



International market prospects for sustainably sourced medicinal and aromatic plants in India

Simon Mills & Joey Lee
Plant Medicine CIC

March 2011

Prepared for the
Whitley Fund for Nature
as part of the project:
**Water Access and
Wasteland Development
for Marginalised Groups in
Himalayan Cold Deserts**
Conducted in partnership
with **Pragya**



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Background

The Whitley Fund for Nature commissioned this report as part of a five year project called “Water Access & Wasteland Development for Marginalised Groups in Himalayan Cold Deserts” (project period 2006- 2011). The project was carried out by Pragma and Whitley Fund for Nature in partnership.

Pragma is a non-profit development organisation with activities in India, Nepal and the United Kingdom, working for appropriate development of vulnerable communities and sensitive ecosystems of the world (www.pragya.org).

The Whitley Fund for Nature (WFN) is a UK registered charity offering profile and funding to outstanding nature conservation leaders around the world. WFN works in partnership with many grantees on an ongoing basis (www.whitleyaward.org).

The aim of the report is to research and consider prospects for selling sustainably sourced medicinal and aromatic plants (MAPs) from rural Himalayan communities into international markets. It should be noted that the status of European markets and specifically the UK is uncertain at the time of publication given the impending implementation of the medicines (Traditional Herbal Medicine Products for Human Use) Regulations (2005) in April 2011. The future of the UK market is dependent on the Government honouring its commitment to introduce the statutory register of herbalists or herbal practitioners, preferably regulated through the Health Professions Council, who will be authorised to supply herbal medicinal products directly to the public in England and Wales, prior to the implementation of the medicine Regulations. A meeting of representatives of the Indian traditional medicines sector was held at the House of Lords in November 2009 to discuss ways of encouraging this development. Analysis and recommendations in this report must be considered in the context of this unresolved regulatory situation.

The report authors, Simon Mills and Joey Lee of Plant Medicine CIC in the UK, were independent of the project. As such, the contents, interpretations and opinions expressed in the report are the views and sole responsibility of the authors. Thanks go to the Natural Resource Management team of Pragma that has provided raw data for the report based on surveys conducted in the Himalayas. The views stated in the report do not necessarily reflect the views of Pragma.

Lead author Simon Mills is an international authority on herbal medicine and has been a pioneer in integrating conventional and complementary health care in the UK, Europe and the USA. In 1987 he co-founded the first university centre to study complementary health, and later the first integrated health programme at a British medical school. He was specialist advisor to the House of Lords committee on Complementary and Alternative Medicine, set up the first master’s programme in herbal medicine in the USA, and has built a unique database in the use of plants in health care. He also established the SustainCare network, a non-profit group linking those around the world working to redefine health care.

We would like to extend our thanks to the many wild medicinal and aromatic plant trade experts - conservationists, academics, suppliers, practitioners – who are too many to name here, for their valuable input on early drafts, as well as to the communities of the Indian high Himalayas, without whom this publication could not have been completed.

International market prospects for sustainably sourced medicinal and aromatic plants from India

Executive Summary

- Context** The Whitley Fund for Nature has supported Pragma, a non-Governmental organisation based in India, in mapping the herbal resources of the high-altitude Himalayan cold deserts, and working with local communities to link local healing traditions with sustainable herbal cultivation. This independently commissioned report explores prospects for international sales channels that may sustain the livelihoods, habitats and traditions of the Himalayan communities involved.
- Pages 11 to 16** The international market for medicinal and aromatic plants (MAPs) is dominated by China, Japan, five European countries and the USA. Sales into Europe from India form a small proportion of the total but are growing. Within Europe there are good reasons to focus on the UK as the primary target for new sales of MAP products from India.
- Pages 17 to 30** The regulatory environment in Europe is complex and uncertain given the impending implementation of the medicines (Traditional Herbal Medicine Products for Human Use) Regulations (2005) in April 2011. To bring MAPs as medicinal products or food supplements onto the open market and sell directly to the consumer will require substantial investment. Selling to the public via practitioners who set up semi-retail operations is a feasible regulatory option for a larger range of finished Indian plant products. However, the future for this option in the UK market is dependent on the Government introducing the statutory register of herbalists or herbal practitioners, which remains uncertain.
- Pages 35 to 40** The shape of any new business exporting Indian MAPs into the UK and Europe will depend on the end route to the consumer. The growth, manufacturing and trading of new products will need to be conducted in co-operation with manufacturing and distribution partners. Various trading options are considered and the basis laid for more specific market planning.
- Pages 41 to 49** Pragma carried out a major survey in 2006-7 of the Indian context for marketing and cultivating Himalayan MAPs, which we have independently analysed in this report. Sales of MAPs in India are increasing and there are moves to improve standards so as to address persistent problems around quality assurance, bureaucratic bottlenecks and a lack of reliable certification. The survey highlighted the complexity of trading channels and challenges for the development of direct buyer-to-grower relationships. For the sector to grow successfully, there is a need for stable supply and bulk orders, improved quality, clarity over the role the trader/agent middle man and incentives for sustainable sourcing.

- Pages 51 to 59* A sample of medicinal species has been considered, consisting of products that are available from the Himalayan region in which Pragma operates. After review, 3 of the 12 listed are both cultivated in a sustainable way and have good marketing prospects in the UK (though legally only via practitioners). 2 have good prospects but are still collected from the wild; 4 have poor prospects and are also still collected from the wild; and 3 are too toxic to be marketed openly in Europe.
- Pages 63 to 75* An analysis of the current policy framework and industry trends in India indicates that the national government, as well as the larger manufacturers in the herbal sector, are aware of the regulatory challenges and are taking measures to address them. They are also aware of the market opportunities for MAPs and therefore the potential for improved livelihoods of marginalised Himalayan communities. Initiatives are underway to remedy constraints and improve access and quality. Significant work is to be undertaken to empower the sector and enable it to navigate the emerging regulatory regime in Europe, but additional interventions may yet be required.
- Recommendation, pages 77 to 79* The principal recommendation from this report is for suppliers of Indian MAPs to form linkages with chosen importing partners interested in good quality, sustainably cultivated niche products. Ideally such partners would have extensive market outlets across Europe. Such partnerships will generate investment and increase long term prospects which will in turn benefit the general development of the Indian market and enable it to compete with larger farms and markets. The development of a range of high-quality transparently-sourced medicinal products from India, backed by an internationally-accepted evidence base and a vigorous educational campaign, for sale initially to health professionals or through them to the public will require significant time and investment.
- Appendix I, pages 81 to 89* The USA market is the largest for the international medicinal plant sector. Regulatory barriers to entry are low making the wide scope for permitted labelling and promotional claims attractive to manufacturers of finished products for the supplement market, but also raising concerns about quality. This may act as a deterrent to entrants from India focused on delivering a high quality and sustainably cultivated product. Whilst the USA may be the most attractive market in the short term, the requirements for transparency and quality in the UK may help to develop a more sustainable Indian market, which benefits marginalised Himalayan communities in the longer term, albeit at a price. For access to the USA, because of the competitive pricing, growers will benefit from partnering with retailers with the necessary muscle. Such a partnership would require bulk production at competitive prices and in the language and conventions of the USA public.

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I. Introduction

The Whitley Fund for Nature is a long-term supporter of the non-governmental organisation, Pragma, in its conservation and sustainability work with the communities of the Himalayas. During 2003-2007, Pragma mapped the herbal resources of the Himalayan cold deserts, working with local traditional healers (amchis/voids), and a range of other administrative and research groups to establish the status of habitats and species, and to develop conservation management strategies. These approaches have an emphasis on reducing environmentally destructive practices that currently result in the decline of wild medicinal and aromatic plants and threaten future natural resources. Pragma's work includes capacity-building measures aimed at upgrading local skills and constituting associations to revitalise traditional systems of medicine and in particular setting up appropriate MAP cultivation with the aim of building sustainable economies for these marginal communities.

India is home to a great variety of ethno-medicinally important plant species, and is ranked sixth among 12 mega-diversity countries of the world. Medicinal plants as a group comprise approximately 8,000 species and account for around 50% of all higher flowering plant species of India. The Himalayas is designated as one of the global biodiversity hotspots (as defined by Conservation International), where ecological, phyto-geographical and evolutionary factors favour high species diversity. A bio-geographically unique region, it has the maximum degree of endemism in the Asian region - it supports about 18,440 species of plants, of which 25.3% are endemic to the region, and has a large repository of medicinal plant species.

Medicinal and aromatic plants (MAPs) are traded both as raw materials and as processed final products. Demand for a wide variety of species is increasing as these markets expand and new end-uses are developed. The price trends of most of the Himalayan species of medicinal plants traded in market have been upwards in the last 3 years. However, about **90% of medicinal plants used by the industries are collected from the wild**. While over 950 species are used in the industry, less than 20 species of plants are under commercial cultivation. The increase in demand increases the threat of depletion in the wild, and there are currently 17 Himalayan medicinal plant species listed in the Red Data Book of Indian Plants (published by the Botanical Survey of India, listing based on IUCN criteria). Nevertheless the role of medicinal plants is important in the Himalayan region: the collection and marketing of these plants provides an important source of income for communities living in mountain areas and the ability to sustainably use such plants is tied closely to future opportunities for high altitude Himalayan communities.

The Himalayan region is diverse also in traditions of medical practice. Apart from the Ayurvedic (Indian) tradition, the Unani (Islamic) and Soarigpa (Tibetan) systems of medicine, as well as diverse folk traditions, are practised in the region.

Aim

The aim of this report is to research and consider prospects for responsible and sustainable trade of Himalayan medicinal and aromatic plants (MAPs) in the UK, Europe and other international markets. There is a particular focus on how to reward the production and supply of quality, sustainably cultivated and fair traded material from rural communities.

Section 1 International opportunities, constraints and expectations

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2 Global market: size and shape. International and European sales figures and trends.	11
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2. Global market

Summary:

The international market for medicinal and aromatic plants (MAPs) is dominated by China, Japan, five European countries and the USA. Sales into Europe from India form a small proportion of the total but are growing. Within Europe there are good reasons to focus on the UK as the primary target for new sales of Indian MAP products.

The largest global markets for medicinal and aromatic plants (MAPs) are China, France, Germany, Italy, Japan, Spain, the UK and the USA. Japan has the highest per capita consumption of botanical medicines in the world.¹

There have been fluctuations in the overall market demand for MAPs, but over the last two decades the average growth rate in volume has exceeded that for the general consumer health industry and has been around 10 per cent per annum in Europe and the USA. It is projected to grow at the same rate.² Exceptions have included a notable flattening in the USA herbal market for several years from the end of the 1990s (now recovering) after several years of frenetic growth and a slowing of the German market as it has matured. However the actual economic value of MAPs has decreased in the last decade due to the shift towards less expensive cultivated products. The data in the following table show the varied sources of MAPs into Germany, the largest non-Asian importer, up to the year 2004 (the latest data available) and second only to the US in 2006. India imports approximately €3 million of MAPs into Germany.

TABLE 2.1: Imports of MAPs into Germany 2000-4

2000 € m	2004 € m		Leading suppliers in 2004 (share in %)	Share (%)
97.4	94.5	Intra-EU	Poland (9%), Belgium (5%), France (4%)	20%
		Extra-EU (non- Developing Countries)	USA (9%), Bulgaria (6%), Australia (4%)	27%
		Extra-EU (DC)	China (8%), Egypt (7%), Chile (6%), South Africa (4%), Turkey (3%), India (3%)	53%

Source: Eurostat 2005

¹ WWF FACTSHEET 4: Trade in medicinal and aromatic plants 2003

² **Herbal medicinal products in the European Union.** Study carried out on behalf of the European Commission by the AESGP (Association Européenne des Spécialités Pharmaceutiques Grand Publique)

MAPs are used in the production of pharmaceuticals, extracts, cosmetics, and colouring agents and these account for most of the €3 million of total imports identified above. This business includes the traditional demand for raw materials for prescribed pharmaceutical medicines, and a large market for specific vegetable alkaloids like opium, ergot, and quinine (especially into the UK). Spices are generally not included in the MAP category, although some (like ginger, turmeric and garlic) are the basis for medicinal or consumer health products and as such may feature in the statistics. Established wholesale and contract suppliers have met the high bulk demands for these few well-established products over many decades.

A wider range of MAPs is sold in diverse and disparate finished products into the mass market, either directly to consumers in the cosmetic and consumer health industry, or as medicinal products through small retail outlets and particularly through practitioners. In the consumer health and cosmetic industries there are again a few well-established commodity markets (e.g. ginger, vanilla, liquorice, peppermint, lavender and other aromatics).

This report will focus initially on the consumer health market as the relevant sector with the strongest dataset and one that is a guide to healthcare demand in general.

Self-medication

In the European Free Trade Area the five countries with the largest self-medication markets (Germany, United Kingdom, France, Italy and Poland) accounted for 68% of the total market in 2006.

Self-medication in the UK

The United Kingdom is the only country in the top 5 to consistently increase its percentage of self-medication in the pharmaceutical market between 2003 and 2007, albeit from low levels (Table 2.2 page 13). This suggests stronger movement to personal choice of health products in that country.

