters.

Ensure ample availability of ethanol for extraction. Please create a system of identifying bonafide users and a single window monitoring agency for such users.

As per a recent meeting with the National Bio-diversity Authority, there are plans to levy additional taxes on collection of herbs, research on any aspect of these herbs and patents on any aspect of these herbs. These will soon come into force on account of the Bio-Diversity

	rules 2004. We would like to request the intervention of Ministry of Commerce in these plans of additional taxation so that our industry remains economically competitive in the global market. We are already paying VAT (value added Tax) and central excise to the tune of 16%. Our plea is that for the National Bio-Diversity Fund a part of our existing taxes be used / diverted for this cause instead of levying new add-on taxes. The VKUY (Vishesh Krishi Upaj Yojana) scheme should be made applicable independent of the EOU benefit to exporters. **OTHER:** The Indian Pharmacopoeial Commission and Indian Council of Medical Research (ICMR) should get the Indian Pharmacopoeia 2007 and the ICMR publication on quality standards registered / recognized as the "official books of reference" at the regulatory agencies globally. Amend the existing Drugs and Cosmetics Act to make a separate category for "Phytomedicines, Health foods and Phytocosmetics" as such a provision does not exist as of now. This new categorization should be done with an aim to take the advantage of the Traditional Knowledge, in terms of efficacy and safety basis of traditional substances, without risking the consumer safety, by adopting a mid path of "reasonable level" of technical data requirement for market authorization. The government of India should set aside a decent budget for "modernization of traditional systems of Indian medicine" under the ongoing 11th plan. Establish a National Repository of Crude Herbs and Phytochemicals, initiate a certification system / services for authentication of raw herbs, certification system for WHO cGMP, Organic cultivation, GAP, non-GMO etc. The national research funding agencies, as of now, believe that research can happen only in academic and research institutions. The industries are considered suitable only for commercialization. Grants-in-aid are not available to deserving / bona fide private research centers under any of the schemes. The responsibility of exports is with the industry and thus they have a clearer understanding of research requirements. The research / technology developed by the research institutions generally lie dormant for decades as there are no takers of the same. The research which is sorely needed by the industry never gets done as the industry does not have the resources to do it all by themselves. There is also an element of "mistrust" between industry and institutions as a result of which the GOI efforts of forging alliances between them have not been successful till date. There is thus a need to create "national research templates" on sector specific areas, where research grants are made available to "all" deserving laboratories (including private labs) for generating the required scientific data on "non-proprietary substances" including the standardization of natural products, bio-activity guided fractionation for identification of active principles, safety profiling and randomized, double blind, placebo controlled, multi-centric, clinical trials. The government of India should set up a taskforce that should interact with AYUSH / Herbal industries frequently on policy matters for improving this sector.
10	1. Support in clinical research – providing Governmental institutes for Phase 1, Phase 2, and Phase 3 studies; 2. Financial assistance for clinical trials; 3. Publishing the work in Governmental journals.
11	The Government of India has proposed the involvement of Exports Inspection Council (EIC) to intervene & facilitate with respect to exports of ASU formulations by installing pre-shipment Quality Assurance checks. The core idea of this programme is laudable, much needed and can deliver huge dividends for Industry, only if, the EIC is successful in forging bilateral agreements with regulatory agencies in importing countries on quality norms. The entire superstructure beginning from 'Farm' to 'Pharm' can be organized in a manner to reassure and deliver quality at every node. This bilateral negotiation and agreement with Trade blocks such as – SAARC countries, ASEAN countries, erstwhile CIS countries, GCC countries, countries of traditional Indian habitation in Africa & West Indies and in times to come EU, USA, Canada & Australia / New Zealand. All activities regarding trading, technical assistance, capacity building on a platform of PPP with a multilateral agency involvement like NMPB, CCRAS, CSIR, PHARMEXCIL, ICAR, etc. can contribute immensely to a plan. This

	entire initiative can efficiently be stewarded through a Steering Committee on International Trade established in PHARMEXCIL with representatives from various agencies. PHARMEXCIL would strengthen the ASU Industry Cell who should competently provide secretarial support. Since ASU members would be a part of the process, markets can then be opened up not for just a few companies but the sector as a whole. Reform within the sector could be overnight with promise of Commerce. The dictum that quality pays will find demonstration and alignment of ASU Industry with global bench marks will be inherent.
12	To develop Research Centers for Natural Products.
13	The Government of India should back the Traditional Systems of Medicines abroad like China is doing. They have treaty with other Governments (Europe, Africa) and their products are cleared quickly.

Question 38: Identify what might be required to improve capacity to support a higher level of exports in the following areas: project/investment financing, trade financing, government fiscal incentives/disincentives, government sectoral export strategy. Table 35 identifies finance and fiscal conditions that the survey respondents believe might be necessary in order to improve the capacity to support increased exports.

Table 35: Finance and Fiscal Conditions Respondents believe are Necessary to Improve the Capacity to Support Increased Exports.

1	No response to this question.
2	Not needed.
3	No response to this question.
4	To support higher level of exports the company not only has to improve on capacity but more importantly has to meet the international GMP norms which would involve a very high level of project investment. Therefore this needs to be addressed in the Government export strategy.
5	Project financing for research and development of new products. Government incentives for marketing activities like trade show participation and advertisements. Government strategy to make the (Indian) herbs known globally, for example like Ginseng from Korea.
6	Not applicable.
7	Governmental sectoral export strategy.
8	Trade financing certificate, market development, market access and market promotions would go along with any assistance to industry to export such products.
9	Same answer as for Question 37. See Respondent #9's response to Question 37.
10	Project finance in clinical research to develop new drugs.
11	a) Investment in R&D — Industry requires duty-free imports of Laboratory and Analytical instruments. Currently organizations with R&D programmes and investments are allowed certain Income Tax benefits at a higher rate of depreciation. For organizations to avail of such benefits, the process is long drawn, cumbersome & involves Department of Science & Technology, whose knowledge about the needs of ASU sector is Limited. To promote R&D investment, the surcharge of Government levies is a dissuading factor it is best that such authority of equal power be vested with the Office of Secretary, Dept. of AYUSH for the ASU Industry to promote greater R & D investments in programmes within the AYUSH Sector. b) Investment in Fundamental Research — Manufacturing of Ayurvedic formulations has been the mainstay of ASU Industry for the better part of last 150 years. Technology absorption, scaling up of operations, basic manufacturing management is experiential wisdom within the sector. Technological developments in the food, dietary supplement and drug sphere need to be dove tailed to the traditional sector also. Most of the knowledge of this sector being traditional, there is very little scope for Intellectual Property (IP) and its protection / exclusivity. Whilst this should be the case in matter relating to traditional medicines, it should not dissuade investment where a fundamental reset will lead to a better presentation of product. Funds must be made available to Industry who are repositories of ancient wisdom to validate, upgrade,

	absorb technology, bring forth World-class dossiers, etc. by which globally acceptable products can be offered for commercial exploitation. The Research here would result in published papers for common good as IP protection is not available.
12	Not required.
13	Government of India should help in making available raw materials at economical rates. These are mostly Medicinal Herbs which require typical environment. Encouragement should be given to Exporters by way of special incentives other than exemption of ED & Taxes. Marketing Development Assistance scheme to be further modified.

Question 39: Identify current support received from the following types of institutions: banking industry, national trade strategy, trade ministry, finance ministry, business training institutions. Most of the survey respondents provided similarly negative answers to Question 39 including not applicable, none, none received, practically no support received, and/or no exceptional support received. Only one respondent reported receiving good finance and fiscal support from financial institutions. Table 36 identifies finance and fiscal support that the survey respondents presently receive from banking and finance institutions.

Table 36: Finance and Fiscal Support Respondents Receive from Finance Institutions

1	Granting working capital such as Cash Credit, Overdraft and Term Loan for purchasing premises and machinery.
2	Not applicable.
3	No response to this question.
4	) None received in FY07/08.
5	) None.
6	Banking industry.
7	Practically no support received.
8	Apart from the Banking Industry we have not received any kind of support from any Institutions. The banking industries though supportive, have their own criteria for techno-commercial evaluation of any industry and probably do not look at Herbal industry as sunrise sector. Their processes are slow and time consuming and many initiatives are lost due to this sluggishness.
9	Loan received from Technical Development Board and from Banking Industry.
10	None.
11	No exceptional support is received by the Industry specially to promote or boost its Commerce potential.
12	We receive good response from above mentioned institutions.
13	Mostly schemes are there, systems are there but delays in processing, e.g. remittance is credited after one week in our account. New Generation Banking is asking money for any document requested.

Question 40: Do you spot-buy your natural ingredients on the open market or do you have long-term supply agreements or contracts with only certain qualified suppliers? Most of the respondents appear to have relationship with qualified suppliers. One enterprise reports buying from same suppliers for 60 to 80 years. Another reports owning their own farm for controlled cultivation. It appears that at least four of the thirteen respondents rely on spot buying in the open market.

Table 37 identifies purchasing and sustainable supply data as to whether the natural ingredients are bought on the spot market or through long-term agreements with qualified suppliers.

Table 37: Raw Materials Purchased on Spot Market or via Supply Agreements

1	Open markets.
2	We buy natural ingredients from traders in the open market against quotations. We have standardized vendors.
3	No response to this question.
4	There is no fixed policy. Buying strategy depends on individual items and their availability at a point of time.
5	) Purchase from qualified suppliers against order received.
6	No. (Note: It is not clear what is meant by "no" in response to this "either / or" question)
7	Via agreements with qualified suppliers.
8	We have our own Farm where we produce medicinal plants and herbs under controlled environmental conditions. We do however spot-but many of the ingredients from qualified suppliers and open auctions by cooperative societies/forest department/etc.
9	We buy the materials from qualified suppliers. We have supply agreements with qualified suppliers and contracts with cultivators.
10	Only qualified suppliers.
11	We procure our inputs through a combination of local purchase and long term contracts from a clutch of medicinal plants Traders who have dealings with our company for over 60-80 years and over 3-4 generations.
12	We spot buy our natural ingredients from the open market.
13	We have developed our suppliers and planned with them the Demand / Supply plan. Our requirement is clearly defined.

Question 41: Can your suppliers guarantee a consistent supply of defined quality raw materials? All but one respondent claims that their suppliers can guarantee a consistent supply of defined quality raw materials. This is an interesting response in light of much contradictory information provided by other stakeholders concerning a lack of consistent supply of pharmacopoeial-quality botanical raw materials in the Indian market. The reasons frequently given for an inconsistent supply are due, in part, to the fact that most botanical species are wild collected rather than cultivated. The wild populations of many species are known to be declining and some important medicinal species are even listed as endangered or threatened. Many wild species are not yet collected in conformance with suitable Good Agricultural and Collection Practices (GACP) for medicinal plants and therefore wrong qualities are sometimes collected, uncontrolled post-harvesting handling and storage conditions sometimes damage quality, and the problem of adulteration or substitution is well known by ethnobotanists and natural products chemists.

In any case, the majority of respondents have a high confidence level that their qualified suppliers do have sustainable resource management capabilities necessary to guarantee an uninterrupted supply of pharmacopoeial quality botanical raw materials. Only one respondent provided an answer to the contrary "*No. Consistent supply of qualify raw materials is a difficult proposition in this business.*"

Question 42: What % of your botanical raw material supply is produced from controlled cultivation and what % is obtained from wild collection? Seven of the thirteen survey respondents (53.9%) were able to provide an estimate. Given what is known about the percentage of botanical species coming to market from wild collection verses controlled cultivation may of the estimates appear to be reasonable. One company states however that they obtain their raw materials from controlled cultivation, presumably implying 100% farmed and 0% wild harvested. By cross referencing their product's lists of ingredients, however, while some certainly are cultivated many other species listed are known to be typically wild collected. Table 38 provides an estimate of the percentage of ingredients obtained from wild collection verses cultivation for the thirteen survey respondents.

Table 38: % of Raw Materials Cultivated vs. % Wild Collected

	% Botanical Raw Materials Cultivated	% Botanical Raw Materials Wild Collected
1	No response to this question.	No response to this question.
2	15 to 20%	80 to 85%
3	No response to this question.	
4	Impossible to pinpoint a % to either. Prefer cultivated sources.	Impossible to pinpoint a % to either.
5	Have not determined.	Have not determined.
6	Not applicable.	Not applicable.
7	5%	95%
8	Approximately 40%	60% from open market or collection centers
9	10%	90%
10	75%	25%
11	30%	70%
12	Not known (varies).	Not known (varies).
13	We are purchasing from controlled cultivation with necessary approvals (presumably this means 100%?)	None reported.

Question 43: Do your raw material suppliers have the capacity for sustainable scale-up in the event that your enterprise was to grow rapidly due to new export market opportunities? Six of the thirteen survey respondents (46.2%) have a high confidence level that their suppliers have the capacity for sustainable scale-up due to increased export demand. This may be wishful thinking as it is not likely that the raw material suppliers have conducted a comprehensive resource assessment for each species in commerce. Three of the respondents acknowledge that sustainable sourcing is a complex and difficult topic. One respondent acknowledges that certain endangered raw materials may not be available in the long run. Table 39 lists opinions on the present capacity of raw material suppliers for a sustainable scale-up that would be necessary in order to meet increased export demand.

Table 39: Capacity of Raw Material Suppliers for Sustainable Scale-up to meet increased Export Demand

1	Yes.
2	Materials which are endangered / critically endangered will not be available in plenty in the long term.
3	No response to this question.
4	The raw material suppliers' ability to scale up will depend on the individual items and the seasonality.
5	Not sure.
6	Yes.
7	Yes.
8	Difficult question to answer. Can probably be answered by the raw material suppliers, and institutions like the National Medicinal Plants Board (NMPB), FRLHT, who could probably take up the initiative in training the raw material suppliers for sustainability.
9	Yes, our suppliers have the capability for sustainable scale up.
10	Yes.
11	The word "sustainable" and its last mile meaning is not yet known. We would not be able to provide assurance that our suppliers would be sensitive to the complete meaning of sustainable in the short run.
12	Yes.
13	No. We do not have this data. We have to search the market or our data bank.

Question 44: If yes, by what methodology was the sustainable supply of wild collected botanicals determined? Based on the responses to Question 44, it appears that most of the survey respondents generally misunderstood the question. Only one respondent (#11) seemed to provide an informed response to this admittedly complex question. Table 40 shows the methods of determining / measuring sustainable wild collection as reported by the survey respondents.

Table 40: Methods of determining Sustainable Wild Collection

1	By testing the ingredients at our own laboratory.
2	Market feedback will inform us of the sustainable supply of wild collected botanicals.
3	No response to this question.
4	Not applicable.
5	No response to this question.
6	By putting requirements.
7	No.
8	Most of our raw herbs are very common and availability is not very difficult and we also look for new areas so that supply is smooth.
9	Project plantations.
10	Yes.
11	We need to employ a basic Input Output Ratio at block level in Forest areas to ensure sustainable extraction. You need to deploy seeds, saplings, etc. in plenty of offset a collection exercise keeping in mind mortality, gestation period and other factors affecting regeneration. Basic GCP needs to employed at first go itself. This and such exercises will spell long term solutions and communities can be incentivized on extraction and regeneration for an optimum use of government funds.
12	By technical method supply of wild collected botanicals determined.
13	No response to this question.

Question 45: Please describe what you believe the Government of India should do specifically to enhance the export of Ayurvedic, Siddha, and Unani Products? Table 41 summarizes the final thoughts of the survey respondents concerning what specifically the Government of India should do for export promotion of ASU products.

Table 41: Summary of Industry Recommendations to Government of India for Export Promotion of ASU Products

1	Government of India should assist the small scale sector of Manufacturers to give concessions for Registration Fees charged by Importing Countries with the help of Embassy of India, High Commission of India, Permanent Mission of India.
2	No response to this question.
3	No response to this question.
4	1) Government should give incentives to the exporters of finished Ayurvedic Products on similar lines as VKUGY scheme (up to 5 – 10% of FOB value of exports) 2) Encouragement and support to develop this sector for adoption of modern technology. 3) More rewards and benefits for investment in this sector.
5	Please refer to an article authored by Jayesh Chaudhary on a similar subject.[80] The article is attached as Appendix X.
6	Government of India should approach and interact through AYUSH to the countries where Ayurvedic products are recognized already or can be accepted by AYUSH efforts.
7	1. Identify 50 products from each which meet environmental considerations and develop

[80] Chaudhary J. Running the export marathon. *Express Pharma*. 16-29 February 2008. Available at: http://www.expresspharmaonline.com/20080229/nutratrends04.shtml

	common monographs on their quality safety and efficacy and get registered with governments of importing countries. 2. Introduce Ayurveda cosmetics and supplements and promote these sectors. 3. Reward investments. 4. Make uniform standards, common pharmacopoeia, Common curriculum for Ayurveda Studies.
8	No response to this question.
9	Same response as for Questions 37 and 38. See Question 37 results.
10	Support for clinical research and drug development. Helping the units for registration of their products in other countries. Financial support for adopting new technology in drug development and production.
11	Some and most of our suggestions to upgrade ASU Industry for domestic and export markets is summarized in our Annexure 3, which is submission to Government of India through the Planning Commission for outlay in XIth Plan Period.
12	Government of India should provide worldwide recognition to Indian Pharmacopoeia because the specifications mentioned in IP are not acceptable in foreign countries because of which most of the Ayurvedic products are not allowed to import in target countries. Flexibility to Indian exporters to export in EU Countries, USA and CIS Countries Strict norms for counterfeiting and drug adulteration Government of India should have all the necessary documents regarding product registration in foreign countries. Details should be provided to exporters on paid basis. Training Programme regarding Export procedures should be given to New Companies
13	1. Government of India should promote Traditional Medicines (Ayurvedic, herbal) while having bilateral talks with other country. 2. The medicinal plant growers should get encouragement and incentives from Govt. to get quality Raw material. 3. Our GMP certification should have reorganization from WHO. Govt. should take such steps as it is questioned again and again.

C. Findings from other Relevant Studies

Report of the Steering Committee on AYUSH: Please see Chapter 3C of this Study for relevant summaries of the "Report of the Sub Group on Research & Industry" of the Steering Committee on AYUSH for the Eleventh Five-Year Plan (2007-2012).[81] The Sub Group on Research & Industry has proposed two export-oriented schemes: "Schemes for Development of New Formulations, Technologies, Tools and Practices with Validation of Existing Products and Procedures," and "Scheme to Identify, Promote and Develop "Star product(s) for the International market" and Brand Promotion for the ASU sector – domestically and internationally." Additionally, the "Report of the Sub-Group on Medicinal Plants" has identified three export-oriented areas of priority concern that need to be addressed over the 11th Five Year Plan period.

Report from ADMA: Challenges to growth for the manufacturers and marketers of ASU finished products, as identified by Pramad Sharma, President, ADMA, include:

- Availability of Natural Resources and Input;
- Standardisation and Quality Assurance norms;
- Database and surveys that estimate and monitor market size and potential;
- Development of globally acceptable botanical drugs; and
- Clinical and safety studies for Herbals and Herbo Mineral ASU Formulations.

[81] Government of India Planning Commission. Annexure 3: *Report of the Steering Committee on AYUSH for the Eleventh Five-Year Plan (2007-1012).* New Delhi: Government of India. December 2006.

The ADMA President states further that ASU Industry is also put to hardship by regulations. ADMA has been pursuing the causes of bringing justice to AYUSH Sector through discussions and submissions to Regulatory Authorities. There have been a lot of deliberations on several critical issues notified in Circulars /Orders/ Draft Notifications by the Regulatory Authorities.[82]

Surveys of Regional Ayurveda Clusters: Some of the major challenges in the Ayurvedic drug manufacturing cluster at Thrissur and Cochin as identified in a (draft) study by Apex Cluster Development Services[83] include the following, among others:

- Organized cultivation of botanicals is necessary in order to meet the growing demand and shortage of raw materials.
- Standard Operating Procedure (SOP) must be developed and implemented in order to regulate those drug manufacturers who have adopted unethical manufacturing practices to compete in price.
- All traditional knowledge needs to be documented in digital form for the benefit of Ayurvedic medicine manufacturers. It must also be protected from piracy.
- Technical support is needed for knowledge on how to control 'variations in quality' among batches of finished medicinal products.
- Need for a 'data bank' for all Ayurvedic medicines with the necessary information about ingredients, botanical names and actions of each ingredient to validate the medicines for export.
- The cluster believes that incentives are not available for Ayurvedic medicines and equipments.
- QC testing of ingredients is expensive in case of complex multi-herb medicinal products.

Another (draft) survey, commissioned by the German GTZ,[84] tentatively identifies the following key recommendations for the SMEs of the Ayurveda Cluster in Uttarakhand:

- ***Training Manpower***: Training needed in GMPs, new product development, market expansion, international quality testing norms.
- ***Financial Support***: For unit's plant & Machinery upgradation as per WHO-GMP norms. Infrastructure development, for example common warehousing facility for product storage and common quality control testing laboratory.
- ***Marketing Support***: SMEs unable to capture market opportunities which require large production quantities, homogeneous standards, and regular supply.
- ***Infrastructure Development***: Establishment of common warehouses. Technical assistance in production and packaging facilities.
- ***Raw Material Sourcing***: Numerous wild collected medicinal plant species in Uttrakhand are threatened. In addition to implementing rational and regulated wild collection, encourage the large-scale cultivation of these species in Uttrakhand.
- ***Export Assistance***: Ayurveda SME units are deterred for exporting due to the complexities and high risks involved. Assistance is needed to increase production capacity and working capital to satisfy the volume requirements of foreign buyers. Technology assistance is needed to meet the quality specifications of export markets. Information on compliance with technical and environmental standards. Market research. Training on effective marketing techniques and brand image creation. Assistance in awareness of export incentives from government schemes.
- ***Support Services***: Strengthening industry associations.

[82] Sharma P. From the President's Desk. *AYURBIZ.* February-April 2008;3(7):1.
[83] Apex Cluster Development Services Pvt Ltd. (Draft) Thrissur and Cochin. 2007
[84] A.F. Ferguson & Co. – Management Consultancy. Draft Report: Survey of Regional Clusters / Value Chains and BDS Providers May 2007 "Ayurveda Cluster – Uttarakhand. GTZ. 2007.

CHAPTER 5 – TRADE SUPPORT INSTITUTIONS NEEDS & CAPACITIES

A. Boards:

a. National Medicinal Plants Board (NMPB), Ministry of Health & Family Welfare

The Medicinal Plants Board was set up a under a Government Resolution notified on 24th November 2000 under the Chairmanship of Union Health & Family Welfare Minister. The objective of establishing a Board is to establish an agency which would be responsible for coordination of all matters relating to medicinal plants, including drawing up policies and strategies for conservation, proper harvesting, cost-effective cultivation, research and development, processing, marketing of raw material in order to promote and develop this sector. The work would continue to be carried out by the respective Departments, organizations but the Board provides focus and gives directions to the activities. The Board has the function of coordinating with Ministries / Department / Organizations / State / UT Governments for development of medicinal plants.

Some areas of trade support presently provided by the NMPD include:

Cultivation Practices: Information on the cultivation of 32 prioritized medicinal plants has been compiled and published as book entitled "*Cultivation Practices of Some Commercially Important Medicinal Plants*,"[85] and the information is also available on-line at: http://nmpb.nic.in/publication.htm

Demand and Supply Study: NMPB initiated a study "Demand and Supply of Medicinal Plants in India 2008,"[86] which was carried out by Drs. D.K.Ved and G.S. Goraya, of the Foundation for Revitalisation of Local Health Traditions (FRLHT), Bangalore. The Study was published as a hard-cover book in 2008 by Bishen Singh Mahendra Pal Singh, Dehra Dun, and is also available on-line at the NMPB website: http://nmpb.nic.in/DS_study.htm

Financial Assistance Schemes: NMPB has formulated schemes and guidelines for financial assistance in different areas of medicinal plants sector covered under Promotional and Commercial schemes applicable both for government and non-government organizations. On 07 May 2008, NMPB issued a notice to all members of ADMA, all members of other ASU Industry Associations, and all Manufacturers of Herbal Extracts concerning the provision of financial assistance for cultivation of medicinal plants.[87] During the 10th Plan, the NMPB released subsidy of about Rs. 72 crores to herb farmers. The experience from this was that in the absence of proper marketing linkage, farmers did not get remunerative prices and therefore discontinued cultivation after one or two years. During the 11th Plan, the outlay for the NMPB has been increased six to seven fold and a substantial portion of this will be for cultivation of medicinal plants in high demand. Therefore, it will be necessary that the financial support for cultivation is directly linked to the industry coming forward to enter into buy back agreements with grower's cooperatives / associations / Self Help Groups (SHGs) in selected clusters.

[85] National Medicinal Plants Board. *Cultivation of Medicinal Plants*. New Delhi, India: National Medicinal Plants Board, Department of AYUSH, Ministry of Health and Family Welfare. 2004.

[86] Ved DK, Goraya GS. *Demand and Supply of Medicinal Plants in India*. Dehra Dun, India: Bishen Singh Mahendra Pal Singh. 2008. Also available at website of NMPB: http://nmpb.nic.in/DS_study.htm

[87] Sajwan BS. Letter to All the members of ADMA, All members of other ASU Industry Associations, All the Herbal Extracts Manufacturers. New Delhi, India: National Medicinal Plants Board, Department of AYUSH, Ministry of Health and Family Welfare. 07 May 2008.

Good Agriculture Practices (GAPs) for Medicinal Plants:[88] The NMPB has formulated (draft) GAPs under a project financed by World Health Organisation (WHO). These guidelines seek to disseminate GAPs for ensuring quality and safety of AYUSH medicines. The guidelines are available at: http://nmpb.nic.in/Draft%20GAPs.pdf

Guidelines for Facilitation Centre for Medicinal Plants:[89] The Facilitation Centre will provide trade support activities including, among others, the organizing of frequent buyer-seller meets (between growers, traders and industry) for establishing linkages between cultivation and marketing and encourage market driven cultivation; the development of modules of training and conduct training programs for herb farmers; the publishing and dissemination of information on agro-techniques, markets, prices, mandies, traders, industries etc. in local languages.

Herbal Tea Promotion: In view of the importance of herbal tea and its acceptance in the community at large, NMPB proposes to develop disease-specific herbal teas under the banner of Medicinal Plants Board. Such tea could be popularized both at national & international levels, which could fetch good revenue. The project is under consideration and can be executed by the agency identified by the Board.

Regional workshops

Weekly On-line Pricing System of Medicinal Plants: Prices for over 100 important Indian medicinal plants are posted on-line with current minimum price (Rs / kg), maximum price, and average price at all of the regional markets where the species is traded: http://nmpb.nic.in/opsnmpb/index.php

In order to address various issues and problems of the medicinal plants sector, the NMPB has identified some areas and formulated schemes for financial support for the development of the medicinal plants sector. These projects could be entrusted to State Medicinal Plants Boards (SMPBs), ICAR, ICFRE, CSIR institutes, State Governments, Agriculture and other Universities, Public, quasi-public, Development Corporations and other organizations. Non-Government Organizations (NGOs) of repute capable of undertaking such projects and who have past experience of at least 3 years in the designated areas are also eligible for financial support except R & D activity. Designated areas for financial support:

b. Spices Board of India (SBI), Ministry of Commerce & Industry

Export promotion programmes of the SBI are included in this report because there is indeed some crossover between producers of medicinal, aromatic, and spice plants and products. Many spices are widely used as medicinal products with the Indian Systems of Medicine. SBI Export Development (X-plan) Schemes include:

- Market Development Assistance for participation in Trade Fair;
- Packaging Development;
- Printing of Promotional Brochures;
- Reimbursement of Freight/Courier Charges for sending samples of spices abroad; and
- Undertaking Export Promotion Tours in Identified Markets Abroad.

[88] National Medicinal Plants Board. *Good Agriculture Practices (GAPs) for Medicinal Plants.* New Delhi, India: National Medicinal Plants Board. 2007. Available at: http://nmpb.nic.in/Draft%20GAPs.pdf.

[89] National Medicinal Plants Board. *Guidelines for Facilitation Centre for Medicinal Plants.* New Delhi, India: National Medicinal Plants Board, Department of AYUSH, Ministry of Health and Family Welfare. Available at: http://nmpb.nic.in/Guidelines%20for%20Facilitation%20Centre.htm

B. Export Councils:

a. Basic Chemicals, Pharmaceuticals & Cosmetics Export Promotion Council

Basic Chemicals, Pharmaceuticals & Cosmetics Export Promotion Council (CHEMEXCIL) was established in 1963 headquartered at Mumbai, with the objective of making concerted efforts to promote exports of basic organic and inorganic chemicals, dyes, pesticides, soaps, detergents, cosmetics, toiletries and other products such as agarbattis (herbal incense sticks), essential oils, and castor oil, among others. CHEMEXCIL has four separate panels, each panel being a specialized unit guiding the export interests of the items covered under its purview:

1) Dyes & Dye Intermediates
2) Basic Inorganic and Organic Chemicals including Agro Chemicals
3) Cosmetics, Toiletries, Essential Oils
4) Agarbattis.

CHEMEXCIL also promotes exports of Castor Oil and Derivatives of Castor Oil. The activities of the Council are governed by the Committee of Administration which is the supreme organ of the Council. Three fourth members of the Committee are elected from amongst industry and trade while the rest are nominees of the Government. In addition to this each of the above group of commodities, known as 'Panels' has its own committee which looks after the specific interests of the panels. The Council also has some functional committees which attend to some specialized aspects of Council's work like Projects, Publicity and Exhibitions, Registration. and Export Assistance, Budget etc.

b. Export Inspection Council (EIC), Ministry of Commerce & Industry

The Export Inspection Council (EIC) was set up by the Government of India under Section 3 of the Export (Quality Control and Inspection) Act, 1963 (22 of 1963), in order to ensure sound development of export trade of India through Quality Control and Inspection and for matters connected thereof. EIC is an advisory body to the Central Government, which is empowered under the Act to:

- Notify commodities which will be subject to quality control and/ or inspection prior to export,
- Establish standards of quality for such notified commodities, and
- Specify the type of quality control and / or inspection to be applied to such commodities.

On 16 April 2008, a preliminary notification order on AYUSH was circulated by EIC to be published in The Gazette of India, entitled "Export of Ayurvedic, Unani and Siddha (Quality Control, Inspection and Monitoring) Rules, 2008."[90] The proposal is to require that ASU products to be subjected to quality control and inspection prior to export according to specifications including maximum allowable limits for heavy metals, pesticides residues, aflatoxins, and microbial contamination. The EIC will monitor the scheme.

c. Pharmaceuticals Export Promotion Council (PHARMEXCIL)

The Pharmaceuticals Export Promotion Council (PHARMEXCIL), set up by the Ministry of Commerce & Industry, Govt. of India, is an export promotion council which handles exports of

[90] Export Inspection Council of India, Ministry of Commerce & Industry, Government of India. Draft rules proposed to be made under section 17 of the export (quality control and inspection) act 1964 (22 of 1963). 16 April 2008. Available at: http://www.eicindia.org/eic/about-main.htm

various pharmaceutical items like bulk drugs and intermediates, formulations, herbal medicinal products, Ayurvedic, Unani and Homoeopathic medicinal products, nutraceutical products, biotech and biological products, diagnostics, surgical, and pharma industry related services, collaborative research, contract manufacturing, clinical trials and consultancy.

PHARMEXCIL was set up on 12.5.2004. With its notification No. 61 dt. 16.3.2005, Director General of Foreign Trade made Pharmexcil the sole agency to issue Registration-cum-Membership Certificates (RCMCs) to all Pharma exporters. The activities of the Council are administered by Committee of Administration consisting of representatives from major Pharma industries in India apart from Govt. officials from Central govt. and Govt. of Andhra Pradesh.

The roles of PHARMECIL are to:

- issue RCMCs
- organize trade delegations;
- organize Buyer-Seller Meetings abroad and in India;
- assist members to get their MDA/MAI claims refunded from Govt. of India;
- issue Certificates of Origin
- organize periodical Seminars and interactive meetings on export-related issues;
- make suggestions to Govt. of India on policy issues relating to Pharma exports;
- make representations to Govt. of India and other agencies in India and abroad to get amicable solutions for the common problems of the industry.

PHARMEXCIL posts various forms on-line to facilitate reimbursements for its memberships. For example, the

- "Application Form for Marketing Development Assistance for participation in Trade Fairs, Exhibitions, Buyer/Seller Meets, and Trade Delegation Abroad" is available at: http://www.pharmexcil.com/V1/Docs/Application%20for%20Participation.pdf
- "Claim Form for Marketing Development Assistance for participation in Trade Fairs, Exhibitions, Buyer/Seller Meets, and Trade Delegation Abroad" is available at: http://www.pharmexcil.com/V1/Docs/Claim%20Form.pdf
- "Form for Claiming Reimbursement of Registration Charges Paid for Registration Abroad of Pharmaceutical / Biotechnological / Agro Chemical Products" is available at: http://www.pharmexcil.com/V1/Docs/ANNEXURE_I.pdf
- "R&D Project Application Form" is available at: http://www.pharmexcil.com/V1/aspx/Download.aspx

PHARMEXCIL has over 200 members. The list of ordinary members as on 06.11.2007 is available on-line at: http://pharmexcil.com/data/uploads/Ord.Memlist.pdf.

d. Shellac and Forest Products Export Promotion Council (SHEFEXCIL)

The Shellac and Forest Produce Export Promotion Council (SHEFEXCIL), sponsored by the Ministry of Commerce, Govt. of India, is an export promotion council which handles export of Lac and Minor Forest Produce such as exudates, gums, oleoresin, and other resins, mucilages, natural dyeing substances (e.g. myrobalan fruits), odoriferous substances (e.g. alcoholic extractives of medicinal plants), as well as vegetable saps and herbal extracts.

Shellac EPC having its registered office at International Trade Facilitation Centre, 1/1 Wood Street, 2nd floor, Kolkata - 700 016 and is registered under Section 25 of the Companies Act of 1956. It functions within the parameters and provisions of Chapter-3 of Export-Import Policy.

In its role of an export facilitator, Shellac EPC acts as a bridge between the Trade and the Government. International developments and Govt. Policies often dictate the course of exports, Shellac EPC activates its umbrella network to monitor and analyze these trends and accordingly Policy anomalies are either modified or changed in the interests of exports.

It is the only Export Promotion Council in India which is doing quality control at export stage, conducting research and looking after the interests of the growers at the grass root level and thus performing the activities of a Commodity Board.

C. Institutes:

a. Central Institute of Medicinal and Aromatic Plants (CIMAP)

Central Institute of Medicinal and Aromatic Plants (CIMAP) is a multi disciplinary multi locational R&D institute dedicated to the cause of medicinal and aromatic plant research, cultivation and business. CIMAP has its foot prints in different agro climatic zones of India in form of its Resource Centers (CRC) and Resource Points (CRP). CIMAP has publications and databases, for example directories for the trade, research and herbal product development, trainings and workshops for producers, and marketing organization services, among other activities.

Certified Organic Production: CIMAP also operates ECOCERT certified organic herb farm production and essential oil production. Product categories include certified organic licorice root (*Glycyrrhiza glabra*), Rauwolfia (*Rauvolfia serpentina*), Safed musli (*Chlorophytum borivilianum*), and Ashwagandha (*Withania somnifera*), among others, as well as organic essential oils. Product categories accredited by ECOCERT are listed on-line at: http://www.cimap.res.in/product_list.html

Herbal Based Formulation: CIMAP R&D has developed numerous herbal based formulations including disinfectants, anti-dandruff shampoos, anti-fungal creams, anti-plaque tooth powders, face and hand wash products, headache relief balms, and mosquito repellents. Product profiles are posted on-line at: http://www.cimap.res.in/product_profile.html

Herbal Source Book: In 1982, CIMAP published its first "Directory of Crude Drugs and Aromatic Plants' Dealers, Producers & Exporters in India,"[91] with 2nd and 3rd edition in 1992 and 1997, respectively. The 2004 CIMAP publication "Herbal Source Book"[92] has evolved from these earlier efforts. This new publication is a Directory-cum Source Diary which serves as a reference book for herbal materials, products and processes providing the functional links with industry, market, production, cultivation and agencies involved in the facilitation of the value chain of plant resources and business. Information on the Herbal Source Book and CD ROM are posted on-line at: http://www.cimap.res.in/publications.html

b. Institute of Economic and Market Research

Institute of Economic and Market Research (IEMR) was established in 1972, to cater to market and economic research needs of Indian Industry and Service Sector as an interdisciplinary research and consultancy organization In the past 30 years, IEMR has completed more than 400 socio economic techno-economic and market research and consultancy projects. IEMR is also affiliated to Centre for Research, Planning & Action (CERPA) a premier research and development institution

[91] Shah NC, Virmani OP. *Information Bulletin No. 1 (Revised). Directory of Crude Drugs and Aromatic Plants' Dealers, Producers & Exporters in India*. Lucknow: Central Institute of Medicinal and Aromatic Plants. 1982.

[92] Khanuja SPS, Hasan SA, Singh J, Yohannan B, Singh AK, Sharma A, Kumar VS. *Herbal Source Book*. Lucknow: Central Institute of Medicinal and Aromatic Plants. 2004.

recognized by DSIR and approved under Foreign Contribution Regulation Act by Ministry of Home Affairs. CERPA is accredited to UNECOSOC and is an approved Centre of Excellence of UNESCAP for HRD. CERPA has developed a portal website for the herbal industry at: http://www.herbalcerpa.org.

Various industrial Sectors have been serviced by IEMR for conducting market research feasibility studies, location studies, export potential studies, customer perception studies etc. Major industrial sectors covered by IEMR include agricultural and allied products such as medicinal plants. IEMR market and related studies involving the medicinal plants trade published thus far include:

Commercial Utilization of Medicinal Plants in North Sikkim (1991): (A Study and Action Plan):[93] Area Profile - Medicinal Plants/Herbs identified in Area under Study - Collection of Medicinal Plants - Marketing of Medicinal Herbs Produce-International Marketing-Profile of Collector Households -Plant Collection and Value in Practice-Support needed for improvement - Perspective Plan on Exploitation of Medicinal Plants for North Sikkim Forests-Annexures.

Commercial Utilization of Medicinal Plants in Selected Areas of Bastar (1988): (A Study and Action Plan):[94] Volume-I: Market size - Prices - International Trade - Traders Profile and opinion - End Users Profile - Household Profile - Credit - Work Plan - Medicinal plant-Role & Relevance - Plants and Area under study. Volume-II: *Tamarindus indica* (Imli) - *Madhuca longifolia* (Mahua) - *Schleichera oleosa* (Kusum) - *Curcuma angustifoila* (Tikhor) - *Storculia urens* (Kullu/Gum Karaya) - *Terminalia chubula* (Hana) - *Shorea robasta* (Sal) - *Emblica officinalis* (Amla) - T*erminalia bellerica* (Bahera) - Minor Plants - Annexures.

Demand Study for Selected Medicinal Plants – Volume-I: Introduction & Method – Demand Estimates – Supply & Prices – Manufacturing, Trade and Storage – Exports and Imports – Respondent Characteristics and Opinions.

Demand Study for Selected Medicinal Plants – Volume-II: Plant Profiles of 162 Plants.

D. Ministries:

a. Ministry of Agriculture, Department of Agriculture & Cooperation

The Department of Agriculture and Cooperation, Ministry of Agriculture, is responsible for the formulation and implementation of National policies and programmes aimed at achieving rapid agricultural growth through optimum utilization of the country's land, water, soil and plant resources. The Department undertakes all possible measures to ensure timely and adequate supply of inputs and services such as fertilizers, seeds, pesticides, agricultural implements and also to provide agricultural credit, crop insurance and ensure remunerative returns to the farmer for his agricultural produce.
The Department is entrusted with the responsibility for collection and maintenance of a wide range of statistical and economic data relating to agriculture, required for development planning, organizing agricultural census, assisting and advising the States in undertaking scarcity relief measures and in management of natural calamities e.g. flood, drought, cyclone, etc.

The Department is responsible for the formulation of overall cooperative policy in the country, matters relating to national cooperative organizations, cooperative training and education. The

[93] Centre for Research, Planning and Action (CERPA). *Commercial Utilization of Medicinal Plants in North Sikkim: (A Study and Action Plan). New Delhi, India: CERPA. 1991.*
[94] Institute of Economic and Market Research (IEMR). *Commercial Utilization of Medicinal Plants in Selected Areas of Bastar (1988): (A Study and Action Plan. New Delhi, India: IEMR. 1988.*

Department also participates in activities of international organizations, for fostering bilateral cooperation in agricultural and allied sectors and for promotion of export in agricultural commodities.

b. Ministry of Commerce & Industry, Department of Commerce

Department of Commerce is headed by a Secretary who is assisted by three Additional Secretaries, ten Joint Secretaries & Joint Secretary level officers and a number of other senior officers. Besides formulating and implementing the Foreign Trade Policy, the Department is also entrusted with responsibilities relating to multilateral and bilateral commercial relations, state trading, export promotion measures and development and regulation of certain export oriented industries and commodities. The Department is functionally organized into eight Functional Divisions and its jurisdiction extends over (a) two Attached Offices, (b) eleven Subordinate Offices, (c) ten Autonomous Bodies, (d) several Export Promotion Councils (EPCs), (e) other Organizations, (f) Advisory Bodies and (g) Public Sector Undertakings.

Department of Commerce bodies, councils, directorates and offices of most relevance to Indian producers and exporters of medicinal natural products include the following:

***Agricultural and Processed Food Products Export Development Authority (APEDA)*:** APEDA has 5 Regional Offices and is entrusted with the task of promoting agricultural exports, including the export of processed foods in value added form.

Directorate General of Foreign Trade (DGFT): This Directorate is responsible for implementing the Foreign Trade Policy with the main objective of promoting Indian exports. The DGFT also issues licenses to exporters and monitors their corresponding obligations through a net work of 33 Regional Offices.

Directorate General of Commercial Intelligence and Statistics (DGCI&S): This Directorate is entrusted with the work of collecting, compiling and publishing / disseminating trade statistics and various types of commercial information required by the policy makers, researchers, importers, exporters, traders as well as overseas buyers. The foreign trade data generated by the Directorate are disseminated through (i) Monthly Press Release, (ii) Foreign Trade Statistics of India by Principal Commodities & Countries, (iii) Monthly Statistics of Foreign Trade of India, and (iv) Statistics of Foreign Trade of India by Countries.

***Export Inspection Council (EIC)*:** The Executive Head of the EIC is the Director of Inspection & Quality Control who is appointed by the Government and is responsible for the enforcement of quality control and compulsory pre-shipment inspection of various commodities meant for export and notified by the Government under the Export (Quality Control and Inspection) Act, 1963. The Council is assisted in its functions by the Export Inspection Agencies (EIAs), which are field organizations located at Chennai, Delhi, Kochi, Kolkata & Mumbai and have state-of-art laboratories for quality certification activities. These Agencies have a network of 38 sub-offices located at different ports or major industrial centres and work under the technical and administrative control of the Council.

***Export Promotion Councils (EPCs)*:** Presently there are fourteen EPCs under the administrative control of the Department of Commerce, three of which are of relevance to the Indian medicinal natural products sectors; CHEMEXCIL, PHARMEXCIL and SHEFEXCIL. These Councils are registered as non-profit organizations under the Companies Act/Societies Registration Act. The Councils perform both advisory and executive functions. The role and function of these Councils are guided by the Foreign Trade Policy 2004-09. These Councils are also the registering authorities for exporters under the Foreign Trade Policy 2004-09.

***Export Promotion Board (EPB)*:** The Export Promotion Board (EPB) functions under the chairmanship of the Cabinet Secretary to provide policy and infrastructural support through greater coordination amongst concerned Ministries for boosting the growth of exports. All Ministries directly connected with facilitating foreign trade are represented on the Board by their Secretaries. This, inter-alia, includes Secretaries of Department of Commerce; Ministry of Finance; Department of Revenue; Department of Industrial Policy & Promotion; Ministry of Textiles; Department of Agriculture & Cooperation; Ministry of Civil Aviation; Ministry of Surface Transport.

***Indian Institute of Foreign Trade (IIFT)*:** The Institute has been conferred "Deemed University" status and is engaged in the following activities:

- Training of personnel in modern techniques of international trade
- Organizing research in problems of foreign trade, marketing research, area surveys, commodity surveys, market surveys and
- Dissemination of information arising from its activities relating to research and market studies.

***Office of Development Commissioner of Special Economic Zones (SEZs)*:** The Special Economic Zones (SEZs) are geographically exclusive enclaves separated from domestic tariff areas. The main objective of SEZs is to provide certain common facilities and a duty free environment for exporters. Each Zone is headed by a Development Commissioner and is administered as per the SEZ Act, 2005 and SEZ Rules, 2006. Units may be set up in the SEZ for manufacturing, trading or for service activity. The units in the SEZ have to be net foreign exchange earners but they are not subjected to any pre-determined value addition or minimum export performance requirements. Sales in the Domestic Tariff Area from the SEZ units are treated as if the goods are being imported and are subject to payment of applicable customs duties. Seven SEZs, set up by Government of India, are in operation at Kandla (Gujarat), Santa Cruz (Maharashtra), Cochin (Kerala), Noida (U.P), Chennai (Tamil Nadu), Falta (West Bengal) and Visakhapattanam (Andhra Pradesh). In addition, 75 SEZs, set up in the public/private sector, are in operation. Further, 171 SEZs have been given formal approval and these were expected to be notified during 2007.

***Spices Board*:** The primary functions of the Board include increasing the production and productivity of small and large cardamom; development, promotion and regulation of export of spices; assisting and encouraging studies and research for improvement of processing; grading and packaging of spices; striving towards stabilization of prices of spices for export; upgrading quality for export. In regard to cardamom, the Board also provides financial and other assistance for cultivation and processing of cardamom; monitoring prices; increasing domestic consumption; improving marketing; undertaking, assisting or encouraging scientific, technological and economic research and improving quality. The Board also implements programmes for development of exotic and high value spices like Vanilla, Herbal Spices, Organic Spices etc. It also supports programmes aimed at better post harvest practices.

***Tea Board*:** The primary functions of the Board include rendering financial and technical assistance for cultivation, manufacture, marketing of tea (*Camellia sinensis*); promoting tea exports; aiding research and developmental activities for augmentation of tea production and improvement of tea quality; encouraging and assisting the unorganized small growers sector financially and technically; collecting and maintaining statistical data and its publication for the benefit of growers, processors and exporters.

c. Ministry of Health & Family Welfare, Department of AYUSH

Department of Indian Systems of Medicine and Homoeopathy (ISM&H) was created in March 1995 and re-named as Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and

Homoeopathy (AYUSH) in November 2003 with a view to providing focused attention to development of Education & Research in Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy systems. The Department continued to lay emphasis on upgradation of AYUSH educational standards, quality control and standardization of drugs, improving the availability of medicinal plant material, research and development and awareness generation about the efficacy of the systems domestically and internationally.

AYUSH Objectives:

- To upgrade the educational standards in the Indian Systems of Medicines and Homoeopathy colleges in the country.
- To strengthen existing research institutions and ensure a time-bound research programme on identified diseases for which these systems have an effective treatment.
- To draw up schemes for promotion, cultivation and regeneration of medicinal plants used in these systems.
- To evolve Pharmacopoeial standards for Indian Systems of Medicine and Homoeopathy drugs.

Central Schemes of most relevance to export development include:

- Scheme for providing Central assistance for development and cultivation of medicinal plants used in Indian Systems of Medicines & Homoeopathy; available at: http://indianmedicine.nic.in/Pdf/Scheme-for-Providing-CentralAssistance-for-Development-and-Cultivation.pdf
- Scheme for providing Central assistance for development of Agro techniques and cultivation of medicinal plants used in Ayurveda, Siddha, Unani and Homoeopathy; available at: http://indianmedicine.nic.in/Pdf/Scheme-for-Providing-CentralAssistance-for-Development-and-Cultivation.pdf
- Promotional and Commercial Schemes of Medicinal Plants Board; available at: http://indianmedicine.nic.in/Promotional%20and%20Commercial%20Schemes%20of%20Medicinal%20Plants%20Board.pdf
- Central Sector Scheme for Promotion of International Co-operation (IC) in AYUSH; available at: http://indianmedicine.nic.in/IC%20Scheme.pdf
- Scheme for development of AYUSH clusters (Department of AYUSH has allocated Rs 500 crores for development of 20-25 clusters in the 11th five-year plan); available at: http://indianmedicine.nic.in/Cluster%20Scheme.pdf

Centrally Sponsored Schemes of most relevance to export development include the:

- Centrally sponsored scheme on Quality Control of AYUSH Drugs; available at: http://indianmedicine.nic.in/NewScheme%20QualityControl.pdf

d. Ministry of Health & Family Welfare, Pharmacopoeial Laboratory for Indian Medicine

Pharmacopoeial Laboratory for Indian Medicine (PLIM) is a subordinate office of the Ministry of Health & Family Welfare, (Deptt. of AYUSH), Govt. of India. This laboratory is a Standards Setting cum Drugs Testing Laboratory at National Level for Indian Medicines which include drugs of Ayurveda, Unani and Siddha systems. PLIM objectives include to lay down standards of single drugs for monographs of the Ayurvedic, Unani and Siddha Pharmacopoeias of India, respectively, and to lay down standards of compound formulations included in the Ayurvedic, Unani and Siddha Formularies of India, respectively. PLIM also analyzes official samples received from Drug Control

Authorities and collects genuine samples of crude botanical drugs from different agro-climatic-zones for pharmacopoeial standardization.

PLIM publications that are essential for the Quality Control Units and Research and Development Departments of Indian producers of medicinal natural products include, among others:

- ***Ayurvedic Formulary of India***. Information at: http://plimism.nic.in/publications.html
- ***Ayurvedic Pharmacopoeia of India.*** Information at: http://plimism.nic.in/publications.html
- ***Legal Status of Ayurvedic, Unani & Siddha Medicines***. Available at: http://plimism.nic.in/Legal_Status.pdf
- ***Phytochemistry, Standardisation and Biotechnological aspects of ISM Drugs.*** Information at: http://plimism.nic.in/publications.html
- ***Production of ISM Drugs with Current Good Manufacturing Practices.*** Information at: http://plimism.nic.in/publications.html
- ***Protocol Testing of Ayurvedic, Unani and Siddha Medicines***. Available at: http://plimism.nic.in/Protocol_For_Testing.pdf

e. Ministry of Micro, Small and Medium Enterprises (MSME)

The President under Notification dated 9th May 2007 has amended the Government of India (Allocation of Business) Rules, 1961. Pursuant to this amendment, Ministry of Agro and Rural Industries (Krishi Evam Gramin Udyog Mantralaya) and Ministry of Small Scale Industries (Laghu Udyog Mantralaya) have been merged into a single Ministry, namely, "MINISTRY OF MICRO, SMALL AND MEDIUM ENTERPRISES (SUKSHMA LAGHU AUR MADHYAM UDYAM MANTRALAYA)"

Scheme of Fund for Regeneration of Traditional Industries (SFURTI) under which 100 traditional industry clusters (of khadi, village industry and coir) would be taken up for comprehensive development over 5 years. The KVIC and the Coir Board are the nodal agencies for the Scheme, which will be the first comprehensive initiative for regeneration of the khadi and village industries sector, based on the cluster development methodology. The guidelines for the SFURTI have been issued on 3.10.2005. All State Governments / Union Territories have been asked to send their proposals for cluster development to this Ministry for consideration/approval. Of the 122 approved clusters under the SFURTI (Khadi-34, Village Industry-62, Coir-26), there is one approved Village Industry Cluster for Siddha & Ayurveda Medicines in Dindigul, Tamilnadu "Siddha & Ayurveda Cluster Dindigul" – Lakshmi Seva Sangam, Gandhigram.[95]

Scheme of Swarnjayanti Gram Swarozgar Yojana (SGSY), launched on 01 April 1999, is a holistic programme covering all aspects of self employment such as organisation of the poor into self-help groups, training, credit, technology infrastructure and marketing. SGSY is funded by the Centre and the States in the ratio of 75:25. The objective of SGSY is to bring the assisted poor families (Swarozgaris) above the poverty line in three years, by providing them income-generating assets through a mix of bank credit and government subsidy. It would mean ensuring that the family has a monthly net income of at least Rs.2000. In order to assist rural entrepreneurs, who may be covered in the scheme, DRDA identified some key activities including medicinal plant cultivation and mushroom cultivation, among other activities.

E. Research Councils:

a. Central Council for Research in Ayurveda & Siddha (CCRAS), Ministry of Health

[95] Ministry of Micro, Small and Medium Enterprises (MSME). Clusters approved under AFURTI scheme. New Delhi, India: MSME. Available at: http://msme.gov.in/Approved%20cluster%20under%20SFURTI.pdf

The Central Council for Research in Ayurveda and Siddha (CCRAS) is an autonomous body under Department of AYUSH, Ministry of Health & Family Welfare, Government of India set up for the formation, coordination, development and promotion of research on scientific lines in Ayurveda and Siddha. Its activities are carried out through its 38 institutes/centres/units located all over India and through a number of Units located in Universities/ Institutes/ Hospitals of Ayurveda and Siddha. The Council is also financing suitable research studies of Ayurveda, Siddha and allied sciences. The emphasis is on finding effective and low-cost remedies for various diseases through systematic research. Research activities of the Council include Clinical Research, Health Care Research, Drug Research, Literary Research and Family Welfare Research. Now the Council has also stepped into the field of Nutraceutical and Cosmeceutical research.

Golden Triangle Partnership (GTP) Scheme: Under the GTP Scheme, Department of AYUSH, through its research Councils – CCRAS, CCRUM, and CCRH, will work together with two other major partners i.e. CSIR and ICMR- to achieve the following objectives:

1. To bring safe, effective and standardized ASHU (Ayurveda, Siddha, Homoeopathy & Unani) products for the identified disease conditions;
2. To develop new Ayurvedic / Siddha / Unani / Homeopathic products effective in the disease conditions of national/global importance. Products should be better than the available products in the market for such disease conditions;
3. The criteria will be to have best quality, safe and effective products. Mechanism will be evolved to make products affordable for the domestic market;
4. To utilize appropriate technologies for development of single and poly-herbal products to make it globally acceptable;
5. To promote collaborative research on AYUSH with modern medicine/modern science institutions.

Patents: There are several Public-Private-Partnership (PPP) projects that have resulted in patents and new drugs. There have been 19 patents obtained thus far by CCRAS, 8 patents have been filed, and 5 patents/processes have been release to the industry. The patents/know how have been assigned to National Research Development Corporation. (NRDC), New Delhi for Commercial exploitation. The list of CCRAS patents is enclosed as Appendix XIV, also available on-line at: http://ccras.nic.in/process.htm.

Product Development Initiatives: Development of Nutraceuticals and Cosmeceuticals is one of the focuses of CCRAS. While the product forms are new drugs, the combination theory applied for the formulations and the indications for use are based on traditional Ayurveda theory.

Product Safety Research: CCRAS is actively conducting safety and toxicity evaluations of traditional Indian metal-based bhasmas. Original papers are being submitted to relevant biomedical journals for publication. Until the medical literature provides ample and conclusive evidence for the safety of bhasmas, this class of Indian products has little chance in the western export markets. This research effort by CCRAS could be among the most important foundational pieces that could contribute to increased export promotion of Indian Systems of Medicine to the west.

Propagation of Ayurveda: Global Reach: Information on CCRAS participation in international conferences, exhibitions, and trade fairs, as well as visits to institutes available at: http://ccras.nic.in/global.htm

Publications: Summaries of CCRAS Clinical Research Studies on Ayurvedic products are available at: http://ccras.nic.in/crs.htm

b. Central Council for Research in Unani Medicine (CCRUM), Ministry of Health

The Central Council for Research in Unani Medicine (CCRUM) was established by the Ministry of Health and Family Welfare, Government of India as an autonomous organisation in the year 1979, to initiate, aid, develop and to co-ordinate scientific research in Unani System of Medicine. The Council is engaged in the multifaceted research activities in the field of Unani medicine. The Council's research programme comprises clinical research, drug standardization, survey and cultivation of medicinal plants and literary research. These research activities are being carried out through a network of 22 Institutes/Units functioning in different parts of the country. These include two Central Research Institutes of Unani Medicine - one each at Hyderabad and Lucknow, eight Regional Research Institutes of Unani Medicine - one each at Chennai, Bhadrak, Patna, Aligarh, Mumbai, Srinagar, Kolkata and New Delhi, six Clinical Research Units - one each at Allahabad, Bangalore, Karimganj, Meerut, Bhopal and Burhanpur, four Drug Standardisation Research Units - one each at New Delhi, Bangalore, Chennai and Lucknow, a Chemical Research Unit at Aligarh, a Literary Research Institute at New Delhi. During the reporting period new clinical studies were initiated in different diseases. Besides, ongoing trials also continued at different centres. In the drug standardization research programme development of Standard Operating Procedures (SOPs) for compound formulations continued. Development of agro techniques for domestication and cultivation of Unani medicinal plants was also continued.

***Collaborations for commercialization of research drugs*:** CCRUM is engaged in collaborative studies with different scientific organizations and medical colleges for the development and clinical testing of Unani drugs. The Council has also signed a Memorandum of Understanding (MoU) with National Research Development Corporation (NRDC) for patenting and commercial exploitation of research drugs developed by CCRUM. The Council also endeavors to collaborate with Council of Scientific and Industrial Research (CSIR) and Indian Council of Medical Research (ICMR) under the Golden Triangle Programme of Department of AYUSH for standardizing and scientifically validating potential Unani classical formulations.[96]

***Directories*:** CCRUM publishes and disseminates various directories for the trade. For example, one directory provides listings with contact details for manufacturers of finished Unani medicinal products, listings of dealers, suppliers and traders, lists of importers and exporters.

***Exposition participation*:** CCRUM participates in national exhibitions on behalf of the Department of AYUSH, along with representatives of other research councils and ministries. The CCRUM exhibition booth displays research activities including medicines developed and used by the Council.[97]

Farmers meetings: CCRUM's Central Research Institute of Unani Medicine (CRIUM), Hyderabad, organizes farmers meetings as part of the Council's ongoing programme to create awareness among farmers about medicinal plants and educate them on their cultivation and marketing practices. At such meetings information is provided on high demand medicinal plants to help farmers make additional income, seedlings of medicinal plants are distributed to farmers free of cost, and free literature is provided on cultivation practices and marketing of some high demand medicinal plant species.[98]

***Financial assistance*:** CCRUM provides financial assistance for short-term projects relating to clinical, pharmacological, toxicological and phytochemical research of Unani drugs. Such

[96] Hakim Mohammed Khalid Siddiqui. *Unani Medicine in India*. New Delhi: Central Council for Research in Unani Medicine. December 2007.

[97] Aminuddin and Irshad Ahmed Khan. Council's participation in exposition at Kolkata. *CCRUM Newsletter*. September - October 2007;28(5):14.

[98] Gupta VC. Farmers' meet on cultivation of medicinal plants. *CCRUM Newsletter*. September – October 2007;28(5): 15-16.

assistance is limited to fellowship and contingency. Thirteen such projects awarded to different universities have been completed. [99]

Patenting of Drugs: CCRUM has filed patents on 24 Unani formulations. These include two drugs each for treatment of rheumatoid arthritis, bronchial asthma, and infective hepatitis, and one drug each for treatment of malaria, gingivitis, and 16 kit medicines for common ailments. Additionally, 18 other formulations are under consideration for patenting.

Promotion and Publishing: To popularize Unani system of medicine, CCRUM published research monographs, technical reports, brochures, booklets, journals and newsletters. So far CCRUM has brought out 143 publications.

Standards and SOPs for Industry: CCRUM's programme of drug standardization is concerned with evolving standards for single and compound Unani drugs of proven efficacy included in National Formulary of Unani Medicine for their incorporation in the official Unani Pharmacopoeia of India. CCRUM standardization of Unani formulations has been undertaken in order to establish standards for the drugs as well as the methods of their manufacture. So far CCRM has finalized standards for 277 single drugs and 385 compound drugs. Based on this work, CCRUM has brought out publications including *Physicochemical Standards of Unani Formulations*, in four parts, and *Standardisation of Single Drugs of Unani Medicine*, in three volumes. Work on development of Standard Operation Procedures (SOPs) for Unani formulations included in the National Formulary of Unani Medicine has also been started by CCRUM.

***Survey & Cultivation of Medicinal Plants*:** CCRUM carries out ethnopharmacological surveys of medicinal plants used in Unani system of medicine in order to study their distribution, availability and threats of medicinal species facing depletion and suggests measures for their protection and conservation by setting up drug farms.

***Traditional Knowledge Digital Library (TKDL)*:** CCRUM was entrusted by the Government of India the work to develop a Traditional Knowledge Digital Library to preserve traditional knowledge of Unani Medicine. In the first phase, a database of 77,000 formulations collected from 14 Unani texts running into 35 volumes has been developed. The database will be translated into various international languages including English, French, German, Japanese, and Spanish and will be made available for prior art search by patent examiners at international level.

c. Central Council for Research in Yoga & Naturopathy (CCRYN)

Central Council for Research in Yoga and Naturopathy (CCRYN) is a society registered under the Societies Registration Act as an autonomous body under the Department of AYUSH, Ministry of Health & Family Welfare. The basic objective of the Council is to conduct Scientific Research in the field of Yoga and Naturopathy. However, in the absence of any other Statutory Body to look after the Education & Training in these systems, the objectives were later amended to include Education, Training and Propagational aspects of these disciplines. 4.5.2 At present, the Council is finding NGOs for the following activities : (i) Clinical Research ; (ii) Treatment-Cum-Propagation Centre; (iii) Patient Care Centre (10/5 Bedded); (iv) Literary Research / Translation / Publication Work (v) Seminar/ Workshop/ Conferences.

d. Council of Scientific & Industrial Research (CSIR)

[99] Hakim Mohammed Khalid Siddiqui. *Unani Medicine in India*. New Delhi: Central Council for Research in Unani Medicine. December 2007.

The Herbal Therapeutics programme of the Council of Scientific & Industrial Research (CSIR) involves efforts to develop herbal preparations as therapeutics. These herbal preparations are being developed only after conducting all the appropriate studies, viz. standardization, biological activity validation, safety, efficacy and clinical studies. Products developed would be then introduced as therapeutics in the Indian and the foreign markets. The CSIR collaboration with the AVS and CCRUM is a major initiative in this direction.

"Evidence based nutraceuticals / herbal products for preventive health and disease management" was an approved CSIR project of the Eleventh Five Year Plan Approved Projects. The Tenth Five Year Plan & Annual Plan 2004-05 included the CSIR programme on "Discovery, Development & Commercialization of New Bioactives and Traditional Preparations." The CSIR coordinated networked programme on discovery of bioactive molecules and traditional preparations involved 20 CSIR labs, 14 University departments, some hospitals and three systems medicine i.e. Ayurveda, Siddha & Unani completed the first phase in March 2003. The progress of the programme was reviewed by the High Powered Committee constituted by DG-CSIR with the members of Governing Body, Advisory Board and Secretaries of the concerned departments.

The programme advanced forward in terms of achievements in plant collection, extraction, bioevaluation, creation of facilities and mechanism studies. Sixty leads were obtained, out of which eight are at single molecule stage, twenty-two are at formulation stage and thirty at fraction stage. Some are at advanced stage of development for diseases like cancer and ulcer. Two entirely new anti-cancer preparations in the area of women's cancer are being developed further with an Indian firm. Also short term toxicity of two entirely new anti-ulcer preparations have been completed and clinical trials protocols have been worked out. The programme resulted in discovery of few new chemical entities as well as new herbal preparations. A few of them have since been licensed to Indian firms.

Some products that have been developed by the CSIR are licensed to foreign companies to market under their brands. For example, Keen Health Pty Ltd of Australia has trademarked the extract Baccdrix™ marketed under license from the CSIR/Central Drug Research Institute. The extract is exported from India under license and Quality Control tests are carried out in India and in Australia prior to manufacture and packaging. Baccdrix™ is the trade mark for the extract of *Bacopa monniera* licensed exclusively to Keen Mind by the CSIR/Central Drug Research Institute of India in Lucknow. It is a standardized extract containing not less than 55% Bacoside A & Bacoside B. The process method is the subject of a patent held by the Central Drug Research Institute of India. Baccdrix™ is used in Keen Mind and other products bearing the Baccdrix™ trademark.[100]

F. Trade Associations & Trade Organizations:

a. Association of Manufacturers of Ayurvedic Medicines (AMAM)

The Association of Manufacturers of Ayurvedic Medicines (AMAM) is a charitable non-profit holistic health association registered under Societies Registration Act 1860. The objectives of AMAM are:

- To promote Science and Technology among the Manufactures of Ayurvedic and Unani Medicines and allied Industries.
- To encourage, assist, extend, promote knowledge and information's connected with Ayurvedic and Unani Medicines.
- To promote research and development in cultivation technology, quality control and related areas.

[100] Keen Health Pty Ltd. Baccdrix™. Product information available at: http://www.keenmind.com.au/baccdrix.htm

- To collect and circulate statistics and information relating to Ayurvedic and Unani medicine manufacturers for the promotion and advancement of Ayurveda and Unani Medicine in India and abroad.
- To promote science and to diffuse useful knowledge relating to Ayurvedic and Unani systems of medicine amongst the members by publishing Newsletter/Journals.
- To do all other things as maybe conducive to the development of Ayurvedic & Unani medicine.

b. Ayurvedic Drug Manufacturers Association (ADMA)

Ayurvedic Drug Manufacturers' Association (ADMA) was founded in 1994 and is a registered body under Society's Registration Act of Maharashtra 1860 and under Bombay Public Trust Act 1950. ADMA Membership comprises large, medium and small companies from all over India in the category of Patron Member, Life Member and Ordinary Member who cumulatively contribute over 80% of the Ayurvedic commerce in India. Certain key principles that guide ADMA actions are:

- To represent the collective aspirations, interests and needs of the healthcare & medical profession and the Ayurvedic & the allied manufacturers in particular.
- To interface on behalf of its members with policy makers, statutory organizations and regulatory bodies with the objective of putting forth view points of the industry.
- To act as a resource for its members to draw upon for technical and scientific needs.
- To kindle the spirit of global outlook, standards and quality amongst its members.
- To always protect and propagate the cause of healthcare needs through the Ayurvedic Industry in all its actions and deeds.