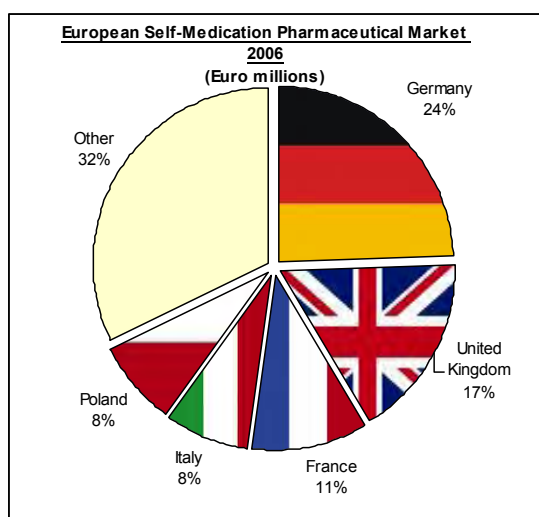


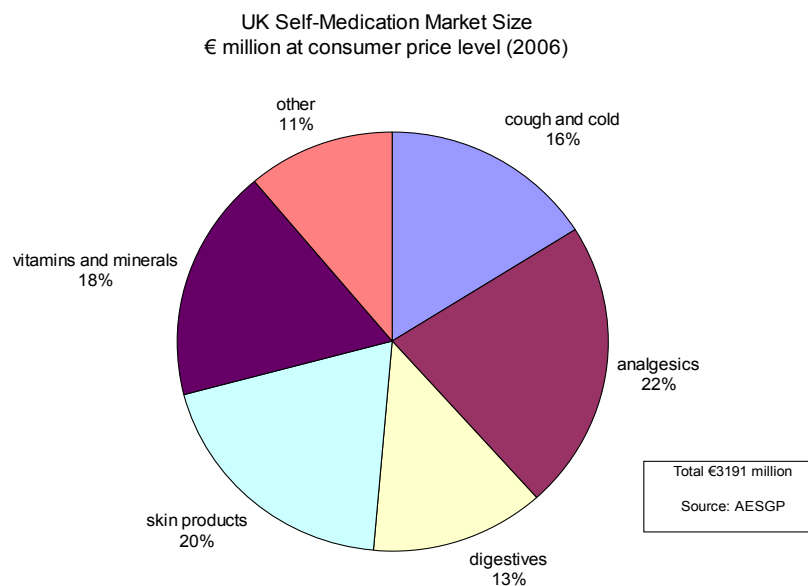
TABLE 2.2: European self medication pharmaceutical market 2003-5

	At consumer prices (euro millions)			% total pharmaceutical market		
	2004	2005	2006	2004	2005	2006
	€ millions			%		
Germany	4631	4749	4530	14.1%	13.5%	12.9%
United Kingdom	2980	3033	3191	11.5%	12.0%	12.3%
France	2020	2165	1989	7.6%	7.5%	6.6%
Italy	1559	1587	1469	8.1%	8.2%	7.7%
Poland	1019	1298	1427	23.7%	24.9%	24.8%
Belgium	577	594	617	14.9%	14.9%	15.6%
Netherlands	561	568	596	11.4%	11.1%	11.2%
Spain	593	600	595	4.8%	4.7%	4.4%
Switzerland	601	594	593	18.1%	17.1%	17.5%
Romania	129	166	364	15.2%	15.3%	23.6%
Sweden	312	326	348	9.0%	9.2%	9.4%
Czech Republic	315	376	375	23.6%	24.6%	25.2%
Greece	297	310	328	8.3%	7.7%	7.3%
Hungary	249	284	301	14.7%	14.1%	14.1%
Austria	279	290	286	8.1%	8.1%	7.6%
Denmark	256	271	284	12.4%	12.1%	11.6%
Ireland	232	248	274	15.3%	14.7%	14.6%
Finland	243	282	242	10.75%	11.5%	9.9%
Norway	131	139	239	7.8%	7.8%	11.7%
Portugal	257	238	214	8.1%	7.1%	6.2%
Croatia	134	143	153	11.0%	10.8%	10.9%
Slovak Republic	105	124	148	12.7%	13.5%	13.7%
Slovenia	29	31	32	7.1%	7.1%	6.8%

Source: AESGP and AESGP National Associations 2007©

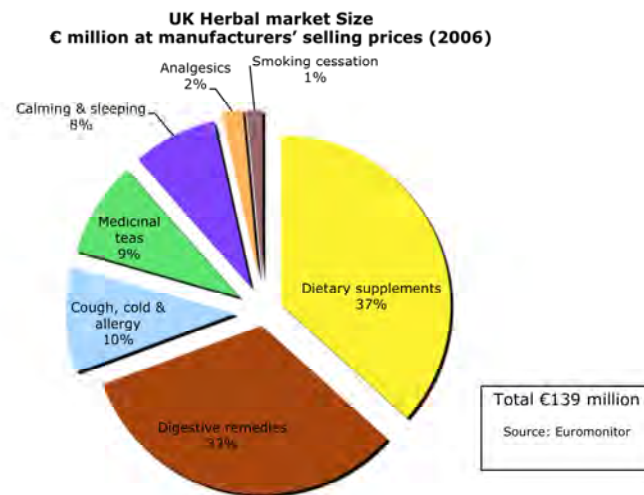
tical market: all medicinal products bought spontaneously by consumers without a medical prescription at public price level, including Value Added Tax (VAT).

In the UK there are firm data on the shape and size of the self-medication market as a whole that point to market opportunities in that country.



OTC remedies

Within the total OTC sector vitamins and dietary supplements represented the strongest performers, with growth in current value terms of nearly 9% in the year to 2004.³ The herbal market is distributed across all OTC categories and has also been growing proportionately well. Among general OTC categories its weight is largest in the digestive (11%) and cough-cold sector (3%). These are the categories therefore in which new growth is most promising.



Homegrown in the UK

The UK imports up to 90% of its medicinal herb requirement: of the remaining 10% home grown the following are prominent. These probably reflect local growing conditions and opportunities rather than their preponderance in the market.

Trade name	total area (hectares)
Borage	2,685
Lavender	367
Peppermint	344
German chamomile	217
Evening primrose	179
Common thyme	179
Roman Chamomile	145
Lemon balm	63
Valerian	52
Rosemary	36

Source: EHGA Europam (2005)

³ CBI Market Information Database • www.cbi.nl

The UK opportunity for Indian MAPs

There are particular reasons why the UK should be a focus for attention when exploring new opportunities for MAPs from India. As table 2.3, below, shows India has a relatively stronger percentage of monitored MAP imports, accounting here for almost 2 million euros per annum, much of this being accounted by the specialist vegetable alkaloid industry. As will be discussed further in this report the UK is also home to a relatively large unmonitored import market of finished Ayurvedic products to complementary practitioners and to consumer stores in Indian communities.

TABLE 2.3: Imports of MAPs into the UK 2000-4

2000 € m	2004 €		Leading suppliers in 2004 (share in %)	Share (%)
39.75	38.4	Intra-EU	Germany (16%), France (12%), Belgium (9%)	45%
		Extra-EU (non-Developing Countries)	USA (16%), Israel (7%), Australia (2%)	29%
		Extra-EU (DC)	China (9%), India (5%) , Egypt (2%), Sudan (2%), Thailand (2%)	26%

Source: Eurostat 2005

There are obvious advantages in starting in markets that can provide cultural recognition (UK is the largest importer of Indian films), as well as early sales among populations from the sub-Continent. Data on relative populations across Europe make it clear the UK is the overwhelming first choice here, followed at a distant second by the Netherlands (See Table 2.4, page 16).

The UK is also an accessible market for consumer health care products, particularly in the herbal sector when compared to the rest of Europe, . The medicines regulator in the UK (the Medicines and Healthcare products Regulatory Agency - MHRA) is notably proactive in establishing pragmatic regulatory frameworks for herbal medicinal products. It has led the way in Europe on the enactment of the Traditional Herbal Medicinal Product Directive (see next chapter) and has engaged with ethnic traditional medicine interests. The UK also has other aspects of the trans-Atlantic liberal free market: it is for example particularly liberal in the sales outlets through which OTC medicines and herbal products may be supplied to the public (many European members states restrict medicinal supply to pharmacies); it is also one of the only major European markets not substantially to limit the scope for distance selling and teleshopping of medicinal products.

Because of the attractions noted above, the UK may be the best market for pioneering the European opportunity.

TABLE 2.4: European populations from the sub-Continent

Country	Total Population (millions)	PIO (people of Indian origin)	NRIs Non-resident Indian	Overseas Pakistanis	Total (millions)	% of population
UK	56.9		1,200,000	800,000	2.0	3.51
Netherlands	15.9	200,000	15,000	40,000	0.255	1.60
France	58.8	55,000	10,000	50,000	0.115	0.20
Germany	82	10,000	25,000	52,668	0.088	0.11
Portugal	10	65,000	5,000	6,000	0.076	0.76
Greece	10.3		7,000	32,500	0.040	0.38
Spain	40	16,000	13,000	2,000	0.031	0.78
Denmark	5.3	900	1,252	20,250	0.022	0.42
Belgium	10.2		7,000	14,500	0.022	0.21
Sweden	8.9	9,000	2,000	5,250	0.016	0.18
Switzerland	7.2	8,400	4,800	2,415	0.016	0.22
Austria	8.1	3,005	8,940	3,500	0.015	0.19
Ireland	3.7	600	1,000	7,000	0.009	0.23
Norway	4.4		5,630	27,000	0.006	0.74
Cyprus	0.7		300	1,100	0.001	0.20

Aggregated data (figures projected to 2004): Yearbook 2004 – 2005, Government of Pakistan, Ministry of Labour, Manpower & Overseas Pakistanis, (Overseas Pakistanis Division), Islamabad <http://www.opf.org.pk/opd/yearbk/YEARBK.pdf>
 Report of the High Level Committee 2001, Non Resident Indians & Persons of Indian Origin Division, Ministry of External Affairs, Delhi, India <http://indiandiaspora.nic.in/diasporapdf/part1-est.pdf>

3. Regulatory options

Summary:

The regulatory environment in Europe is complex and uncertain given the impending implementation of the medicines (Traditional Herbal Medicine Products for Human Use) Regulations (2005) in April 2011. To bring MAPs as medicinal products or food supplements onto the open market and sell directly to the consumer will require substantial investment. Selling to the public via practitioners who set up semi-retail operations is a feasible regulatory option for a larger range of finished Indian plant products. However the future for this option in the UK market is dependent on the Government introducing the statutory register of herbalists or herbal practitioners, which remains uncertain.

The sale of herbs as healthcare products is more tightly regulated than other commodities. Even the less formal and less regulated “borderline” area, within which many natural products have been supplied, will disappear altogether after 2010 when the medicines (Traditional Herbal Medicine Products for Human Use) Regulations (2005) is implemented if individual country measures are not taken that enable registration of these products as per the product registration schemes outlined by MHRA. Any significant new investment in the sector will need to consider the regulatory choices carefully and make clear decisions about the options as a core part of any business plan.

Essentially for the sale of MAPs directly to the consumer, there are two regulatory options: as **medicinal products** or **food supplements**.

Both options involve complicated restrictions for MAPs. Herbal products deemed medicinal by the UK Medicines and Healthcare products Regulatory Agency (MHRA) and brought onto the market since 2004 must have a licence or registration, otherwise their supply constitutes a criminal offence. However, it is possible to register rather than fully license traditional herbal medicine products, which is significantly less onerous. Food supplements must be accompanied by a “presumption of safety” or face significant reporting and information requirements from the European Food Standards Agency. The requirements for food supplements deemed ‘novel foods’ by the ‘Novel Foods Regulation’ may be even more stringent. It will be necessary to position new products very carefully.

The following review of regulatory options will begin with the medicinal route and then consider the options for food supplement status.

MAPs as medicines

European medicines legislation⁴ provides two definitions of ‘medicinal product’: one relating to presentation, the other to function.

⁴ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use. Official Journal L – 311, 28/11/2004

By **presentation**:

Claims, e.g. on the label, to relieve symptoms, or to cure, remedy or heal a specific disease or adverse condition of body or mind would be regarded as medicinal claims.

The European Court of Justice takes “... the view that a product is presented for treating or preventing disease, whenever **any averagely well-informed consumer gains (that) impression....**” [Van Bennekom 1982]

In judging the possibility that a product is associated with medicinal claims the MHRA considers, in context, all claims made for the product, both explicit and implicit, including any made on linked ‘helplines’ or in linked publications. ‘Implicit’ claims may include product names. Where a product is sold on, or has links to a website which presents that product as a medicine, the website will be used as evidence of a claim. Similarly, where a customer is directed from a website selling a product, to another website for more information about the substances contained in a product and their uses, that may also be used as evidence.

Regulatory categories for herbal products in the UK

Legal category	Foodstuffs	Food Supplements	- BORDERLINE -	Registered herbal medicines (traditional use)	Licensed medicines
UK regulator		Food Standards Agency (FSA)	-----> ? <-----	Medicines and Healthcare products Regulatory Agency (MHRA)	
EU regulator		European Food Standards Agency (EFSA)	-----> ? <-----	European Medicines Agency (EMA)	
		Directive 2002/46/EC		Directive 2004/24/EC	
EU legislation	Directive 2001/13/EC			Directive 2001/83/EC	
	Regulation 1924/2006				

By **function** (and intended use of the product)

The inherent pharmacological properties of a product are the main factor used to determine whether it may be administered to human beings with a view “to restoring, correcting or modifying physiological function in human beings”, i.e. whether it is a medicine.

Some herbs have well-known pharmacological effects and would usually only be found in products for a medicinal purpose. The MHRA has produced a list of herbs with pharmacological effects that covers almost all those likely to be marketed in the UK. In the case of a new MAP product the MHRA is likely to consider the use to which the plant concerned has traditionally been put: if it was always used medicinally rather than as a food product then it is likely that the product would be classified as ‘medicinal by function’.

Traditional Herbal Medicinal Products⁵

Registration as a medicine (rather than full licensing) is now possible under new European legislation specifically for herbal products with traditional use. This will excuse the manufacturer from providing evidence of efficacy and certainly provides **the best status for any herbal product**. However, in the case of Indian MAPs, this option is only available where there is evidence of at least 15 years of traditional use somewhere in the European Union plus at least 15 years elsewhere (i.e. a total of 30 years).

All herbal medicinal products will need to be registered by 2011 or be withdrawn from the market. It used to be legal without a licence to sell a simple herbal medicinal product - without claims or brand name (under ‘Section 12.2’ of the 1968 Medicines Act). This no longer applies. The new herbal Directive was published on 30 April 2004. Any product which was legally on the UK market under ‘12:2’ on that date has **‘transitional protection’** and is not required to comply with the Directive until 30 April 2011. After that date it must have either a traditional herbal registration or a marketing authorisation (full licence) or it can no longer be placed on the market. **This transitional protection does not apply to any products placed on the UK market at any time after 30 April 2004.**

This new legislation effectively makes it impossible legally to place a new herbal product with medicinal purpose or effect on the open market in UK and Europe without it being registered as a medicinal product. While this will require major investment decisions, registration is less arduous than full licensing. However standard pharmaceutical dossiers for quality and safety are required and this has proved demanding for manufacturers who are not used to producing herbal products in a pharmaceutical environment. Partnering with a manufacturer with the appropriate expertise and infrastructure who could make the necessary investments may be the best way of addressing these demands.

MAPs as food supplements

Note: following the US example herbal products used as food supplements are referred to as ‘botanicals’

If a product is not a medicinal product then the MHRA will not be involved in its regulation. Many herbal products are supplied as herbal food supplements, and less formally, in an area the MHRA calls the ‘borderline’. These products are potentially determinable as medicines but large numbers remain unclassified. It is still possible to launch such products in the market

⁵ Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC

as food supplements. There are however significant factors to consider in positioning into this sector.

The regulatory burdens for the manufacturer of food supplements are much reduced, notably in that pharmaceutical Good Manufacturing Practice is not required and there have been far fewer requirements to assure and monitor safety (but see below). However there are many restrictions on the claims for benefit that can be made for food supplements. Below is a brief outline of some of the European legislative measures that apply.

The European Food Standard Agency has become increasingly exercised by the potential safety of 'botanicals' and its Scientific Committee has adopted for public consultation a guidance document for safety assessment, in which botanicals or botanical preparations for which an adequate body of knowledge exists could benefit from a "presumption of safety". Under their plans safety assessment of botanicals and botanical preparations for which a "presumption of safety" is not possible, would require additional data.