ADMA has been at the forefront in voicing and representing the problems of the Ayurvedic & Allied Industries for the past decade. ADMA has successfully carried forward the message and today enjoys the goodwill of the Policymakers as well as the Ayurvedic Industry Colleagues as the lead voice. ADMA has been successfully meeting the challenges, defining the scope, communicating the objectives and contributing to formulation of policy in matters concerning departments of Environment & forests, Backward Integration, Export & Globalization, etc. Representatives from ADMA sit on key Committees which contribute to policy formulation and guidelines at Central and State Government level. As such, ADMA plays a key role in defining tomorrow for the Ayurvedic sector.

ADMA has collaborated with policy makers like Ministry of Health & other related Ministerial Departments, Scientific Institutes like CCRAS & CSIR as well as Industry bodies like CII and IDMA in deliberations and organizing events for the benefit of its members. Some of these are:

1. Deliberations of the National Medicinal Plants Board
2. Co ordination of Activities for Export Promotion
3. Meetings and Seminars with CII on the issues about backward area development
4. Presentation to the House of Lords Committee & Interaction with the Medicine Control Agency, UK
5. Participations at WHO meets in Geneva

ADMA successfully coordinated two important studies commissioned by the Ministry of Commerce and monitored by the Department of AYUSH, namely H.S. Code classification for Ayurvedic Products & Mapping of the US Herbal Products Market.

c. Central Herbal Agro Marketing Federation of India (CHAMF)

The Central Herbal Agro Marketing Federation of India (CHAMF) is a non-profit association of Indian organic herbal grower farmers. The federation is committed for growth and prosperity of the farmers by certified organic cultivation and marketing of OTC product. Founded in October 2002, CHAMF is a registered organization under societies Registration Act 1973 under section 44 vide Registration Number CG 554 on 28 th March 2003

The Federation envisages boosting economic growth in rural areas by creating jobs in cultivation and small value addition on rural levels. The Federation is networking the farmers, growers, traders, manufactures and consumers to benefit from bio-technology revolution in herbal farming. The federation has all India network to support the farmers in cultivation, technology, processing and marketing. At present there are 20,000 members who have benefited from the 14 technical consultancy cells of CHAMF operating in over 19 States in India.

CHAMF Services:

- Marketing of organic herbs, wild crafted herbs and essential oil in National and International market
- Supply of organic planting material of medicinal and aromatic plants.
- Soil testing and product testing services.
- Training for medicinal and aromatic plants on cultivation and processing.
- Dissemination of information about research, marketing, products and Processing.

d. Federation of Indian Herbal Industry (FIHI)

Objectives of the Federation of Indian Herbal Industry (FIHI), founded in February 2004, are:

- To function as a common platform for interaction and manufacturers, scientists, policy makers, and research development instructions and policy makers involved in the herbal sector.
- To develop cohesive thinking and coordinated action among the stakeholders involved in the herbal cultivation, promotion, quality control, standardization processing and manufacturing of value added products, with scientific validation.
- To identify the existing and on-going research and other activities in the different systems of herbal / traditional medicines and facilitate effective coordination.
- To initiate necessary steps for promoting, supporting and upgrading the herbal industry including interacting with government agencies, legislators, non-governmental organization and public opinion makers for formulation of policies and practices beneficial for the industry.
- To safeguard the interests of different stakeholders involved in the herbal industry like the farmers and producers of herbal products, research and development institutions, NGOs, Manufacturers, Importers and Exporters.
- To gather, consolidate and disseminate all information pertaining to promote the herbal industry at International, national and state level. Also make efforts for the spread and sharing of knowledge concerning the herbal industry, besides creating awareness on the endangered species of medicinal plants and herbs.
- To persuade the Government of India, through its missions abroad, to export Ayurvedic, Siddha, Unani and other Traditional Indian Systems of Medicines and have their books translated, published and distributed in the US, EU, African and other countries in their languages.
- To conduct seminars, conferences and organize training courses and consultancy facilities, to guide and assist members and extent technical and commercial guidance for establishing

Good Manufacturing Practices (GMP) and quality management standards, and institute awards and recognition for qualifying products manufactured by members.

e. Health Foods and Dietary Supplements Association of India (HADSA)

Health Foods and Dietary Supplements Association is a national non-profit trade association with 90 members founded in April 2002 with the following aims and objectives:

- To represent the interest of health foods, dietary supplements, nutraceuticals and healthcare industry in general comprising of manufacturers and suppliers of vitamins, minerals, botanical products, sports nutrition products and herbs.
- To support science based environment to ensure responsible marketing of health foods, dietary supplements and nutraceuticals.
- To promote and defend regulatory environment conducive to health foods, dietary supplements, nutraceuticals and healthcare industry in general as well as consumer protection.
- To prevent, eradicate malpractices, if any, in the health foods, dietary supplements and nutraceuticals industry and to establish a code of ethics, for observance by its members in the line with the prevailing regulations.
- To initiate timely actions that are likely to improve the regulatory climate, reputation and consumer confidence in health foods, dietary supplements, nutraceuticals and healthcare industry.
- To secure the most favorable duty / tax structure for the health foods, dietary supplements, nutraceuticals and healthcare industry segment.

f. Herbs and Herbal Export Promotion Association of India (HEPAI)

Founded in 1998, Herbs & Herbals Export Promotion Association of India (HEPAI) is a national trade association focused primarily on natural and herbal products. HEPAI's activities are focused on its mission, to promote the responsible commerce of herbal & natural products, and are undertaken to maintain and improve market opportunities for companies that sell herbs, herbal products and other health-related products. HEPAI objectives include:

- Promote the export of herbs in crude or processed form.
- Provide assistance to farmers.
- Establish research institutions, centres, laboratories for farmers for improving the quality of herbs & production for exports.
- Develop techniques of hybrid breeding, mutation crops & promote contract breeding & contract farming.
- Conduct regular public relations campaigns to promote Indian herbal trade.
- Collect statistics & other information regarding the production, trade, or use of herbs & herbals from various countries.
- Propagate information useful to farmers, cultivators, traders, processors of herbs & herbals by lectures, books, seminars, conferences.
- Communicate regularly with Chamber of commerce or other mercantile & public bodies throughout the world.
- Assist government authorities in appraisal of a plan for herbal products.
- Enquire & investigate complaints received from foreign imports or Indian exports in respect of quality.
- Participate in Domestic & International trade fairs.

g. India Trade Promotion Organisation

India Trade Promotion Organisation (ITPO) is the nodal agency of the Government of India for promoting the country's external trade. ITPO, during its existence of nearly three decades, in the form of Trade Fair Authority of India and Trade Development Authority, has played a proactive role in catalyzing trade, investment and technology transfer processes. Its promotional tools include organizing of fairs and exhibitions in India and abroad, Buyer-Seller Meets, Contact Promotion Programmes, Product Promotion Programmes, Promotion through Overseas Department Stores, Market Surveys and Information Dissemination.

Trade events organized by ITPO of particular relevance to this study include the "AROGYA Comprehensive International Health Fair on Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy" in collaboration with the Department of AYUSH.

h. Indian Drug Manufacturers Association (IDMA)

Indian Drug Manufacturers' Association (IDMA) is the publisher of the *Indian Herbal Pharmacopoeia* (IHP) Revised New Edition 2002.[101] The IHP 2002 provides 52 comprehensive monographs with color photographs, macroscopic and microscopic descriptions, TLC identity tests, qualitative and quantitative standards, chemical constituents and structure, HPLC methods for assay, pharmacology, safety and therapeutics.

i. Medicinal, Aromatic & Dye Plants Stakeholders' Consortium

Medicinal, Aromatic and Dye Plants Stakeholders' Consortium (MAPSCON), is a multi-stakeholder, membership-based umbrella organisation meant to serve the relatively undeveloped but hugely promising sector of medicinal, aromatic and dye plants. MAPSCON evolved over two years as the outcome of a process led by Oxfam GB in participation with major stakeholders of the sector and international organizations. In March 2004, participants attending the 'International Conference for Herbs & Herbal Products: Livelihoods & Trade Options' at New Delhi, organized by Oxfam GB & Community Enterprise Forum International (CEFI), gave a call for developing a members' consortium to realize the potential of the MADPs sector.

MAPSCON is a nonprofit institution led by Oxfam GB pivated by a national secretariat based in New Delhi, India. MAPSCON's National Secretariat is coordinated by CEFI, New Delhi. The Specific activity areas of MAPSCON in terms of long interest and interventions are:

- Building Brand India in MADPs and Herbal Products
- Events
- Quality Assurance
- Member Services
- Trade Data
- Partnership with Government
- Promotion Initiatives
- Research and Development
- Campaigns

j. The Associated Chambers of Commerce and Industry of India (ASSOCHAM)

The Associated Chambers of Commerce and Industry of India (ASSOCHAM), founded in 1920, is the oldest apex chamber with 300 associated regional chambers. It covers the interests of over 250,000 direct and indirect members from every segment of business. ASSOCHAM was the

[101] Indian Drug Manufacturers' Association. *Indian Herbal Pharmacopoeia* Revised New Edition 2002. Mumbai: IDMA. 2002.

organizer of the 2008 "hi-MAPS'-Herbal International Summit cum Exhibition on Medicinal & Aromatic Products and Spices" in New Delhi, co-organized with Rawal Medherbs Consultants Pvt. Ltd. ASSOCHAM services to industry include:

Information Dissemination

- ASSOCHAM assists its members by timely dissemination of information and know-how on the latest policy and technical developments.
- Publications. periodicals, discussion papers.
- Policy Analysis monthly new service addresses contemporary economic issues.

Training and Consultancy

- Organizing training programmes, workshops, seminars, exhibitions & conferences.
- Advise members on diverse subjects such as industrial growth, monetary and fiscal policy, economic planning, taxation and corporate laws etc. through secretariat or through expert committees.

Industry-Government Interface

- Continuous dialogue with the Central and State Governments for better appreciation of trade and industry view points.
- Participation in Government advisory committees to help formulate policy conducive to business growth. ASSOCHAM has been provided representation on apex policy making committees constituted by the Government which include:
    - The Prime Minister's Council on Trade and Industry
    - National Advisory Committee on Information Technology Development
    - Council for Telecom Sector
    - Board of Trade
    - Working Group on Small Scale Industries (SSI) Sector for the Tenth Plan
    - Tenth Plan Steering Committee
    - Steering Committee on Village and Small Industries Sector and
    - Trustee of Major Ports
    - Submission of representations / memoranda.

Enhancing International Business Relations

- Day-to-day networking with Indian Missions and our counterpart organizations across the globe.
- Businessmen's forum invites Chief Executives of transnational corporations for interaction with Indian entrepreneurs.
- Forges working relations through Memoranda of Understanding (MoUs) with counterpart organizations abroad.
- Organizing one to one meetings with business delegations or Assocham Business Delegations visiting abroad.\

G. Other Organizations or Consultancies Providing Support to Industry

a. Apex Cluster Development Service Pvt. Ltd. (ACDS)

ACDS has recently prepared a profile of Ayurvedic drug manufacturing clusters in Thrissur and Cochin of Kerala State as well as a fragrance industry cluster profile in Kannauj, Uttar Pradesh, and

a fruit & vegetable processing cluster in Pune titled "Implementing Business Development Services for Micro, Small & Medium Enterprises."

ACDS's work on cluster development strategies involves helping stakeholders formulate a collective 'vision' and practical strategy. ACDS works with stakeholders to formulate new public–private partnerships. ACDS advises on innovative institutional frameworks that are required to successfully manage the increasing velocity of change that characterized many national and artisan economies of today.

ACDS has conducted number of cluster diagnostic studies as a part of Cluster Development Programme of UNIDO in India from 1998 to 2004. The team members have helped Regional Governments to develop investment, planning and policy responses in order to build cluster strength and depth.

b. Asian Medicinal Plants & Health Care Trust (AMPTRUST)

In 2004, the Asian Medicinal Plants & Health Care Trust (AMPTRUST), Jodhpur, published an "*International Directory of Medicinal & Aromatic Plants*,"[102] compiled by N.D. Prajapati, Member, National Medicinal Plants Board (NMPB), New Delhi, and Tarun Prajapati of Gujarat Ayurved University, Jamnagar.

The aim of the directory was to provide developing countries and economies in transition with a reference book of useful addresses that will help establish contacts with, and encourage a direct flow of trade among buyers and suppliers. The directory was intended to be useful for farmers, exporters, extractors, importers, seed production companies, scientists, consultants and other stack holders of medicinal and aromatics plants. While this directory is now somewhat dated it is not known whether AMPTRUST is planning an updated and revised edition.

c. Foundation for MSME Clusters

The Foundation for MSME Clusters has participated with the Entrepreneurship Development Institute of India in a survey of regional clusters / value chains and BDS providers in the pharmaceutical cluster[103] which includes analysis of the Ayurvedic enterprises.

The Foundation for MSME Clusters seeks to achieve the following objectives:

- Cluster initiatives become inclusive.
- Cutting edge methodologies, tools, information and resources with respect to a cluster development program are accessible.
- Effective linkages emerge between clusters and important thematic institutions in the area of finance, infrastructure, environment, investment, RD, social responsibility and local governance.
- Trained and competent professionals and institutions are available to facilitate cluster-based development.
- Models of strong community based civil society organizations emerge to take up cluster based sustainable development initiatives.

[102] Prajapati ND, Prajapati T. *International Importers Directory of Medicinal & Aromatic Plants*. Jodhpur: Asian Medicinal Plants & Health Care Trust. 2004.

[103] Entrepreneurship Development Institute of India & Foundation for MSME Clusters. Draft Report on Survey of Regional Clusters / Value Chains and BDS Providers: Indore Region. New Delhi, India: German Technical Cooperation. 31 January 2007.

d. Foundation for Revitalisation of Local Health Traditions (FRLHT)

The National Medicinal Plants Board (NMPB), Ministry of Health & Family Welfare, Department of AYUSH, initiated a study "Demand and Supply of Medicinal Plants in India 2008,"[104] which was carried out by Drs. D.K.Ved and G.S. Goraya, of the Foundation for Revitalisation of Local Health Traditions (FRLHT).

FRLHT is a registered Public Trust and Charitable Society, which started its activities outlined below in March 1993. The Ministry of Science & Technology recognizes FRLHT as a scientific and research organization. The Ministry of Environment and Forests has designated FRLHT as a National Center of Excellence for medicinal plants and traditional knowledge. The institutional agenda of the Foundation for Revitalisation of Local Health Traditions (FRLHT) is derived from its vision: "to revitalize Indian medical." FRLHT has identified three thrust areas to fulfill this vision. These are:

i) Conserving natural resources used by Indian Systems of Medicine
ii) Demonstrating contemporary relevance of theory and practice of Indian Systems of Medicine
iii) Revitalisation of social processes (institutional, oral and commercial) for transmission of traditional knowledge of health care for its wider use and application

All the current programmes and projects of FRLHT can be covered under these three thrust areas.

e. Herbal Centre for Research, Planning & Action (CERPA)

The Centre for Research, Planning & Action (CERPA) was established In 1972 in the name and style of Institute of Economic & Market Research and Registered in 1978 under the Societies Registration Act-XXI of 1860, It is a non-partisan, non-political and Non-profit organisation working with the important object of betterment of relatively disadvantaged population groups. The Centre is a Research, Training & Consultancy Organisation recognized by Department of Scientific and Industrial Research (DSIR) Ministry of Science & Technology, Govt. of India as an R & D Institution. CERPA is accredited to UNECOSOC (United Nations Economic and Social Council) and an approved UNESCAP Centre of Excellence in HRD.

The main objectives of the Herbal CERPA web portal (http://www.herbalcerpa.org) include, among others:

- To provide relevant economic data such as prices, availability, demand, exports / imports
- To provide information on importers and exporters of herbal and plants and natural products in India and abroad
- To facilitate e-marketing of medicinal plants and herbal products by bringing together providers, collectors and buyers in Indian and abroad
- To present such information to the Central and State level Medicinal Plant Boards, NABARD and other banking institutions, Centre and State Institutes, associations of manufacturers of herbal products, and cultivators and wild collectors of plants, etc...

Services provided by CERPA that are available to the medicinal natural products industry include:

[104] Ved DK, Goraya GS. *Demand and Supply of Medicinal Plants in India*. Dehra Dun, India: Bishen Singh Mahendra Pal Singh. 2008. Also available at website of NMPB: http://nmpb.nic.in/DS_study.htm

Directory of Manufacturers of Indian Systems of Medicine & Homeopathy Drugs:[105] CERPA publishes a directory of manufacturers which contains about 10,000 addresses organized state and district wise. Institute of Economic and Market Research (IEMR) will be updating the list of manufacturers from time to time.

Monthly Report on the Status of Herbal Industry in India: CERPA publishes each month a status report on herbal sector which keeps it readers informed of up-to-date domestic and international developments in the herbal sector. Subscription is Rs. 2000 for 12 months.

***Medicinal Plants in India: Report and Directory*:**[106] Published by Institute of Economic and Market Research, priced at Rs. 2000/-. The report is based on CERPA Report prepared for the World Health Organization (WHO) and contains Demand Estimates, Supply, Prices, Trade and Storage, Imports and Exports and similar details found very useful by the stakeholders in this sector. Since only limited copies of the report published by CERPA were prepared and the same are not available to general public, the Institute of Economic & Market Research (IEMR), a sister organisation of CERPA, took the initiative to print the present "Market Research Report and Directory of Medicinal Plants." The important parameters, findings, and suggestions as developed by the CERPA for the study on Demand for Selected Medicinal Plants carried out on behalf of Dept. of AYUSH and the WHO, have been incorporated in this Report and Directory.

f. Rawal Medherb Consultants Pvt. Ltd. (RMCPL)

Rawal Medherbs Consultants Pvt. Ltd.' (RMCPL) was founded in 2001 with a mission to accommodate different need levels of highly scattered trade sector of Medicinal Plants' in Asia to explore the possibilities of rapid growing recognition of herbal ingredients & their products throughout the world. RMCPL focused on data collection of different stakeholders related to medicinal plants' trade and survey market related projects at grass root level in India and other Asian countries.

In 2003 RMCPL began publishing information directories called "Medherb Green Pages," which covered the medicinal plants trade in India and related countries. Each directory contains over 300 pages of data. The directories published thus far include:

- Medherb Green Pages India 2003
- Medherb Green Pages India and Nepal 2004
- Medherb Green Pages India and Pakistan 2005
- Medherb Green Pages India, Sri Lanka and Dubai 2006
- Medherb Green Pages India and the Netherlands 2007
- Medherb Green Pages India and Germany 2008
- Medherb Green Pages India and Indonesia 2009

RMCPL also provides consultancy services to the herbal industry such as project feasibility studies and reports, market identification and marketing, exports and imports procedures and formalities, demand assessment, forecasting, demand and supply analysis, etc.

[105] CERPA. *Directory of Manufacturers of Indian Systems of Medicine & Homeopathy Drugs*. New Delhi: Institute of Economic and Market Research. 2003.

[106] CERPA. *Market Research Report and Directory of Medicinal Plants*. New Delhi: Institute of Economic and Market Research. 2003.

CHAPTER 6 – CURRENT RESPONSE AND ONGOING TECHNICAL ASSISTANCE

A. Agricultural Marketing Information System: A Central Sector Scheme of Directorate of Marketing & Inspection, Department of Agriculture & Cooperation, Ministry of Agriculture

The Agricultural Marketing Information System provides market information for a range of medicinal natural ingredients that are used in Indian Systems of Medicine and medicinal natural products. As a step towards globalization of agriculture, the Directorate of Marketing & Inspection (OMI) has embarked upon an ICT project: NICNET based Agricultural Marketing Information System Network (AGMARKNET) in the country, during the Ninth Plan, for linking all important APMCS (Agricultural Produce Market Committees), State Agricultural marketing Boards / Directorates and OMI regional offices located throughout the country, for effective information exchange on market prices NIC implements this project on a turn-key basis. This AGMARKNET project has already networked 735 Agricultural Produces Wholesale Markets (APWMs), 75 State Agricultural Marketing Boards/ Directorates and DMI Regional Offices during 2000-02 and embarked upon additional 2000 Markets during the Tenth Plan Period (2002-2007).

Indian medicinal natural ingredient commodities for which marketing information is provided through AGMARKNET include, among others: http://www.agmarknet.nic.in/commodity1.htm

- Ajowan fruit (*Trachyspermum ammi*)
- Amla fruit (*Phyllanthus emblica*)
- Anise fruit (*Pimpinella anisum*)
- Belleric myrobalan fruit (*Terminalia bellerica*)
- Betel leaf (*Piper betle*)
- Betelnut palm dried ripe seed (*Areca catechu*)
- Black pepper fruit (*Piper nigrum*)
- Castor seed (*Ricinus communis*)
- Chebulic myrobalan fruit (*Terminalia chebula*)
- Cinnamon inner bark (*Cinnamomum verum*)
- Clove flower bud (*Syzygium aromaticum*)
- Coconut oil & seed (*Cocos nucifera*)
- Coriander fruit (*Coriandrum sativum*)
- Cumin fruit (*Cuminum cyminum*)
- Fenugreek seed (*Trigonella foenum-graecum*)
- Garlic bulb (*Allium sativum*)
- Ghee
- Ginger rhizome (*Zingiber officinale*)
- Honey
- Indian cassia leaf (*Cinnamomum tamala*)
- Jujube fruit (*Ziziphus jujuba*)
- Kacholam rhizome (*Kaempferia galanga*)
- Moa tree flower and seed (*Madhuca longifolia*)
- Neem seed (*Azadirachta indica*)
- Pomegranate fruit (*Punica granatum*)
- Psyllium husk (*Plantago ovata*)
- Sesame seed (*Sesamum indicum*)
- Tamarind fruit (*Tamarindus indica*)
- Tea leaf (*Camellia sinensis*)
- Turmeric rhizome (*Curcuma longa*)

B. Capacity Building to enhance Competitiveness of Indian Agriculture and Registration of Organic Products Abroad: Ministry of Agriculture, Department of Agriculture & Cooperation

The "Capacity Building to enhance Competitiveness of Indian Agriculture and Registration of Organic Products Abroad" scheme[107] could be relevant for producers and exporters of certified organic medicinal natural products. This scheme aims to address some limited micro-level capacity creation issues. The capacity building under this scheme may be in the form of either academic, relevant research or in the form of creation of physical assets critical to agriculture in the international context. The scheme shall be operated on a cost sharing basis with State Governments or other private, semi government, non-government organizations. In the formulation of the scheme, no provision has been made for establishment related expenses including hiring of additional manpower. The proposed activities under the scheme have been outlined below.

SCOPE: The following activities will be eligible for financial assistance under the scheme:

- Research studies/ consultancy on various aspects of the international competitiveness of Indian agriculture.
- Support for awareness, creation and training programmes relating to the WTO Agreement on Agriculture and related Agreements among farmers/agricultural scientists/administrators in the country, preferably by State Agricultural Universities.
- Support to Farmers'/ Agri Related Organizations for creation of computerized commodity specific market information systems.
- Creation of product specific/country specific database on Sanitary / Phyto-sanitary measures, Quality Standards and Environmental Standards affecting trade in agricultural products.
- Creation/improvement of infrastructure in Laboratories engaged in examining standards for agricultural products including the work relating to MRL testing.
- Use of ICT and development/purchase of software on WTO matters by Department of Agriculture and Cooperation (Trade Division).
- Reimbursement of Organic Product Registration charges abroad and liaison with embassies abroad on matters pertaining to market intelligence and trade.

ELIGIBLE AGENCIES: Under the Scheme, financial assistance may be given to:

- Departments of Central Government/State Governments and Organization of Central/State Governments
- Commodity Boards
- Apex recognized trade bodies, farmers' organizations, research institutions etc.
- Individual entrepreneurs (only for reimbursement of organic product registration charges).

[107] Ministry of Agriculture, Department of Agriculture & Cooperation. *Capacity Building to enhance Competitiveness of Indian Agriculture and Registration of Organic Products Abroad.* Government of India, Ministry of Agriculture, Department of Agriculture & Cooperation. December 2007. Available at: http://agricoop.nic.in/Fwd_%20Scheme%20of%20Trade%20section.html

C. Central Scheme for Development of AYUSH Clusters, Department of AYUSH

The fourteen-page Scheme document is available to download at the AYUSH website at: http://indianmedicine.nic.in/Cluster%20Scheme.pdf

The Scheme

(a) The Scheme termed as 'Scheme for Development of AYUSH Clusters', is a Central Sector Scheme and would be co-terminus with the 11th Five year plan
(b) Department of AYUSH would allocate Rs 100 Crores in the 11th five year plan to fund the pilot projects under the scheme
(c) The Scheme would be implemented on a Public Private Partnership (PPP) format. Support from Department of AYUSH would be by the way of grant to the Special Purpose Vehicle (SPV), formed by group of entrepreneurs from AYUSH sector
(d) The assistance would be restricted to 60 % of the Project Cost subject to a maximum of Rs 10.00 crores. The remaining 40% would be required to be arranged by the SPV through equity, borrowings from Banks / Financial Institutions and other sources.

Objectives of the scheme:

(a) To fill in the critical gaps in the sector especially related to standardization, quality assurance and control, productivity, marketing, infrastructure and capacity building through a cluster based approach
(b) To encourage the level of organisation in the sector thereby creating social capital for sustainability of collective initiatives.

D. Centrally Assisted Schemes for Medicinal Plants: National Medicinal Plants Board (NMPB), Department of AYUSH, Ministry of Health & Family Welfare

National Medicinal Plants Board (NMPB) has published operational guidelines for financial assistance under the Centrally Assisted Schemes for Medicinal Plants.[108] Project proposals can be submitted to NMPB in the following areas:

NMPB Promotional Schemes

1. Survey and inventorization of medicinal plants.
2. In-situ conservation and ex-situ cultivation of medicinal plants.
    - To encourage in-situ conservation and ex-situ cultivation of selected medicinal plants, particularly endangered species which have appeared in Indian Red Data Book (IRDB) and negative list of CITES.
    - To create region-wise and species-wise medicinal plants demonstration centres (herbal gardens).
3. Production of quality planting material
    - To produce germplasms of quality planting materials in bulk by developing improved agro-techniques and other appropriate technology.
4. Extension activities- Information, education and communication:
    - Awareness through audio-visual aids, talks, seminars, training, workshops etc.

[108] National Medicinal Plants Board. *Centrally Assisted Schemes for Medicinal Plants: Operational Guidelines for Financial Assistance*. New Delhi, India: National Medicinal Plants Board, Department of AYUSH, Ministry of Health and Family Welfare, Government of India. February 2004.

- Training & visit of growers and collectors to demonstrations plots, research centres and other related organizations in the country.
- Activities encouraging cultivation for growing medicinal plants.
- Extension material on medicinal plants.

5. Study demand supply position and marketing of medicinal plants for domestic and global market.
    - Study in respect of state-of-art creating and developing infrastructure for the purpose of value addition, shelf life, storage & packing of drugs conforming international standards.
6. Research & Development in medicinal plants sector.
7. Strengthening capabilities of NMPB
    - The Scheme related to man-power for NMPB including pay and allowances to staff, office infrastructure, computerization etc

NMPB Commercial Schemes

1. Production and ensure supply of quality planting material in bulk.
2. Area expansion for selected species and cultivation in more than 2 ha. land area.
3. Value addition - for developing proper harvesting techniques, semi-processing of produces viz. collection, grading, drying, storage, packing etc.
4. Develop innovative marketing mechanism.

E. Centrally Sponsored Scheme of Quality Control of Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs, Department of AYUSH:

On 10 December 2007, S.K. Chadha, Director, Department of AYUSH, issued an office memorandum[109] on the subject "Implementation of Revised Centrally Sponsored Scheme for Quality Control of Ayurveda, Siddha, Unani & Homoeopathy (ASU&H) Drugs during the 11th Plan." A copy of the memo is enclosed as Attachment XII. The scheme as implemented in the 10th Plan has been suitably revised based on the evaluation and the feedback received from various States / UTs for implementation of the 11th Plan.[110] The Scheme is available on-line at the Department of AYUSH website: http://indianmedicine.nic.in/NewScheme%20QualityControl.pdf

In order to provide financial assistance to the States for strengthening their ASU&H drug Enforcement Mechanism, the Centrally Sponsored Scheme for Quality Control of ASU&H Drugs was introduced towards the end of the 9th plan with an outlay of Rs. 40.00 Crores with the approval of Standing Finance Committee (SFC). So far 29 State Drug Testing Laboratories and 44 State Pharmacies of Ayurveda, Siddha, Unani and Homoeopathy have been financially assisted. In addition to assistance to States for the above purposes, a provision was also made for providing back ended subsidy to Ayurveda, Siddha and Unani manufacturing units to become Good Manufacturing Practices compliant. The off take under enforcement mechanism and Good Manufacturing Practices component has been rather negligible. Only 13 States took some assistance for strengthening of State Drug Enforcement Mechanism and 48 Ayurveda, Siddha, Unani units have been assisted for becoming Good Manufacturing Practices compliant. An expenditure of Rs. 88.14 crore has been incurred during 9th & 10th plan period under this scheme.

Components of the revised scheme in 11th Plan

[109] Chadha SK. Office Memorandum: *Implementation of Revised Centrally Sponsored Scheme for Quality Control of Ayurveda, Siddha, Unani & Homoeopathy (ASU&H) Drugs during the 11th Plan*. New Delhi: Department of AYUSH, Ministry of Health & Family Welfare, Government of India. 10 December 2007.

[110] Department of AYUSH. *Centrally Sponsored Scheme for Quality Control of Ayurveda, Siddha, Unani & Homoeopathy (ASU&H) Drugs*. New Delhi, India: Department of AYUSH, Ministry of Health and Family Welfare, Government of India. December 2007.

- Reimbursement of expenditure incurred by States for Strengthening of Enforcement Mechanism of Ayurveda, Siddha and Unani drugs at the State level and expenditure incurred in testing of ASU&H medicines by NABL accredited laboratories subject to States having a functional Drug Testing Laboratory and a separate functional enforcement establishment for Ayurveda, Siddha, Unani and Homeopathy drugs.
- Release of balance of financial assistance to strengthen State AYUSH Drug Testing Laboratories and Pharmacies subject to the States filling up vacant posts and ensuring availabilities of trained personnel for their proper functioning.
- Assistance to ASU&H manufacturing units to establish in-house quality control laboratories for batch to batch testing of raw materials and finished products for ensuring quality control of ASU&H medicines.
- Assistance to ASU&H units to upgrade their infrastructure to acquire WHO Good Manufacturing Practices /US FDA/ EU Good Manufacturing Practices certification for export purposes.

a. Scheme No. 4: Assistance to ASU Drug Manufacturing Units to Establish in In-house Quality Control Laboratory

Assistance to ASU&H drug manufacturing units having an annual turnover of up to Rs. 20.00 crores for acquisition of prescribed essential quality control equipment for in-house Quality Control Lab shall be limited to Rs. 30.00 lakhs or 30% of expenditure incurred on the basis of a MoU between the manufacturing unit / State Drug Controller and Department of AYUSH with a condition that the quality control equipment purchased with Government of India assistance shall not be disposed of and that Government of India will have lien on such equipment in case of company going into liquidation.

The acquisition of quality control equipments would be as per Annexure (see pages 16-18 of Scheme) for setting up an in-house quality control laboratory for testing of all ingredients and finished products as per Pharmacopoeial and other standards laid down by Deptt. of AYUSH / WHO from time to time. In the 10^{th} Plan an assistance of up to Rs.5.00 lakh as back-ended subsidy was allowed to all ASU manufacturing units for becoming Good Manufacturing Practices (GMP) compliant. However, the off take in the scheme was negligible on account of assistance being very meager. Further, it has been felt that Good Manufacturing Practices notified under Schedule 'T' of the Drugs & Cosmetics Act, 1940 and Rules, 1945 does not provide for a mandatory in-house laboratory for every manufacturing unit as a result of which most of the manufacturing units have obtained Good Manufacturing Practices on the basis of having a tie up with an outside laboratory. For all practical purposes testing of all raw material and finished products is not commercially viable unless a manufacturing unit has an in-house laboratory. Development of quality control laboratory is highly capital-intensive. Acquisition of equipments like Atomic Absorption Spectrometer, High Performance Thin layer Chromatography Spectrometer, etc for an in-house quality control laboratory entails heavy expenditure. Small and medium units find it very burdensome to obtain loans without any subsidy. The Parliamentary standing Committee of Ministry of Health & Family Welfare has also recommended substantial increase in assistance to manufacturing units for becoming Good Manufacturing Practices compliant. The grantee institute/State Govt. may apply in the following performa 4 for seeking grant-in-aid under the scheme.

b. Scheme No. 5: Assistance to ASU Manufacturing Units having a Turnover of up to Rs 20.00 Crores for Acquiring US FDA/EU GMP Certification

Most of the countries are insisting on a higher Good Manufacturing Practices (GMP) like US FDA / EU GMPs for granting market authorization to products made by ASU manufacturing units. This

may entail substantial expenditure on infrastructure development in addition to establishment/strengthening of in-house testing laboratories. Any applicant manufacturing unit desirous of obtaining assistance under this component shall make an application along with a Project Report duly appraised by a scheduled commercial bank indicating the various items of expenditure to be incurred. The application may be forwarded by the State Directorate of ISM&H or PHARMEXIL. ASU manufacturing units having a turnover of up to Rs. 20.00 crores shall be provided with assistance of 30% or Rs. 30.00 lakh, whichever is less for upgradation of the facilities to US FDA / EU GMP certification standards. This would be released through the scheduled commercial bank on receipt of report of disbursement of loan by the Bank and certificate issued by PLIM/ PHARMEXCIL to the effect that the expenditure has been already incurred and US FDA/EU Good Manufacturing Practices certificate has been obtained by the firm.