Food Supplement Directive⁶

'Food supplements' are foodstuffs which supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.

Food Labelling Directive⁷

The rules on labelling under this Directive prohibit the use of information that could mislead the purchaser or attribute medicinal properties to foodstuffs, including on all presentations and advertising.

Food labelling shall bear the following particulars:

- a) the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances;
- b) the portion of the product recommended for daily consumption;
- c) a warning not to exceed the stated recommended daily dose;
- d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;
- e) a statement to the effect that the products should be stored out of the reach of young children.

⁶ **Directive 2002/46/EC** of the European Parliament and Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements 12.7.2002 EN Official Journal of the European Communities L 183/51

⁷ **Directive 2000/13/EC** of the European Parliament and Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs as amended by **Directive 2003/89/EC** of the European Parliament and Council of 10 November 2003

Health Claims Regulation⁸

This recent European measure applies general principles applicable to all claims made on foods (a European Regulation is centrally binding on all Member States in contrast to Directives which each Member State enacts in its own legislation). There are different forms of health claim that can be considered for food supplements.

Nutrition claim: 'any claim that a food has particular nutritional properties due to: the energy it provides, provides at a reduced or increased rate, or does not provide, or the nutrients or other substances it contains, contains in reduced or increased proportions, or does not contain'.

Health claim: 'any claim that a relationship exists between a food category, a food or one of its constituents and health'.

Reduction of disease risk claim: 'any claim that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease'. This is a specific exemption from the absolute ban on reference to 'prevention, treatment or curing' of disease and has been introduced **providing the claims have been authorised** in accordance with the Regulation. The label of products with such claims will also have to state that the disease(s) have multiple risk factors and that altering one of these factors may or may not have a beneficial effect.

Claims must not

- be false, ambiguous or misleading;
- create doubt about the safety and/or nutritional adequacy of other foods;
- encourage or condone excess consumption of a food;
- state or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients (except for some specific national conditions);
- refer, in words or through pictures, graphics or symbols, to changes in bodily functions that could give rise to, or exploit consumer fear.

Claims must

- be taken from a new Community Register held by the Commission on the basis of European Food Standard Agency (EFSA) evaluation of national submissions, conditions of use and scientific supporting references (and subject to scrutiny by the Member States and the European Parliament), relating to either generic health claims or those specific to the product concerned
- Member States must submit their lists by 31 January, 2008; the Commission Register must be finalised by 31 January, 2010 at the latest.
- **or**, assessed *de novo* by EFSA on the basis of full scientific assessment and subsequent authorisation by the Commission:

Claims referring to general, non-specific benefits related to good health or well-being will only be permitted if the product also carries a specific, authorised health claim.

Trade marks, brand names and fancy names which were in use before January 2005 and which might be interpreted as health or nutrition claims may only be used if the products concerned also carry a claim specifically approved under the new Regulation.

⁸ **Regulation 1924/2006** of the European Parliament and of the Council on nutrition and health claims made on foods OJ: 404 30.12.2006

Companies may continue to use generic health claims prior to the adoption of the Community list (31 January 2010, latest) under their own responsibility, provided that they comply with the principles of the Regulation and with existing national provisions. There is no transition beyond this date for claims that are not included on the final list.

Novel foods

The 'Novel Foods Regulation,⁹ is primarily directed at the manufacture of genetically modified or other technologically enhanced foods,. However it generally applies "to the placing on the market within the European Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories: (*inter alia*)

foods and food ingredients consisting of or isolated from plants ... except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use."

The manufacturer or importer of any product that could be considered as a novel food will be required to submit a request to the Member State in which the product is to be placed on the market for the first time (forwarding also a copy of the request to the Commission) containing "the necessary information, including a copy of the studies which have been carried out and any other material which is available" to demonstrate that the food or food ingredient presents no danger for the consumer "as well as an appropriate proposal for the presentation and labelling, ... of the food or food ingredient. In addition, the request shall be accompanied by a summary of the dossier." There follow up to 5 months of responses and possible challenges across Europe to this application.

Food status – summing up

For MAPs originating in India the food supplement option will in practical terms be limited to products that are familiar as foods, culinary herbs and spices in the UK or elsewhere in Europe (some borderline Indian foods widely consumed as therapeutic in traditional homes may be acceptable as well). Established food supplement products on the market are likely to come under increasing scrutiny by the regulators. New medicinal products that claim food status are likely to be considered as 'novel foods' and the level of documentation and research required remains unclear

Practitioner status

In European terms 'authorised health professionals' have rights to supply medicinal products that are not otherwise available to the public. These rights vary. The physician can prescribe, and take clinical responsibility for, a very wide range of substances. A pharmacist can dispense anything on this prescription and has professional rights to supply the full range of non-prescription medicinal products. Prescribing nurses, midwives and other health professionals with recognised qualifications may supply a range of prescription medication within a medical practice.

⁹ Regulation (EC) No 258/97 of the European Parliament and Council of 27 January 1997 concerning novel foods and novel food ingredients

Thus far there have been few statutorily regulated professionals linked to the herbal medicinal product sector. In Germany various Lander (States) license *Heilpraktikers* as non-medical health professionals able to supply a range of natural medicinal products including herbs. In the rest of continental Europe there is no such category of practitioner. Unless herbal medicinal products are licensed for sale over the counter (OTC) in the open market, their supply is largely restricted to pharmacists and physicians.

The notable exceptions in Europe have been the UK and Ireland, both of which have maintained in this area the common law right to consult who one chooses about one's health needs. The UK has developed the most elaborate structures around this principle, notably in allowing in the 1968 Medicines Act, an exemption ('Section 12.1') from licencing for any herbal medicine that is supplied individually to a person and "in that person's presence ..." and "in premises closed so as to exclude the public".

It has thus been legal for anyone to set themselves up as herbal practitioners and supply herbal medicinal products, as long as they do not claim to be registered medical practitioners and do not practise protected disciplines such as dentistry, midwifery, and veterinary medicine or supply medicines limited to prescription. This came close to more formal legal recognition: in 1978 there was an attempt within the terms of the Medicines Act (Statutory Instrument 2130) to identify herbal remedies that while not being safe enough for open sale could be provided by such practitioners (this was not fully enacted).

However Section 12.1 has been judged essentially incompatible with European law and a process of regulatory reform is underway. The UK Government has expressed a commitment to introduce a statutory register of herbalists or herbal practitioners, most likely regulated through the Health Professions Council, who will be authorised to supply herbal medicinal products directly to the public in England and Wales. A meeting of representatives of the Indian traditional medicines sector was held at the House of Lords in November 2009 to discuss ways of ensuring this commitment is honoured.

The practitioner market is currently small but already accounts for the vast majority of finished Ayurvedic products imported into the UK. There is a precedent for practitioners to set up semi-retail operations (like the former apothecaries) combining OTC and personalised supply of herbal products. This option will be identified later in this report (in Section 5) as the most promising channel through which to market new Indian MAP products into the UK. However, the future for this option in the UK market is entirely dependent on the government introducing the statutory register of herbalists or herbal practitioners and uncertainty remains until the government clarifies their position on this.

4. Quality issues — I) Sustainability

Summary:

When investing in the international MAP trade, modern social, environmental and quality-related expectations are increasingly important and are ignored inadvisably. At the international level there is general consensus on the need to manage sustainability of use within the MAP sector. European buyers increasingly expect verifiable labels, codes of conduct and management systems. Regulatory requirements also increasingly stipulate independently-verified standards of cultivation, harvesting and manufacture. Whilst important for the development of a transparent market in quality products made from sustainably collected MAPs, these standards raise the cost of both raw materials and finished goods. Any new MAP venture from India into Europe should factor these requirements into its business plan from the outset.

Collection ('wild crafting')

Cultivation rather than wild collection is the direction in which international trade in MAPs is moving (and accounts for the reduction of costs in the business overall). Only with cultivated MAPs can concerns about species and habitat loss be allayed. Unfortunately many MAPs are critically endangered in the wild, and if inappropriately collected (e.g. the whole plant is removed, or too much of the root) it can easily lead to local extinctions, loss of livelihoods for local people, and in other ways can threaten local habitats.

Where collection is still carried out there are a number of international agencies that work together with governments and NGOs to agree guidelines for the safe exploitation of wild plant species. The intention is to establish sustainable collection practices for MAPs but critics argue that supervision of collection is rudimentary in practice and that it is difficult for a few rangers to assure that sustainable standards have been met. If this was done by local people self-interest might prevent abuse of habitats, as was the case traditionally. However today collection is frequently undertaken by contracted labour or migrant workers with permits from state forest departments; with hourly-paid gatherers there are clear incentives to maximise yields.

International agencies setting standards for ensuring sustainability and quality of plant material include the following.

CITES - (www.cites.org/eng/resources/species.html)

CITES (the Convention on International Trade in Endangered Species of Wild Fauna and Flora) is an international agreement between governments. Its aim is to ensure that international trade in specimens of wild animals and plants does not threaten their survival. A CITES listing should halt international trade. **NOTE Indian endangered plants are listed at the bottom of the CITES webpage (link above) and include three species discussed on pages 45-49).**

IUCN – (cms.iucn.org/resources/index.cfm)

The World Conservation Union is the world's largest and most important conservation network. The Union brings together 83 States, 110 government agencies, more than 800 NGOs, and some 10,000 scientists and experts from 181 countries. The Union's mission is to influence, encourage and assist societies throughout the world to conserve the integrity and diversity of nature and to ensure that any use of natural resources is equitable and ecologically sustainable.

WWF – (www.wwf.org.uk)

WWF uses its practical experience, knowledge and credibility to create long-term solutions for the planet's environment.

TRAFFIC – (www.traffic.org/home/category/plants-medicinal-and-aromatic)

TRAFFIC is the wildlife trade monitoring network of WWF and IUCN. Its mission is to ensure that trade in wild plants and an animal is not a threat to the conservation of nature. On 4–6 April 2008 TRAFFIC India and WWF-India promoted the International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants (ISSC-MAP) at an International Summit on organised by The Associated Chambers of Commerce and Industry of India in New Delhi.

The International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants – (www.floraweb.de/MAP-pro/)

ISSC-MAP was developed by WWF-Germany, the IUCN/SSC Species Survival Commission Medicinal Plant Specialist Group (MPSG), TRAFFIC and the German Federal Agency for Nature Conservation.

ISSC-MAP provides clear principles, criteria, indicators and verifiers that will enable industry, resource managers, collectors and other stakeholders to assess and monitor the sustainability of wild resources and collection practices. The Standard focuses on ecological aspects of good collection practices (GCP), the need for thorough but cost-effective resource assessments and the determination of sustainable yields. Social and economic factors are also addressed. ISSC-MAP builds on but does not replace existing principles, guidelines, and standards for sustainable forest practices, organic production and good agricultural practices, fair trade, and product quality.

Sourcing

Increasingly consumers in the developed world value evidence that food and other commodities are sourced directly to growers and that the greater benefits from sale of these products go back to that source. A number of initiatives now exist to provide such assurance, with one notable example:

Fairtrade – (www.fairtrade.org.uk)

The FAIRTRADE Mark is an independent consumer label which appears on products as an independent guarantee that disadvantaged producers in the developing world are getting a

better deal. There are more than 20 different fair trade standards available around the world and an Indian fairtrade standard is being developed. Certifiers such as the Soil Association, IMO, EcoCert, and Rainforest Alliance have developed their own fairtrade systems, some of which can well be used for MAPs. So far it has not extended its reach very far into the world of medicinal and aromatic plants.

Quality: Good Agricultural and Collection Practice

There are specific legal requirements for the import into Europe of medicinal products from natural sources. These are designed to help assure the quality of the finished product and are taken along with Good Manufacturing Practice (see next chapter) for this purpose. However where the end product is to be medicinal they also help significantly to assure sustainability and particularly transparency as well.

Quality of herbal products depends directly on the quality of the plant material inputs. Since material of a plant species in the wholesale or manufacturing sectors may have originated from various harvesting areas, it makes it very difficult to identify sources of materials and to impose quality controls. The lengths of trade chains and the perceived need to protect information lead to a lack of transparency. The European Medicines Agency's Guideline on Good Agricultural and Collection practice (GACP) for starting materials of herbal origin requires that medicinal plants/herbal substances are produced hygienically in order to reduce microbiological counts to acceptable levels, and that they are handled with care so that they are not adversely affected during collection, cultivation, processing and storage. When medicinal products are the endpoints all stages require verification. The WHO has developed guidelines for the implementation of GACP.

GACP includes recommendations for all participants from primary producers to traders and processors. The key points are summarised below:

- In order to ensure quality assurance, agreements between producers and buyers must be based on the applicable recognised national specification (e.g. as required by the European Union) and be in written form, including details such as content of the active principle, macroscopical and olfactory properties, limit values for microbial contamination, chemical residues and heavy metals etc
- Primary processing procedures must conform to regional/national guidelines on food hygiene; staff welfare must be ensured; personnel must be protected from toxic or allergenic substances; persons suffering from diseases must be suspended; appropriate clothing must be worn; personnel should receive adequate botanical knowledge where necessary and collectors must have sufficient knowledge of the plant they have to collect.
- The building used in the processing and harvesting must be clean and provide adequate protection for the harvested plants/substances; packaged substances must be stored appropriately and there must be changing and washing facilities according to national regulations
- The equipment used in plant cultivation must be clean, regularly serviced and avoid cross-contamination.
- All processes and procedures that could affect the quality must be documented.
- Seeds should originate from plants that have been accurately identified and should be traceable. The presence of different species, varieties or different plant parts has to be controlled during the entire production process.

- Medicinal plants should not be grown in contaminated soil; manure applied should be thoroughly composted; fertilising agents should be applied sparingly and in accordance with the needs of the particular species.
- Irrigation should be controlled and water used should comply with regional/national quality standards.
- Tillage should be adapted to plant growth and requirements. Pesticide and herbicide should be avoided as far as possible.

In collection, individuals should be designated to identify and verify plants/substances. Collection must be carried out in line with regional/national legislation. Endangered medicinal plants/herbal substances must not be collected without relevant authorisation.

- Harvest must take place when best quality is possible and under the best possible conditions.
- Damaged plants need to be excluded or limited.
- Contamination from the soil must be kept at a minimum.
- The harvested medicinal plant/herbal substances must be promptly collected without contact with the soil and transported to clean, dry conditions.
- Care should be taken that no toxic weeds mix with the harvested plants.
- All containers must be clean and free of contamination from previous harvests.
- Freshly harvested medicinal plants/herbal substances must be delivered as quickly as possible to processing plants.
- Harvested crops must be protected from pests and pest control measures must be documented

Primary processing must follow regional/national regulations and should be carried out as soon after harvesting as possible.