An Ayurveda, Siddha and Unani (ASU) manufacturing unit shall be entitled to assistance either for in-house quality control component or the higher Good Manufacturing Practices upgradation component but not both. See pages 22-23 of the Scheme for the Eligibility Criteria: http://indianmedicine.nic.in/NewScheme%20QualityControl.pdf

F. Export Development (X-Plan) Schemes: Spices Board of India (SBI), Ministry of Commerce and Industry

SBI offers marketing development assistance to individual exporters for export promotion activities abroad, participation in EPC etc. led trade delegations/trade fairs / exhibitions/BSMs with Commodity Board/Authorities.

1. Exporting companies with an f.o.b. value of up to Rs.15 crores, in the preceding year, will be eligible for any grant for participation in trade delegations/BSMs/fairs/exhibitions abroad to explore new markets for export of their specific product(s) and commodities from India in the initial phase. This will be subject to the condition that the exporter is having complete 12 months membership with concerned EPC etc. and filing of returns with concerned EPC/organization regularly.
2. The assistance would be permissible on travel expenses by air, in economy excursion class fair and/or charges of the built up furnished stall. This would, however, be subject to an upper ceiling mentioned in the table per tour.

Sl.No	Area/Sector	No. of visits	Maximum Financial ceiling per event
1	Focus LAC	1	Rs.1,80,000/-
2	Focus Africa (including WANA countries)	1	Rs.1,50,000/-
3	Focus CIS	1	Rs.1,50,000/-
4	Focus ASEAN+2	1	Rs.1,50,000/-
5	General Areas	1	Rs.80,000/-
	Total	5	

The participation of individual exporting companies in the above activities shall be subject to the following conditions:-

i. For EPC etc. led Trade Delegations/BSMs only air-fare by Economy Excursion class up to a maximum of Rs.70,000 (Rs.1,00,000 in case of Focus LAC) shall be permissible.

For participation in Trade Fairs/Exhibitions reimbursement shall be permissible subject to ceilings mentioned in the column 4 in the above table.

ii. Maximum number of permissible participations shall be five in a financial year as indicated in above table (No travel grant is permissible for visit to General Areas).
    a. Assistance shall be permissible to one regular employee / director / partner / proprietor of the company. Assistance would not be available to exporter of foreign nationality or holding foreign passport.
    b. The company shall not be under investigation / charged / prosecuted / debarred / black listed under the Foreign Trade Policy of India or any other law relating to export and import business.
    c. Maximum MDA assistance shall be inclusive of MDA assistance received from all Government bodies/FIEO/EPCs/Commodity Boards/Export Development Authorities/ITPOs etc.
    d. A maximum of three participations in a particular trade fair / exhibition would be eligible for MDA assistance and exporting companies after availing assistance three times including past cases for a particular fair / exhibition, have to participate in that fair, if any, on self-financing basis.
    e. Intimation application must be received in the concerned EPC etc. with a minimum of 14 days clear advance notice excluding the date of receipt of application in the office of the concerned organization and the date of departure from the country**.**

Guidelines for grant-in-aid for "Undertaking Export Promotion Tours in Identified Markets Abroad." The objective of the scheme is to encourage the Indian exporters to develop personal rapport with the overseas buyers and to build business relationship with the importers besides convincing them about the product capabilities achieved in the areas of spice processing/value addition in terms of quality in India.

Natures of tours covered under the scheme are:

- Participating in International Trade Fairs/Exhibitions, meetings, Conferences/ Seminars/ Promotional Trips etc.
- Individual sales promotion tours abroad.

Eligibility**:** The exporters of spices who have obtained Indian Spices Logo and/or Spice House Certificate issued by the Board and those exporters whose brand name has/have been registered with the Board are eligible to avail assistance under this scheme. The exporters can undertake the tour for one or more purposes mentioned in a year during the Xth plan period subject to the ceiling of financial assistance stipulated.

Nature of Assistance**:** Assistance in the form of reimbursement of travel expenses and stall rent etc. in Indian currency for undertaking the export promotion tour abroad. The financial assistance will be limited to 50% of the economy class airfare or Rs.1.50 lakh whichever is less in the case of Spices Logo/Spice House Certificate holders and Rs.40,000/-in the case of exporters whose brand/s is/are registered with the Board.

Application**:** Application in the prescribed form should be submitted by the exporters for obtaining an approval from the Spices Board prior to the commencement of the tour.

G. Market Access Initiative (MAI) Scheme: Ministry of Commerce and Industry

Ministry of Commerce & Industry, Government of India has announced several schemes for promoting exports of various commodities from India, including the Market Access Initiative (MAI) Scheme.[111] The commodities covered by the MAI Scheme include medicinal natural products under the prevue of PHARMEXCIL, whose members are advised to submit proposals to them for further taking up with Government of India. The 14 page MAI Scheme is available on-line at: http://www.pharmexcil.com/V1/docs/MDA/mai_guide_2007.pdf

The scheme is formulated on focus product-focus country approach to evolve specific market and specific product through market studies/survey. Assistance would be provided to Export Promotion Organizations/ Trade Promotion Organizations/ National Level Institutions/ Research Institutions/ Universities/ Laboratories, Exporters, etc., for enhancement of export through accessing new markets or through increasing the share in the existing markets. Under the Scheme the level of assistance for each eligible activity has been fixed.

The following activities will be eligible for financial assistance under the Scheme:

i) Marketing Projects Abroad:

To support marketing projects abroad based on focus product or focus country approach. Under marketing projects, the following activities will be funded:

a) Opening of Showrooms & Warehouses;
b) Organizing "Trade Festival of India" – a multi-sectoral event to be organized in select centers abroad to promote 'Brand India' by showcasing our strength in services like Health (Ayurveda & Yoga), Taste of India (Indian Cuisine), Tourism, Culture, etc., besides merchandise;
c) National Level Participation in Major International Trade Fairs etc.;
d) Display in International departmental stores;
e) Publication of World Class Catalogues;
f) Publicity Campaign and Brand Promotion;
g) Research and Product Development;
h) To support Recognized associations in Industrial clusters for marketing abroad;
i) Reverse visits of the prominent buyers, etc., from the project focus countries.

ii) Capacity Building:

- For imparting training to the Indian Exporters with regard to export in general and on specific region/country basis;
- For up-gradation/improvements in Laboratories, Universities, Research Institutions on stand alone or Public Private Partnership basis for fulfilling SPS measures/related testing etc. including reimbursement of testing charges;
- For quality up-gradation of select products for export markets (by skill upgradation using experts/designers, production process improvements, reduction in rejections etc.);
- For developing Common facility centers; design centers; packaging, etc.;
- For hiring consultants in the buyer/prospective country

[111] Government of India, Ministry of Commerce & Industry, Department of Commerce, E&MDA Section. *Revised Market Access Initiative (MAI) Scheme*. 04 January 2007. Available at: http://www.pharmexcil.com/V1/docs/MDA/mai_guide_2007.pdf

iii) Support for Statutory Compliances:

- Charges/expenses for compliance of statutory requirements in the buyer country including Testing charges for engineering products abroad; Registration charges for product registration abroad for pharmaceuticals, bio-technology and agro-chemicals clinical trials for drugs/pharmaceuticals & medical disposables, medical equipment etc.
- Other commodities/product groups and the nature of compliance covered for reimbursement under the scheme shall be as approved by the Empowered Committee on a case to case basis.
- For contesting litigation(s) in the foreign country concerning restrictions/anti dumping duties etc. on particular product(s) of Indian origin. The commodity/ product groups, nature of litigation to be supported and the extent of support shall be as decided by the Empowered Committee on a case to case basis.

iv) Studies:

- Market studies/survey for evolving proper marketing strategies;
- Export Potential Survey of the States;
- Projects/Study which further the objectives of the schemes;
- WTO studies for evolving WTO compatible strategy;
- All Trade related studies including Joint Study Group (JSG), Free Trade Agreement (FTA), Regional Trade Agreement (RTA) studies etc. Only specific markets studies would be undertaken and these studies would be entrusted to reputed professional organizations.

v) Project Development:

- To generate focused projects leading to substantial improvement in market access, a shelf of projects shall be prepared by engaging reputed professional organizations. A special focus would be on preparation of projects pertaining to priority sectors and sectors having substantial employment generation potential.

vi) Miscellaneous:

- Developing Foreign Trade Facilitation web Portal (data bases and systems for dissemination of information (electronic or otherwise to Indian Exporters);
- To support Cottage and handicrafts units.

H. Marketing Development Assistance (MDA) Scheme, Ministry of Commerce & Industry

The Marketing Development Assistance (MDA) Scheme[112] is under operation through the Department of Commerce to support the under mentioned activities:

(i) Assist exporters for export promotion activities abroad
(ii) Assist Export Promotion Councils (EPCs) to undertake export promotion activities for their product(s) and commodities
(iii) Assist approved organizations/trade bodies in undertaking exclusive nonrecurring innovative activities connected with export promotion efforts for their members

[112] Government of India, Ministry of Commerce & Industry, Department of Commerce. *Marketing Development Assistance Scheme*. Revised Guidelines W.E.F. 01 April 2006. Available at: http://www.pharmexcil.com/V1/docs/MDA/MDA_April2006.pdf.

(iv) Assist Focus export promotion programmes in specific regions abroad like FOCUS (LAC), Focus (Africa), Focus (CIS) and Focus (ASEAN + 2) programmes.
(v) Residual essential activities connected with marketing promotion efforts abroad.

Grantee organizations under the MDA code include, among others, the export promotion councils CHEMEXCIL, PHARMEXCIL, and SHEFEXCIL, which are the relevant organizations to this study. The 29-page Marketing Development Assistance (MDA) Scheme is available on-line at: http://www.pharmexcil.com/V1/docs/MDA/MDA_April2006.pdf.

I. Registration-cum-Membership Certificate (RCMC), PHARMEXCIL

PHARMEXCIL is vested with the powers to process and issue Registration-cum-Membership Certificates (RCMCs).[113] Any medicinal product company, which intends to export its products can be registered with Pharmexcil to avail the benefits under the foreign trade policy of the Government of India. The registered members can avail benefits extended by Director General Foreign Trade like Duty Entitlement Pass Book (DEPB) scheme and others. An RCMC holder apart from getting benefits under foreign trade policy will be entitled to participate in foreign delegations and avail 90 per cent reimbursement. Moreover, around 50 per cent of the charges incurred for registration of the product in foreign countries will be reimbursed. Further, the members can avail of discount of around 50 per cent on the charges for booking a stall at trade fairs and exhibitions organized by Pharmexcil. The council will route trade enquiries from members to the embassies of various countries and gives the feedback to them. Apart from all these advantages, Pharmexcil will act as a facilitator between the exporters and the government and also keeps its members updated on the policies and export scenario.

J. Technology Development and Demonstration Programme (TDDP), Department of Scientific and Industrial Research (DSIR), Ministry of Science & Technology

The Technology Development and Demonstration Programme (TDDP) is a plan scheme of DSIR to promote industry's efforts in development and demonstration of indigenous technologies, development of capital goods and absorption of imported technologies. Recently there have been TDDP grant recipients in the medicinal herbal products sector. For example, in May 2008 Sabinsa Corporation announced that Sami Labs, its research and manufacturing arm in Bangalore, India, received funding from the DSIR to perform pilot trials on two novel research projects. Sami Labs was awarded $185,000 under the TDDP. The grant will be used in part to develop and test a plant-derived cosmetic active, with expected market availability in late 2008. In addition, the grant will assist Sami Labs in developing a novel method to manufacture Resveratrol utilizing Sami Labs' patented synthetic Demethylation strategy.[114]

TDDP has addressed itself for following broad objectives to achieve self-sufficiency in industrial growth:

- Supporting industry for technology absorption, development and demonstration
- Building indigenous capabilities for development and commercialization of contemporary products and process of high impact.
- Involvement of national research organizations in joint projects with industry

[113] Satyapal Menon. Exporters registered with Pharmexcil can avail several benefits. *Express Pharma Pulse*. 05 May 2005. Available at: http://www.expresspharmaonline.com/20050505/conversation01.shtml
[114] Anon. Sabinsa's Facilities Receive Funding, Recognition from Government of India. *NPIcenter.com.* 27 May 2008.

To achieve the above objectives, the Department provides on a selective basis partial financial support to research, development, design and engineering (RDDE) projects to be proposed by industry in the following areas:

- Development and Demonstration of new or improved product and process technologies including those for specialized capital goods, for both domestic and export markets.
- Absorption and upgradation of imported technology

The partial financial support by DSIR is primarily meant for covering expenditure involved in prototype development and pilot plant work, test and evaluation of products flowing from such R&D, user trials etc. Bulks of costs of the project are from the industry's resources.

K. Vishesh Krishi Upaj Yojana Scheme, SHEFEXCIL

Under India's Foreign Trade Policy (2004-2009), a new scheme called *Vishesh Krishi Upaj Yojana* (Special Agricultural Produce Scheme)[115] was introduced to boost exports of minor forest products and their valued-added products. Exports have been liberalized with a view to promote export of medicinal plants and herbal products. As of 27 April 2005 amendments were made providing details of items which qualify for export benefits. The list of medicinal plants and extracts, categorized as minor forest produce under the new scheme includes, among others, those listed in Table 42:

Table 42: List of selected export items allowed under the Vishesh Krishi Upaj Yojana Scheme

HS Code	Description
	Lac:
13012000	Gum Arabic (*Acacia senegal*)
	Natural gum:
13019013	Asafoetida (*Ferula foetida*)
	Gum resins:
13019031	Myrrh (*Commiphora* spp.)
13019032	Olibanum of Frankincense (*Boswellia serrata*)
	Oleoresins:
13019041	Of Seeds
13019042	Of Fruits
13019043	Of Leaves
13019044	Of Spices
13019045	Of Flowers
13019046	Of Roots
	Extracts:
13021200	Of Licorice root (*Glycyrrhiza glabra*)
13021300	Of Hop strobile (*Humulus lupulus*)
13021911	Of Belladonna (*Atropa belladonna*)
13021912	Of Cascara sagrada bark (*Frangula purshiana*)
13021913	Of Nux Vomica (*Strychnos nux-vomica*)
13021914	Of Ginseng root (including powder) (*Panax* spp.)
13021916	Of Neem (*Azadirachta indica*)
13021917	Of Gymnema (*Gymnema sylvestre*)

[115] DIRECTOR GENERAL OF FOREIGN TRADE and EX-OFFICIO ADDITIONAL SECRETARY TO THE GOVT. OF INDIA. DGFT PUBLIC NOTICE NO. 04/2005 dated 27.4.2005 Amendments in the HB (Vol I): Appendix-37A of HB. (Vol.I) giving the details of items which qualify for export benefits under Vishesh Krishi Upaj Yojana. Available at: http://www.ieport.com/2005-2006/public_notices/pn04.htm

13021918	Of Garcinia (*Garcinia cambogia*) or gambodge (*Garcinia hanburyi*)
	Myrobalans:
14041061	Amla (*Phyllanthus emblica*)
14041070	Wattle Bark (Mimosa bark)
	Soap-nuts:
14049040	Betel leaves (*Piper betle*)
14049050	Indian Katha
14049070	Rudraksha seeds (*Eleaocarpus* spp.)
33029020	**Mixtures of Odoriferous Substances and Mixtures (including alcoholic solutions) based on one or more of these substances used as raw materials:**
	African basil (*Ocimum grattisshnum*)
	Andrographis (*Andrographis paniculata*)
	Annatto (*Bixa orellana*)
	Arjuna (*Terminalia arjuna*)
	Ashwagandha (*Withania somnifera*)
	Asoka tree (*Saraca indica*)
	Bael tree (*Aegle marmelos*)
	Basil leaf (*Ocimum basilicum*)
	Belleric myrobalan (*Terminalia bellerica*)
	Bhui Aonla, Bhumi Amiaki (*Phyllanthus fraternus*)
	Black nightshade (*Solanum nigrum*)
	Brahmi (*Bacopa monnieri*)
	Celastrus (*Celastrus dependens*)
	Ceylon citronella (*Cymbopogon nardus*)
	Ceylon leadwort (*Plumbago zeylanica*)
	Chamomile (*Matricaria recutita*)
	Chebulic myrobalan (*Terminalia chebula*)
	Chinese mint (*Mentha arvensis*)
	Cyperus (*Cyperus scariosus*)
	East Indian lemongrass (*Cymbopogon flexiosus*)
	Flamelily (*Gloriosa superba*)
	Forskohlii (*Plectranthus barbatus*)
	Garden cress (*Lepidium sativum*)
	Gotu kola (*Centella asiatica*)
	Guggul (*Commiphora mukul*)
	Gymnema (*Gymnema sylvestre*)
	Henbane (*Hyoscyamus niger*)
	Holy basil (*Ocimum sanctum*)
	Indian kino tree (*Pterocarpus marsupium*)
	Indian tinospora (*Tinospora cordifolia*)
	Jasmine (*Jasminum officinale*)
	Java citronella (*Cymbopogon winterianus*)
	Lavender (*Lavandula indica*)
	Lemon mint (*Mentha citrata*)
	Licorice (Glycyrrhiza glabra)
	Long pepper (*Piper longum*)
	Neem (*Azadirachta indica*)
	Patchouli (*Pogostemon patchouli*)
	Palmarosa grass (*Cymbopogon martini*)
	Peppermint (Mentha × piperita)
	Psyllium (*Plantago ovata*)
	Rajnigandha (*Pollanthus tuberosa*)

	Rauwolfia (*Rauvolfia serpentina*)
	Safed Musli (*Chlorophytum borivillianum*)
	Saua (*Anetheum sowa*)
	Senna (*Cassia angustifolia*)
	Shatavari (*Asparagus racemosus*)
	Vetiver (*Vetiveria zizanoides*)
	Vidanga (*Embelia ribes*)

L. Other Indian Governmental Responses

According to a 2007 "*Policy and Status Paper on Cluster Development in India*,"[116] prepared by the Foundation for MSME Clusters, during 2002 to 2003 holistic cluster development programmes began to gather noticeable momentum at the national level, with the initiation of a programme by the then Ministry of SSI (now Ministry of MSME). Over the past two decades of cluster development initiatives, about 24 schemes / programmes have been supported or continue to be supported. Nine have been part of three Ministries of Central Government, namely, the Ministry of Textiles, Ministry of MSME and Ministry of Commerce and Industry. Department of AYUSH has allocated Rs 500 crores for development of 20-25 clusters in the 11th five-year plan. The State Governments of Gujarat, Orissa, Kerala, Rajasthan and Madhya Pradesh have also initiated schemes/programmes at the state level covering clusters across sub-sectors. Additionally, financial and technical institutions such as SBI, SIDBI, NABARD, NMDFC, NEDFi and NMCC have also devised schemes to support clusters. International institutions like UNIDO and ILO are also implementing various cluster development programmes. Some techno-commercial institutions at the national and state level (e.g. CII13, RUDA14 etc.) are also involved in several cluster based developmental activities.

M. Technical Cooperation from other Governmental or International Organizations

a. German Technical Cooperation (GTZ) in India

India has been a priority partner country of German Development Cooperation for more than 40 years. GTZ has been active in India on behalf of the German Federal Ministry for Economic Cooperation and Development (BMZ) for almost all of this period. The following are the priority areas for cooperation with India:

- Sustainable Economic Development
- Energy
- Environmental policy, conservation and sustainable use of natural resources

GTZ operates an office in New Delhi. Together with GTZ, the KfW Bankengruppe (KfW banking group) and Deutsche Investitions- und Entwicklungsgesellschaft mbH (DEG) of the KfW Bankengruppe form a joint office compound. GTZ cooperates with the central government and various state agencies. Further, GTZ International Services works on behalf of international organizations.

GTZ has provided technical assistance for SME development in selected Project Regions of India, working in cooperation with regional branches of public banks as well as the Small Industries Development Bank of India (SIDBI). One of the components of the GTZ Technical Assistance (TA) will be to support market oriented Business Development Service (BDS) to SMEs and

[116] Foundation for MSME Clusters. Policy and status paper on cluster development in India. New Delhi: Foundation for MSME Clusters. November 2007. Available at: http://nmcc-vikas.in/IndianClusterProjects/PDF/Policy%20and%20Status%20Paper_Cluster%20Development_SME%20Foundation.pdf

commercial banks. For example, in 2006 and 2007 an analysis of BDS market in pharmaceutical cluster of Indore Region was carried out which includes analysis of 120 Ayurvedic manufacturing units. These units manufacture tablets, syrups, capsules, and ointments, among other products.

GTZ has also commissioned surveys of regional Ayurveda clusters / value chains and BDS providers. The objectives of GTZ TA in these cases are to improve Ayurveda SME access to financial services and BDS. The GTZ TA has two main components, promoting the development of strategies and programs concerning market based development of BDA and development, training and advisory services to participating banks.

b. International Trade Centre (ITC) / UNCTAD / WTO Export-Led Poverty Reduction Programme (EPRP)

Export-led poverty reduction (EPR) projects focus on sectors showing high potential to contribute to poverty reduction through exports. While working on the identification of sectors, ITC assesses market demand, ascertains national supply potential, and gauges the potential for job creation and, more generally, income generation for poor communities. Please click in the following links for more information on: identifying producers; identifying product and market; as well as on matching product-market-producers. ITC is currently developing/implementing EPR projects covering the following sectors:

- Agricultural products (fresh & processed);
- Community–based tourism; and
- Textiles (fibers & clothing).

Integrated Community-based Export Development Project (ICEDP): An initial opportunity study describing the most promising market niches, targeted communities and potential support organizations has been finalized in November 2007. First project activities will build partners' skills for product adaptation, packaging, branding, and innovation. Later working on marketing and branding capacities in partnership with existing SME exporters and tourism market links, the project will convert trade opportunities into actual business with benefits primarily accruing to the local communities. The Spice Board of India and a state tourism authorities will be the lead counterparts at the local level, while the Department of AYUSH under the Ministry of Health will act as counterparts at national level. Specialized agencies and private sector partners, such as the ExIm Bank, the IIFT and the Taj Group, will also be involved in specific components. Project implementation would be assured through local NGOs with extension services and hands-on support being provided. Whereas the project will be implemented by ITC, the World Bank would be an important source for resource mobilization and information.

Empowerment of Rural Communities in India to Export Organic Spices: This project assists small-scale producers in India to penetrate the premium export market for organic spices. It aims at empowering rural communities to exploit the business opportunities available in this rapidly growing market. Under this project, producers form groups, assisted by local NGOs and the Spices Board India a national support institution. These NGOs train the farmers in organic production, quality control and marketing. They also elaborate business plans, maintain records for organic certification and establish contacts with local exporters and overseas importers. In some cases, the exporters handle the marketing and shipment of the spices. The project also integrates existing poverty reduction schemes, such as micro-credit programmes. The Spices Board India and ITC provide technical guidance while playing a catalytic role. The World Bank financed this initiative through an award to ITC in its Development Marketplace competition in 2000.

c. International Trade Centre (ITC) / UNCTAD / WTO South-South Trade Promotion Programme

The ITC South-South Trade Promotion Programme is a set of tools designed to identify trade and investment opportunities and translate them into business transactions by bringing importers and exporters together. The tools are assembled in a customized mix to suit the specific requirements of partner enterprises, organizations and countries. The main tools are:

- ***Trade Flow Analyses***, that identify import, export and related investment opportunities across groups of countries;
- ***Supply and Demand Surveys***, that document market characteristics and identify opportunities and potential beneficiaries through field research on a product and country basis; and
- ***Buyers/Sellers Meetings***, which serve as platforms for companies to conduct business transactions and take advantage of the identified opportunities.

Follow-up action, at enterprise, institutional and government level, aims at sustaining south-south business links. Special applications of the programme include linking developing country enterprises with international aid agencies operating in their region; and facilitating backward and forward linkages in the creation of regional value chains.

In 2008, the ITC South-South Trade Promotion Programme published a study entitled "*India: Supply and Demand Survey on Pharmaceuticals and Natural Product*s,"[117] which is available on-line at: http://www.intracen.org/docman/OEVE11928.pdf. The Export-Import Bank of India (Exim Bank) was designated as the national cooperating institution for carrying out the supply and demand study for drugs and pharmaceutical industry in India. This study, undertaken by Exim Bank, has identified specific products of drugs and pharmaceuticals having potential in the participating countries.

The study has also appended detailed company profiles of Indian pharmaceutical players, including Ayurvedic and Unani product manufacturers, for dissemination among prospective importers / exporters. These company profiles were submitted to ITC for the AsiaHealthCare 2008, which took places March 2008 in Kuala Lumpur, Malaysia. For example, the Company Profile Form completed by the Indian natural products company Sandu Brothers Pvt Ltd is enclosed here as Appendix XIII. The ITC survey has mainly taken into consideration all the products covered under the ITC - HS Code Heading No. 30, and select chemical products (that are used in production of pharmaceuticals) covered under ITC HS Code Heading No. 29. In addition, the survey has considered the medicinal plant products (which are used in manufacture of herbal medicines, covered under ITC – HS Code Heading Nos. 06, 09, 12, 13 and 14.

d. United States Agency for International Development (USAID) in India

To promote sustainable growth in India, USAID supports reform in agriculture and links small farmers to new markets; work to build confidence in financial markets; helps state governments improve fiscal decision-making; and generates financing for urban services.

In 1997, USAID participated in a program entitled "Increased Conservation and Availability of Crop-Related Germplasm." The purpose of the program was to increase India's capability in conservation and availability of crop-related germplasm for national, regional and global research and exchange. USAID is supporting the construction of four quarantine greenhouses and a major genebank facility to store about 800,000 germplasm samples. Regional quarantine facilities have

[117] ITC South-South Trade Promotion Programme. Annex XI: Enterprise/product profile forms "AsiaHealthCare 2008", Malaysia, March 2008. In: *India: Supply and Demand Survey on Pharmaceuticals and Natural Products.* Geneva: International Trade Centre / UNCTAD / WTO. December 2007.

accelerated conservation and exchange of endangered medicinal and herbal plant species used in the multi-billion dollar global medicine and cosmetic industry.

Presently, Dr. Aleen Mukherjee, USAID Project Mgt. Specialist, Office of the Economic Growth, American Embassy, serves as a Member of the National Consultative Committee of the Medicinal and Aromatic Plants Stakeholders Consortium (MAPSCON).

CHAPTER 7 – PRIORITY OBJECTIVES

The priority objectives are the shared views of all interested partners about the priorities to be addressed and in which order, with due consideration being given to the issues of ownership, absorptive capacity and sustainability.[118] Therefore this section of the study can be finalized after a Priority-Setting exercise between AYUSH and ITC and possibly other interested parties.

Preliminarily, listed here below are some potential areas to consider and to expand upon following the Priority-Setting exercise.

What do the Indian enterprises need to do?

Publication: Indian enterprises need to submit their laboratory and clinical research papers to international peer-reviewed biomedical journals to collectively contribute to the scientific medical literature in ways that demonstrate the efficacy, quality and safety of Indian medicinal natural products, especially those products that have significant market access obstacles in western countries due to the traditional use of ingredients that are controversial and/or illegal in some western countries.

What does the Government of India need to do?

Common dossier: Industry would find it helpful if the Government of India were to prioritize the development of common dossiers for classical formulations which could be available to Indian enterprises to include in their submission packets for product listings or registrations with foreign regulatory agencies.

Education: Industry would benefit from the Government of India initiating formal contact with accredited colleges or universities of naturopathic medicine in selected export destination countries. It is within the scope of naturopathic medicine education to offer students dual tracks of naturopathy with other training, for example acupuncture and oriental medicine, homoeopathy, midwifery, and nutrition. Naturopathic institutions should be interested in adding training in Indian Systems of Medicine to their curriculum so long as expert support and resources from governmental educational institutions in India were available.

Lobbying: Industry would benefit from continued lobbying efforts made by Government of India to their regulatory counterparts in selected export markets for the purpose of promoting and supporting the establishment of legal frameworks in those countries for the education and licensing of practitioners of Indian Systems of Medicine, accreditation of schools of Indian Systems of Medicine, licensure of practitioners, and a corresponding regulatory framework that permits the import, wholesale distribution and retail sale of natural medicinal products necessary for the practice of Indian Systems of Medicine. Additionally, the Government of India can play a role in educating their regulatory counterparts with high levels of evidence in support of the efficacy, quality and safety of natural medicinal products exported by Indian manufacturers.

[118] International Trade Centre. *Needs Assessment and Programme Design: A Methodological Approach and Road Map*. Geneva, Switzerland: International Trade Centre. March 2000.

Market access handbook: Industry would find it helpful if the Government of India were to produce a technical handbook for exporters that outlines the specific legislative requirements of selected foreign countries for the licensing, listing, notification, or registration of Indian natural medicinal products. Pharmexcil has already prepared some country reports covering Drug Product Registration requirements of the countries, with information on local pharmaceutical importers, mostly based on reports received from Embassies of India located in those countries. However these reports are not exhaustive, may not be up-to-date, and do not cover all export destination countries of relevance to the Indian medicinal natural products sector.

Trainings and workshops: Industry would benefit from Government of India sponsored trainings and workshops for exporters on the legislative market access requirements and non-legislative expectations of selected foreign markets.

CHAPTER 8 – ESTIMATED RESOURCE REQUIREMENTS

Estimated resources requirements can be considered after agreement on the project priorities between the collaborating interested parties Department of AYUSH and ITC/UNCTAD/WTO.

CHAPTER 9 – FUTURE STEPS

Following priority setting exercises and after agreement is reached between the project collaborators, Department of AYUSH and ITC/UNCTAD/WTO, a description of the future steps to be take in order to convert the identified priorities (immediate objectives) into a sequence of outputs and activities can be made.

Preliminarily it is recommended that future steps be designed and differentiated at levels appropriate to size of enterprise, micro-, small-, medium-, or large. It may not be appropriate to design an export promotion program for micro-sized enterprises who will not be well-funded enough to establish sales, marketing and brokerage networks in foreign markets, not to mention the legislative costs of market access. A program to assist micro- and small- sized companies grow sustainably within their local or regional markets may be the most appropriate program approach.

Small- to medium- sized enterprises may be best served by export promotion programs that focus on either South-South Trade or Commonwealth Trade. Legislative and non-legislative market access costs to enter neighboring South Asian countries could be conceivable for some small but many medium-sized enterprises. Costs and complexities of market access for medicinal products in the Australian, European and North American markets are probably out of reach for most small- to medium-sized enterprises, with some exception. However, many of the Commonwealth countries have regulatory frameworks that are the most supportive of Traditional Medicines, such as Ayurvedic, Chinese, Siddha, and Unani medicines. Obtaining pre-marketing authorization for Indian medicinal natural products should have the best chances of success in Commonwealth countries.

Concerning the highly regulated European markets for medicinal products, interviews conducted with stakeholders during the first mission in India revealed that probably no more than 50 Indian manufacturers and marketers of medicinal natural products are large enough and/or well-funded enough to consider the high costs of pre-marketing authorization (e.g. CTD format safety, efficacy and quality dossiers), post-marketing legal requirements (e.g. Periodic Safety Update Reports (PSUR) and Pharmacovigilance System), as well as ongoing high costs of in-country sales and marketing staff, brokers, warehousing and distribution. Some of the larger Indian enterprises are already planning on product licensing in the EU Member States.

*Commonwealth Trade***:** A Commonwealth oriented trade program could be elaborated specifically for Indian medium- to large-sized enterprises that have the legal and technical capacities to meet the pre-marketing authorization legal requirements to enter the markets of some of the non-European Commonwealth Member Nations. Some of the larger Indian manufacturers and marketers of medicinal natural products already have some of their products licensed in certain Commonwealth Nations such as Bangladesh, Malaysia, Pakistan, Singapore, Sri Lanka, and Tanzania, and some are presently working on product licensing in other Commonwealth Nations including Canada and South Africa. An export promotion program could focus on a selected group of non-European Commonwealth Nations, those that already have a suitable regulatory pathway for the acceptance of Indian ASU products. The target export markets could include, possibly among others, Australia, Bangladesh, Brunei Darussalam, Canada, Kenya, Malaysia, Mauritius, New Zealand, Pakistan, Singapore, South Africa, Sri Lanka, and Tanzania.

South-South Trade: A South Asia regional trade promotion program could be elaborated specifically for Indian SMEs that have the resources necessary to consider a small level of export business but do not have the capacity or resources to approach the costly western export markets in the Americas and Europe. This program would provide support that focuses mainly on market access and sales and marketing for Indian natural medicinal products and services in Afghanistan, Bangladesh, Bhutan, Maldives, Myanmar, Nepal, Pakistan, Sri Lanka, and possibly others.

Based on analysis of export data, it must also be taken into consideration that a significant amount of Ayurvedic products are presently being exported to Commonwealth of Independent States (CIS) Members, in particular, Russian Federation, Ukraine, and Kazakhstan. A unique strategy for export promotion to CIS Members might also be considered for medium- to large-sized enterprises.