The GACP has strict guidelines in relation to packaging as well as storage and distribution, including cleanliness, pest control, contamination and temperatures. The reduction of microbiological levels in a plant is particularly challenging. Adhering to principles of GACP will help reduce bacterial counts in starting materials and make it easier for such produce to satisfy the strict requirements of medicinal manufacture.

5. Quality issues — I) Manufacturing

Summary:

International standards in the quality control of medicinal plant materials have increasingly been accepted in what has always been a notoriously unregulated, low quality, herbal market. Europe, Australasia, Canada and Japan, which each require transparent and verifiable medicinal production standards for at least some of their herbal products set a model for other countries in which substitutions and adulterations remain common and product ranges often do not contain what the labels say.

In recognition of the role that medicine preparation processes play in assuring the safety and efficacy of herbal medicines, the World Health Organisation (WHO), has developed guidelines for manufacturing A WHO publication¹⁰ lays out pragmatic guidelines that it hopes could be applied all over the world. The following are the more rigorous requirements for the manufacture or import of medicinal products into Europe.



Good Manufacturing Practice

Good Manufacturing Practice (GMP) is that part of quality assurance which ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the medicine licence or product specification. GMP is concerned with both production and quality control. The latest European medicines legislation (Council Directive 2001/83/EC – see Chapter 3 – with amending Directive 2004/27/EC) lays down the latest requirements for the manufacture of medicinal products in the EC.

For the manufacturer, GMP is critical, involving assuring standards for independent inspection. Verified compliance with every element is essential to maintain a Manufacturing Licence. Without a rigorous independent inspection system that can close a manufacturer's premises for non-compliance then claims to GMP have no meaning.



Good Manufacturing Practice includes:

- validation of equipment and processes;
- documented Standard Operating Procedures covering every aspect of manufacture;
- documented cleaning and calibration logs for equipment;
- control of the manufacturing environment, air and water;
- quarantining and unique identification and testing of raw materials, labels and packaging;
- comprehensive batch record documentation;
- reconciliation of raw materials, product, packaging and labels;
- quarantining and testing of finished products;

¹⁰ World Health Organisation. Quality control methods for medicinal plant materials. Geneva 1998 ISBN 92 4 1545 10 0

- documented release-for-sale procedures;
- testing of stability of finished products;
- documentation of customer complaints and recall procedures.

In the case of herbal ingredients, identification must be confirmed by comparison with a verified reference material for that particular plant part and species. In practice this means that a pharmacopoeial reference will be important.

In the UK, the Medicines and Healthcare Products Agency (MHRA) produces a book '*Rules and Guidance for Pharmaceutical Manufacturers and Distributors*', commonly known as the 'Orange Guide', which contains an Annex: Manufacture of Herbal Medicinal Products, that includes extra requirements for the GMP manufacture of herbal medicines.

Pharmaceutical GMP, sometimes known as pGMP, is an essential requirement for the manufacture of medicinal quality products. By definition it is not self-determined (in spite of some herbal products claiming it on their labels) and is meaningful only when subject to national inspectorates. The UK recognises pGMPs from other Member States of Europe, from the USA, Japan, Australia and Canada, the latter three having the further advantage that they apply these to at least some of their herbal products. Any manufacturer applying Indian GMP is subject to secondary inspection by the UK authorities.

Section 2 Current state of European demand and Indian supply

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7 Indian supply and trade: the Pragya survey. A nationwide survey investigating the medicinal plant sector in India.	41
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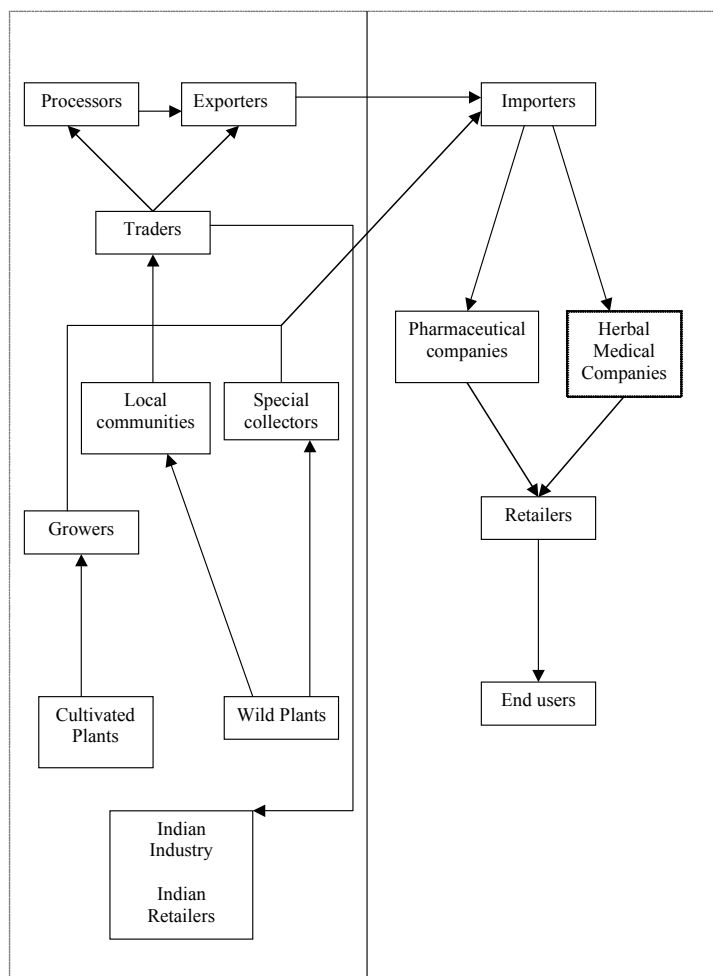
6. Market outlets and product categories in Europe

Summary:

The shape of any new business exporting Indian MAPs into the UK and Europe will depend on the end route to the consumer. The growth, manufacturing and trading of new products will need to be conducted in co-operation with manufacturing and distribution partners. Various trading options are considered and the basis laid for more specific market planning.

There are well-established fixtures in the passage from Indian growers to destination international markets.

EXPORTING COUNTRY IMPORTING COUNTRIES



Major herbal extract exporters include: Sanat Products Ltd., New Delhi; Sami Labs Ltd., Bangalore; Laila Impex/Chemiloids, Vijaywada; Natural Remedies Pvt. Ltd., Bangalore; Indfrag, Bangalore; Dhanwantari Botanicals, Bangalore; Arjuna Natural Extracts Ltd., Always; Avestagen, Bangalore.

Potential outlets for herbal remedies from India within Europe include the following (see below):

Finished product manufacture

There is a strong market for MAPs as raw materials in the pharmaceutical, nutraceutical, personal care, cosmetic, perfumery and food preparation businesses (see also Chapter 2). Generally speaking, most such manufacturers still buy from traders and distributors to keep their supplier base narrow (see also below). Demand in this area is for a relatively small range of plant products and the requirements are for high volume and competitive costs which may be difficult for growers scattered across remote areas to meet. However, European suppliers of plant extracts increasingly purchase material directly from countries of origin to improve traceability and to keep the supply chain short. Some end-manufacturing industries, particularly herbal medicine producers which carry out in-house procurement and processing, may also import directly from developing countries. There are also distributors representing well-known suppliers/manufacturers with pharmaceutical grade ingredients. They typically have their own principals with whom they deal. There are already indications that Himalayan producers may be able to contract for the supply of some commodities.

To elaborate on the immediate demands for medicinal plants in this sector, the Pragya team conducted an extensive market survey on the prices of high-value medicinal plants that are traded frequently at Khari Baoli, New Delhi, the largest market for raw/part-processed MAP material in India dealing with both domestic and export markets.

These prices are as follows:

Rank	Species	2008 Price (Rupees/kg)
1	<i>Valeriana jatamansi</i>	230-235
2	<i>Swertia chirayta</i>	225
3	<i>Picrorhiza kurrooa</i>	270
4	<i>Bunium persicum</i>	350
5	<i>Dactylorrhiza hatagirea</i>	1800-3100
6	<i>Nardostachys jatamansi</i>	165

All these plants feature in the market assessment in Chapter 8. The average quantity traded from Khari Baoli is between 400-500 tonnes per annum for each. About 80% of this is exported. The primary international customers for this market are Germany, Austria and Netherlands. According to the information collected, these three countries account for more than 50% of the exports of this market. As *Picrorhiza* is on the CITES endangered list and *Nardostachys jatamansi* (and by confusion *Valeriana jatamansi*) can be substituted by another plant on this list (see page 45) some of this trade is disturbing.

Physician prescription and pharmacy sales

In France and Germany physicians still prescribe or recommend herbal medicines, and pharmacies account for the majority of herbal sales. Physicians in the UK have rarely provided herbal products directly although there are pointers that support from doctors for herbal self-medication is increasing.

Pharmacies have increasingly provided herbal products in their general sales outlets and if an Indian product was to gain a medicine registration it could be sold this way. As an authorised health professional, a pharmacist is also able personally to supply herbal medicinal products that would otherwise require a licence as long as professional responsibilities to the pharmacist's governing body are upheld: this is an option very rarely applied to the supply of herbal medicinal products. With substantial business support, dedicated pharmacies for herbal products may be a sustainable option.

Non-physician prescription

In the UK (and Ireland), the status of traditional herbal medicine is protected under common law and up to two thousand self-employed individuals practise as medical herbalists in the western traditions, often after taking a first degree at one of 6 universities. They have been able to supply herbal medicinal products without a licence under general exemptions to the 1968 Medicine Act ('Section 12:1'): here a herbal medicinal product is exempt from licensing if supplied after personal consultation. This exemption will cease to apply when UK medicine legislation is fully harmonised with European law in 2011. Ahead of that deadline herbal practitioners in a number of traditions of western, traditional Chinese and Ayurvedic medicine, have worked together as the European Herbal and Traditional Practitioners Association (EHTPA - www.ehpa.eu) with advice from the Department of Health, to develop Statutory Self Regulation (SSR). They thus hope to attain their own authorised health professional status, allowing them to supply some herbal medicinal products not otherwise available to the public. In the case of Ayurvedic practitioners, there are 40 members of the Ayurvedic Practitioner Association (www.apa.uk.com) as well as those in the Ayurvedic Medical Association (see above) and the Maharishi Ayurveda Practitioners Association. There are likely to be a larger group not registered with these bodies.

Direct sourcing in developing countries is more common in this specialist channel. The vast majority of the trade in Ayurvedic medicines in the UK is with these end users. Major Indian companies in this business include

Dabur India Ltd. (www.dabur.com) is India's largest Ayurvedic medicine supplier Dabur's Ayurvedic Specialities Division has over 260 medicines – however these constitute only 7% of Dabur's total revenue (< 50 million dollars)

Sri Baidyanath Ayurvedic Bhawan Ltd. ('Baidyanath') (www.baidyanath.com) has a sales volume of about 350 million dollars, but most of the product sales are in the cosmetic range. The company reports having over 700 Ayurvedic products.

Zandu Pharmaceutical Works (www.zanduayurveda.com) focuses primarily on Ayurvedic products but has a chemicals and cosmetics division. Its total sales volume is about 45 million dollars.

The Himalaya Drug Company (www.himalayahealthcare.com) has a turnover of about 500 million dollars and has a U.S. distribution division (Himalaya USA). It sells directly into UK/Europe and has a dedicated website (www.himalayadirect.com)

An important conclusion for this report is that **there are fewer regulatory restrictions on the supply of medicinal plants via practitioners** (see Chapter 3). It is noteworthy that already sales of Indian medicines go beyond the Ayurvedic practitioner base to other non-physician practitioners, usually on the back of information

materials distributed through local networks. There are established markets for such products outside the UK, in Italy, the Netherlands, Germany (among Heilpraktikers) and Spain. The model of providing educational packages to practitioners will be explored in Chapter 10. However, this is a currently low-turnover business with many individual products turning over only hundreds of pounds per annum: even the relatively large group of western herbalists accounts for only 1-4% of the total herb volumes sold in the UK (possibly between £1.5-3 million pa).¹¹

Health food stores

Non-pharmacy retail sales of herbal remedies are most obviously channelled through health food outlets. In the United Kingdom, there are around 1,500 health food shops (including 800 run by the major franchise Holland & Barrett). In recent years this sector has become dominated by the US dietary supplement industry and quality standards, both in presentation and in content, have been very variable. Industry sources suggest that the health food sector in the UK has lost market share of herbal sales to pharmacies, though penetration in the latter remains relatively low. The sector has also been slow to position itself for the years after 2010.

One manufacturer, Pukka herbs (www.pukkaherbs.com) have successfully penetrated the sector with a range of Indian products, especially teas. Occasionally, e.g. the Nutra Centre at Hales Clinic in London, these health food shops provide a wider range of Indian remedies. However this remains a largely undeveloped prospect for new food supplement products or teas.

Supermarkets

Vitamins, dietary supplements and other natural products have increasingly moved into mass market outlets in recent years. Although herbals remain a relatively small part of supermarkets' product range, industry sources suggest that the proportion is increasing. Indian spice herb and tea products are also found in supermarkets in relevant population centres. One established performer is the Indian company based in USA and UK, Vitabiotics (www.vitabiotics.com). With increasing difficulties in establishing food supplement status for Indian MAPs, this is not a promising option for new entrants from the India sector. Although there are regulatory restrictions regarding food supplement status (see chapter 3) any products that achieved a medicine registration would have immediate access to this market.

Asian outlets and other specialist channels

Asian communities across Europe often support small traditional herbal practices based on crude or finished products imported directly from their original countries. In the UK such products are found in convenience stores in larger cities and in areas with high populations of immigrants from the sub-Continent. The Indian manufacturers listed above are prominent in these outlets.

There is a possible precedent in another ethnic sector. Chinese businesses have been particularly successful in taking their products onto the high street with dedicated shops appealing to the western consumer. Unfortunately this activity has been controversial with some claims and products apparently in breach of medicines legislation and it has proved difficult to regulate a sector that does not always use English-language labels. The Chinese retail model will become even more challenging after 2010 as their main business is selling medicinal products that do not have licences or registrations (see Chapter 3). **One future**

¹¹ Authors' assessment from personal marketing exercises and surveys in the UK

option for the Ayurvedic sector is to adapt the former apothecary model and have a practitioner on the premises during opening hours. If statutory regulation is successful, the practitioner will (as an ‘authorised health professional’) be able, like a pharmacist, to supervise the supply of medicinal herbal products to individual customers. However, this option remains dependent on the outcome of the implementation of the medicine Regulations (2005) in 2011 (see chapter 3).

Mail order and Internet

Mail order herbal sales are a frequent feature of advertisement pages in popular newspapers, glossy and health magazines and have become a prominent feature of many commercial internet sites. Claims are made for these products that sometimes appear to breach medicines legislation and there remains a long-term challenge to make Internet Service Providers and those responsible for the printed media more aware of the legislation and the risks to the public. Increasingly this US-dominated sector is has been joined by Indian companies selling Ayurvedic products directly to consumers worldwide. It was estimated in the year 2000 that the mail order market in the United Kingdom accounted for herbal sales of between £40-50 million per annum. This is almost certainly increasing faster than in any other sector. It is difficult to police international websites and a ruthless manufacturer of finished products can breach European and other national regulations with impunity. The only prospect for a prosecution is where there is an agent located in a European Member State. There is always the risk of a prosecution by a national medicines regulator, especially as new operating agreements are made with ISPs and national governments. In this case all it would take would be a mutually advantageous agreement on pharmaceutical standards between the Government of India and the European Union, for example, and such businesses could disappear.

Trading options

The international MAP business has generally been conducted with wholesalers and agents. They link manufacturers of finished products with suppliers of raw materials: the supplier seeks contracts or spot orders from the agent or wholesaler; the manufacturer contacts the wholesaler for assured supplies. Both supplier and manufacturer can rely on the light-footedness of the wholesaler/agent in keeping supply lines intact. Without this middleman there is the real likelihood of failures in the supply chain.

In the case of finished products from India there has also been a modest pipeline of direct sales to retailers and distributors in the UK and elsewhere. With the onset of fairtrade practices it is now more common for manufacturers to contract directly with the supplier of foods, coffee and tea, for example. So far there has been almost no fairtrade business in medicinal plants.

A new MAP operation therefore has three main trading routes open to it, each more or less determined by the sales outlet being sought from the list above.

- 1) **The wholesaler route.** Although some wholesale contracts can be quite small-scale, they usually involve relatively large-scale cash crops of standard commodities in the pharmaceutical, personal care and food sectors. The advantage could be a relative secure income over several years. There are disadvantages for small-scale rural growers:
 - a) competition with international prices and established industrial producers, particularly if there are logistic difficulties in taking crops to distribution centres,

- b) subjection to the whims of a large and impersonal market, growing crops that are not likely to be indigenous, and
 - c) the likelihood that returns to the grower communities will be small relative to others in the supply chain.
- 2) Direct to practitioner and retailer.** This has been a traditional supply line used by manufacturers in India into developed markets. Most products have been supplied into the unregulated borderline sector with minimum involvement from the regulator. The route involves a manufacturer in most cases targeting his main production to the Indian market. Re-labelling may or may not then follow for the export market. This route could be significantly developed with improved product quality and educational packages to practitioners (see below) but such developments are dependent on the outcome of the implementation of the medicine Regulations (2005) in 2011 (see chapter 3).
- 3) New high-quality niche products.** This is a relatively new prospect, in the wake of new fairtrade awareness among consumers and the presence of a premium niche market for high quality transparently-sourced products. It involves creating new market opportunities with partners in developed countries like the UK. However because of the regulatory difficulties placing medicinal products on the market in Europe (see Chapter 3) such routes will need to be carefully planned and may involve developing the market with practitioner suppliers.

The evidence strongly supports the view that a future operation to market MAPs into UK/Europe will require substantial long-term planning, close co-operation with manufacturing and distribution partners and effective skills. The need for high and transparent standards at every step of the process necessitates a pitch to the top end of the market. Our report will develop the available prospects from this position.

7. Indian supply and trade: the Pragma survey

Summary:

Pragma carried out a major survey in 2006-7 of the Indian context for marketing and cultivating Himalayan MAPs that we have independently analysed in this report. Sales of MAPs in India are increasing and there are moves to improve standards so as to address persistent problems around quality assurance, bureaucratic bottlenecks and a lack of reliable certification. The survey highlighted the complexity of trading channels and challenges for the development of direct buyer-to-grower relationships. For the sector to grow successfully, there is a need for stable supply and bulk orders, improved quality, clarity over the role the trader/agent middle man and incentives for sustainable sourcing.

Background on Indian MAPs

The role of medicinal plants is particularly important in the Himalayan region. As a natural heritage traditionally stewarded by the indigenous Himalayan communities, these herbal resources are used for consumption needs in food and medicines, for themselves and their cattle. People in rural India depend considerably on wild edibles. Especially in the Himalayan region where the cultivation season is short, only staples are cultivated. Knowledge of health promoting properties of various wild plants exists among the rural folk, and fruits, seeds, roots, leaves, are collected as per these properties and consumed, as food supplements.

As has been mentioned earlier in this report, traditional, plant-based systems of healthcare have significant contemporary relevance in helping developing countries such as India meet the aim of 'Health for All', with an accessible, affordable and generally effective healthcare system. Marginalised communities without access to formal and mainstream healthcare delivery systems and those in poverty without the means to access available systems, are served by a large network of practitioners in India.

Rural Livelihoods

The MAP sector is estimated to generate about 40 million days of employment nationwide per annum. In addition to contributing to national GDP, a major proportion of this labour contributes to the livelihoods of some of the poorest and most disadvantaged in Indian society. As in all other remote regions in the world that lack alternate livelihood avenues and are primarily subsistence economies, wild collection of Himalayan herbs contributes cash incomes to the households of primitive and indigenous communities, the landless, and poor and marginalised farmers, in the Himalayas. A study in the Central Himalayas indicated that about 2,000 person-days/year of direct employment is generated through MAP related work in a 150 household village, of which 50 households are involved in such work; in addition indirect livelihoods (50,000 person-days) are generated through MAP collection for consumption purposes.

Cultivation of many of the high-value Himalayan herbs has begun on a micro scale. Since these species are habitat-specific and can be grown with ease only in the Himalayan climes where they evolved, there is a distinct competitive advantage for the Himalayan farmer who undertakes commercial cultivation of Himalayan MAPs. MAP harvest is challenging and is a long-term enterprise, with most species requiring a gestation period of up to 3 years before

the first harvest. The typical farmer has only small landholdings in which to cultivate food crops for subsistence, and therefore finds it difficult to commit land for MAP production. MAP output is small and there is also the distance to markets, lack of roads, and the mountainous terrain. Many farmers find these combined challenges insurmountable, in spite of the advantages of favourable agro-climatic conditions and value to weight ratio of the harvests. However, with adequate support and facilities, the small Himalayan farmer would find in MAP cultivation a route out of poverty.

The survey

Pragya carried out a comprehensive study in 2006-7 on Himalayan MAP species, investigating their status in the wild, their sustainable management needs, their position in trade and the needs of industry in their regard. The study involved the following:

- *a survey of perceptions and needs of Himalayan communities vis-à-vis conservation and cultivation related issues.* In order to elicit these Pragya conducted two all-Himalayas workshops (2006-2007) with participation of communities from various Himalayan districts.
- *a review of literature and a nationwide survey investigating the medicinal plant sector in India, with specific focus on Himalayan species.* The trade survey conducted (Jan-March 2007) collected primary data through interviews with traders, wholesalers and manufacturers, trade associations, small pharmacies, indigenous healers, and research, conservation and regulatory authorities; secondary data compiled from National and International publications on MAPs, Reports of NGOs, government and semi-government-sponsored studies (Task force and Commission reports). The EXIM Bank, CERPA (Centre for Research, Planning & Action) and others also provided valuable insights into the market for Himalayan MAPs.

The survey covered eight regional markets in the country and two national markets noted for the trading of medicinal plant material. These were:

- **Regional Markets:** Amritsar, Ludhiana, Saharanpur, Bareilly, Haridwar, Ramnagar, Tanakpur, Kolkata, Siliguri
- **National Markets:** Delhi (Khari Baoli), Mumbai (Navi Mumbai)

In each regional market, retailers, wholesalers, manufacturers/pharmacies, and trade associations, were interviewed. Apart from these, regional research organisations and NGOs with interests in the herbal sector, were also surveyed. In the national markets, exporters and regulatory bodies were also interviewed.

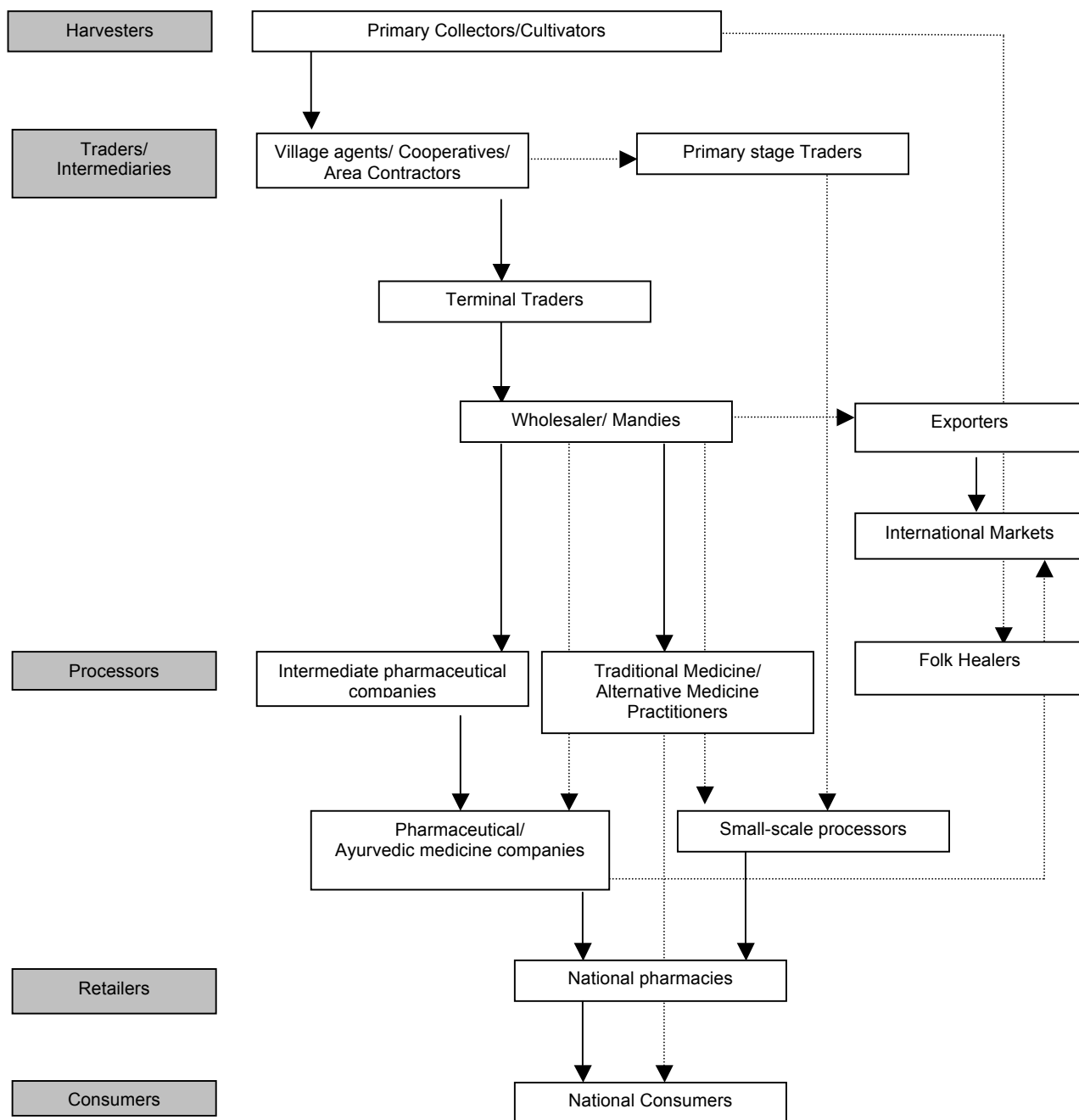
Marketing channels

The medicinal plants sector includes a number of stakeholders with divergent interests. Among the final pre-consumer users of medicinal plant material are: a) small-scale users of medicinal plant materials, who serve the health needs of the rural poor and village folk healers, traditional birth attendants, and bone setters; b) practitioners of the codified systems of traditional medicine and alternative therapies, viz, Unani, Ayurvedic, Homeopathic, Sowaigpa and Siddha specialists, acupuncture therapists, Yoga practitioners, Reiki masters and others, who are also typically small-scale users; c) large-scale buyers who bring out packaged and branded plant-based products: pharma/cosmetic majors comprising pharmaceutical companies, phyto-pharmaceutical companies, manufacturers of health products and cosmetics, and manufacturers of branded traditional and alternative medicines.

Buyers. There are more than 750,000 registered practitioners and licensed pharmacies of the various traditional systems of medicine, in India. Folk healers and unregistered practitioners are not included in this number.

Broad channel structure. Medicinal plant material moves through several intermediaries from the primary collector/cultivator before it reaches the final processor, either the small-scale traditional/alternative medicine practitioner or the large pharma/cosmetic major. The schematic overview of various stakeholders involved in the MAP Sector is represented in fig. 7.1. However, it must be noted that this is a highly informal structure and characterised by a lack of clear flows and norms.

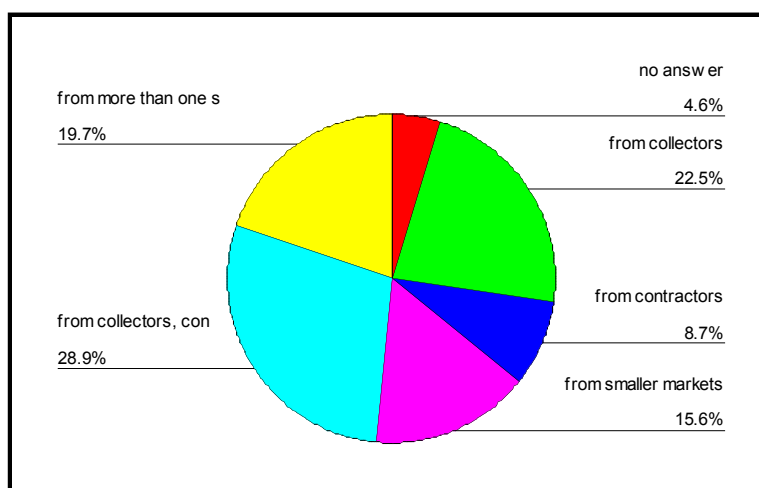
Fig. 7.1 Medicinal and Aromatic Plants trade channels in India



(Adapted from Belt et al, 2003)

Unstructured market. The survey revealed that a majority of traders interviewed source their raw materials from at least two sources and 43% from multiple sources, including collectors, contractors and small traders. The fact that the contractors, collectors and small retailers in the minor markets are suppliers of the larger traders implies that there is no clear delineation among the different levels and the same player may play multiple roles in the MAP trade. Fig. 7.2 shows how respondents identified their sources.

Fig. 7.2 Sourcing of raw materials



The Pragma study also indicated that 41% of the primary-level traders source their material only through collection, only 14% source it purely from cultivation, and 45% follow a mixed sourcing, i.e., from both collection and cultivated sources.