APPENDICES
APPENDIX I

PROPOSAL TO SEEK SUPPORT FROM ITC FOR DEVELOPMENT OF INTERNATIONAL TRADE OF INDIAN MEDICINE PRODUCTS.

Preamble

Herbal sector in India has its roots in the very rich and diverse health care traditions that include the codified systems like Ayurveda, Unani, Siddha and Homeopathy on one hand and folk lore on the other. These traditions rely mainly on medicinal plants, which are used singly or in combination with other ingredients to prepare health care products. The salient feature of Ayurveda, Siddha and Unani medicines is that the raw materials are used by and large in wholesome form providing synergy of the phyto-constituents to form the basis of therapeutic effect.

It is generally estimated that over 6000 plants in India are in use in traditional, folk and herbal medicine, representing about 75% of the medicinal needs of the Third World countries. Three of the ten most widely selling herbal medicines in the developed countries, namely preparations of *Allium sativum*, *Aloe barbedensis* and *Panax* sp. are available in India.

Indian Industry and Regulatory mechanism

Presently, India has 9493 licensed manufacturing units. Acquisition of license with GMP-compliant manufacturing facilities is mandatory by law. Government has taken a number of administrative and legislative measures for ensuring quality and safety of Ayurveda, Siddha and Unani medicines. A separate chapter in Drugs & Cosmetics Act, 1940 deals with the regulatory provisions for manufacturing of Ayurveda, Siddha and Unani medicines. Labeling provisions and adulterated, spurious and misbranded drugs are defined in the

Act along with penalty provisions for those, who act in contravention of the legal requirements. Parameters of identity, purity and strength of medicinal plant parts used in Ayurveda, Siddha and Unani medicines are defined in the Pharmacopeias. Pharmacopeial work has been given lot of thrust, which is being done at thirteen different laboratories including Pharmacopeial Laboratory of Indian Medicine. Testing of drugs for heavy metals from accredited laboratories is notified and no herbal medicine without certification of free from heavy metals can be exported. A centralized mechanism for export certification of products is also on the cards. Government has implemented schemes to support industry for capacity building, R&D activities and participation in international exhibitions & fairs and market development.

Scope & Challenges

The present value of the entire Ayurvedic production in India is estimated at US$ one billion while annual exports are pegged at US$ 100 Million. Of the total exports 60% is crude herbs , 30 % is finished products shipped abroad for direct sales to consumers and the remaining 10% is partially prepared products to be finished in the foreign countries.

Renewed global resurgence of interest in the plant remedies has over the years given a tremendous fillip to the growth of traditional medicine sector in the country, where classical medicines described in the recognized texts of Ayurveda, Siddha and Unani systems as well as the proprietary & patent formulations are regulated under the provisions of Drugs and Cosmetics Act, 1940. There has been phenomenal growth of the sector at an annual rate of more than 10% with domestic trade in botanicals worth Rs. 384 crores estimated for the year 2001 and Rs. 463 crores in 2003. Presently, India contributes comparatively less than China to the global market; however it is fast emerging as a key player of medicinal plants and traditional medicinal products in Europe and USA. Holistic approach and wholesome use of plant materials for health care are the key

points that attribute to the emerging global interest for Ayurveda and other Indian systems of medicine.

With the proliferation of domestic herbal industry, which mainly comprises of small & medium manufacturing units and big players are a few in number, there is continuous rise in the exports. Apart from traditional medicinal products, which constitute a small part of the total Indian export of herbal materials, plant extracts, raw plant materials etc are also exported. But medicinal plant materials are not listed under any specific major category of HS codes that are followed internationally. Most of the materials fall under HS (ITC) code 1211 and its subsets. These commodities constitute the major category linked to medicinal plants but there are many other commodities covered under various HS code categories.

Large industry units like Dabur, Himalaya, Charak and Zandu are hardly fourteen in number each with average annual turnover more than Rs. 50 crores. These entrepreneurs contribute major part of the export of herbal health care products. There are many medium and small units having a good range of R&D based quality health products, but there presence in global market is not seen owing to numerous reasons, the prominent being stringent regulations and high registration fee for market authorization. Such entrepreneurs having potential to enter foreign markets need hand holding and support.

What is required?

Understanding of global market and emerging trends is the basic pre-requisite to prepare for entry of Indian herbal products in international markets. Consultancy on this aspect is, therefore, required to be provided to small and medium Indian manufactures for taking strategic actions for positioning of quality health care products in global market. The objective of the proposal is to promote market presence of Ayurveda products so as-

a) To see development of India's strong presence for AYUSH therapies and remedies for addressing global health problems;

b) To devise strategy for creation of a sound market base for traditional Indian medicine and homeopathy; and

c) To look at the entire supply chain at the back end and suggest improvements, if any to the industry associations.

Help from ITC is solicited to guide Indian entrepreneurs on the following-

i) International regulatory requirements that Indian traditional medicinal/ herbal products can fulfill.

ii) How to avail flexibilities/concessions available within the market authorization regulations for herbal/traditional medicinal products.

iii) Global disease conditions for which Ayurveda, Siddha and Unani products can best fit in to bridge the health care gap.

iv) Assessment of market for Indian products in countries where Ayurveda and other Indian medicinal products have presence.

v) What should be the branding, packaging and marketing strategies ?.

vi) Does HS coding system need to have a separate categories for health foods, food supplements, medicinal products, OTC products of Ayurveda etc.?

vii) What commodities have adequate export potential, Classical / Generic medicines, prescription and branded medicines, herbal remedies, dietary supplements/ health foods, products made of herbal extracts/phytochemicals, Cosmetics with herbal/Ayurvedic Actives.

APPENDIX II

Framework for Cooperation between Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH), Ministry of Health and Family Welfare, Government of India and International Trade Centre (ITC), UNCTAD/WTO, Geneva, Switzerland.

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The Government of India and the International Trade Centre have had a long history of collaboration in different areas of trade development. Both sides wish to build on the strong relationship established over the years by promoting new initiatives with various institutions in India as a direct response to needs articulated by them.

Based on the exchange of communications and discussions between the Department of AYUSH, Ministry of Health & Family Welfare, Government of India and the ITC, the following areas have been agreed to for collaboration and for determining sources of funding:

Market Analysis

(1) Undertake studies to analyze global markets for over-the-counter (OTC) medication and prescription medication for different disease categories.

(2) Analyze India's current range of natural product offerings to help prioritize Indian finished products holding the best potential for building and maintaining a strong Indian quality brand image in the global market and for scaling up for increased export promotion utilizing sustainably produced Indian raw materials, traditional knowledge and appropriate technologies.

(3) Undertake a market survey on the market for Indian Ayurvedic, Siddha, and Unani (ASU) Finished Products in selected countries with analysis of market share (by product, by category, by country) and with information on competition and market potential.

Sector Development

(4) Provide a full-fledged ASU sector development programme with particular emphasis on the international competitiveness of the sector.

Product Development and Market Positioning

(5) Assist in developing and implementing branding, packaging and marketing strategies for specific ASU finished products customized for each target market.

(6) Promote branding and promotion of well-known and important natural health ingredients as native products of India, resulting in a beneficial carry-over effect to other ASU ingredients or finished products.

(7) Address intellectual property issues related to the sector.

Market Access

(8) Provide training on market access requirements for the ASU sector for different markets and customized analysis of minimum mandatory legal requirements for pre-marketing authorization for different markets.

(9) Prepare an expert opinion on the best categorization(s) and grouping(s) of Indian ASU products for purposes of trade analysis within the existing HS Coding system and looking into the possibility of expanding HS code classification.

(10) Prepare an "Exporter and Marketing Manual for Indian Producers of ASU Products" for use in Capacity Building and Training Sessions customized for ASU business sector.

ITC confirms its interest and commitment in collaborating with the Department of AYUSH and other relevant institutions in the above-mentioned areas to ensure sustainable export development of the sector. In this context, ITC in collaboration with the Department of AYUSH will prepare a project document for further consideration.

(Patricia Francis)
Executive Director
International Trade Centre

(Anita Das)
Secretary
Department of AYUSH

Date & Place: New Delhi (India), 23rd October 2007.

Appendix III
List of Stakeholders met on Mission

Stakeholders met from Governmental Organizations

1. Mr. Shiv Basant, Joint Secretary, Department of AYUSH
2. Mr. B.S. Sajwan, CEO, National Medicinal Plants Board, Department of AYUSH
3. Dr. G.S. Lavekar, Director, Central Council for Research in Ayurveda & Siddha
4. Dr. M.K. Siddiqui, Director, Central Council of Research in Unani Medicine
5. Prof. Dr. B.T. Chidananda Murthy, Director, Central Council for Research in Yoga & Naturopathy
6. Dr. D.R. Lohar, Director, Pharmacopoeia Laboratory of Indian Medicine
7. Dr. D.C. Katoch, Deputy Advisor (Ay.), Department of AYUSH
8. Dr. P.V. Appaji, Executive Director, PHARMEXCIL
9. Mr. G. Vijay Kumar, Consultant Advisor, PHARMEXCIL
10. Mr. Raghuveer Kini, Addl. Executive Director, PHARMEXCIL

Media

1. Mr. Ashu Singh, Independent Film Maker
2. Mr. Piyush Babele, Senior Correspondent, The Economic Times
3. Dr. Rajesh Sharma, Chief Editor, Sanjivani Medical Times

Stakeholders met from Trade Organizations

1. Mr. S.S. Chawla, Director (E & E), ASSOCHAM
2. Mr. O.P. Poojari, Secretary General, ADMA
3. Mr. Ajay B. Pradhanang, Treasurer, Nepal Herbs and Herbal Products Association
4. Mr. Ranjit Puranik, General Secretary, ADMA
5. Dr. B.K. Rao, Chairman Health Committee, ASSOCHAM

Stakeholders met from Consultancies and Service Organizations

1. Mr. Mohan R. Bajikar, Chairman & M.D., Fetchus Consultancy & Innovators Pvt. Ltd.
2. Mr. Mohan Ram Choudhary, Secretary, Jal Grahan Vikas Sansthan Osian-I
3. Mr. Don Greenberg, Team Leader, DAI SME Financing and Development Project
4. Mr. Pushp Jain, CEO, Nature & People Research and Support Group
5. Mr. Giridhar Kinhal, Indian Forest Service, FRLHT
6. Dr. S. Narendar, Research Consultant for Botanical Medicine & Ayurveda
7. Mr. B.S. Sudarshan Rao, Business Development Advisor
8. Mr. Janak Raj Rawal, Managing Director, Rawal Medherb Consultants Pvt. Ltd.
9. Ms. Uma Shukla, Technical Advisor, Apex Cluster Development Services Pvt. Ltd.
10. Mr. Anant P. Singh, Director, Apex Cluster Development Services Pvt. Ltd.
11. Dr. Gurinderjit Singh Goraya, Jt. Director, FRLHT
12. Mr. D.K. Ved, Addl. Director (Research & Adm), FRLHT

Stakeholders met from Enterprises

1. Dr. Gazalla Amin, Fasiam Agro Farms
2. Dr. Amit Agarwal, Director R&D, Natural Remedies
3. Mr. Sonaal Aggarwal, Export Division, Jairamdass Khushiram
4. Dr. K. Anilkumar, Executive Director, Kerala Ayurveda Ltd.
5. Mr. R.D. Bali, Marketing Manager, Northern India Drug Company

6. Mrs. Anuradha Bansal, CEO, Anuraah Premium Herbal Soaps
7. Mr. Kamal Bhatia, CMD, Indo Himaliyan Herbs Inc.
8. Mr. Jitendra Dagaonkar, Chief Manager Market Alliances, Nicholas Piramal India Ltd.
9. Dr. Manoj KR. Dash, Chief Physician, Multani Pharmaceuticals Ltd.
10. Mr. Chetan Doshi, Excelsior Trading Co. Herbal & Spices
11. Mr. Saurabh Kumar Garg, Aryan International
12. Mr. Pradip K. Ghatnagar, Senior Vice President New Drug Discovery, Ranbaxy Labs Ltd.
13. Dr. Deepika Gunawant, Head Global Regulatory Affairs, Dabur India Ltd.
14. Mr. Vinod Haritwal, Chairman, AayurMed Biotech P. Ltd.
15. Mr. Maqbool Hasan, Managing Director, Nature & Nurture Healthcare Pvt. Ltd.
16. Mr. Naveen Kamani, S.K. Herbal & Bio Extracts
17. Dr. Kiran, Manager International Business, Aimil Pharmaceuticals (India) Ltd.
18. Dr. Vijay P. Kushvaha, VP Sales & Marketing, Agron India Pvt. Ltd.
19. Mr. Jainesh Jain, Director, Unidrug Innovative Pharma Technologies Ltd.
20. Mr. Sanjeev Jain, Business Manager Technical, Yasham Bio-Science Pvt. Ltd.
21. Mr. Rhishikesh Lakhote, Partner, Shree Dhootapapeshwar Limited
22. Mr. M. Lakshmanan, Export Manager, Sriniwas Trading Company
23. Dr. Jayant N. Lokhande, Director, GMP Chem Tech Pvt. Ltd.
24. Dr. Deepak M., Sr. Manager Phytochemistry, Natural Remedies
25. Mr. Mahendra Mehta, Product Specialist Food & Cosmetics, Merck Limited
26. Mr. Milan V. Mehta, Managing Partner, Rym Exports
27. Mr. Rajendra B. Mehta, Director, Anuja Pharmaceuticals Pvt. Ltd.
28. Mr. R. Lakshmi Narasimhan, Sri Raghavendra International
29. Mr. J.S. Narayana, Vice President, Masy Malladi Agro Systems Pvt. Ltd.
30. Mr. Gautam Ostwal, CEO, Elegant Drugs Pvt. Ltd.
31. Dr. Ashutosh D. Panchotia, G.M. Marketing, Tulsi Amrit Pvt. Ltd.
32. Mr. Aravind Padiyar U., General Manager Herbal Division, Plethico Pharmaceuticals Ltd.
33. Dr. Rangesh Paramesh, Head R&D, Himalaya Drug Company
34. Dr. Ramesh P.R., Superintendent & Chief Medical Officer, Arya Vaidya Sala Kottakkal
35. Dr. Indra Reddy, Product Manager, Nandan Biomatrix Limited
36. Mr. Wikram Sanadi, VP Sales & Marketing, GCI Nutrients (India) Pvt. Ltd.
37. Dr. Nagesh Sandu, Head Research & Technical, Sandu Research Foundation Pvt. Ltd.
38. Mr. Shashank Sandu, Director, Sandu Brothers (P) Ltd.
39. Mr. Amitranjan Sarkar, Export Manager, Dey's Medical Stores (Mfg.) Ltd.
40. Dr. Satpal, MD, Sambex Drugs Pharma
41. Dr. P.V. Satyanarayana, Ambica Business Corporation Nutraceuticals Division
42. Mr. Hasan Sayed, Northern India Drug Company
43. Mr. Nilesh Shah, Pure Herbs (India)
44. Mr. Brij Bhushan Sharma, Managing Director, Grassroots Oils and Herbs Pvt. Ltd.
45. Dr. Dev Lat Sharma, M.D., Omatek Laboratories Pvt. Ltd.
46. Dr. Navin K. Sharma, Group Leader Herbal Drug Research, Ranbaxy Laboratories Ltd.
47. Mr. Pramod Sharma, Director, Shree Baidyanath Ayurved Bhawan Pvt. Ltd.
48. Mr. S. Sheik, Partner, K. Mohamed & Company Senna Leaves & Herbs Export
49. Mr. Arshad Siddiqui, Chief Marketing Officer, Hamdard (WAKF) Laboratories
50. Dr. S.D. Singh, Conservator of Forests, Uttarakhand Forest Development Corporation
51. Dr. G. Sivaraman, Managing Director, Arogya Healthcare Pvt. Ltd.
52. Mr. Jitender Sodhi, Managing Director, Ayush Herbs (P) Ltd.
53. Mr. Sanjay Srivastava, Director, Maharishi Ayurveda Products Pvt. Ltd.
54. Mr. Hardik Ukani, Manager International Business, Vasu Healthcare Pvt. Ltd.
55. Dr. K. Venkateshwartu, Medical Advisor Ayurveda, Natural Remedies
56. Dr. G. Venkateswara Rao, Principal Scientist, CavinKare Research Centre
57. Mr. Prabhat Verma, Assistant Manager Exports, Multani Pharmaceuticals Ltd.

Appendix IV
Enterprise Survey

I. ENTERPRISE DESCRIPTION

1. Name and address of your Enterprise:

MANUFACTURING LICENSE NO:	
Issued By:	
Name:	
Address:	
State:	Pin Code:
Tel:	Fax:
e-mail:	Web site:
Name of the Principal Contact:	
Designation:	Tel:
e-mail:	Cell:

2. Size of Enterprise:

Micro	-	(Less than Rs. 1 Cr.)	-	☐
Small	-	(1 Cr. < 5 Crs)	-	☐
Medium	-	(5 Crs < 20 Crs)	-	☐
Large	-	(More than Rs. 20 Crs)	-	☐

(Please indicate above for your group as a whole and turnover from Ayurved, Siddha & Unani medicine and related trade / marketing only)

3. Year Established: ☐

4. Type of Enterprise:

☐	Co-operative Body	☐	Trust
☐	Foundation (Sec. 25/C Company)	☐	Proprietary Firm
☐	Partnership Firm	☐	Private Limited Company
☐	Public Limited Company	☐	Other

5. Number of employees:

- ❖ 1 – 10 employees ☐
- ❖ 10 – 50 employees ☐
- ❖ 50 – 100 employees ☐
- ❖ More than 100 employees ☐

(Please indicate the above on basis of manpower strength for your group including marketing personnel – direct / indirect)

6. NAMES OF OTHER GROUP COMPANIES INVOLVED IN AYURVED, SIDDHA & UNANI MEDICINES AND RELATED BUSINESS UNDER CONTROL OF SAME PROMOTER GROUP:

NAME OF ORGANISATION	MANUFACTURER / TRADE / MARKETERS
a.	
b.	
c.	
d.	
e.	

7. Range of products offered:

	% of Turnover
Botanical raw materials	_____
Botanical extracts and oils (value-added ingredients)	_____
Traditional Ayurvedic, Siddha or Unani finished products	_____
Patent & Proprietary Ayurvedic, Siddha & Unani Medicines	_____
Non-traditional finished natural health products	_____
Natural body care and cosmetics products	_____

8. Is Your Organization looking towards Increase in Export Business in coming 3 years?

9. Markets: % domestic____, % export (by destination):

- ❖ Australia / New Zealand
- ❖ Canada
- ❖ China
- ❖ EU-27 Member States
- ❖ Japan
- ❖ Korea
- ❖ South Africa
- ❖ South Asian Nations (e.g. Bangladesh, Bhutan, Malaysia, Myanmar, Nepal, Pakistan, Singapore, Sri Lanka)
- ❖ SOUTH AMERICAN COUNTRIES
- ❖ United States of America
- ❖ Other (please list):

II. PRODUCTS AND PRODUCTION

Needs: In this section please describe your current export production capacity and identify what might be required to improve your "products and production" capacity to increase your exports.

10. Describe any needs your enterprise has for increasing exports in areas of production technology, product quality, packaging, inventory control, staffing, etc.:

11. Do you have documentary evidence of Good Agricultural and Collection Practice (GACP) compliance for your raw material supply and Good Manufacturing Practice (GMP) compliance for your product manufacturing? If yes, which specific GACP and/or GMP does your enterprise operate according to?

12. Do you operate your own in-house quality control laboratory or do you make use of governmental or independent contract laboratories for the testing and release of your ingredients and finished products?

13. Are your natural ingredients tested and released in conformance to established pharmacopoeial quality standards (e.g. API, IP, PhEur, USP)? ____ If not, what are your specifications based on?

14. Please list the specific tests that are performed on your exported finished products, the specifications and limits, and the costs if carried out by outside laboratories.

15. Which are your top five products?
    - For marketers of finished natural products, please list the product trade names. Please also provide the list of ingredients for each product and indications for use (e.g. copy of your Product License document or product labels):

    - For marketers of natural ingredients, please list the botanical names and form of the ingredients (e.g. dried cut roots, dried powdered extracts; for branded ingredients provide ® trade names); if possible please also provide typical specification sheets:

16. For your top five products, what is the annual turnover by value (Rs) and volume for the Indian domestic market?

17. Which Harmonized System (HS) Tariff Codes are you using for your top 5 exported products?

	PRODUCT DESCRIPTION	**HS CODE**
1.		
2.		
3.		
4.		
5.		

Capacity: availability and limitations: In this section please identify your firm's capacity to address "products and production" requirements for export growth internally and through access to services provided by support institutions.

18. Please identify current support received from the following types of institutions: technology extension centres, standards bureaus, public sector institutions, technology consulting firms, business training institutions:

III. DISTRIBUTION AND LOGISTICS

Needs: In this section please describe your firm's current export "distribution and logistics" capacity and identify what might be required if export production were to increase.

19. Describe any needs your enterprise has for transport, warehousing, freight forwarding, telecommunications, customs, freight insurance, distribution and logistics staffing:

20. Please list any current facility registrations that your enterprise maintains with any foreign food and/or drug regulatory agencies (e.g. Australian TGA, Canadian NHPD, UK MHRA, US FDA):

Capacity: availability and limitations: In this section please identify your firm's capacity to address "distribution and logistics" requirements to handle current and higher volumes of export internally and through services provided by support institutions.

21. Please identify current support (and limits thereof) received from the following types of institutions: transport carriers, freight-forwarding industry, telecommunications, customs, business training institutions:

IV. MARKETING AND PROMOTION

Needs: In this section, many of the questions assume that your enterprise already has some amount of export business. If you are not yet exporting, answer only the relevant questions. In either case, please describe your current export "marketing and promotion" capacity and identify what might be required to improve that capacity to support a sustainable level of exports appropriate for your scale.

22. Describe any needs your enterprise has for export promotion, market access conditions, sales and marketing staffing:

23. In the export markets where your products already have a presence, are your products:
- ❖ Marketed under your own brand by an exclusive wholesale distribution company? ☐
- ❖ Licensed to an established company that markets your products under their brand name? ☐
- ❖ Marketed by your own sales and marketing personnel and assigned brokerage networks? ☐
- ❖ Sold direct to consumers by internet or catalogue sales? ☐
- ❖ Sold only to patients through practitioner clinic dispensaries? ☐

24. Do you already have pre-marketing authorization and product licenses in any countries? If yes, please list which of your products are licensed, notified, or registered, in which countries, and what are the product license numbers?

25. Have you had any product license applications rejected by a foreign regulatory agency? If yes, by which countries and what were the main reasons for rejection?

26. Are any of your products or product ingredients non-importable in target countries due to negative or positive lists or other regulatory issues? If yes, which ingredients in your products have been restricted from access, by which specific countries, and under which regulatory framework (e.g. cosmetic, dietary supplement, food, medicine)?

27. Are your "company name", "finished product brand names," and/or "branded ingredient names" registered trademarks in each export country? If so, in which countries do you own and maintain trademarks? Are your trademarks also registered with World Intellectual Property Organization (WIPO)?

28. Do you hold any patents for any products or processes? If so, please list patent numbers and countries where your patents are registered?

29. What levels of evidence do you already have compiled in support of the safety, efficacy, and quality of your top 5 products (e.g. product license application dossiers or substantiation files)?

30. Are there any published studies in which the investigational product was supplied by your company? If so, please list citations of published studies.

31. Do any of your products carry any "value-adding" ecological-, quality-, social-, or religious-certifications that may be important market access expectations by consumers in certain export markets? For example:

    - Ecological Certifications: (e.g. Biodynamic Certified (Demeter), Certified Organic (EU or USDA), Rainforest Alliance Certified (Sustainable Agriculture Network), or conformance with the International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants (ISSC-MAP)):

    - Quality Certifications: (e.g. GACP, GMP, HACCP, ISO, USP):

    - Religious Certifications: (e.g. Halal Certified or Kosher Certified):

    - Social Certifications: (e.g. Fair Trade Certified; Fair Wild Certified; IMO Social & Fair Trade Certified):

    - Other certifications (please list):

32. What specific problems or market access barriers do you believe are most in the way of reaching the export sales goals?

    Capacity: availability and limitations: In this section, please identify your firm's capacity to address "marketing and promotion" requirements to handle current and higher volumes of exports internally and through access to services provided by support institutions.

33. Is your company a member of any trade associations, for example:

- ❖ Association of Manufacturers of Ayurvedic Medicines (AMAM) ☐
- ❖ Ayurvedic Drug Manufacturers Association (ADMA) ☐
- ❖ Central Herbal Agro Marketing Federation of India (CHAMF) ☐
- ❖ Federation of Indian Herbal Industry (FIHI) ☐
- ❖ Herbs & Herbal Export Promotion Association of India (HEPAI) ☐
- ❖ Indian Drug Manufacturers Association (IDMA) ☐
- ❖ Medicinal, Aromatic and Dye Plants Stakeholders' Consortium (MAPSCON) ☐
- ❖ Pharmaceuticals Export Promotion Council (PHARMEXCIL) ☐
- ❖ Shellac and Forest Products Export Promotion Council (SHEFEXCIL) ☐
- ❖ The Associated Chambers of Commerce and Industry of India (ASSOCHAM) ☐
- ❖ Other trade associations ☐

34. Please describe the levels of support that you receive through your trade organization membership(s)?

35. Please describe any technical support programs that your enterprise has participated in through governmental organizations (GOs), international governmental organizations (IGOs), and/or non-governmental organizations (NGOs), such as:

- Indian GO Programmes (e.g. Financial assistance through the Centrally Assisted Schemes for Medicinal Plants through the National Medicinal Plants Board (NMPB); or Market Access Initiative (MAI) Scheme of Ministry of Commerce and Industry; Embassy of India, High Commission of India, Permanent Mission of India):

- Foreign GO Programmes (e.g. Netherlands Centre for Promotion of Imports from Developing Countries (CBI), German Organization for Technical Cooperation (GTZ), Swiss Import Promotion Programme (SIPPO), U.S. Agency for International Development (USAID)):

- NGOs (e.g. FRLHT, WWF-India):

- IGO Programmes (e.g. ITC/UNCTAD/WTO, UNDP, World Bank):

36. Are you aware of the public–private–partnership opportunities available for the branding and marketing of ASU products that have been developed and researched by GOs such as CCRAS and CCRUM respectively?

37. What type of other technical assistance, training or capacity building, or public-private-partnership (PPP) activities do you believe the Government of India should focus on in ways that could help the overall Indian natural products industry become more successful in the export markets?

V. FINANCE AND FISCAL CONDITIONS

Needs: In this section please describe the current financing and fiscal conditions to support export growth.

38. Identify what might be required to improve capacity to support a higher level of exports in the following areas: project/investment financing, trade financing, government fiscal incentives/disincentives, government sectoral export strategy.

Capacity: availability and limitations: In the section please identify your capacity to address "financing and fiscal requirements" to handle current and higher volumes of exports internally and through access to services provided by support institutions.

39. Identify current support received from the following types of institutions: banking industry, national trade strategy, trade ministry, finance ministry, business training institutions.

VI. PURCHASING and SUSTAINABILITY OF SUPPLY

Needs: In this section please identify any needs in the way of purchased inputs, availability and sustainability of supply, quality and price issues.

40. Do you spot-buy your natural ingredients on the open market or do you have long-term supply agreements or contracts with only certain qualified suppliers?

41. Can your suppliers guarantee a consistent supply of defined quality raw materials?

42. What % of your botanical raw material supply is produced from controlled cultivation and what % is obtained from wild collection?

43. Do your raw material suppliers have the capacity for sustainable scale-up in the event that your enterprise was to grow rapidly due to new export market opportunities?

44. If yes, by what methodology was the sustainable supply of wild collected botanicals determined?

VII. FINAL THOUGHTS

45. Please describe what you believe the Government of India should do specifically to enhance the export of Ayurvedic, Siddha, and Unani Products?

Appendix V
List of Enterprise Survey Respondents

	NAME OF ENTERPRISE AND NAME OF CONTACT PERSON	DATE OF RESPONSE
1	ANUJA PHARMACEUTICALS PVT LTD. RAJENDRA B. MEHTA	12 MAY 2008
2	ARYA VAIDYA SALA, KOTTAKKAL K.P. NAIR	26 MAY 2008
3	BIPHA DRUG LABORATORIES AJAY G VARGHESE	21 MAY 2008
4	DABUR INDIA LIMITED DEEPIKA GUNAWANT	21 MAY 2008
5	JHAWAR CHEMICALS PRIVATE LIMITED PREM JHAWAR	29 MAY 2008
6	EXOTIC NATURALS JAYESH CHAUDHARY	06 JUNE 2008
7	KERALA AYURVEDA LTD. SONJOY MOHANTHY	08 MAY 2008
8	MAHARISHI AYURVEDA PRODUCTS SANJAY SRIVASTAVA	19 MAY 2008
9	NATURAL REMEDIES SHIVAPRASAD HN	20 MAY 2008
10	PROGEN RESEARCH LABS DR. SHRINIVAS	22 MAY 2008
11	SHREE DHOOTSPAPESHWAR LTD RANJIT PURANIK	15 MAY 2008
12	VASU HEALTHCARE PVT LTD HARDIK UKANI	31 MAY 2008
13	ZANDU PHARMACEUTICAL WORKS VIVEK POTDAR	15 MAY 2008

Appendix VI
Monographs Published in Ayurvedic Pharmacopoeia of India

MONOGRAPHS

Monographs Published in Ayurvedic Pharmacopoeia of India

PART-I, VOL. I

1.	Ajagandha (Sd.)	*Cleome gynandra* Linn.
2.	Ajamoda (Frt.)	*Apium leptophyllum* (Pers.) F.V.M. ex Benth.
3.	Amalaki (Fr. Frt. Pulp)	*Emblica officinalis* Gaertn.
4.	Amalaki (Drd. Frt.)	*Emblica officinalis* Gaertn.
5.	Aragvadha (Frt. Pulp.)	*Cassia fistula* Linn.
6.	Arka (Rt.)	*Calotropis procera* (Ait.) R. Br.
7.	Arka (Lf.)	*Calotropis procera* (Ait.) R. Br.
8.	Asana (Ht.Wd.)	*Pterocarpus marsupium* Roxb.
9.	Ashoka (St. Bk.)	*Saraca asoca* (Rosc.) DC. Willd.
10.	Asvagandha (Rt.)	*Withania somnifera* Dunal.
11.	Asvattha (Bk.)	*Ficus religiosa* Linn.
12.	Atasi (Sd.)	*Linum usitatissimum* Linn.
13.	Atibala (Rt.)	*Abutilon indicum* (Linn.) Sw.
14.	Ativisa (Rt.)	*Aconitum heterophyllum* Wall. ex Royle
15.	Babbula (St.Bk.)	*Acacia nilotica* (Linn.) Willd. ex Del. sp. *indica* (Benth.) Brenan
16.	Bakuci (Frt.)	*Psoralea corylifolia* Linn.
17.	Bibhitaka (Frt.)	*Terminalia belerica* Roxb.
18.	Bilva (Frt. Pulp)	*Aegle marmelos* Corr.
19.	Candrasura (Sd.)	*Lepidium sativum* Linn.
20.	Citraka (Rt.)	*Plumbago zeylanica* Linn.
21.	Dhanyaka (Frt.)	*Coriandrum sativum* Linn.
22.	Dhataki (Fl.)	*Woodfordia fruticosa* (Linn.) Kurz.
23.	Eranda (Rt.)	*Ricinus communis* Linn.
24.	Gambhari (Rt. Bk.)	*Gmelina arborea* Roxb
25.	Goksura (Rt.)	*Tribulus terrestris* Linn.
26.	Goksura (Frt.)	*Tribulus terrestris* Linn.
27.	Guduci (St.)	*Tinospora cordifolia* (Willd.) Miers.
28.	Guggulu (Exudate)	*Commiphora wightii* (Arn.) Bhand.
29.	Gunja (Sd.)	*Abrus precatorius* Linn.
30.	Haridra (Rz.)	*Curcuma longa* Linn.
31.	Haritaki (Frt.)	*Terminalia chebula* Retz.
32.	Hingu (Oleo-Gum-Resin)	*Ferula foetida* Regel.
33.	Jatamansi (Rz.)	*Nardostachys jatamansi* DC.
34.	Jatiphala (Sd.)	*Myristica fragrans* Houtt.
35.	Kampilla (Frt.)	*Mallotus philippinensis* Muell.-Arg.
36.	Kancanara (St. Bk.)	*Bauhinia variegata* Blume

37.	Kankola (Frt.)	*Piper cubeba* Linn. f.
38.	Kantakari (W.P.)	*Solanum surattense* Burm. f.
39.	Kanyasara (Lf.)	*Aloe barbadensis* Mill.
40.	Karanja (Sd.)	*Pongamia pinnata* (Linn.) Merr.
41.	Karavira (Lf.)	*Nerium indicum* Mill.
42.	Karkatasrngi (Gall)	*Pistacia chinensis* Burgo
43.	Karpasa (Sd.)	*Gossypium herbaceum* Linn.
44.	Kaseru (Rz.)	*Scirpus kysoor* Roxb.
45.	Ketaki (Rt.)	*Pandanus tectorius* Soland. ex Parkinson
46.	Khadira (Ht.Wd.)	*Acacia catechu* (Linn. f.) Willd.
47.	Kiratatikta (W.P.)	*Swertia chirata* Buch.-Ham.
48.	Krsnajiraka (Frt.)	*Carum carvi* Linn.
49.	Kulattha (Sd.)	*Vigna unquiculata* (Linn.) Walp.
50.	Kustha (Rt.)	*Saussurea lappa* C.B. Clarke
51.	Kutaja (St. Bk.)	*Holarrhena antidysenterica* (Roth) A. DC.
52.	Lavanga (Fl. Bud)	*Syzygium aromaticum* (Linn.) Merr. & M.Perry
53.	Lodhra (St. Bk.)	*Symplocos racemosa* Roxb.
54.	Madana (Frt.)	*Xeromphis spinosa* (Thunb.) Keay
55.	Misreya (Frt.)	*Foeniculum vulgare* Mill.
56.	Nyagrodha (St. Bk.)	*Ficus bengalensis* Linn.
57.	Pasanabheda (Rz.)	*Bergenia ciliata* (Haw.) Sternb.
58.	Patha (Rt.)	*Cissampelos pareira* Linn.
59.	Puga (Sd.)	*Areca catechu* Linn.
60.	Punarnava (Rakta) (W.P.)	*Boerhaavia diffusa* Linn.
61.	Saptaparna (St. Bk.)	*Alstonia scholaris* (Linn.) R. Br.
62.	Sati (Rz.)	*Hedychium spicatum* Ham. ex Smith
63.	Snuhi (St.)	*Euphorbia neriifolia* Linn.
64.	Suksmaila (Frt.)	*Elettaria cardamomum* (Linn.) Maton
65.	Sunthi (Rz.)	*Zingiber officinale* Roxb.
66.	Svarnapatri (Lf.)	*Cassia angustifolia* Vahl.
67.	Svetajiraka (Frt.)	*Cuminum cyminum* Linn.
68.	Sveta Sariva (Rt.)	*Hemidesmus indicus* (Linn.) R. Br.
69.	Tagara (Rz.)	*Valeriana wallichii* DC.
70.	Tamalaki (Rt., St. & Lf.)	*Phyllanthus fraternus* Webst.
71.	Tvak (Bk.)	*Cinnamomum zeylanicum* Blume
72.	Tvakapatra (Lf.)	*Cinnamomum tamala* (Buch.-Ham.) Nees & Eberm.
73.	Udumbara (Bk.)	*Ficus racemosa* Linn.
74.	Upakuncika (Sd.)	*Nigella sativa* Linn.
75.	Varuna (St. Bk.)	*Crataeva nurvala* Buch.-Ham.
76.	Vasa (Lf.)	*Adhatoda vasica* Nees
77.	Vidanga (Frt.)	*Embelia ribes* Burm.f.
78.	Vijaya (Lf.)	*Cannabis sativa* Linn.
79.	Yasti (St. & Rt.)	*Glycyrrhiza glabra* Linn.
80.	Yavani (Frt.)	*Trachyspermum ammi* (Linn.) Sprague ex Turril

PART-I, VOL. II

1.	Akarakarabha (Rt.)	*Anacyclus pyrethrum* DC.
2.	Aksoda (Cotldn.)	*Juglans regia* Linn.
3.	Amrata (St. Bk.)	*Spondias pinnata* (Linn. f.) Kurz.
4.	Apamarga (W.P.)	*Achyranthes aspera* Linn.
5.	Aparajita (Rt.)	*Clitoria ternatea* Linn.
6.	Ardraka (Rz.)	*Zingiber officinale* Rosc.
7.	Arimeda (St.Bk.)	*Acacia leucophloea* Willd.
8.	Arjuna (St.Bk.)	*Terminalia arjuna* W.& A.
9.	Bhallataka (Frt.)	*Semecarpus anacardium* Linn.
10.	Bhrngaraja (W.P.)	*Eclipta alba* Hassk.
11.	Brahmi (W.P.)	*Bacopa monnieri* (Linn.) Wettst.
12.	Brhati (Rt.)	*Solanum indicum* Linn.
13.	Cavya (St.)	*Piper retrofractum* Vahl.
14.	Dadima (Sd.)	*Punica granatum* Linn.
15.	Daruharidra (St.)	*Berberis aristata* DC.
16.	Dronapuspi (W.P.)	*Leucas cephalotes* Spreng.
17.	Ervaru (Sd.)	*Cucumis melo* var. *utilissimus* Duthie & Fuller
18.	Gajapippali (Frt.)	*Scindapsus officinalis* Schoott.
19.	Gambhari (Frt.)	*Gmelina arborea* Roxb.
20.	Gangeru (St.Bk.)	*Grewia tenax* (Forsk.) Aschers & Schwf.
21.	Gunja (Rt.)	*Abrus precatorius* Linn.
22.	Iksu (St.)	*Saccharum officinarum* Linn.
23.	Indravaruni (Rt.)	*Citrullus colocynthis* Schrad.
24.	Indravaruni (Lf.)	*Citrullus colocynthis* Schrad.
25.	Jambu (Sd.)	*Syzygium cuminii* (Linn.) Skeels
26.	Jambu (St.Bk.)	*Syzygium cuminii* (Linn.) Skeels
27.	Jayapala (Sd.)	*Croton tiglium* Linn.
28.	Jayanti (Lf.)	*Sesbania sesban* (Linn.) Merr.
29.	Jyotismati (Sd.)	*Celastrus paniculatus* Willd.
30.	Kadamba (St.Bk.)	*Anthocephalus cadamba* Miq.
31.	Kakamaci (W.P.)	*Solanum nigrum* Linn.
32.	Kamala (Fl.)	*Nelumbo nucifera* Gaertn.
33.	Kapittha (Frt.Pulp)	*Feronia limonia* (Linn.) Swingle
34.	Karamarda (St.Bk.)	*Carissa carandas* Linn.
35.	Karanja (Rt.Bk.)	*Pongamia pinnata* (Linn.) Merr.
36.	Karanja (Rt.)	*Pongamia pinnata* (Linn.) Merr.
37.	Karanja (St.Bk.)	*Pongamia pinnata* (Linn.) Merr.
38.	Karanja (Lf.)	*Pongamia pinnata* (Linn.) Merr.
39.	Karavallaka (Fr. Frt.)	*Momordica charantia* Linn.
40.	Katuka (Rz.)	*Picrorhiza kurroa* Royle ex Benth.
41.	Kokilaksa (W.P.)	*Asteracantha longifolia* Nees
42.	Kokilaksa (Rt.)	*Asteracantha longifolia* Nees
43.	Kokilaksa (Sd.)	*Asteracantha longifolia* Nees
44.	Kozuppa (W.P.)	*Portulaca oleracea* Linn.

45.	Lajjalu (W.P.)	*Mimosa pudica* Linn.
46.	Madhuka (Fl.)	*Madhuca indica* J.F. Gmel.
47.	Matsyaksi (W.P.)	*Alternanthera sessilis* (Linn.) R. Br.
48.	Methi (Sd.)	*Trigonella foenum-graecum* Linn.
49.	Mulaka (W.P.)	*Raphanus sativus* Linn.
50.	Mulaka (Rt.)	*Raphanus sativus* Linn.
51.	Mura (Rt.)	*Selinium candollei* DC.
52.	Murva (Rt.)	*Marsdenia tenacissima* Wight. & Arn.
53.	Nagakesar (Stmn.)	*Mesua ferrea* Linn.
54.	Nili (Lf.)	*Indigofera tinctoria* Linn.
55.	Nili (Rt.)	*Indigofera tinctoria* Linn.
56.	Nimba (Lf.)	*Azadirachta indica* A. Juss.
57.	Nimba (St.Bk.)	*Azadirachta indica* A. Juss.
58.	Palasa (St.Bk.)	*Butea monosperma* (Lam.) Kuntze
59.	Paribhadra (St.Bk.)	*Erythrina indica* Lam.
60.	Pippalimula (St.)	*Piper longum* Linn.
61.	Plaksa (St.Bk.)	*Ficus lacor* Buch.-Ham.
62.	Prasarini (W.P.)	*Paederia foetida* Linn.
63.	Priyala (Sd.)	*Buchanania lanzan* Spreng.
64.	Priyangu (Infl.)	*Callicarpa macrophylla* Vahl.
65.	Sali (Rt.)	*Oryza sativa* Linn.
66.	Sankhapuspi (W.P.)	*Convolvulus pluricaulis* Choisy
67.	Saptala (W.P.)	*Euphorbia dracunculoides* Lam.
68.	Satahva (Frt.)	*Anethum sowa* Roxb. ex Flem.
69.	Sigru (Lf.)	*Moringa oleifera* Lam.
70.	Sthulaela (Sd.)	*Amomum subulatum* Roxb.
71.	Tejovati (St.Bk.)	*Zanthoxylum armatum* DC.
72.	Tulasi (W.P.)	*Ocimum sanctum* Linn.
73.	Tulasi (Lf.)	*Ocimum sanctum* Linn.
74.	Vaca (Rz.)	*Acorus calamus* Linn.
75.	Vatsanabha (Rt.)	*Aconitum chasmanthum* Stapf ex Holmes
76.	Vidari (Tub.Rt.)	*Pueraria tuberosa* DC.
77.	Yava (Frt.)	*Hordeum vulgare* Linn.
78.	Yavasaka (W.P)	*Alhagi pseudalhagi* (Bieb.) Desv.

PART-I, VOL. III

1.	Adhaki (Rt.)	*Cajanus cajan* (Linn.) Millsp.
2.	Agnimantha (Rt.)	*Clerodendrum phlomidis* Linn. f.
3.	Ambasthaki (Rt.)	*Hibiscus sabdariffa* Linn.
4.	Amra (Sd.)	*Mangifera indica* Linn.
5.	Amra (St. Bk.)	*Mangifera indica* Linn.
6.	Amrata (St.)	*Spondias pinnata* (Linn.f.) Kurz.
7.	Apamarga (Rt.)	*Achyranthes aspera* Linn.
8.	Araluka (St. Bk.)	*Ailanthus excelsa* Roxb.
9.	Arka (St. Bk.)	*Calotropis procera* (Ait.) R. Br.

10.	Asana (St. Bk.)	*Pterocarpus marsupium* Roxb.
11.	Asthisamhrta (St.)	*Cissus quadrangularis* Linn.
12.	Atmagupta (Sd.)	*Mucuna prurita* Hook.
13.	Bharangi (Rt.)	*Clerodendrum serratum* Linn.
14.	Bijapura (Frt.)	*Citrus medica* Linn.
15.	Bilva (Rt.)	*Aegle marmelos* Corr.
16.	Bimbi (W.P.)	*Coccinia indica* W. & A.
17.	Cangeri (W.P.)	*Oxalis corniculata* Linn.
18.	Cirabilva (Frt.)	*Holoptelea integrifolia* Planch
19.	Danti (Rt.)	*Baliospermum montanum* Muell-Arg.
20.	Dhattura (Sd.)	*Datura metel* Linn.
21.	Draksa (Frt.)	*Vitis vinifera* Linn.
22.	Durva (Rt.)	*Cynodon dactylon* (Linn.) Pers.
23.	Eranda (Lf.)	*Ricinus communis* Linn.
24.	Eranda (Sd.)	*Ricinus communis* Linn.
25.	Gambhari (St.)	*Gmelina arborea* Roxb.
26.	Gojihva (Aer. Pt.)	*Onosma bracteatum* Wall.
27.	Granthiparni (Rt.)	*Leonotis nepetaefolia* R. Br.
28.	Hamsapadi (W.P.)	*Adiantum lunulatum* Burm
29.	Hapusa (Frt.)	*Juniperus communis* Linn.
30.	Indravaruni (Frt.)	*Citrullus colocynthis* Schrad.
31.	Indrayava (Sd.)	*Holarrhena antidysenterica* Wall.
32.	Isvari (Rt.)	*Aristolochia indica* Linn.
33.	Jati (Lf.)	*Jasminum officinale* Linn.
34.	Kadali (Rz.)	*Musa paradisiaca* Linn.
35.	Kakajangha (Rt.)	*Peristrophe bicalyculata* Linn.
36.	Kakanasika (Sd.)	*Martynia annua* Linn.
37.	Kakoli (Tub. Rt.)	*Lilium polyphyllum* D. Don
38.	Kamala (Rz.)	*Nelumbo nucifera* Gaertn.
39.	Karavira (Rt.)	*Nerium indicum* Mill.
40.	Karinkara (Rt.)	*Carissa carandas* Linn.
41.	Kasa (Rt. Stock)	*Saccharum spontaneum* Linn.
42.	Katphala (Frt.)	*Myrica esculenta* Buch.-Ham. ex D. Don
43.	Katphala (St. Bk.)	*Myrica esculenta* Buch.-Ham. ex D. Don
44.	Kola (Frt. Pulp)	*Zizypus jujuba* Lam.
45.	Kola (St. Bk.)	*Zizypus jujuba* Lam.
46.	Kosataki (W.P.)	*Luffa acutangula* (Linn.) Roxb.
47.	Kumuda (Fl.)	*Nymphaea alba* Linn.
48.	Kusa (Rt. St.)	*Desmostachya bipinnata* Stapf.
49.	Langali (Rz.)	*Gloriosa superba* Linn.
50.	Lasuna (Bulb)	*Allium sativum* Linn.
51.	Mahabala (Rt.)	*Sida rhombifolia* Linn.
52.	Manjistha (St.)	*Rubia cordifolia* Linn.
53.	Marica (Frt.)	*Piper nigrum* Linn.
54.	Masaparni (W.P.)	*Teramnus labialis* Spreng.
55.	Masura (Sd.)	*Lens culinaris* Medic.

56.	Mudga (Sd.)	*Phaseolus radiatus* Linn.
57.	Mulaka (Sd.)	*Raphanus sativus* Linn.
58.	Munditika (Lf.)	*Sphaeranthus indicus* Linn.
59.	Musta (Rz.)	*Cyperus rotundus* Linn.
60.	Nagavalli (Lf.)	*Piper betle* Linn.
61.	Narikela (Endo.)	*Cocos nucifera* Linn.
62.	Nicula (Frt.)	*Barringtonia acutangula* (Linn.) Gaertn.
63.	Nili (W.P.)	*Indigofera tinctoria* Linn.
64.	Nirgundi (Lf.)	*Vitex negundo* Linn.
65.	Padmaka (Ht. Wd.)	*Prunus cerasoides* D. Don
66.	Patalai (Rt.)	*Stereospermum suaveolens* DC.
67.	Phalgu (Frt.)	*Ficus hispida* Linn.
68.	Phalgu (Rt.)	*Ficus hispida* Linn.
69.	Prapunnada (Sd.)	*Cassia tora* Linn.
70.	Raktacandana (Ht.Wd.)	*Pterocarpus santalinus* Linn.
71.	Raktapunarnava (Rt.)	*Boerhaavia diffusa* Linn.
72.	Ramasitalika (W. P.)	*Amaranthus tricolor* Linn.
73.	Rasna (Lf.)	*Pluchea lanceolata* Oliver & Hiem.
74.	Sahacara (W.P.)	*Barleria prionitis* Linn.
75.	Sahadevi (W.P.)	*Vernonia cinerea* Lees.
76.	Saileya (Lichen-'Thallus')	*Parmelia perlata* (Huds.) Ach.
77.	Saka (Ht. Wd.)	*Tectona grandis* Linn.
78.	Sakhotaka (St. Bk.)	*Streblus asper* Lour.
79.	Salaparni (Rt.)	*Desmodium gangeticum* DC.
80.	Sali (Frt.)	*Oryza sativa* Linn.
81.	Salmali (St.Bk.)	*Bombax ceiba* Linn.
82.	Sana (Sd.)	*Crotolaria juncea* Linn.
83.	Sara (Rt.)	*Saccharum bengalense* Retz.
84.	Sarala (Ht. Wd.)	*Pinus roxburghii* Sargent
85.	Sarala (Rt.)	*Pinus roxburghii* Sargent
86.	Sarsapa (Sd.)	*Brassica campestris* Linn.
87.	Satapatrika (Fl.)	*Rosa centifolia* Linn.
88.	Simsapa (Ht. Wd.)	Dalbergia *sissoo* Roxb.
89.	Simsapa (St. Bk.)	*Dalbergia sissoo* Roxb.
90.	Sirisa (St. Bk.)	*Albizzia lebbeck* Benth.
91.	Sthauneya (Lf.)	*Taxus baccata* Linn.
92.	Surana (Corm.)	*Amorphophallus campanulatus* (Roxb.) Bl.
93.	Svetacandana (Ht.Wd.)	*Santalum album* Linn.
94.	Syonaka (Rt.)	*Oroxylum indicum* Vent.
95.	Tala (Infl.)	*Borassus flabellifer* Linn.
96.	Trivrta (Rt.)	*Operculina turpethum* (Linn.) Silva Manso
97.	Tumbini (Frt.)	*Lagenaria siceraria* (Mol.) Standl.
98.	Udambara (Frt.)	*Ficus glomerata* Roxb.
99.	Usira (Rt.)	*Vetiveria zizanioides* (Linn.) Nash
100.	Utpala (Fl.)	*Nymphaea stellata* Willd

PART-I, VOL. IV

1.	Adhaki (Sd.)	*Cajanus cajan* Linn.
2.	Agaru (Ht. Wd.)	*Aquilaria agallocha* Roxb.
3.	Aklari (Endm.)	*Lodoicea maldivica* Pers.
4.	Aparajita (Lf.)	*Clitoria ternatea* Linn.
5.	Atmagupta (Rt.)	*Mucuna prurita* Hook.
6.	Bilva (St. Bk.)	*Aegle marmelos* Corr.
7.	Champaka (Fl.)	*Michelia champaca* Linn.
8.	Cinca (Ft. Pl.)	*Tamarindus indica* Linn.
9.	Dadima (Fr. Fruit)	*Punica granatum* Linn.
10.	Dadima (Ft. Rind)	*Punica granatum* Linn.
11.	Dadima (Lf.)	*Punica granatum* Linn.
12.	Devadaru (Ht. Wd.)	*Cedrus deodara* (Roxb.) Loud.
13.	Dhattura (W.P.)	*Datura metel* Linn.
14.	Durva (W.P.)	*Cynodon dactylon* (Linn.)
15.	Gambhari (St. Bk.)	*Gmelina arborea* Linn.
16.	Iksu (Rt. Stock)	*Saccharum officinarum* Linn.
17.	Kadali (Fl.)	*Musa paradisiaca* Linn.
18.	Karcura (Rz.)	*Curcuma zedoaria* Rosc.
19.	Kasturilatika (Sd.)	*Hibiscus abelmoschus* Linn.
20.	Kataka (Sd.)	*Strychnos potatorum* Linn. f.
21.	Kharjura (Drd. Ft.)	*Phoenix dactylifera* Linn.
22.	Kharjura (Fr. Ft.)	*Phoenix dactylifera* Linn.
23.	Krsnasariva (Rt.)	*Cryptolepis buchanani* Roem. & Schult.
24.	Kunduru (Exud.)	*Boswellia serrata* Roxb.
25.	Kunkuma (Sty. & Stg.)	*Crocus sativus* Linn.
26.	Kusmanda (Ft.)	*Benincasa hispida* (Thunb.) Cogn.
27.	Madayanti (Lf.)	*Lawsonia inermis* Linn.
28.	Mahanimba (St. Bk.)	*Melia azedarach* Linn.
29.	Mandukaparni (W.P.)	*Centella asiatica* (Linn.) Urban
30.	Mayakku (Gall)	*Quercus infectoria* Oliv.
31.	Mudgaparni (W.P.)	*Vigna trilobata* (Linn.) Verdc.
32.	Munditika (W.P.)	*Sphaeranthus indicus* Linn.
33.	Nayagrodha Jata (Ar. Rt.)	*Ficus bengalensis* Linn.
34.	Nimbu (Fr. Ft.)	*Citrus limon* (Linn.) Burm. f.
35.	Nirgundi (Rt.)	*Vitex negundo* Linn.
36.	Palasa (Fl.)	*Butea monosperma* (Lam.) Kuntze.
37.	Palasa (Gum)	*Butea monosperma* (Lam.) Kuntze.
38.	Palasa (Sd.)	*Butea monosperma* (Lam.) Kuntze.
39.	Parpata (W.P.)	*Fumaria parviflora* Lam.
40.	Patalai (St. Bk.)	*Stereospermum chelonoides* (L.F.)DC.
41.	Pattanga (Ht. Wd.)	*Caesalpinia sappan* Linn.
42.	Pippali (Ft.)	*Piper longum* Linn.
43.	Plaksa (Ft.)	*Ficus lacor Buch.* – Ham.
44.	Priyala (St. Bk.)	*Buchanania lanzan* Spreng.

45.	Priyangu (Fruit)	*Callicarpa macrophylla* Vahl.
46.	Prsniparni (W.P.)	*Uraria picta* Desv.
47.	Puskara (Rt.)	*Inula racemosa* Hook. f.
48.	Rudraksa (Sd.)	*Elaeocarpus sphaericus* Gaertn. K. Schum
49.	Saraja (Exud.)	*Vateria indica* Linn.
50.	Satavari (Rt.)	*Asparagus recemosus* Willd.
51.	Sigru (Rt. Bk.)	*Moringa oleifera* Lam.
52.	Sigru (Sd.)	*Moringa oleifera* Lam.
53.	Sigru (St. Bk)	*Moringa oleifera* Lam.
54.	Srngataka (Drd.Sd)	*Trapa natans* Linn.
55.	Sruvavrksa (Lf.)	*Flacourtia indica* Merr.
56.	Sruvavrksa (St. Bk)	*Flacourtia indica* Merr.
57.	Talamuli (Rz.)	*Curculigo orchioides* Gaertn.
58.	Talisa (Drd. Lf.)	*Abies webbiana* Lindl.
59.	Tila (Sd.)	*Sesamum indicum* Linn.
60.	Tulasi (Sd.)	*Ocimum sanctum* Linn.
61.	Tumburu (Ft.)	*Zanthoxylum armatum* DC.
62.	Utingana (Sd.)	*Blepharis persica* (Burm.f.) O. Kuntze.
63.	Varahi (Rz.)	*Dioscorea bulbifera* Linn.
64.	Varsabhu (Rt.)	*Trianthema portulacastrum* Linn.
65.	Vasa (Rt.)	*Adhatoda zeylanica* Medic.
66.	Visamusti (Sd.)	*Strychnos nux-vomica* Linn.
67.	Vrscikalli (W.P.)	*Tragia involucrata* Linn.
68.	Yava (W.P.)	*Hordeum vulgare* Linn.

PART-I, VOL. V

1.	Amra Haridra (Rz.)	*Curcuma amada* Roxb.
2.	Anisoon (Fr.)	*Pimpinelia anisum* Linn.
3.	Ankola (Lf.)	*Alangium salviifolium* (Linn.f.) Wang.
4.	Aragvadha (St.Bk.)	*Cassia fistula* Linn.
5.	Asphota (Rt.)	*Vallaris solanacea* Kuntze
6.	Bastantri (Rt.)	*Argyreia nervosa* (Burm.f.) Boj.
7.	Bhurja (St.Bk.)	*Betula utilis* D.Don
8.	Canda (Rt.)	*Angelica archangelica* Linn.
9.	Coraka (Rt. & Rt. Stock)	*Angelica glauca* Edgw.
10.	Darbha (Rt.)	*Imperata cylindrica* (Linn.) Beauv.
11.	Dhanvayasa (Wh.Pl.)	*Fagonia cretica* Linn.
12.	Dravanti (Sd.)	*Jatropha glandulifera* Roxb.
13.	Dugdhika (Wh.Pl.)	*Euphorbia prostrata* W. Ait.
14.	Elavaluka (Sd.)	*Prunus avium* Linn.f.
15.	Gandira (Rt.)	*Coleus forskohlii* Briq.
16.	Gavedhuka (Rt.)	*Coix lachryma-jobi* Linn.
17.	Ghonta (Fr.)	*Ziziphus xylopyrus* Willd.
18.	Gundrah (Rz. & Rt.)	*Typha australis* Schum. and Thonn.
19.	Himsra (Rt.)	*Capparis spinosa* Linn.

20. Hingupatri (Lf.)	*Ferula jaeschkeana* Vatke
21. Itkata (Rt.)	*Sesbania bispinosa* W.F.Wight
22. Itkata (St.)	*Sesbania bispinosa* W.F.Wight
23. Jalpippalika (Wh.Pl.)	*Phyla nodiflora* Greene
24. Jivak (Pseudo-bulb)	*Malaxis acuminata* D.Don
25. Kadara (Ht. Wd.)	*Acacia suma* Buch.-Ham.
26. Kakajangha (Sd.)	*Peristrophe bicalyculata* (Retz.) Nees
27. Kakanaja (Fr.)	*Physalis alkekengi* Linn.
28. Kapitan (St.Bk.)	*Thespesia populnea* (L.) Soland. ex Correa
29. Karkash (Rt.)	*Momordica dioica* Roxb. ex Willd.
30. Karnasphota (Sd.)	*Cardiospermum halicacabum* Linn.
31. Karnasphota (Rt.)	*Cardiospermum halicacabum* Linn.
32. Kattrna (Wh.Pl.)	*Cymbopogon citratus* (DC.) Stapf
33. Kebuka (Rz.)	*Costus speciosus* (Koerning ex Retz.) Smith.
34. Khaskhas (Sd.)	*Papaver somniferum* Linn.
35. Khatmi (Rt.)	*Althaea officinalis* Linn.
36. Khatmi (Sd.)	*Althaea officinalis* Linn.
37. Khubkalan (Sd.)	*Sisymbrium irio* Linn.
38. Kodrava (Grain)	*Paspalum scrobiculatum* Linn.
39. Ksirakakoli (Bulb)	*Fritillaria roylei* Hook.
40. Kshiravidari (Rt.)	*Ipomoea digitata* Linn.
41. Kulanjan (Rz.)	*Alpinia galanga* Willd.
42. Kumbhikah (Sd.)	*Careya arborea* Roxb.
43. Latakaranja (Sd.)	*Caesalpinia bonduc* (Linn.) Roxb.
44. Lavaliphala (Fr.)	*Phyllanthus acidus* (Linn.) Skeels
45. Madhulika (Rt.)	*Eleusine corocana* (L.) Gaertn.
46. Mahameda (Rz.&Rt.)	*Polygonatum cirrhifolium* Royle
47. Mahdusnuhi (Tub.Rt.)	*Smilax china* Linn.
48. Maramanjal (Rt. & St.)	*Coscinium fenestratum* (Gaertn.) Colebr.
49. Medasakah (St.Bk.)	*Litsea chinensis* Lam.
50. Medasakah (Wd.)	*Litsea chinensis* Lam.
51. Mesasrngi (Lf.)	*Gymnema sylvestre* R.Br.
52. Mesasrngi (Rt.)	*Gymnema sylvestre* R.Br.
53. Nandi (Rt.)	*Ficus arnottiana* Miq.
54. Nilajhintika (Rt.)	*Barleria strigosa* Willd.
55. Nimba (Rt.Bk.)	*Azadirachta indica* A.Juss.
56. Nimba (Fl.)	*Azadirachta indica* A.Juss.
57. Nimba (Fr.)	*Azadirachta indica* A.Juss.
58. Palas (Sd.)	*Butea monosperma* (Lam.) Kuntze
59. Palas (Fl.)	*Butea monosperma* (Lam.) Kuntze
60. Parasikayavani (Sd.)	*Hyoscyamus niger* Linn.
61. Pattura (Wh.Pl.)	*Aerva lanata* (Linn.) Juss.
62. Pilu (Fr.)	*Salvadora persica* Linn.
63. Pilu (Lf.)	*Salvadora persica* Linn.
64. Pilu (Rt.Bk.)	*Salvadora persica* Linn.
65. Potagala (Rt.)	*Typha elephantina* Roxb.

66.	Pudina (Aerial Part)	*Mentha viridis* Linn.
67.	Pullani (Lf.)	*Calycopteris floribunda* Lam.
68.	Pullani (Rt.)	*Calycopteris floribunda* Lam.
69.	Pullani (St.)	*Calycopteris floribunda* Lam.
70.	Putikaranjah (St.Bk.)	*Caesalpinia crista* Linn.
71.	Renuka (Fr.)	*Vitex negundo* Linn.
72.	Riddhi (Tuber)	*Habenaria intermedia* D.Don
73.	Rohisa (Wh.Pl.)	*Cymbopogon martinii* (Roxb.) Wats
74.	Rumimustagi (Resin)	*Pistacia lentiscus* Linn.
75.	Sarala (Exudate)	*Pinus roxburghii* Sargent
76.	Sarpagandha (Rt.)	*Rauwolfia serpentina* (Linn.) Benth. ex Kur
77.	Svetapunarnava (Rt.)	*Boerhaavia verticillata* Poir.
78.	Tailaparna (Lf.)	*Eucalyptus globulus* Labill.
79.	Tinisha (Wd.)	*Ougeinia oojeinensis* (Roxb.) Hochr.
80.	Tintidika (Aerial Part)	*Rhus parviflora* Roxb.
81.	Trapusa (Sd.)	*Cucumis sativus* Linn.
82.	Tuni (St.Bk.)	*Cedrela toona* Roxb.
83.	Vanda (Lf.)	*Dendrophthoe falcata* (Linn.f.) Ettingsh.
84.	Vanda (St.)	*Dendrophthoe falcata* (Linn.f.) Ettingsh.
85.	Vanda (Aerial Rt.)	*Dendrophthoe falcata* (Linn.f.) Ettingsh.
86.	Vanda (Fl.)	*Dendrophthoe falcata* (Linn.f.) Ettingsh.
87.	Vanda (Fr.)	*Dendrophthoe falcata* (Linn.f.) Ettingsh.
88.	Vanyajiraka (Fr.)	*Centratherum anthelminticum* (L.) Kuntze
89.	Vidarikand (Tuber)	*Pueraria tuberosa* DC.
90.	Virala (St.Bk.)	*Diospyros exsculpta* Buch.-Ham.
91.	Visala (Rt.)	*Trichosanthes bracteata* (Lam.) Voigt
92.	Vyaghranakhi (Fr.)	*Capparis horrida* Linn.