Dominance of the middleman. Almost half (47%) of the manufacturers interviewed source over 75% of their raw materials from middlemen rather than directly from collectors. Only 23% of all traders source their produce from cultivators alone. The cultivators (individuals and growers' cooperatives) were revealed to be still only a minor player in this trade. The two major reasons are: the lack of economically viable volumes of raw materials available with the growers and the inability of the growers to meet quality requirements. 88% of companies procuring from traders gave a high priority to the regularity of supply. The lack of direct interaction between growers and manufacturers is a constraint in the development of a sustainably cultivated MAP sector, but it is almost impossible to eliminate the middleman in the trade.

77% of the retailers interviewed procure their materials from the smaller regional markets. 50% of the respondents stated that they source materials from both small markets and collectors. Thus, in the retail trade of medicinal plants, the smaller regional markets play a very important role. However these markets are unregulated and in most cases, controlled by traders' cartels.

Procurement/Supply Patterns

Large volumes, low price. A majority of the traders and retailers considered price as the main priority. In order to procure cheap raw materials they preferred dealing in bulk trade and reducing the role of small growers and suppliers. One study has revealed that 18% of procurement occurs in the 1000-2000 tonnes range, 32% in the 500-1000 tonnes range,

18% in the 400-500 tonnes range, and 32% in the 1-400 tonnes range. Thus traders usually buy their stocks from the cheapest sources, which may vary from year to year. Often the traders employ local agents to collect medicinal plant parts directly from the villagers at lowest cost, which make cultivation of MAPs uneconomical and encourage illegal extraction of the wild population of different endangered species. The paid collectors of the medicinal plants use unsustainable and non-regenerative practices of collection, since they are interested in maximizing the gains in the short term.

Stable supply. 89% of the terminal traders and 70% of manufacturers procure their material throughout the year. However MAP species typically follow annual harvesting cycles, forcing the intermediate traders to store their products year round. As the growers usually lack storage facility, they are forced to sell their produce soon after harvest and cannot take the advantage of price premiums during the rest of the year. These factors mitigate against growers as suppliers.

Risk to habitats. Many trade demands are for plant parts that require destructive forms of harvesting. 63% of the material in trade comprises roots and another 5% comprise whole plants. This indicates the urgency of the need for using cultivated material where possible, and active movements to conserve of wild resources.

Demand-supply gaps. **There is generally a large demand-supply gap in MAPs, estimated at around 400,000 tonnes** (Planning Commission, Government of India). While for a significant majority of the major Himalayan species in trade demand far outstrips supply, there are a few species that have the opposite demand-supply equation. Plants on CITES endangered list are in red:

High demand/ High supply, Equal demand- supply relation	High demand/ Low supply; Demand greater than supply	Low demand/ High supply, Demand lower than supply	Low demand/ Low supply, Equal Demand- supply relation
<i>Usnea longissima</i> / <i>Usnea sikkimensis</i>	<i>Aconitum heterophyllum</i>	<i>Hippophae rhamnoides</i>	<i>Berberis aristata</i>
<i>Allium carolinianum</i>	<i>Dactylorhiza hatagirea</i>	<i>Heracleum candicans</i>	<i>Urtica dioica</i>
<i>Betula utilis</i>	<i>Picrorhiza kurrooa</i>	<i>Rheum australe</i>	
<i>Cedrus deodara</i>	<i>Cordyceps sinensis</i>	<i>Selenium vaginatum</i>	
<i>Valeriana jatamansi</i>	<i>Angelica glauca</i>	<i>Corydalis govaniiana</i>	
	<i>Nardostachys grandiflora</i>	<i>Pinus roxburghii</i>	
	<i>Jurinea</i>		
	<i>Saussurea costus</i>		
	<i>Pleurospermum angelicoides</i>		
	<i>Taxus baccata</i> subsp. <i>wallichiana</i>		
	<i>Podophyllum hexandrum</i>		
	<i>Swertia chirayita</i>		

Most respondents in the survey had little idea about how MAPs moved from local region to the tertiary market. However, in the case of some MAP species (e.g. *Aconitum heterophyllum*, *Inula racemosa*, *Jurinea dolomiaea*, *Saussurea costus*, *Picrorhiza kurrooa*, *Berberis aristata*, *Arnebia benthamii* and others), species-specific regional channels from origin through the common routes could be discerned from discussions with experienced traders, mainly from Punjab and West Bengal.

Prices & revenues

Price trends. The survey revealed that 82% of the major Himalayan species in trade have experienced a continual upward price movement over the last 3 years; the remaining 18% too have held constant and none have shown a downward trend. The value of *Aconitum heterophyllum* in the market, for instance, has shown an 84.6% price escalation in 3 years; *Podophyllum hexandrum* has shown a 46.6% price escalation in the same period; endangered *Saussurea costus* increased 183.3% in 3 years.

Revenue sharing. The collectors/cultivators get a small part of the total earnings, ranging from 18% for *Picrorhiza kurroa* to 30% for *Podophyllum hexandrum*.

Quality & adulteration

Quality priority. About 61% of the traders and a great majority of retailers place high priority on product quality, and this plays an important role in determining the price of procurement. Many traders procure unprocessed material and carry out limited post-harvest processing facilities before further sale. Most of the manufacturers were similarly concerned about quality of the raw materials, the improper harvesting and post-harvest processes used with the medicinal plant parts, impurities/adulterants mixed in the raw materials. The lack of established quality standards emerges as a bottleneck for MAP trade and a serious concern at almost every level of the trade channel.

Quality assessment parameters. Quality of the material procured is found to be generally dependent on the time the trader has been in business. The larger more established traders usually put a premium on their brand name and make efforts to maintain high quality standards, while the smaller traders may be more inclined to increase their profit margins instead of going in for costly Quality Control initiatives. An overwhelming 88% of the traders and all small-scale manufacturers and retailers interviewed, use organoleptic quality assessment (relying on the physical characteristics of the produce such as its visual appearance, colour and odour). Only about 36% of the respondents, mainly the exporters and the bigger manufacturers, used laboratory-based, scientific chemical analysis of the raw materials.

Traders and retailers also attach a high priority to the place of origin of the produce while determining quality of and grading the produce. For instance, *Aconitum heterophyllum* roots sold in the national market in Delhi is primarily sourced from Kashmir in the western Himalayas and from Uttarakhand in the central Himalayas- the former is 80% of the price of the latter. The provenance is determined by the colour and size of the material- Aconite roots from the central Himalayas is white in colour and thicker than the material from the western Himalayas.

Adulteration. Impurities and adulterants are identified and eliminated from the produce by experienced traders. Adulteration, when it happens, is of three kinds: a) through lack of ability to identify the species among the collectors and traders, plants of a different species but same genus are used; b) artificial colours may be used to disguise inferior quality roots as higher grade material; c) straw, grass, rice husk, sand, soil, dried branches and other similar looking or smelling materials, may be used to add volume. Some prominent alternate species substitutes are:

- *Valeriana hardwickii* for *V. jatamansi* (as sources of the drug Valerian);
- *Valeriana jatamansi* for *Nardostachys grandilora*;
- *Andrographis paniculata* for *Swertia chirayita* (latter is a high altitude species, high in demand and endangered);
- *Gentiana kurrooa* for *Picrorhiza kurrooa*;
- *Inula racemosa* for *Saussurea costus*;
- *Gentianella moorcroftiana* and *G. paludosa* for *G. kuroo*.

Some adulterants that are mixed with the species in high demand are: *Selinum vaginatum* with *Valeriana jatamansi*,

- *Chaereophyllum villosum* with *Aconitum heterophyllum*,
- *Carica papaya* seeds with *Piper nigrum*,
- *Arctium lappa* with *Saussurea costus*.

Regulatory regime

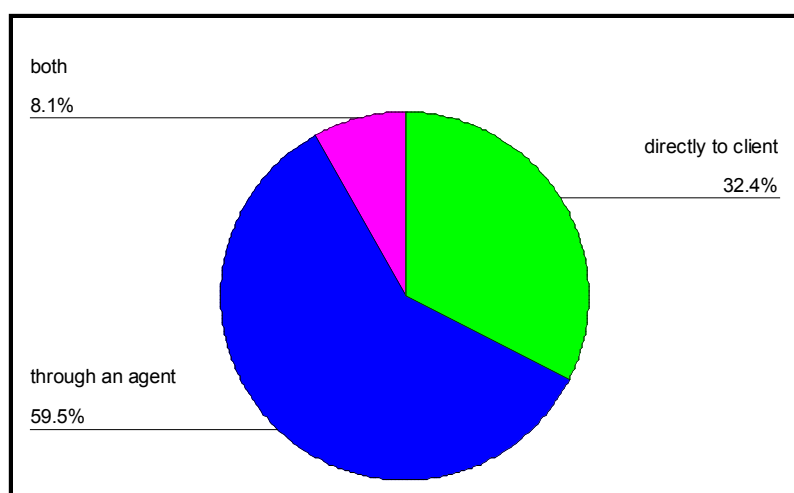
Information gaps. Almost all the respondents agreed that all concerned in the supply chain should keep records. However the majority of them were not aware of the importance of traceability of raw materials. The respondents believed that documentation at individual level would help reduce data loss. 83% of the manufacturers and 80% of the retailers identified traders as the group in which most data is missing. While some of this is because of lack of documentation, some is deliberate, because of the high volume of illegal trade. Another area of data loss was identified to be collection/harvesting stage, followed by losses at the level of domestic end users and during export. Lack of information on trade data is a major impediment to framing an effective policy for regulation of medicinal plants.

Effect of regulation. 63% of respondents found existing regulations to be restrictive while 21% found them helpful. It is felt that there is no uniformity in the regulation of MAPs trade among the different States. This leads to confusion during transit of raw materials from one State to another. There is confusion regarding the list of species restricted for extraction and trade as these lists vary from State to State. 60% of retailers were found to be unaware of current laws relating to the MAP trade. An even greater percentage of the people in the trade are unaware of the emerging requirement for traceability and related regulations - only 18% of those interviewed were aware of it.

Export

Export channels. Almost a third of exporters dealt directly with their clients (fig. 7.3), while the remaining depended on agents.

Fig. 7.3 Export of MAPs from India



Material traded. Only 22% of respondent traders were engaged in export of medicinal plants and plant products. 60% of exporters dealt in dried plant parts. 5% exported only powdered raw material, while 35% dealt in both the forms. A study by the Exim Bank of India indicated that of 880 plants traded in India, 48 species are exported. An assessment by the Bank in 2004 revealed that the revenue share of herbal products in the export of medicinal plant materials and Ayurvedic products from India has been steadily increasing over the years so that by 2003 herbal products accounted for as much 55% of total revenues.

Issues in most need of attention

Respondents highlighted those issues in MAP trade which they felt most needed modification.

Procedures and red tape need to be reduced. The major bottlenecks generally involve bureaucratic delay such as difficulties in obtaining licences for new entrants and transit permits, restrictions regarding volume of trade and storage, obscure official quality standards, and so on. Respondents suggested that these issues would be improved by the implementation of countrywide legal procedures for cultivation and trade which ensured transparency at all stages.

Norms and standards need to be established. The lack of standards in formulations and finished product ingredients is one of the major hindrances for sustainable growth of this sector. Respondents believe that this could be addressed by the formulation of a recognised central or regional authority with responsibility for introducing and ensuring norms and standards in the sector.

Market conditions typical of a small and growing market. Constraints faced by the Himalayan medicinal plants sector also include: absence of a steady market with fluctuations in demand and shortage of materials during high demand, inadequate awareness among the Himalayan farmers regarding MAP species and their marketing, the long growing period of some MAP species, lack of governmental support in this sector and the dominance of middle men and agents over the trade. Sustainable cultivation will go some way to addressing these issues, but direct links between the collectors and the trading community,

with a commensurate reduction in the role of the middle man, will also significantly improve market conditions.

Challenges in export trade. The major difficulties faced by export traders are: difficulty in getting export licenses for the species mentioned in CITES and meeting their clients' quality parameters. Other challenges include difficulties in obtaining export-import (IE) codes for MAP products and high license fees. Other constraints that discourage the dealers of medicinal plants from exporting are: obtaining sufficient quantities for export orders, complicated procedures, meeting requirements for organic produce and the absence of certifying agencies. A summary of suggestions put forward by the stakeholders to address issues with export trade and other issues mentioned above were:

- implementation of simplified, uniform, countrywide legal procedures; publication of 'open for trade' lists for MAPs; simplifying procedures for obtaining LPC (Legal Procurement Certificate); regular reviews of banned species lists;
- promotion of cultivation by the government;
- special relaxations for species used in life-saving drugs and ones that are presently being imported;
- providing proper infrastructural facilities for storage and marketing;
- standardization of market prices and quality parameters;
- reducing freight rates, providing tax exemptions;
- developing direct links between the farmers/collectors and the trading community to reduce the influence of middle men;
- improved documentation at the buyers' and the suppliers' stage, either at individual levels or collectively through trade associations;
- sharing of information regarding demand, price fluctuation, stable markets and marketing contacts, etc through information centres, newspapers, trade associations or marketing cooperatives, and regular buyer-seller meets.

8. Indian medicines in Europe: the Himalayan sample

Summary:

A sample of medicinal species has been considered, consisting of products that are available from the Himalayan region in which Pragma operates. After review, 3 of the 12 listed are both cultivated in a sustainable way and have good marketing prospects in the UK (though legally only via practitioners). 2 have good prospects but are still collected from the wild; 4 have poor prospects and are also still collected from the wild; and 3 are too toxic to be marketed openly in Europe.

Familiarities and differences

Although most Himalayan species are unknown to the mainstream European market there are a good number that are well recognised. These are highlighted in the following list of classical Ayurvedic preparations.