APPENDIX VII

List of Quality Standards Monographs Published in the European Pharmacopoeia (PhEur) and/or United States Pharmacopeia (USP)

Botanical Species	Plant Part or Form	PhEur	USP
Acacia senegal	Dried gummy exudate from the stems and branches	X	X
"	Spray-dried solution of Acacia	X	
Acacia seyal	Air-hardened, gummy exudate from trunk and branches	X	
"	Spray-dried solution of Acacia	X	
Achillea millefolium	Dried flowering tops	X	
Actaea racemosa	Dried rhizome and roots		X
"	Fluidextract of dried rhizome and roots		X
"	Powdered extract of dried rhizome and roots		X
"	Tablets prepared from powdered extract		X
Aesculus hippocastanum	Dried seeds		X
"	Powdered dried seeds		X
"	Powdered extract from the dried seeds		X
Agrimonia eupatoria	Dried flowering tops	X	
Agropyron repens	Washed and dried rhizome	X	
Alchemilla xanthochlora	Dried, flowering aerial parts	X	
Allium sativum	Fresh or dried compound bulbs		X
"	Powdered dried compound bulbs	X	X
"	Fluidextract from fresh or dried bulbs		X
"	Powdered extract from fresh bulbs		X
"	Delayed-released tablets from powdered bulb or extract		X
Aloe barbadensis	Dried latex (juice) of the leaves	X	X
"	Standardized dry extract	X	
Aloe ferox	Dried latex (juice) of the leaves	X	X
"	Standardized dry extract	X	
Aloe ferox & hybrids with *A. africana* & *A. spicata*	Dried latex (juice) of the leaves	X	X
Aloysia citriodora	Dried leaf	X	
Althaea officinalis	Dried leaf	X	
"	Dried root	X	
Angelica archangelica	Dried rhizome and root	X	
Arctostaphylos uva-ursi	Dried leaf	X	
Arnica montana	Dried flowerheads	X	
"	Arnica Tincture	X	
Artemisia absinthium	Dried basal leaves or slightly leafy, flowering tops	X	
Ascophyllum nodosom	Dried thallus	X	
Astragalus gummifer	Dried gummy exudation (tragacanth)		X
Atropa belladonna	Dried leaf and flowering or fruiting top	X	X
"	Prepared leaf powder (adjusted if necessary)	X	
"	Powdered extract from dried leaf	X	X
"	Tablets prepared from powdered extract		X
"	Hydroalcoholic tincture of leaf	X	X
Avena sativa & *A. byzantina*	Powder resulting from grinding and further processing of whole grain (colloidal oatmeal)		X
Ballota nigra	Dried flowering tops	X	
Betula pendula and/or B. pubescens	Dried leaf	X	
Borago officinalis	Refined (starflower) oil	X	
Boswellia serrata	Air-dried gum-resin exudate from stem or branches	X	
Calendula officinalis	Dried and fully opened flowers, detached from receptacle	X	
Capsicum annuum	Dried ripe fruit	X	X
"	Oleoresin (alcoholic extract of dried ripe fruits)	X	X
"	Standardized Capsicum Tincture	X	

Botanical Species	Plant Part or Form	PhEur	USP
Capsicum frutescens	Dried ripe fruit	X	X
"	Oleoresin (alcoholic extract of dried ripe fruits)	X	X
Carica papaya	Purified proteolytic substance (papain)		X
Carthamus tinctorius	Dried flower	X	
"	Fatty oil obtained from seeds	X	
Carum carvi	Dried ripe fruit	X	X
"	Essential oil distilled from dried ripe fruit	X	X
Cassia acutifolia (C. senna)	Dried leaflet	X	X
"	Dried ripe fruits	X	X
"	Senna fluidextract		X
"	Senna Oral Solution prepared from fluidextract		X
"	Partially purified natural complex of anthraquinone glucosides from leaflets or pods (sennosides)		X
"	Standardized dry extract of leaf	X	
"	Tablets containing sennosides		X
Cassia angustifolia	Dried leaflet	X	X
"	Dried ripe fruits	X	X
"	Senna Fluidextract		X
"	Senna Oral Solution prepared from fluidextract		X
"	Partially purified natural complex of anthraquinone glucosides from leaflets or pods (sennosides)		X
"	Standardized dry extract of leaf	X	
"	Tablets containing sennosides		X
Centaurium erythraea	Dried flowering aerial parts	X	
Centella asiatica	Dried aerial parts	X	
Cephaëlis acuminata, Cephaëlis ipecacuanha	Dried rhizome and roots	X	X
"	Powdered dried rhizome and roots	X	X
"	Ipecac Oral Solution from powdered ipecac & glycerin		X
"	Standardized liquid extract of root	X	
"	Standardized tincture of root	X	
Cetraria islandica	Dried thallus	X	
Chamaemelum nobile	Dried flower-heads	X	
Chelidonium majus	Dried flowering aerial parts	X	
Chondrus crispus or C. *ocellatus*	Hydrocolloid obtained by extraction with water or aqueous alkali (carrageenan)		X
Cinchona pubescens, C. calisaya or hybrids	Dried bark	X	
"	Standardized liquid extract of dried bark	X	
Cinchona spp.	Sulfate of an alkaloid obtained from the bark		X
Cinnamomum camphora	Ketone obtained from (natural camphor)	X	X
"	Essential oil from leaves & young branches	X	
"	Essential oil distilled from leaves	X	
Cinnamomum zeylanicum	Dried bark freed from outer cork and underlying parenchyma of shoots	X	
"	Essential oil of bark of the shoots	X	
"	Tincture of bark of the shoots	X	
Citrus aurantium ssp. aurantium	Dried epicarp and mesocarp of ripe fruit	X	
"	Tincture of dried epicarp and mesocarp	X	
"	Dried, unopened flower	X	
"	Essential oil distilled from fresh flowers	X	
Citrus × limon	Essential oil from fresh peel of fruit	X	X
"	Tincture of outer yellow rind of fresh ripe fruit		X
"	Essential oil from fresh peel of fruit	X	
Citrus sinensis	Essential oil from fresh peel of ripe fruit	X	X
"	Tincture from outer rind of fresh, ripe fruit		X
Cocos nucifera	Refined fixed oil from the seeds	X	X

Botanical Species	Plant Part or Form	PhEur	USP
Cola nitida or Cola acuminata	Dried seeds freed from the testa	**X**	
Commiphora molmol	Oleo-gum-resin obtained from stems and branches	**X**	**X**
"	Myrrh Topical Solution (alcoholic tincture)	**X**	**X**
Copernicia cerifera	Wax obtained from the leaves	**X**	**X**
Coriandrum sativum	Dried cremocarp	**X**	
"	Essential oil from the dried ripe fruit	**X**	**X**
Crataegus azarolus	Dried flower bearing branches	**X**	
Crataegus monogyna or C. laevigata	Leaf and flower; dried tips of the flower-bearing branches	**X**	**X**
"	Powdered leaf and flower		**X**
"	Dry extract of leaf and flower	**X**	
"	Quantified liquid extract of leaf and flower	**X**	
"	Dried false fruits	**X**	
Crataegus nigra	Dried flower bearing branches	**X**	
Crataegus pentagyna	Dried flower bearing branches	**X**	
Curcuma xanthorrhiza	Dried rhizome	**X**	
Cyamopsis tetragonolobus	Gum obtained from the ground endosperms	**X**	**X**
Cymbopogon winterianus	Essential oil distilled from fresh or partially dried aerial parts	**X**	
Cynara scolymus	Dried leaf	**X**	
Datura stramonium	Dried leaf	**X**	
"	Prepared Stramonium	**X**	
Digitalis purpurea	Dried leaf	**X**	**X**
"	Powdered dried leaf		**X**
"	Capsules containing powdered leaf		**X**
"	Tablets containing powdered leaf		**X**
"	Cardiotonic glycoside obtained from (digitoxin)	**X**	**X**
"	Cardiotonic glycoside obtained from leaf (digoxin)	**X**	**X**
Echinacea angustifolia	Dried rhizome and roots	**X**	**X**
"	Powdered dried rhizome and roots		**X**
"	Powdered extract from dried rhizome and roots		**X**
Echinacea pallida	Dried rhizome and roots	**X**	**X**
"	Powdered dried rhizome and roots		**X**
"	Powdered extract from dried rhizome and roots		**X**
Echinacea purpurea	Dried aerial parts (flowering)	**X**	**X**
"	Dried rhizome and roots	**X**	**X**
"	Powdered dried rhizome and roots		**X**
"	Powdered extract of dried root and/or aerial parts		**X**
Elaeis guineensis	Refined fixed oil obtained from kernel of fruit		**X**
Elettaria cardamomum	Dried ripe seed		**X**
"	Essential oil distilled from the seed		**X**
Eleutherococcus senticosus	Dried rhizome with roots	**X**	**X**
"	Powdered dried rhizome with roots		**X**
"	Powdered extract from dried rhizome & roots		**X**
Equisetum arvense	Dried sterile aerial parts	**X**	
Eucalyptus globulus	Dried leaves of older branches	**X**	
"	Essential oil distilled from fresh leaves or fresh terminal branchlets	**X**	
Eucalyptus polybractea	Essential oil distilled from fresh leaves or fresh terminal branchlets	**X**	
Eucalyptus smithii	Essential oil distilled from fresh leaves or fresh terminal branchlets	**X**	
Eucheuma cottonii or *Eucheuma spinosum*	Hydrocolloid obtained by extraction with Water or aqueous alkali (carrageenan)		**X**
Eucheuma gelatinae	Hydrocolloid obtained by extraction with water or aqueous alkali (galageenan)		**X**
Euphorbia antisyphilitica	Purified wax obtained from the leaves		**X**

Botanical Species	Plant Part or Form	PhEur	USP
Fagopyrum esculentum	Dried aerial parts (flowering)	X	
Filipendula ulmaria	Dried herb / flowers	X	
"	Essential oil distilled from dried ripe fruit		X
Foeniculum vulgare Sp. vulgare var. dulce	Dried cremocarps and mericarps	X	
Foeniculum vulgare sp. vulgare var. vulgare	Dried cremocarps and mericarps	X	
"	Essential oil distilled from the ripe fruits	X	
Fraxinus excelsior or F. oxyphylla	Dried leaf	X	
Fucus serratus	Dried thallus	X	
Fucus vesiculosus	Dried thallus	X	
Gelidium cartilagineum	Dried, hydrophilic, colloidal substance (agar)	X	X
Gentiana lutea	Dried underground organs	X	
"	Tincture of dried underground organs	X	
Gigartina acicularis, G. pistillata, G. radula, G. stellata	Hydrocolloid obtained by extraction with Water or aqueous alkali (carrageenan)		X
Ginkgo biloba	Dried leaf	X	X
"	Powdered extract from dried leaf		X
"	Capsules containing powdered extract		X
"	Tablets containing powdered extract		X
Glycine max & Glycine soja	Refined fixed oil obtained from soya seeds	X	X
Glycyrrhiza glabra	Dried roots, rhizomes and stolons	X	X
"	Powdered dried roots, rhizome and stolons		X
"	Fluidextract of dried root, rhizome and stolon	X	X
"	Powdered extract of dried root, rhizome & stolon		X
Glycyrrhiza inflata	Dried root and stolons	X	
"	Standardized liquid extract of root and stolons	X	
Glycyrrhiza uralensis	Dried roots, rhizome and stolons	X	X
"	Powdered dried roots, rhizome and stolons		X
"	Fluidextract of dried root, rhizome and stolon	X	X
"	Powdered extract of dried root, rhizome & stolon		X
Gracilaria confervoides	Dried, hydrophilic, colloidal substance (agar)		X
Hamamelis virginiana	Dried leaf	X	
"	Clear, colorless distillate prepared from recently cut and partially dried dormant twigs		X
Harpagophytum procumbens	Dried tuberous secondary roots	X	
"	Dry extract of dried tuberous secondary roots	X	
Hedera helix	Dried leaf	X	
Hibiscus sabdariffa	Dried calyces and epicalyces	X	
Humulus lupulus	Dried, female inflorescences	X	
Hydrastis canadensis	Dried roots and rhizomes	X	X
"	Powdered dried root and rhizome		X
"	Powdered extract from pulverized root & rhizome		X
Hypericum perforatum	Dried flowering tops or aerial parts	X	X
"	Powdered dried flowering tops		X
"	Powdered extract from dried flowering tops		X
Illicium verum	Dried composite fruit	X	
"	Essential oil from dried, ripe fruit	X	X
Juniperus communis	Dried ripe cone berry	X	
"	Essential oil distilled from ripe, non-fermented berry cone	X	
Juniperus oxycedrus	Empyreumatic volatile oil from woody portions		X
Krameria triandra	Dried underground organs	X	
"	Tincture of dried underground organs	X	

Botanical Species	Plant Part or Form	PhEur	USP
Lavandula angustifolia	Dried flower	**X**	
"	Essential oil distilled from flowering tops	**X**	
Leonurus cardiaca	Dried flowering aerial parts	**X**	
Levisticum officinale	Dried rhizome and root	**X**	
Linum usitatissimum	Dried, ripe seeds	**X**	
"	Virgin linseed oil	**X**	
Liquidambar orientalis	Balsam obtained from the trunk (storax)		**X**
Liquidambar styraciflua	Balsam obtained from the trunk (storax)		**X**
Lycopersicon esculentum	Ethyl acetate extract of the natural tomato lipids produced from the pulp of ripe fruits		**X**
Lythrum salicaria	Dried flowering tops	**X**	
Malva sylvestris	Dried flower	**X**	
Marrubium vulgare	Dried leaves and flowering tops	**X**	
Matricaria recutita	Dried flower heads (capitula)	**X**	**X**
"	Essential oil distilled from fresh or dried flowering tops	**X**	
"	Liquid extract of dried capitula	**X**	
Melaleuca alternifolia, M. linarifolia, M. dissitiflora	Essential oil distilled from the foliage and terminal branchlets	**X**	
Melilotus officinalus	Dried aerial parts	**X**	
Melissa officinalis	Dried leaf	**X**	
Mentha canadensis	Essential oil distilled from fresh flowering aerial parts	**X**	
Mentha × piperita	Dried leaf and flowering top		**X**
"	Dried leaf	**X**	
"	Essential oil distilled from fresh aerial parts	**X**	**X**
"	Peppermint Spirit		**X**
"	Peppermint Water		**X**
Menyanthes trifoliata	Dried leaf	**X**	
"	Essential oil distilled from dried and crushed kernels	**X**	
Myroxylon balsamum	Balsam obtained from trunk	**X**	**X**
"	Oleo-resin obtained from trunk	**X**	
"	Tolu Balsam Syrup		**X**
"	Tolu Balsam Tincture		**X**
Oenothera biennis	Refined oil	**X**	
Olea europaea	Dried leaf	**X**	
"	Fixed oil obtained from ripe fruit	**X**	**X**
Ononis spinosa	Dried root	**X**	
Origanum onites or O. vulgare subsp. hirtum	Dried leaves and flowers separated from stems	**X**	
Orthosiphon stamineus	Dried leaves and tops of stems	**X**	
Palaquium gutta	Coagulated, dried, purified latex (gutta percha)		**X**
Panax ginseng	Dried roots	**X**	**X**
"	Powdered dried roots		**X**
"	Powdered extract from dried roots		**X**
"	Tablets prepared from powdered extract		**X**
Panax notoginseng	Dried root	**X**	
Panax quinquefolius	Dried root		**X**
"	Powdered dried roots		**X**
"	Powdered extract from pulverized dried roots		**X**
Papaver rhoeas	Dried flower petals	**X**	
Papaver somniferum	Air-dried milky exudate from unripe capsules	**X**	**X**
"	Powdered Opium (adjusted if necessary)	**X**	**X**
"	Standardized dry extract of opium	**X**	
"	Standardized opium tincture	**X**	**X**
Passiflora incarnata	Dried aerial parts	**X**	
"	Dry extract of dried aerial parts	**X**	
Payena spp.	Coagulated, dried, purified latex (gutta percha)		**X**
Pelargonium sidoides or P.	Dried underground organs	**X**	

reniforme			
Botanical Species	**Plant Part or Form**	**PhEur**	**USP**
Peumus boldus	Dried leaf	**X**	
Pimpinella ansium	Dry cremocarp	**X**	
"	Essential oil from dried, ripe fruit (cremocarp)	**X**	**X**
Pinus mugo	Essential oil of pine needles	**X**	
Pinus pinaster	Bark of stems		**X**
"	Extract from pulverized bark of stems		**X**
"	Essential oil distilled from the oleoresin (turpentine oil)	**X**	
Pinus sylvestris	Essential oil	**X**	
Pistacia lentiscus var. latifolius	Dried resinous exudate from stems and branches	**X**	
Plantago afra	Ripe, dry seeds	**X**	
Plantago arenaria	Cleaned, dried epidermis (husk)		**X**
Plantago indica	Cleaned, dried, ripe seed	**X**	**X**
Plantago lanceolata	Dried leaf and scape	**X**	
Plantago ovata	Cleaned, dried, ripe seed	**X**	**X**
"	Hemicellulose; alkali soluble fraction of the husk		**X**
"	Cleaned, dried epidermis (husk)	**X**	**X**
"	Psyllium Hydrophilic Mucilloid for Oral Suspension		**X**
Plantago psyllium	Cleaned, dried, ripe seed		**X**
Podophyllum peltatum	Dried rhizomes and roots		**X**
"	Powdered mixture of extracted resins		**X**
"	Podophyllum Resin Topical Solution		**X**
Polygala senega	Dried root and root crown	**X**	
Polygonum aviculare	Dried aerial parts	**X**	
Polygonum bistorta	Dried rhizome	**X**	
Potentilla erecta	Dried rhizome, freed from the roots	**X**	
"	Tincture prepared from dried rhizome	**X**	
Primula veris or Primula elatior	Dried rhizome and root	**X**	
Prunus africana	Dried bark of stems and branches	**X**	**X**
"	Extract prepared from pulverized bark		**X**
"	Capsules containing extract		**X**
Prunus cerasus	Liquid expressed from the fresh ripe fruit		**X**
Quercus robur, Q. petraea & Q. pubescens	Dried bark from fresh young branches	**X**	
Rauvolfia serpentina	Dried root		**X**
"	Powdered dried root		**X**
"	Tablets containing powdered dried root		**X**
Remijia pedunculata	Gluconate of an alkaloid obtained from		**X**
"	Sulfate of an alkaloid obtained from		**X**
Rhamnus frangula	Dried bark of the stems and branches	**X**	
"	Standardized dry extract of bark	**X**	
Rhamnus purshiana	Dried bark, aged	**X**	**X**
"	Dried extract	**X**	**X**
"	Fluidextract prepared with boiling water		**X**
"	Fluidextract prepared with magnesium oxide, Sweeteners, essential oils, alcohol, and water		**X**
"	Tablets prepared from extract		**X**
Rheum officinale	Dried underground parts	**X**	
Rheum palmatum	Dried underground parts	**X**	
Ricinus communis	Fixed oil obtained from seed	**X**	**X**
"	Aromatic Castor Oil (with flavors)		**X**
"	Capsules containing castor oil		**X**
"	Castor Oil Emulsion		**X**
Rosa alba	Essential oil distilled from fresh flowers		**X**
Rosa canina	Receptacle and remains of dried sepals	**X**	
Rosa centifolia	Essential oil distilled from fresh flowers		**X**

Botanical Species	Plant Part or Form	PhEur	USP
"	Stronger Rose Water		X
Rosa damascena	Essential oil distilled from fresh flowers		X
Rosa gallica	Essential oil distilled from fresh flowers		X
Rosa pendulina	Receptacle and remains of dried sepals	X	
Rosmarinus officinalis	Dried leaf	X	
"	Essential oil distilled from flowering aerial parts	X	
Ruscus aculeatus	Dried underground parts	X	
Salix daphnoides, S. fragilis, S. purpurea	Dried bark of young branches or dried pieces of current year twigs	X	
Salvia fruticosa	Dried leaf	X	
Salvia officinalis	Dried leaf	X	
"	Tincture of dried leaf	X	
Salvia sclarea	Essential oil distilled from fresh or dried flowering stems	X	
Sambucus nigra	Dried flowers	X	
Serenoa repens	Dried, ripe fruit	X	X
"	Powdered partially dried, ripe fruit		X
"	Extract obtained from comminuted dried ripe fruit		X
"	Capsules containing extract		X
Silybum marianum	Dried ripe fruit (devoid of pappus)	X	X
"	Powdered dried ripe fruit		X
"	Powdered extract of dried ripe fruit	X	X
"	Capsules containing powdered extract		X
"	Tablets containing powdered extract		X
Solidago gigantea or S. canadensis	Dried flowering aerial parts	X	
Solidago virgaurea	Dried flowering aerial parts	X	
Styrax benzoin	Balsamic resin (benzoin)	X	X
"	Benzoin Tincture	X	
Styrax paralleloneurus	Balsamic resin (benzoin)	X	X
"	Benzoin Tincture	X	
Styrax tonkinensis	Balsamic resin (benzoin)	X	X
"	Benzoin Tincture	X	
Syzygium aromaticum	Dried whole flower buds	X	
"	Essential oil distilled from dried flower bud	X	X
"	Dried fruit		
Tanacetum parthenium	Dried leaf		X
"	Powdered dried leaf		X
"	Dried aerial parts	X	
Theobroma cacao	Powder from roasted, cured kernels of ripe seed		X
"	Fat obtained from the seed		X
Thymus vulgaris, or T. zygis	Leaves and flowers separated from dried stems	X	
"	Essential oil distilled from fresh flowering aerial parts	X	
Thymus serpyllum	Dried flowering aerial parts	X	
Tilia cordata, T. platyphyllos, or T. × vulgaris	Dried inflorescence	X	
Trifolium pratense	Dried inflorescence		X
"	Powdered dried inflorescence		X
"	Powdered extract from dried inflorescence		X
"	Tablets containing powdered extract		X
Trigonella foenum-graecum	Dried, ripe seeds	X	
Triticum aestivum, T. compactum & T. durum	Outer fraction of the cereal grain (pericarp, seed coat (testa), nucellar tissue, and aleurone layer)	X	X
Ulmus rubra	Dried inner bark		X
Urtica dioica ssp *dioica* &	Dried roots and rhizomes		X

U. urens			
Botanical Species	**Plant Part or Form**	**PhEur**	**USP**
"	Powdered dried root and rhizome		**X**
"	Powdered extract from dried root & rhizome		**X**
"	Dried leaf	**X**	
Vaccinium macrocarpon	Bright red juice derived from the fruits		**X**
Vaccinium myrtillus	Dried ripe fruit	**X**	
"	Fresh or frozen ripe fruit	**X**	
Valeriana officinalis	Subterranean parts (rhizome, root, stolon)	**X**	**X**
"	Powdered subterranean parts		**X**
"	Powdered extract of subterranean parts	**X**	**X**
"	Tablets containing powdered extract		**X**
"	Tincture of dried underground parts	**X**	
Vanilla planifolia & V. tahitensis	Cured, full-grown, unripe fruit		**X**
"	Vanilla Tincture		**X**
Verbascum thapsus, V. densiflorum, & V. phlomoides	Dried flower, reduced to the corolla and the androecium	**X**	
Verbena officinalis	Dried aerial parts	**X**	
Viola arvensis	Dried flowering aerial parts	**X**	
Viola tricolor	Dried flowering aerial parts	**X**	
Vitex agnus-castus	Dried ripe fruit	**X**	**X**
"	Powdered dried ripe fruit		**X**
"	Powdered extract of dried ripe fruit		**X**
Zea mays	Granules separated from the mature grain of corn	**X**	**X**
Zingiber officinale	Dried rhizome	**X**	**X**
"	Powdered dried rhizome		**X**
"	Capsules containing powdered dried rhizome		**X**
"	Hydroalcoholic Tincture		**X**

APPENDIX VIII

Export Inspection Council (EIC) Export of Ayurvedic, Unani and Siddha (Quality Control, Inspection and Monitoring) Rules, 2008

[TO BE PUBLISHED IN THE GAZETTE OF INDIA PART II, SECTION 3, SUB-SECTION (ii)]

GOVERNMENT OF INDIA
MINISTRY OF COMMERCE AND INDUSTRY
(DEPARTMENT OF COMMERCE)
NEW DELHI

New Delhi, Dated the 16-4-2008

ORDER

S O - Whereas in exercise of the powers conferred by section 6 of the Export (Quality Control and Inspection) Act, 1963 (22 of 1963), the Central Government is of the opinion that it is necessary and expedient to do so for the development of the export trade of India that Ayurvedic, Unani and Siddha products should be subject to quality control and inspection prior to export----;

And whereas, the quality standards prescribed by the Department of AYUSH vide Order F No 11020/5/97-DCC(AYUSH) dated the 14th October, 2005 and subsequent Orders issued thereafter have been taken into account;

And whereas, Ayurvedic, Unani and Siddha products are in principle free of contamination and micro-organisms but contamination and subsequent decomposition may occur when handled and treated un-hygienically;

And, therefore, the essential requirements should be laid down for correct hygienic handling of Ayurvedic, Unani and Siddha products at all stages of production and during harvesting, processing, handling, storage and transport;

And whereas, it is the primary responsibility of the processor to ensure that Ayurvedic, Unani and Siddha products meet the requirements laid down in the proposal;

And whereas, the competent authority nominated by the Central Government shall ensure the effective compliance of the quality standards in the country;

And whereas, the Central Government has formulated the proposal specified below for the said purpose and has forwarded the same to the Export Inspection Council as required by sub-rule (2) of rule 11 of the Export (Quality Control and Inspection) Rules,1964;

Now, therefore, in pursuance of sub-rule (2) of rule 11of the Export (Quality Control and Inspection) Rules, 1964, the Central Government hereby publishes the proposal for information of the general public likely to be affected thereby, and notice is hereby given that any person who desires to make any objection or suggestion with respect to the said proposals may forward the same within **thirty days** of the date of publication of this Order in the Official Gazette to the Export Inspection Council of India, 3rd Floor, New Delhi YMCA Cultural Centre Building, 1, Jai Singh Road, New Delhi – 110001

PROPOSAL

1 To notify that Ayurvedic, Unani and Siddha products shall be subjected to quality control and inspection prior to export;

2 To specify the type of quality control and inspection in accordance with the draft Export of Ayurvedic, Unani and Siddha (Quality Control, Inspection and Monitoring) Rules, 2008 set out in the Annexure appended to this Order;

3 To recognise the specifications as set out in the Schedule as appended to this Order as the standard specification for Ayurvedic, Unani and Siddha products; and

4 To prohibit the export of Ayurvedic, Unani and Siddha products in the course of international trade unless it conforms to the standard specifications applicable to it and is accompanied by a certificate of inspection or certificate that such unit is approved and monitored by the Export Inspection Agency established under section 7 of the Export (Quality Control and Inspection) Act, 1963 including its sub offices located at various places of the region.

SCHEDULE

Specifications for Ayurvedic, Unani and Siddha products recognised as per section 6 of the Export (Quality Control and Inspection) Act, 1963 shall be –

(a) Of national standards of the importing countries; or

(b) Contractual specifications agreed to between the foreign buyer and the exporters provided the same are satisfying the health requirements of the importing countries;

(c) In the case of any Ayurvedic, Unani and Siddha products for which no standard is available at (a) and (b) above, the standards, if any, as formulated by the Specialist Committee constituted under the provisions of the Export (Quality Control and Inspection) Act, 1963

APPENDIX

SPECIFICATIONS OF AYURVEDIC, SIDDHA AND UNANI PRODUCTS INTENDED FOR EXPORTS

1. Permissible Limit of Heavy Metals :

S.No.	Heavy Metal Content (1)	Permissible Limits (2)
1	Lead (Pb)	10 ppm
2	Cadmium (Cd)	0.30 ppm
3	Arsenic (As)	3 ppm
4	Mercury (Hg.)	1 ppm

2. Pesticides Residues :

S.No.	Pesticides (1)	Permissible Limits (2)
1	Quinolphos	0.01 ppm
2	DDE+DDT+DDD sum of	1.00 ppm
3	Alderin+ Dieldrin sum of	0.05 ppm
4	HCH (Hexa Chloro Cyclohexane)	0.30 ppm
5	HCB (Hexa Chloro Benxene)	0.10 ppm
6	Alachlor	0.02 ppm
7	Lindane	0.60 ppm
8	Chlordane	0.05 ppm
9	Endosulfan & its isomers	3.00 ppm

3. Aflatoxins :

S.No.	Aflatoxin (1)	Permissible Limits (2)
1	B1	5.0 ppb
2	B1+ G1 + B2 +G2 sum of	10.0 ppb

4. Microbial Contamination Limits:

S.No.	Parameters (1)	Permissible Limits (2)
1	*Staphylococcus aureus*/g.	Absent
2	*Salmonella sp.*/10g.	--do--
3	*Pseudomonas aeruginosa*	--do--
4	*E.Coli*/10g.	--do--
5	Total Plate Count (TPC)	10^5 /g.[+]
6	Total Yeast & Mould	10^3 /g.

[+] For topical use, the limit shall be 10^7 /g

1) Tests for heavy metals are not applicable for products meant for topical use
2) The above specifications limits shall not be applicable to Ayurvedic, Unani and Siddha products, having non-human application (internal or external).
3) Testing reference to be made to the publication "PROTOCOL FOR TESTING - Ayurveda, Unani and Siddha medicines", Pharmacopoeia Laboratory for Indian medicines, Ghaziabad, March, 2007; and Ayurvedic Pharmacopoeia of India and Unani Pharmacopoeia of India, issued by Department of AYUSH, Ministry of Health and Family Welfare, Government of India

Annexure

DRAFT RULES PROPOSED TO BE MADE UNDER SECTION 17 OF THE EXPORT (QUALITY CONTROL AND INSPECTION) ACT 1963 (22 of 1963)

1. **Short title and commencement** –

(1) These rules may be called the Export of Ayurvedic, Unani and Siddha (Quality Control, Inspection and Monitoring) Rules, 2008

(2) They shall come into force on the date of their final publication in the Official Gazette;

2. **Definitions** .- In these rules, unless the context otherwise requires -,-

(a) **"Act"** means the Export (Quality Control and Inspection) Act, 1963 (22 of 1963) ;

(b) **"Ayurvedic, Siddha or Unani drug"** includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of (disease or disorder in human beings or animals, and manufactured) exclusively in accordance with the formulae described in the authoritative books of (Ayurvedic, Siddha and Unani Tibb systems of medicine);

(c) **"Agency"** means any one of the Export Inspection Agency at Chennai, Delhi, Kolkata, Kochi, and Mumbai established under sub-section (1) of section 7 of the Act;

(d) **"Batch"** means a quantity of Ayurvedic, Unani and Siddha Products collected or processed from the same source of raw materials on the same day;

(e) **"Council"** means Export Inspection Council established under section 3 of the Export (Quality Control and Inspection) Act 1963;

(f) **"Competent Authority'** means any one of the Export Inspection Agencies (EIAs) established under section 7 of Export (Quality Control and Inspection) Act, 1963 at Chennai, Delhi, Kochi, Kolkata and Mumbai;

(g) **"Consignment"** means a quantity of Ayurvedic, Unani and Siddha products processed and subsequently intended for one or more customers;

3. **Types of Inspection or Certification**-- In order to ensure the safety and quality of Ayurvedic, Unani and Siddha products exported from India and facilitate smooth trade of these products, any one of the three types of inspection or certification systems shall be followed, namely:-

Level 1: Consignment wise inspection for ensuring safety with regard to contaminants such as heavy metals, pesticides, aflatoxins and microbes;- or
Level 2: Systems approach to include end-product quality as well as implementation of Good Manufacturing Practices (GMP) by the processor;- or
Level 3: Safety, quality and efficacy through independent review of dossier submitted by the manufacturer

4. **Basis of compliance** .-

(1) Ayurvedic, Unani and Siddha products intended for exports shall comply with the standards notified in the Appendix to the Schedule. In addition, the product shall also comply with the following requirements, namely:-

I Implementation of Good Manufacturing Practices (GMP) Notified under Drugs and Cosmetic Act, 1940 (as revised on the 23rd June 2000) for Ayurvedic, Unani and Siddha medicine, if certified under Level 2
II Compliance of the Dossiers to the requirements of the importing country as per bilateral agreements between the two countries, if certified under Level 3

(2) Certification under Level 2

(a) It is the primary responsibility of the industry or processor to ensure that Ayurvedic, Unani and Siddha products intended for export are processed and handled at all stages of production, storage, and transport under proper hygienic and manufacturing conditions and that the products conforms to the specifications given in the Order by the Central Government under section 6 of the Act-;

(b) The Competent Authority shall conduct regular monitoring of the establishments to ensure that Good Manufacturing Practices (GMP) and Good Hygienic Practices (GHP) are adopted by the establishment at all stages of production, storage and transport of Ayurvedic, Unani and Siddha products For effective monitoring of the Scheme, Export Inspection Council will issue necessary instructions in this regard;

(c) Having satisfied itself that the establishments meet the requirements with regard to nature of activities they carry out, the Competent Authority shall accord approval to establishments. The Council shall draw up a list of approved establishments, each of which shall have an official number.

(3) The Council shall issue necessary instructions from time to time for effective monitoring of the inspection or certification as specified in rule 3

5. Packing and labelling .-

Ayurvedic, Unani and Siddha products for export shall be packed in hygienically clean food grade packing material as per the provisions laid down in Rule 161 of Drugs and Cosmetic Act, 1940.

Each package shall be legibly and indelibly marked with the following information, namely:-

(i) Name of the drug
(ii) List of all ingredients
(iii) Gross weight and net weight/ numbers/ volume
(iv) Name and address of processor or manufacturer.
(v) Manufacturing Licence Number
(vi) Batch or lot number
(vii) Date of manufacture
(viii) Ayurvedic/Siddha/Unani medicines
(ix) Use the words "FOR EXTERNAL USE ONLY", if the medicine is for external application

6. Issuance of certificate .-

On request from the processor or exporter, the Competent Authority shall issue certificate (s) for export of Ayurvedic, Unani and Siddha products as per the requirements of the importing country.

7. Certification fee .-

Certification fee shall be paid by the applicant to the Export Inspection Agency at following rates, namely : -

(a) Level 1 Certification : @ Rs.5,000 for every consignments + Laboratory test charges on actual basis, batch wise
(b) Level 2 Certification : @ Rs. 50,000 / Annum
(c) Level 3 Certification : based on actual charges incurred.

8. Appeal.-

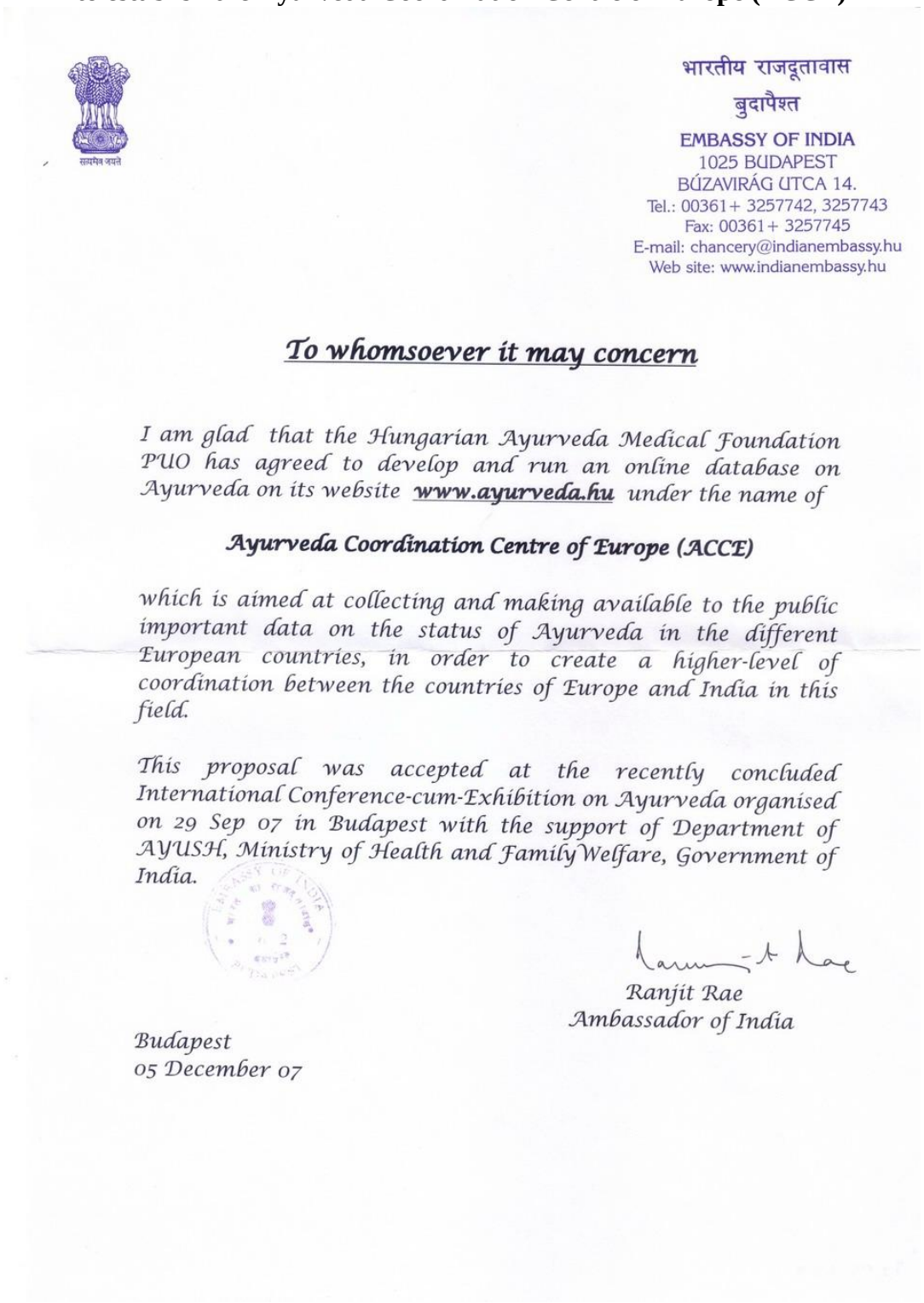
(1) Any applicant aggrieved by the decision of the Export Inspection Agency either under Level 1or 2 or 3 Certification, may, within 10 days of the receipt of the communication of such refusal prefer an appeal which will be referred by the Agency to the Director (I&QC). The appeal shall be disposed of within fifteen days from the date of receipt of application. The decision of the Director(I&QC) to such an appeal shall be final.

[File No. 3/14/2007-EI&EP]

Indira Murthy,
Deputy Secretary.

APPENDIX IX

Letter of Assignment to Hungarian Ayurveda Medical Foundation PUO by H.E. Mr. Ranjit Rae, Ambassador of India to Hungary to establish the Ayurveda Coordination Centre of Europe (ACCE)



भारतीय राजदूतावास
बुदापैश्त
EMBASSY OF INDIA
1025 BUDAPEST
BÚZAVIRÁG UTCA 14.
Tel.: 00361+ 3257742, 3257743
Fax: 00361+ 3257745
E-mail: chancery@indianembassy.hu
Web site: www.indianembassy.hu

To whomsoever it may concern

I am glad that the Hungarian Ayurveda Medical Foundation PUO has agreed to develop and run an online database on Ayurveda on its website ***www.ayurveda.hu*** *under the name of*

Ayurveda Coordination Centre of Europe (ACCE)

which is aimed at collecting and making available to the public important data on the status of Ayurveda in the different European countries, in order to create a higher-level of coordination between the countries of Europe and India in this field.

This proposal was accepted at the recently concluded International Conference-cum-Exhibition on Ayurveda organised on 29 Sep 07 in Budapest with the support of Department of AYUSH, Ministry of Health and Family Welfare, Government of India.

Ranjit Rae
Ambassador of India

Budapest
05 December 07

APPENDIX X

Chaudhary J. Running the export marathon. *Express Pharma*. 16-29 February 2008. Available at: http://www.expresspharmaonline.com/20080229/nutratrends04.shtml

Running the export marathon

Jayesh Chaudhary

India's growth in Ayurvedic exports has remained flat over the years, unlike exports of pharma generics and contract services, which are seeing phenomenal growth rates. In the race to put up branded goods on the consumer shelf, Ayurveda remains far behind Chinese, Korean and South American traditional medicines. Our natural products exports are a mixed bag of finished goods, but also include therapeutic and food ingredients (flavouring), large number of excipients (gums) and essential oils for foods, perfumery, etc. In fact, yoga has scored far better than Ayurveda as a 'product of India' on the international scene. Ayurveda or herbal products of Indian origin have not made a significant mark either in nutraceuticals or in pharmaceuticals in the global healthcare markets. There is no third side to this coin. Our current herbal offerings (APIs or formulations) lack either the strong branding needed for the nutra markets or the foolproof science for the pharma approvals, or both. So we are nowhere. Proof is in the statistics. To be fair to the greens, even the pharma team has not yet won the innings in the 'innovation series', though there have been commendable openings by the likes of Glenmark and Dr Reddy's.(source: DGFT Website)

Speak the right language

The West does not understand Ayurveda but we keep harping on Ayurvedic medicines and herbal products. These classes of goods do not exist in the West. When an American consumer gets into a health food store like GNC or a pharmacy store like Walgreen, she wants to buy a dietary supplement for her aching knee joints. She has heard of glucosamine sulphate and picks a bottle. She doesn't care if it is Ayurvedic, plant-based or animal origin. The pharmacy chain stocks it because it can sell it legally in the US as a dietary supplement. On the other hand, Ayurvedic medicine as a cure is not understood and not acceptable. Indian marketers would be better off first getting a presence in the existing segments of dietary supplements, functional foods and herbal personal care products and then build a new segment like Ayurveda. Ayurvedic medicines as a regulatory class are recognized in some countries now, but their collective brand equity is questionable. Present day leading Ayurvedic houses must either shed their traditional ideologies or be content with a domestic market. Recently, a new class of regulated products has emerged in the US and EU under the terms botanical drug products (BDPs) and herbal medicinal products (HMPs) respectively. This is an opportunity for the proponents of Ayurveda who constantly claim that 'Ayurvedic products are medicines and not food supplements'. However, they must take up the challenge and ensure that their Ayurvedic medicines measure up to the standards set by the Western boys to protect their own pharma turf. I believe that Ayurveda is a superior science; however, if we go knocking on someone's doors for business we have to play the music he likes to hear and not the trumpet of our '5000 year old tradition'. The choice of the language will be based on the brand we decide to build for Indian exports.

Market research

Clearly any national effort has to be collective. The Government via its policy makers, regulators and export promotion councils is clearly responsible, but the various trade bodies (Indian Drug Manufacturers' Association (IDMA), Ayurvedic Drug Manufacturers Association (ADMA), Association of Manufactures of Ayurvedic Medicines (AMAM), The Health Foods and Dietary Supplements Association (HADSA), etc.) need to talk to each other more openly. There are non-governmental agencies like GTZ, Germany, that are actively supporting herbal exports from India. Policy-makers and the industry must have a clear understanding of the markets. We must engage

the best market research firms to survey all the major markets for health foods, supplements and herbal drugs and advise on the best positioning for Indian companies as each market is different. Top marketing gurus from pharma, foods, Fast Moving Consumer Goods (FMCG), ad agencies and academia can also be roped in. Primary research is available from international consulting firms, publishing houses, as well as industry specialists. The market survey will lay down the roadmap for the Government and the industry and channelize the investments effectively.

Building brands

Whichever route is chosen, brand-building still is an effort. The biggest brands in this industry have been built on science but grown by smart marketing. Big brands have been backed with data supporting their marketing claims and differentiating also the technology from competition. This data may be sometimes sketchy and sometimes strong. But India clearly has the advantage in low cost research facilities -preclinical and clinical. Brand-building and growing will require a sustained effort and investment in the best practices for R&D, manufacture, packaging, quality control and export logistics of Indian nutraceutical products.

Investment-friendly environment

There is a market opportunity. With appropriate market research done we will even have a road map. We already have the Ayurvedic research engine to drive product innovation. What the existing players need is capital. Given the sensible policies, money will flow in. Research grants and soft loans (free/cheap money) are always welcome, but we need to infuse capital from investors (smart money) who will help in building a solid business. Investments could be from existing players in Indian pharma, foods, FMCG, and other sectors. Smart money like Foreign direct investment (FDI), Venture capital (VCs) and Private Equity (PE) firms should be welcomed.

International best practices

India's indigenous medicine manufacturers have to cater to the price-sensitive domestic healthcare needs, whereas for global compliance, we need to follow international guidelines. With no compromises, we can formulate separate set of regulations to accommodate realities of the overseas and domestic markets. This way exports can develop without blocking access of the Indian consumer to affordable traditional medicine. Industry must reciprocate and implement international best practices in design and development, manufacturing, packaging, quality control and marketing of export-worthy produce.

Industry's attitude to quality

The industry should stop giving excuses that natural product quality is difficult to control and there will be variability in polyherbal product specifications from batch-to-batch and over the claimed shelf life. US FDA in its botanical drug products guidelines and the European medicines agency in its herbal medicinal products guidelines, give practical and not so expensive suggestions on controlling finished product quality. We should stop complaining about lack of HPLC marker compounds and expensive methods as a lot can be done with some innovative thinking and more importantly, the right mindset. The US Pharmacopoeia and NSF International Dietary Supplements Verification programs in India are also going in the right direction. The spotlight on heavy metals for last two years has diluted our focus on actives. Let us raise a toast to our strong Ayurvedic actives and kill the negative hype.

Encouraging R&D spend

With a wonderful drug discovery platform like Ayurveda at our disposal, it's a pity that we don't have any blockbusters like Ginseng from India. The Government, along with the industry must invest in high class pre-clinical and clinical pharmacology, safety pharmacology, and of course in intellectual property protection to ensure return on R&D investments. These technologies then may be commercialized on Indian players or licensed to strong overseas partners ensuring commercial success and not just academic laurels. The Government must also recognize and encourage Contract Research Organizations (CROs) that can better penetrate and serve the industry than any public lab or hospital. Extension of 150 percent IT sop to even non-DST approved in-house and stand alone research units will help.

Strengthening export regulations

Periodically, we hear some noise about regulating newly launched patent and proprietary Ayurvedic medicines. One year, the local FDAs announce that they will need analytical methods before they approve a new patent and proprietary (P&P) medicine for manufacturing and sale. Another year they announce that they will need clinical trial data. I think this and an entry barrier to new-comers while old products continue to flourish even if they are sub-standard is not practical. The policy drawn must instead lay down easier and practical norms to be fulfilled and then enforced fiercely without fear of lobbies. Don't ask for data which can be easily faked and only lead to corruption (eg. clinical trial data). Quality standardization is more important than clinical evidence of efficacy and is definitely tougher to fake by unscrupulous applicants. Data submission for re-approval by FDAs should be made mandatory based on the domestic sales of the P&P medicine and for all export items regardless of size of business. I whole-heartedly welcome strong inspection norms for export shipments by Export Inspection Agency (EIA). I think that the EIA will become a partner rather than an obstacle for ASU exporters under the able leadership of current Director Shashi Sareen. Some of these policies may hit our exports for one year but we will emerge much stronger in the long run. Pharmaceutical Export Promotion Council (Pharmexcil) should stop sponsoring our industry colleagues for their foreign jaunts and divert these funds for sponsoring genuine quality improvement projects. Pharmexcil should support exporters for EIA inspection costs. That will be a true market development assistance. Let us develop world class quality then the customers will come running to India instead of us going abroad with a begging bowl.

Developing specialized talent

Neither of the graduates-Ayurvedic (BAMS), pharmacy (BPharm) or lifescience-today understand clearly the business requirements of the global herbal industry. Even the multitude of pharmaceutical management programmes that have sprung up in the country has zero focus on the natural products market. I urge entrepreneurs in the training industry and the appropriate government bodies to consider instituting a one year program on the technology and business management of borderline healthcare products in order to meet the growing demand of talent who understand the international business of the phytomedicines and dietary supplements. Some universities and institutes have made small beginnings, but need to get better industry participation.

It's a marathon

Let us admit that the Indian herbals image is a little better than battered in some of the major markets. Brand-rebuilding is a marathon not a sprint. Let us run to win. Indian natural product industry has to mature as a global player or be content with domestic business. If a traditional Ayurvedic medicine (Liv 52) can top the charts of pharma brands in India, we surely have the potential to write a success story internationally as well.

(The author is MD and CEO of Vedic Lifesciences, a Mumbai-based CRO. He can be reached on jayesh@ayuherbal.com).

APPENDIX XI

National Medicinal Plants Board Financial Assistance for Cultivation of Medicinal Plants, 07 May 2008

F. No. Z – 18020/17/2008/ NMPB
National Medicinal Plants Board
Department of AYUSH
Ministry of Health & Family Welfare
Government of India

Chandralok Building,
36 Janpath,
New Delhi – 110001
Tel: 011 – 23319360
Fax: 011 – 23319356
Dated: 7th May, 2008

To,

1. All the members of ADMA
2. All members of other ASU Industry Associations
3. All the Herbal Extracts, Manufacturers

Dear Sirs,

You are aware that National Medicinal Plants Board (NMPB) has been providing financial assistance for cultivation of medicinal plants. During the 10th Plan, the Board released subsidy to the tune of Rs. 72 crores for cultivation to the farmers in different states. It has, however, been experienced that in the absence of proper marketing linkage farmers do not get remunerative prices for their produce and, therefore, discontinue cultivation after the initial one or two years. Though there is a system of MoU between the grower and the buyer, it is rarely enforced and often it is the farmer who is the looser. On the other hand, the industry continues to source most of its raw material from the traders. Therefore, there is a disconnect between the growers and the industry.

2. During the 11th Plan, the outlay for the NMPB has been increased six to seven fold and a substantial portion of this will be for cultivation of plants in high demand. Therefore, it is necessary that the financial support for cultivation is directly linked to the industry coming forward to enter into buy back agreements with growers cooperatives/ associations/Self Help Groups (SHGs) in selected clusters.

3. It is, therefore, suggested that industries identify clusters which they would like to cover for cultivation of selected medicinal plants and organize growers into cooperatives, associations, SHGs and get bankable proposals prepared for assistance under NMPB scheme. The industry also needs to facilitate supply of QPM/quality seeds, technology dissemination along with a buy back for the purchase of raw material. The proposal, duly appraised by a scheduled bank, may be forwarded to SMPBs who in turn, after necessary scrutiny will forward these to NMPB together with their recommendation. This is essential as the NMPB subsidy is credit linked. The NMPB would like to provide

support for cultivation only if proper backward and forward linkages as indicated above are tied up and industry is fully involved in the activity.

4. The Department of AYUSH, is also providing assistance to the Special Purpose Vehicles (SPVs) constituted for AYUSH industry clusters during the 11th Plan. The SPVs are also advised to identify cultivation clusters in adjacent areas so that cultivation and processing can be synergistically linked. The SPVs may simultaneously come up with proposals for financial assistance under NMPB schemes to the cooperatives/SHGs of farmers for cultivation in clusters of the medicinal plants species relevant to the agro-climatic region.

Yours faithfully,

(B.S. Sajwan)

Copy to:

- The Growers Association of Medicinal and Aromatic Plants. (As per list)

APPENDIX XII

AYUSH MEMO: Implementation of Revised Centrally Sponsored Scheme for Quality Control of Ayurveda, Siddha, Unani & Homoeopathy (ASU&H) Drugs during the 11th Plan

F. Diary No.9544/Director (SKC)/2007
Government of India
Ministry of Health & Family Welfare
Department of AYUSH
.....

IRCS Building,1, Red Cross Road,
New Delhi -1 dated the 10th December, 2007

OFFICE MEMORANDUM

Subject :Implementation of Revised Centrally Sponsored Scheme for Quality Control of Ayurveda, Siddha, Unani & Homoeopathy (ASU&H) drugs during the 11th Plan.

The undersigned is directed to inform that the Centrally Sponsored Scheme for Quality Control of Ayurveda, Siddha, Unani & Homoeopathy (ASU&H) as implemented in the 10th Plan has been suitably revised based on the evaluation and the feedback received from various States/UTs for implementation in the 11th Plan.

A copy of the revised Scheme for implementation in the 11th Plan is attached for kind perusal. It is requested that the Scheme may be given wide publicity among stakeholders including AYUSH industry associations so that the proposals for funding can be forwarded to this Department for consideration for funding as per the provisions of the Scheme.

A copy of the Scheme is also available on the website of the Department of AYUSH **(indianmedicine.nic.in).**

(S.K. Chadha)
Director
Telefax:: 23327669

Encl.: As above.

APPENDIX XIII

Asia Health Care 2008 Company Profile Form

International Trade Centre UNCTAD/WTO
Centre du commerce international CNUCED/OMC
Centro de Comercio Internacional UNCTAD/OMC

COMPANY PROFILE FORM
"ASIAHEALTHCARE 2008"
Malaysia, March 2008

Name and Title:	Mr. SHASHANK SANDU, Managing Director	
Company name:	SANDU BROTHERS Pvt Ltd	
Street – POB:	Sandu Nagar, DK Snadu Marg, Chembur	
City – Country:	Mumbai-India-400071	
Email: sandu@bsnl.com; sbsandu@sandu.in	Tel: 91-22-25284402 / 25283306	Fax: 91-22-25282403
Year established: 1899	Bank Ref: DENA BANK, Chembur branch, Mumbai-71	Legal status: Private limited company
Website: www.sandubrothers.com	Headquarters location: Mumbai	Other office(s) location(s): Mfg plants @1. New Mumbai, 2. Goa; and 15 branch officers all over India
Quality certification (ISO; GMP): GMP-certified n ISO-9001-certified	Annual turnover (USD): appo-11.5 mn	Share exported (%): 15%
Current export/import markets:	US, Europe, CIS, Nepal, Mauritius, East Africa, West Africa	
Registration with export promotion bodies, chambers of commerce, business associations (specify): PHARAMEXCIL		

ACTIVITIES

☒ Manufacturer/Producer	☐ Wholesaler/Retailer	☐ Trader	☐ Service provider: quality control, packaging, machinery, business information (specify):

EXPORT/IMPORT INTEREST

	ESSENTIAL DRUGS	Active Pharma Ingredients (API)		Formulas/ Finished Products	
1	*Anaesthetics:* ☐ General anaest. & oxygen ☐ Local anaesthetics ☐ Preoperative med. and sedation	I ☐	E ☐	I ☐	E ☐
2	*Analgesics, Antipyretics, Anti-inflammatory, Non-steroidal (NSAIMs), medicines used to treat gout and disease modifying agents in rheumatoid disorders (DMARDs):* ☒ NSAIMs ☐ Opioid analgesics ☒ Used to treat gout ☒ DMARDs	I ☐	E ☐	I ☐	E ☒
3	*Antiallergics and medicines used in anaphylaxis*	I ☐	E ☐	I ☐	E ☐
4	*Antidotes and other substances used in poisoning:* ☐ Non-specific ☐ Specific	I ☐	E ☐	I ☐	E ☐
5	*Anticonvulsants / Antiepileptics*	I ☐	E ☐	I ☐	E ☐
6	*Anti-Infective medicines:* ☒ Anthelminthics ☒ Antibacterials ☐ Antifungal ☒ Antiviral ☒ Antiprotozoal	I ☐	E ☐	I ☐	E ☒
7	*Antimigraine medicines:* ☐ For treatment of acute attack ☒ For prophylaxis	I ☐	E ☐	I ☐	E ☒
8	*Antineoplastic, Immunosuppressives and medicines used in palliative care:* ☐ Immunosuppressive ☐ Cytotoxic medicines ☐ Hormones and antihormones ☐ Medicines used in palliative care	I ☐	E ☐	I ☐	E ☐
9	*Antiparkinsonism medicines*	I ☐	E ☐	I ☐	E ☒
10	*Medicines affecting the blood:* ☒ Antianaemia medicine ☐ Medicines affecting coagulation	I ☐	E ☐	I ☐	E ☒
11	*Blood products and plasma substitutes:* ☐ Plasma substitutes ☐ Plasma fractions for specific use	I ☐	E ☐	I ☐	E ☐
12	*Cardiovascular medicines:* ☐ Antianginal ☐ Antiarrhythmic ☒ Antihypertensive ☐ Used in heart failure ☐ Antithrombotic ☒ Lipid-lowering	I ☐	E ☐	I ☐	E ☒
13	*Dermatological medicines:* ☐ Antifungal ☒ Anti-infective ☒ Anti-inflammatory /antipruritic ☐ Astringent ☒ Skin differentiation /proliferation ☐ Scabicides/pediculicides ☐ Ultraviolet	I ☐	E ☐	I ☐	E ☒
14	*Diagnostic agents:* ☐ Ophthalmic ☐ Radiocontrast media	I ☐	E ☐	I ☐	E ☐
15	*Disinfectants and Antiseptics:* ☐ Antiseptics ☐ Disinfectants	I ☐	E ☐	I ☐	E ☐
16	*Diuretics*	I ☐	E ☐	I ☐	E ☒

17	*Gastrointestinal medicines:* ☒ Antacids and other antiulcer ☒ Antiemetic ☒ Anti-inflammatory ☒ Laxatives ☒ Used in diarrhoea	I ☐	E ☐	I ☐	E ☒
18	*Hormones, other endocrine medicines and contraceptives:* ☐ Adrenal/synthetic substitutes ☐ Androgens ☐ Contraceptives ☐ Estrogens ☐ Insulins/oth. Antidiab.agents ☐ Ovulation inducers ☐ Progestogens ☐ Thyroid hormones/antithyroid medicines	I ☐	E ☐	I ☐	E ☐
19	*Immunologicals:* ☐ Diagnostic agents ☐ Sera and immunoglobulins ☐ Vaccines	I ☐	E ☐	I ☐	E ☐
20	*Muscle relaxants (Peripherally-acting) and cholinesterase inhibitors*	I ☐	E ☐	I ☐	E ☐
21	*Ophthalmological preparations:* ☐ Anti-infective agents ☐ Anti-inflammatory agents ☐ Local anaesthetics ☐ Miotics and antiglaucoma ☐ Mydriatics	I ☐	E ☐	I ☐	E ☐
22	*Oxytocics and Antioxyytocics:* ☐ Oxytocics ☐ Antioxytocics (tocolytics)	I ☐	E ☐	I ☐	E ☐
23	*Peritoneal Dialysis Solution*	I ☐	E ☐	I ☐	E ☐
24	*Psychotherapeutic medicines:* ☐ Used in psychotic disorders ☒ Used in mood disorders ☒ Used in generaliz. anxiety & sleep disorders ☐ Used in obsess. compulsive disorders & panic attacks ☐ Used in substance dependence programmes	I ☐	E ☐	I ☐	E ☒
25	*Medicines acting on the respiratory tract* ☒ Antiasthmatic and medicines for chronic obstructive pulmonary disease ☒ Other medicines acting on the respiratory tract	I ☐	E ☐	I ☐	E ☒
26	*Solutions correcting water, electrolyte and acid-base disturbances:* ☐ Oral ☐ Parenteral ☐ Miscellaneous	I ☐	E ☐	I ☐	E ☐
27	*Vitamins and Minerals*	I ☐	E ☐	I ☐	E ☐

NATURAL RAW MATERIALS, EXTRACTS & OILS

28	Ajowan (seed) fruit (Trachyspermum ammi)	I☐	E☒	29	Gymnema (Gymnema sylvestre)	I☐	E☒
30	Aloe Vera (A.vulgaris lam)	I☐	E☒	31	Gynostemma herb (Gynostemma pentaphyllum)	I☐	E☐
32	Amla fruit (Phyllanthus emblica)	I☐	E☒	33	Hawthorn (Fructus crataegi)	I☐	E☐
34	Arjuna (Terminalia arjuna)	I☐	E☒	35	Hop strobile (Humulus lupulus)	I☐	E☐
36	Artemisia (Artemisia annua)	I☐	E☒	37	Jujube date powder (Ziziphus jujuba)	I☐	E☐
38	Asafoetida oleoresin (Ferula asafoetida) or Oleogum resin	I☐	E☒	39	Kelp thallus (Laminaria japonica)	I☐	E☐
40	Ashwaagandha (Withania somnifera)	I☐	E☒	41	Kudzu root (pueraia lobata)	I☐	E☐
42	Astragalus root pwd (Astragalus membranaceus)	I☐	E☐	43	Licorice root (Glycyrrhiza uralensis)	I☐	E☒
44	Belleric myrobalan fruit (Terminalia bellerica	I☐	E☒	45	Lycium fruit (Lycium barbarum)	I☐	E☐
46	Bosewellia (Bosewellia serrata)	I☐	E☐	47	Madagascar Periwinkle (catharanthus roseus)	I☐	E☐
48	Caralluma extract(Caralluma fimbriata)	I☐	E☐	49	Magnolia bark (Magnoliae officinalis)	I☐	E☐
50	Chebulic myrobalan fruit (Terminalia chebula)	I☐	E☒	51	Manjishta (Rubia cordifolia)	I☐	E☒
52	Cherokee rose hip (Rosa laevigata)	I☐	E☐	53	Neem leaf (Azadirachta indica)	I☐	E☒
54	Chicory root (Cichorium intybus)	I☐	E☐	55	Niuri (Phyllanthus amarus)	I☐	E☒
56	Chinese Hibiscus (Hibiscus rosasinensis)	I☐	E☐	57	Parmelia lichen extract (Parmelia cryptochloropbaea)	I☐	E☐
58	Chirata herb (Swertia chirayita)	I☐	E☒	59	Prisniparni (Uraria picta)	I☐	E☒
60	Corydalis (Corydalis yanhusuo)	I☐	E☐	61	Psyllium husk (plantago ovata)	I☐	E☐
62	Dang gui (Angelica sinensis)	I☐	E☐	63	Rhodiola (Rhodiola rosea)	I☐	E☐
64	Eleuthero root (Eleutherococcus senticosus)	I☐	E☐	65	Safed musli tuber (Chlorophytum borivillianum	I☐	E☒
66	Epimedium herb (Epimedium brevicornum)	I☐	E☐	67	Sandalwood heartwood (Santalum album)	I☐	E☒
68	Garcinia Fruit (Garcinia bambogea)	I☐	E☐	69	Sargassum alga (Sargassum pallidum)	I☐	E☐
70	Garlic bulb (Allium sativum)	I☐	E☐	71	Sarpagandha (Rauwolfia serpentia)	I☐	E☒
72	Ginger rhizome (Zingiber officinale	I☐	E☒	73	Schisandra fruit (Schisandra chinensis)	I☐	E☐
74	Ginkgo leaf (Ginkgo biloba)	I☐	E☐	75	Sea buckthorn (Hippophae rhamnodies)	I☐	E☐
76	Ginseng root (Panax ginseng)	I☐	E☐	77	Shatavari root (Asparagus racemosus)	I☐	E☒
78	Green tea (Camellia sinensis)	I☐	E☐	79	Star anise fruit (Illicium verum)	I☐	E☐
80	Gotu Kola (Centella asiatica)	I☐	E☒	81	Tribulus terrestris (Tribulus zygophyllacae)	I☐	E☒
82	Guduchi (Tinospora cordifolia)	I☐	E☒	83	Vanilla fruit (Vanilla planifolia)	I☐	E☐
84	Guggul (Commiphora mukul)	I☐	E☒	85	Velvet bean (Mucuna pruriens)	I☐	E☒

EXCIPIENTS							
86	Binders (pre gelatinized cellulose, lactose)	I☐	E☐	87	Colors (titaium dioxide)	I☐	E☐
88	Compression aids (dextrose, lactose, microcrystalline cellulose)	I☐	E☐	89	Disintegrants (sodium starch glycolate, croscarmellose)	I☐	E☐
90	Fillers/diluents (dicalcium phosphate, starches sucrose)	I☐	E☐	91	Film formers/coating (maltodextrin, hydroxyl, methyl prophyl cellulose	I☐	E☐
92	Flavours (Sodium chloride, citric acide)	I☐	E☐	93	Glidants (flow enhancers) (silicon dioxide, cellulose, titanium dioxide, talc)	I☐	E☐
94	Lubricants (Magnesium stearate, talc)	I☐	E☐	95	Preservatives (citric acid, sodium citrate, methyl paraben)	I☐	E☐
96	Suspensing / dispersing agents (gelatins, starches, gums)	I☐	E☐	97	Sweeteners (surcrose, fructose, dextrose annitol)	I☐	E☐
98	Others (specify):					I☐	E☐

INTEREST IN OTHER BUSINESS PARTNERSHIPS		
	My company is seeking for:	**My company is offering:**
Joint sourcing	☐	☐
Joint distribution	☐	☐
Complementary production	☐	☐
Concerted marketing / promotion	☒	☐
Technology transfer	☐	☒
Development of new product / technology	☐	☐
Product registration	☐	☐
Contract manufacturing	☐	☐
Other (specify):	☐	☐

OTHER INFORMATION

To obtain maximum benefit from your participation in "AsiaHealthCare 2008", it is highly important that you bring full details regarding your product specifications and quality standards, indicative prices, stock availability, production capacity, information about your company, and customer references. You may also wish to bring a large supply of business cards and brochures, which will contribute to the success of your business consultations. Space for the display of a limited range of samples will be available. A detailed programme and request to confirm your participation will be sent to you within the next weeks. For more information, please contact ITC at: betemps@intracen.org

APPENDIX XIV

CCRAS Formulation and Process Patents

Patents Obtained By CCRAS

Number of patents taken.....19

Patents filed…….…….....8
Patents/Processes released to the Industry….5

FORMULATION PATENTS:

- AYUSH-64 - An anti-malarial preparation (Patent No. 152863 dated 28.7.1980).
- AYUSH-56 - An anti-epileptic preparation (Patent No. 141170 dated 28.7.1976).
- 777 Oil A medicated oil for Psoriasis (Patent No. 166740 dated 11.9.1987)
- Ksharsutra - A medicated thread for Ano- rectal diseases (Patent No.186243 dated 15.2.2002)

PATENT FILED

1) AYUSH GHUTTI - A herbomineral preparation for Cough, Cold, Fever & Diarrhea for children.

2) BAL RASAYAN - A herbomineral preparation for general resistance in children.

3) A novel technology for in vitro propagation of Celastrus paniculatus Wild through leaf culture.

4) A novel technology for in vitro propagation of Celastrus paniculatus Wild through cotyledon culture.

5) A Process for the Preparation of Novel Composition from Swertia chirata Buch. Ham. (Gentianaceae) having Anti-carcinogenic (cancer Preventive) and anti- Tumor (Cancer Therapeutic) Action. Patent Application No.168/Cal/02 dated 26.3.2002.

6) A Process for the Isolation of Amarogentin, Novel Seco-Iridoid Glycoside Possessing Anti-carcinogenic (Cancer Preventive) and Anti- Tumor (Cancer Therapeutic) Action. Patent Application No.169/cal/02 dated 26.3.2002.

7) A novel Anti-Cancer composition from Plant Source with Anti-carcinogenic (Cancer Preventive) and Anti-Tumor (Cancer Therapeutic) Action. Patent Application No.167/Cal/02 dated 26.3.2002.

8) A novel Anti-Cancer compound Amarogentin, A Seco- Iridoid Glycoside with Anti-Carcinogenic (Cancer Preventive) and Anti- tumor (Cancer Therapeutic) Action. Patent Application No.166/Cal/2002 dated 26.3.2002.

PROCESS PATENTS:

1) Patent No. 138350 - A process for the production of a Lactonic glycoside from Nerium indicum Mill. (syn. N. odorum Sol.) 26.9.73

2) Patent No. 139868 - A process for the production of an Extract useful in the treatment of Bronchial asthma from Mesua ferrea Linn. Seeds 4.4.74

3) Patent No. 140032 - A process for the production of a Sodium Salt of a natural methyl chromone isolated from the podsof Cassia siamea. 24.4.74

4) Patent No. 140321 - A process for the isolation of a Pongaflavone from Pongamia Pinnata (L.) Pierre (syn. P.glabra). 4.4.74

5) Patent No. 140367 - A process for the isolation of 2.3.-a, a- Dimenthylchromen – 1- methoxy9-hydroxy-10y,y-demethylallyl pterocarpan, known as Gangetin, from the roots of Desmodium gangeticum. 4.4.74

6) Patent No. 139869 - A process for the production of a Benzofuran derivative from kojic acidand catechol. 4.4.74

7) Patent No. 140381- A process for the isolation of Tomatid-5-en-3b-ol from the leaves of Solanum trilobatum. 4.4.74

8) Patent No. 140382 - A process for the isolation of Methylangolensate and Deoxyandirobin from the bark of Soymida febrifuga. 10.5.74

9) Patent No. 140384 - A process for the production of a new triterpenoid glycoside named Entanin isolated from the seed kernels of Entada scandens Benth. 10.5.74

10) Patent No. 145858 - A process for the isolation of Liriodenine, a 7-oxo aporphine from the heartwood of Aquilaria agallocha. 11.5.97

11) Patent No. 147936 - A process for the isolation of 2-Hydroxy-3 (3-methyl- 2butenyl)-1, 4-napthaquinone, known as Lapachol from the root of Steriospermumtetragonum DC. 14.8.78

12) Patent No. 140367 - A process for the preparation of 9,13-Epoxy-6 b-hydroxy-8a- Labdana-16,15: 19,2-diolactone known as Nepetaefolinol from the whole plant of Leonotis nepetaefolia Linn. 14.8.78

13) Patent No. 150019 - A process for the isolation of vincristine from Vinca rosea. 21.6.79

14) Patent No.150024 A process for the preparation of vinblastine from Vsinca. 21.6.79

15) Patent No. 545/DEL/84 Nimbatiktam – for the management of Psoriasis (Kitibha).