System	Classical preparation	Himalayan species
Digestive	Kshudakari vati (OTC)	Zingiber officinalis, Carum carvi, Citrus spp
	Kankayan vati (Pres)	<i>Hedychium spicatum</i> , Acorus calamus
	Bilvadi churna (Pres)	Zingiber officinalis, Coriandrum sativum, Cannabis sativa
	Dantoded gangatak rasa (Pres)	Curcuma longa , <i>Barberis aristata, Bunium persicum</i>
Respi-ratory	Som churna (Pres)	<i>Ephedra gerardiana</i> , Acorus calamus, Zingiber officinalis
	Kafkatrairas (Pres)	<i>Achyranthus aspera, Solanum indicum, Acorus calamus</i>
	Pushkaramuladi churna (Pres)	<i>Inula racemosa, Hedychium spicatum, Acorus calamus</i>
Musculo-skeletal	Rasnadi churna (Pres)	<i>Angelica glauca, Pluchea lanceolata</i>
Urino-genital	Mahasudarshan churna (Pres)	Swertia chirayta , <i>Hedychium spicatum, Barberis aristata, Tinospora cordifolia</i>
	Muktadi vati (OTC)	<i>Cyperus rotundus, Crocus sativus, Rosa webbiana</i>
	Pushyanug churna (Pres)	Rubia species, Zingiber officinalis, Cyperus rotundus
	Chandraprabhavati (Pres)	Acorus calamus, Cyperus rotundus, Swertia chirayata, Cedrus deodara
	Ashokarista (Pres)	Zingiber officinalis, Barberis aristata, Cyperus rotundus
Nervous	Brahmi vati (OTC)	Centella asiatica, Acorus calamus, Nardostachys jatamansi
	Brahma rasayana (OTC)	Asparagus racemosus, Centella asiatica, Acorus calamus
Blood-vascular	Mehmudgar vati (Pres)	<i>Cedrus deodara, Swertia chirayata, Zingiber officinalis</i>
	Rakshodak vati (Pres)	<i>Picrorrhiza kurroa, Barberis aristata, Rubia spp</i>
	Sarivadi vati (Pres)	<i>Saussurea costus, Rubia cordifolia, Tinospora cordifolia</i>

Himalayan MAPs also have non-prescription prospects as follows:

Uses	Species
Analgesics	<i>Aconitum ferox</i> , <i>Bunium persicum</i> , <i>Inula racemosa</i> , <i>Panax pseudoginseng</i> , <i>Saussurea costus</i>
Soothing/Sleeping	<i>Dactylorhiza hatagirea</i> , <i>Nardostachys jatamansi</i> , <i>Panax pseudoginseng</i> , <i>Saussurea costus</i>
Herbal teas	<i>Nardostachys jatamansi</i> , <i>Panax pseudoginseng</i> , <i>Valeriana jatamansi</i>
Cough, Cold, Allergy	<i>Aconitum ferox</i> , <i>Bunium persicum</i> , <i>Nardostachys jatamansi</i> , <i>Picrorhiza kurrooa</i> , <i>Saussurea costus</i> , <i>Taxus baccata</i> , <i>Valeriana jatamansi</i>
Digestive remedies	<i>Bunium persicum</i> , <i>Podophyllum hexandrum</i> , <i>Saussurea costus</i> , <i>Taxus baccata</i>
Dietary supplements	<i>Bunium persicum</i>
Smoking cessation	<i>Valeriana jatamansi</i>
Aphrodisiac	<i>Dactylorhiza hatagirea</i> , <i>Inula racemosa</i> , <i>Nardostachys jatamansi</i>
Antiseptic	<i>Inula racemosa</i> , <i>Podophyllum hexandrum</i> , <i>Taxus baccata</i>

Snapshots of the medicinal properties and value of the twelve Himalayan medicinal and aromatic plant species considered in detail are presented below. These plants are selected on the basis of endemism, vulnerable status, market demand and origin of supply.

<i>Aconitum ferox</i>	<i>Inula racemosa</i>	<i>Podophyllum hexandrum</i>
<i>Aconitum heterophyllum</i>	<i>Nardostachys jatamansi</i>	<i>Saussurea costus</i>
<i>Bunium persicum</i>	<i>Panax pseudoginseng</i>	<i>Taxus baccata</i>
<i>Dactylorhiza hatagirea</i>	<i>Picrorhiza kurooa</i>	<i>Valeriana jatamansi</i>

All twelve species are listed as endangered or critically endangered in the Red Data Book of Indian Plants (those in red are also on the CITES endangered list); all are endemic to the Himalayas or specific stretches of Himalayas, occurring over the height of 2000m. *Inula racemosa* and *Saussurea costus* are in cultivation, *Podophyllum hexandrum*, *Valeriana jatamansi*, *Panax pseudoginseng*, and *Taxus baccata* are cultivated as well as collected from wild, while *Aconitum ferox*, *Aconitum heterophyllum*, *Bunium persicum*, *Dactylorhiza hatagirea*, *Nardostachys jatamansi* and *Picrorhiza kurooa*, are still obtained mostly from the wild, however, all twelve have established cultivation protocols. Agro-technologies for the species on the CITES list (*Nardostachys jatamansi*, *Saussurea costus*, *Taxus baccata* and *Picrorhiza kurooa*) and *Aconitum heterophyllum* are also available, although in limited use. But government and NGO support for cultivation of the species is being provided to encourage sustainable supply of these species, and maximise their potential for poverty alleviation of Himalayan farmers.

In the following 4 pages the realistic prospects for international sales of these 12 herbs are outlined.

Sample herbs that are currently available to practitioners in the UK which are cultivated (ie sustainable) AND which have strong market prospects

Names and plant part	Significant constituents	Traditional characterisation	Likely modern applications	Level of efficacy data	Quality and safety issues	Comments
<i>Inula racemosa</i> 'pushkara' root	Essential oil; alantolactone, iso-alantolactone and dihydralactone.	Warming expectorant and aromatic digestive, also used as a component of remedies to modulate the inflammation of arthritis and with reputed effects against intestinal worms; expectorant action used in tuberculosis	Beneficial component of remedies in debilitated conditions marked by poor digestion and particularly chest infections; reputed to relieve a variety of chest pains.	Adrenergic beta-blocking activity observed in patients with ischaemic heart disease (no controls); some pharmacological data: eg decreases cortisol and blood glucose in rats and mice; and unknown constituent slows heart beat in isolated frog heart	<i>In vivo</i> sensitizing effects of alantolactone. Confusion with other <i>Inula</i> species is likely; can be substituted for <i>Saussurea costus</i> (below)	Used widely in practitioner formulations
<i>Saussurea costus</i> root	Essential oil: incl. camphene (0.4%), aploayene (20%), costene (6%), phellandrene (0.4%), alpha-costene (6%), costol costus acid (14%), costol (7%), costus lactone (11%), and dihydrocostus lactone (15%)	Expectorant now used as an antispasmodic in asthmatic conditions; carminative; a nervous depressant with mild opiate like properties; used also as in-inflammatory diseases of joint and skin.	Promising remedy in inflammatory conditions with tension or anxiety component.	<i>In vivo</i> research demonstrate anti-inflammatory, anti-ulcer, anticancer and hepatoprotective activities; <i>in vitro</i> antioxidant effects confirmed	In the UK the main species is considered to be <i>S. lappa</i> ('costus root') – also from the Himalayas and stated as an ingredient in PADMA-28: these two species may be the same. Opiate reputation requires further investigation	Saussurea extract is used as ear drops and applied as poultice over painful joints and boils. An essential oil is used in medicines, perfumery, incense, as a hair rinse, as an insecticide and insect repellent. NOTE on CITES endangered list
<i>Valeriana jatamansi</i> 'tagara' root	Essential oils; pinene, camphene, borneol and bornyl isovalerate valepotriates; flavone glycosides (acacetins); iridoids, (valtrates)	Delirium, insomnia and convulsions; abdominal and pelvic remedy for menstrual disorders and urinary pain and to calm spasm anywhere	Possible alternative for European valerian and as a remedy for anxiety conditions.	No data.	Accepted substitute for <i>V. wallichii</i> the main Indian species in use in the UK, all confused with <i>V. officinalis</i> (and other species eg. <i>V. procerca</i> , <i>V. edulis</i> , and <i>V. sitchensis</i>). Also likely to be confused as 'jatamansi' with <i>Nardostachys</i> (below)	Common prescription in formulations for tension disorders. Need to be botanically authenticated before use in any quality product

Sample herbs that are currently available to practitioners in the UK have relatively strong market prospects, if current wild collection ceases

Names and plant part	Significant constituents	Traditional characterisation	Likely modern applications	Level of efficacy data	Quality and safety issues	Comments
<i>Nardostachys jatamansi</i> 'jatamansi' 'spikenard' rhizome	Essential oil (1.9% ('spikenard oil'), resin, bitter principle, an alcohol and its isovaleric ester; jatamansic acid ketones (jatamansone and nardostachone);, sesquiterpenes, (delta 1(10)-aristolene-9-beta-ol, debilol, nardosinone, kanshone A); a diterpene; monoterpenes (jatamansone found to be equivalent to valeranone in <i>Valeriana officinalis</i>)	Calming, even sedative tonic and digestive; anti-ischemic, antioxidant, spasmolytic neuroprotective, diuretic, stomachic and laxative activities	Prospect as a contender in the ginkgo and kava sectors	Many animal studies point to CNS and anticonvulsant effects with potential benefit in cognitive deficits: 200-600mg had a dopaminergic effect in rats; 200mg/kg in mice significantly improved learning and memory; cardioprotective effect at very high doses (500mg/kg) <i>ex vivo</i> in rats possibly mediated through antioxidant effects; <i>in vitro</i> anticholinesterase activity has been identified as possible leads for the treatment of Alzheimers..	Possible overlap and even confusion with <i>N. grandiflora</i> (spikenard) which is listed separately here as the main species in trade figures. Also likely to be confused as 'jatamansi' with <i>Valeriana jatamansi</i> NOTE N. grandiflora is on the CITES endangered list	Well-known remedy with used as basis for ancient perfume and even with its relative <i>Valeriana jatamansi</i> . Possible component of hair applications. Need to be botanically authenticated before use in any quality product especially as can be confused with an endangered species.
<i>Picrorrhiza kurrooa</i> katuka Rhizome, root	Iridoid glycosides: picroside-I and kutkoside; apocynin	Bitter tonic, febrifuge, hepatic/choleretic, stomachic and occasional laxative. In more modern times applied in inflammatory diseases and cases of asthma and hypertension.	To stimulate digestion and bile flow and as hepatoprotective in mild biliary conditions or after eating rich food or alcohol.	Clinical studies show benefits in viral hepatitis. <i>In vivo</i> hepatoprotective effects and stomach ulcer healing effects in mice; potent <i>in vitro</i> immunostimulant, stimulating both cell-mediated and humoral immunity; <i>in vitro</i> hepatoprotective and antioxidant properties of constituents	Skin rashes reported; high doses may cause diarrhoea.	Currently used in practitioner formulations NOTE on CITES endangered list

Sample herbs which are wild collected and also have weak market prospects in the UK

Names and plant part	Significant constituents	Traditional characterisation	Likely modern applications	Level of efficacy data	Quality and safety issues	Comments
Aconitum heterophyllum 'atis' root	Atisine- a non-crystalline, relatively non-toxic, intensely bitter alkaloid; aconitic acid, tannic acid.	A bitter tonic used to cool fever, treat digestive infections and relieve respiratory conditions...		No antipyretic effect observed in rabbits	Toxicological studies show relative <i>in vivo</i> safety up to 1.6g/kg in rabbits ? <i>Endangered species list restricting exports from India?</i>	Used in mixed formulations and alone only in case of an emergency; as a member of aconite family likely to have a limited future in Europe whatever the safety data.
Bunium persicum 'zira' seeds	Essential oil 2.5% (incl 45-65% carvone??, gamma-terpinene, limonene, p-cymene, beta-pinene, alpha-pinene, cuminaldehyde, and myrcene).	Nervine tonic used with nerve, muscle and abdominal pain and liver problems. Carminative and aromatic digestive.	Likely to be a useful digestive remedy applicable to griping colic problems.	<i>In vitro</i> antifungal effects linked to presence of cuminaldehyde and p-cymene	No data.	Not used as medicinal but as flavouring spice ('black cummin')
Dactylocteniza hatagirea root	Mucilage, traces essential oil	Nutritive tonic	Likely to have demulcent properties that could be beneficial for inflamed digestive disturbances and topically for wounds.		Said to be contraindicated in hypertension but this is puzzling.	
Panax pseudoginseng rhizome	Numerous saponins (ginsenosides mainly Rf - 40.57% and Ro - 19.60%.)	Relaxing tonic and appetite stimulant Suggested use in reducing hypertension, as immune stimulant, managing blood sugar and lipid levels		Little evidence for this species and claims based on those for <i>P. ginseng</i>	No data.	Concern that this remedy is riding on the back of the reputation of Asiatic ginseng without strong grounding in traditional medical systems.

Sample herbs that are wild collected and are currently too toxic for legal sale in the UK/Europe

Names and plant part	Significant constituents	Traditional characterisation	Likely modern applications	Level of efficacy data	Quality and safety issues	Comments
Aconitum ferox root tubers	Alkaloid: aconitine; diterpenoid alkaloid vakognavine, and norditerpenoid alkaloids: chasmaconitine, crassaualine-A, falconericine, bikhaconine, pseudoaconine, neoline, senbusine-A, isotalatizidine and columbianine.	Used in painful arthritic disease, neuralgia, fever management, as vermifuge and cardiac stimulant; processed in water or cows urine to convert aconitine to less toxic aconine	None likely – this is a remedy from era and location when there no modern pharmaceuticals.		Highly toxic plant often processed in cows urine in India to make it less so.	No future in Europe
Podophyllum hexandrum Root, fruit	'(Indian) podophyllin resin' 7-15% (incl podophyllotoxin or 'podophyllin'); essential oil incl podophyllol	(Root) cathartic and emetic, bitter and choleric, and vermifuge (for Ascaris); (fruits) expectorant	.	Provides over 80% whole-body radioprotection in mice	Podophyllin resin is a well-known toxic cathartic and worm remedy to be handled with extreme care; podophyllin is a neurotoxin	It has been historically used as an ointment for infected and necrotic wounds. The plant is poisonous but is processed to for medicinal purposes
Taxus baccata leaf	Poisonous alkaloid: taxine; taxol (though not in clinically significant levels	Metabolic depressant and known poison	Anticancer properties based on association with presence of taxol and suggested formulation as 'encapsulated taxol'; this is present at very low concentrations in whole plant and has been a challenge to isolate in therapeutic levels.	No data for plant	Inherently toxic – sales would be unacceptable especially for a taxol formulation	No future in Europe NOTE: <i>Taxus baccata</i> subsp. <i>wallichiana</i> – the variety often traded, is on the CITES endangered list

Non-prescription and non-medicinal uses of Indian MAPs

Indian MAPs have non-medicinal prospects as well, particularly in the personal care sector. For example the following are the conventional uses and potential applications within India of the sample of 12 Himalayan species categorised by the various segments of the herbal market.

Plant Species	Uses				
	Prescription	OTC	Cosmetics	Spices/ Food supplements	Ornamental uses
<i>Aconitum ferox</i>	✓	*	-	-	*
<i>Aconitum heterophyllum</i>	✓	✓	-	-	*
<i>Bunium persicum</i>	✓	✓	✓	✓	*
<i>Dactylorhiza hatagirea</i>	✓	✓	✓	-	✓
<i>Inula racemosa</i>	✓	✓	✓	-	-
<i>Nardostachys jatamansi</i>	✓	*	✓	-	✓
<i>Panax pseudoginseng</i>	✓	✓	✓	✓	-
<i>Picrorhiza kurrooa</i>	✓	✓	-	-	-
<i>Podophyllum hexandrum</i>	✓	*	-	-	-
<i>Saussurea costus</i>	✓	✓	-	-	-
<i>Taxus baccata</i>	✓	*	*	-	-
<i>Valeriana jatamansi</i>	✓	✓	✓	-	-

✓ Present use

* Potential use

One example of international development of Ayurvedic nutraceuticals and cosmeceuticals is the Sabinsa Corporation (www.sabinsa.com), a wholly-owned subsidiary of Sami Labs Ltd., India. It has brought to the market over fifty standardised botanical extracts (mostly into the USA but also as cosmeceuticals into Europe through its German subsidiary) from among the following herbs:

Adhatoda vasica	Andrographis paniculata	Asparagus racemosus
Bacopa monniera	Boswellia serrata	Cassia angustifolia
Centella asiatica	Coleus forskohlii	Commiphora mukul
Curcuma longa	Emblica officinalis	Glycyrrhiza glabra
Gymnema sylvestre	Inula racemosa	Melia azadirachta
Momordica charantia	Ocimum sanctum	Phyllanthus amarus
Picrorhiza kurroa	Piper longum	Piper nigrum
Pterocarpus marsupium	Rubia cordifolia	Terminalia arjuna
Terminalia belerica	Terminalia chebula	Tinospora cordifolia
Trigonella foenum graecum	Tylophora indica	Withania somnifera
Zingiber officinale		

Some strong Indian medicinal candidates for international sales

There are some Indian medicinal plants for which there is already a substantial evidence base and which have been increasingly supplied to practitioners/health professionals around the world. In addition to *Inula* and *Picrorhiza* in the sample these include:

Botanical name	Common name	Main area of activity supported by evidence
<i>Adhadota vasica</i>	Amalaka	Chest problems, (topically) gum disease
<i>Albizzia lebbek</i>	Shirish	Allergic conditions, asthma, skin disease
<i>Andrographis paniculata</i>	Kirata	Bitter tonic, anti-inflammatory, immune stimulant
<i>Bacopa monniera</i>	Brahma	Sedative, spasmolytic, tonic
<i>Centella asiatica</i>	Gotu kola	Ulceration, slow healing wounds
<i>Coleus forskohlii</i>	Makandi	Cardiovascular disease, hypertension
<i>Commiphora mukul</i>	Guggula	Cardiovascular disease
<i>Crataeva nurvala</i>	Varuna	Urinary and prostatic disease
<i>Gymnema Silvestre</i>	Gurmar	Diabetes, high cholesterol
<i>Hemidesmus indica</i>	Anantamul	Inflammatory diseases
<i>Phyllanthus amarus</i>	Bahupatra	Viral hepatitis
<i>Terminalia arjuna</i>	Arjuna	Ischaemic heart disease, angina
<i>Tylophora indica</i>	Anthrapachaka	Asthma, hypersensitivity inflammatory diseases
<i>Wlthania somniferum</i>	Ashwaghanda	chronic stress and exhaustion

(Ref: K. Bone. 1996. *Clinical applications of Ayurvedic and Chinese Herbs*. Phytotherapy Press, Queensland)

Section 3 The sustainable way forward for MAPS from India

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9. Prospects and initiatives within India

Summary:

An analysis of the current policy framework and industry trends in India indicates that the national government, as well as the larger manufacturers in the herbal sector, are aware of the regulatory challenges and are taking measures to address them. They are also aware of the market opportunities for MAPs and therefore the improved livelihoods of Himalayan communities and initiatives are underway to remedy constraints and improve access and quality. Significant work is yet to be undertaken to empower the sector and enable it to navigate the emerging regulatory regime in Europe and additional interventions may yet be required.

Prospect of markets outside India

Apart from the requirement of medicinal plants for internal consumption, India is one of the major exporters of crude drugs mainly to the six developed countries: USA, Germany, France, Switzerland, UK and Japan who share between them 75 to 80% of the total export of crude drugs from India.

Exports of Ayurvedic medicines have reached a value of 215 million dollars a year (about 10% the value of the entire Ayurvedic industry in India). About 44% of this is crude herbs (to be manufactured into products outside India), about 36% is finished product shipped abroad for direct sales to consumers, and the remaining 20% is partially prepared products to be finished in the foreign countries.

Most of the larger Ayurvedic medicine suppliers provide materials other than Ayurvedic internal medicines, particularly in the areas of foods and toiletries (soap, toothpaste, shampoo, etc.), where there may be some overlap with Ayurveda, such as having traditional herbal ingredients in the composition of toiletries

Entrepreneurs in India seeking to break into the market for natural products have determined, rightly, that after growth trends as high as 20% annually encountered in the late 1990s the demand for traditional style Ayurvedic medicines both inside and outside the region will now flatten. They have aimed to bolster interest by carrying out scientific research into promising herbs and formulas that are based on Ayurveda but not necessarily reflecting traditional practices. Of necessity, such research eventually focuses on finding of active ingredients, and this has led to the development of isolates from plants that are sold as "nutraceuticals". For these, there is still a growing worldwide demand.

To achieve improvement in this area, products must be identified which are relevant to conditions found in the developed world. There are challenges involved in tapping the substantial potential for utilising medicinal, aromatic and natural dyes plants of Himalayas in Indian, as well as export markets.

According to the Convener of CHEMEXCIL, the national pharmaceutical market in India is of the order Rs. 12,500 crores (around US\$300 million), inclusive of the Ayurvedic market. Out of this, Rs. 2,000 crores (\$250 million) is in the OTC sector and Rs. 500 crores in the ethical (prescription) range. The domestic market of Ayurvedic, Unani and homoeopathic medicines

is of the order of Rs.4,000 crores (\$500 million) and rising. The Ayurveda drug market alone is of the order of Rs. 3,500 crores. However, all the raw materials used by the pharmacies are not of indigenous origin, significant supplies are received from Nepal, Bhutan, Bangladesh, Pakistan, Afghanistan, Singapore and other countries, and often through informal routes.

It is estimated that nearly three fourths of the plant-derived prescription drugs used worldwide were discovered following leads from local medicine. According to WHO About 25% of modern medicines are descended from plants that were first used traditionally. Likewise, almost 70% of modern medicines in India are derived from natural products.

The world market for plant-derived chemicals – pharmaceuticals, fragrances, flavours, and colour ingredients, exceeds several billion dollars per year. It is estimated that Europe alone annually imports about 400,000 tonnes of medicinal plants with an average market value of US\$ 1 billion from Africa and Asia. China is the largest exporter to the world market, accounting for over 120,000 tonnes p.a. In the case of India, around 80% of the 32,000 tonnes per annum of medicinal plant exports (US\$ 133.28 million in 2001-02). According to the statistics released by DGCIS at the end of the year 2003, India's total export earnings from the sale of crude drugs and herbal extracts stood at around Rs. 512 crores per annum. India's export turnover in medicinal and aromatic plants is probably of the order of Rs. 971 crores.

Constraints for sale/processing of Himalayan medicinal plants

Some of the constraints associated with the sale/processing of medicinal plants from India, which may result in reducing their competitiveness in increasingly regulated global markets are as follows:

Production of plant material. Much of the plant material traded is wildcrafted (collected from the wild) and therefore is of inconsistent quality. There is no standardisation in agricultural practices for the few species being cultivated, leading to low yields and poor quality of produce. The use of chemical fertilisers and pesticides is not always tightly controlled, and the soils on which the plants are cultivated often have high levels of these agrichemicals; on the other hand, especially in relation to organic materials about 30-40% of the raw material received by manufacturers gets rejected due to the presence of microbial contaminants; heavy metal levels can also be a problem. Harvesting methods and post-harvest treatment practices may be inappropriate, often damaging the constituent characteristics of the material. There is insufficient information on species and standards of active principle content; little research on the development of high-yielding varieties, and of propagation and cultivation protocols. Shelf life is given least attention at the time of harvesting quality raw material, and much deterioration of quality occurs during post harvest handling, packaging and transportation. Authentication and quality assurance of plant material is currently based on physical parameters assessed purely through observation. This has always caused variation in drug potency, but has lately begun resulting in adulteration as well, as availability in the wild has shrunk. This is also likely to affect the product credibility and market size in times to come.

Production of plant-based products. Medicinal plant parts are identified and their grading and quality assurance are carried out purely through crude, physical observation methods. Good manufacturing practices (GMPs) are not generally followed in the manufacture of plant-based drugs- technologies are sometimes antiquated and inadequate attention is given to quality control. There are about 9000 pharmacies/manufacturing units for the production of plant-based medicinal products based on traditional systems of medicine, in addition to several more units manufacturing extracts and other herbal products; most of

these are however not GMP compliant. There is a serious dearth of trained and quality personnel in the industry. There is very little R&D on product and process development, and standards and efficacy measures of drugs are not established.

Marketing and sale of herbal products. Growers of medicinal plants have little direct access to the market, resulting in high degree of wastage, and low returns for farmers. The marketing channel for medicinal plant parts in particular, is unorganised and unregulated. This allows a great amount of illegal trade, unfair practices and share of revenues, and inadequate attention paid to quality control. Lack of information on the source of raw materials, the actual traded volumes, toxicity and heavy metals related information, are some other key concerns of this burgeoning sector. New national and international regulations will hopefully begin to have some impact on this area at least.

Regulations and procedures. The regulatory framework is confusing and tends towards duplication at the state and national level. An Indian State has certain schemes for development, as well as certain powers of legislation and taxation and in some cases, an individual would have to deal with both national and State laws and taxation for the same item. Movement of goods from one State to (or through) another State could involve a plethora of permits and various restrictions.

The solutions to the above have to be addressed at several levels below.

The Policy & Regulatory Framework

In the year 2000, in recognition of the potential of the herbal sector to transform the lives of marginalised Himalayan communities, the government set up the **National Medicinal Plants Board (NMPB)** with the responsibility for coordination of all matters relating to medicinal plants including:

- drawing up policies and strategies of conservation,
- proper harvesting,
- cost-effective cultivation
- research and development
- post-harvesting activities including processing and value addition
- marketing of raw material in order to protect and sustain development of the sector.

Several schemes have been initiated by the Board, but are yet to stabilise and begin delivering desired results. Under its Contractual Farming Scheme, the Board has facilitated medicinal plants cultivation on 33,190 hectares of land, although there has been little focus yet on the Himalayan region. Under its Promotional Scheme, the NMPB has helped conservation on 23,000 hectares (primarily on forest dept. land) and the creation of 141 projects for the production of quality planting material. The latter however has not been very effective, hindered by inadequate networking between them and the cultivators/users.

Good Agricultural Practices are being developed for priority species, including development of cultivars and agrotechnologies, and cultivation on an intensive scale is being promoted for these with provision of adequate quality planting material. A total of 300,000 hectares is targeted to be covered through contract farming of priority medicinal plant species, and subsidies will be provided for such intensive cultivation, but with certain conditions: adoption of quality standards, growing of rare or threatened plants and priority species, farmers who provide certified materials. Promotion of organic farming and introduction of bio-fertilisers and bio-pesticides, has also been determined as a major initiative.

There are also 35 **State Medicinal Plant Boards (SMPB)** created to improve financial support to the grassroots; however the flow of loans and subsidies has been inadequate as well. Marketing has been found to be a critical and unaddressed weakness with only about 50% of the cultivators having been successful in selling all their production. As a response, organisations will be identified at the State level for the purpose of marketing of medicinal plant material and these will be provided financial support to in turn provide a sustainable price to cultivators of medicinal plants to cushion them from the risks of market fluctuations and vagaries of climate. Differential subsidy amounts are planned with higher levels of subsidy for endangered and long gestation species

MAPs in National Plans and Policies

In India, the deliberations of the Planning Commission, a body headed by the Prime Minister and tasked to provide the Government with inputs in Policy formulation, has indicated the government's recognition of the need for substantial increase in its activities in the herbal sector, in view of the emerging opportunities and challenges. The following initiatives have been identified for the herbal sector in the period 2007 - 12, designated the 11th Plan period:

Financial outlay and support. The budget allocation for the National Medicinal Plant Board has been proposed to be increased from a nominal Rs.1450 million to Rs.20000 million during the 11th Plan. Funds transfer and monitoring of projects is proposed to be improved through transfer of some schemes from Centrally-sponsored to Centrally-supported schemes thereby enabling speedier and more effective roll out and utilization of funds in this sector.

Promotion of priority species. 32 priority species had been identified for governmental promotion and support, and this list is being enhanced, ensuring representation of all geo-climatic zones in the country. Specific focus has been given to the Himalayan region in this exercise This includes species on CITES Appendix I & II, Schedule VI of Wildlife (Protection) Act, and negative list of plants for export and plants presently imported. Higher levels of support (75%) will be provided for the cultivation of endangered species. Support to prioritised species in earlier years has been successful in mainstreaming a few species in the farming/trade system.

Promotion of cultivation. Special subsidised energy rates and tax exemptions have also been proposed for MAP growers. Several NGOs are working with local communities in MAP rich areas, trying to facilitate viable livelihoods based on collection and cultivation. These organisations carry out training at the grassroots, and some facilitate the packaging, sale and marketing of the plant material. A few organisations are also assisting the production of plant-based cosmetics and spices and OTC health foods and wellness products..

Value-addition and marketing. The cluster approach is also being promoted for medicinal plants, with cultivation hubs in each region being developed with **Processing Zones** equipped with facilities for value-addition, processing and marketing, including export. Post-harvest management (storage with drying, grading, and sorting), marketing (price support, commodity markets, brand promotion), will be activities carried out in the MAP Processing Zones. A network of storage facilities for part-processing will be set up near major collection centres and cultivation areas, and managed by the government or growers' combines. This will overcome the current issues with respect to inadequate coordination and help synergise the different components in the sector. In order to address the information gap, e-networks and web portals are proposed with complete information on demand, supply, markets, species, etc.; on-line trading of medicinal plants will also be enabled. Registration of

traders and manufacturers and maintenance of mandatory records will be instituted in order to ensure traceability of plant material.

Improved production technologies. Production firms will be provided subsidies. A Venture Capital Fund or Technology Upgradation Fund is proposed to be created for the modernisation of existing pharmacies and production units, towards increasing the competitiveness of these units and their products in the global marketplace.

Quality assurance. An independent certification mechanism is planned for the sector that will stretch from seeds to products, and include planting material, plant produce and herbal products. Certified medicinal plant nurseries will be promoted towards ensuring quality planting material for cultivation of priority species. Similarly certification will be set in place for growers and manufacturers; group certification is planned for small and marginal farmers backed by organic farming, and collectors backed by Good Agricultural and Collection Practices (GACPs). R&D will be initiated on uptake of contaminants by medicinal plants and technologies to minimise this. The existing network and structures for testing and QA of agricultural produce will be extended to medicinal plant material as well, and the public-private partnership mechanism will be leveraged to enhance the network and upgrade testing facilities.

Export promotion. There is a thrust in the development and adoption of GACP, GAP and GMP towards achieving the potential of the export sector. At the same time, comprehensive monographs based on scientific research, have been planned on important medicinal plants to establish quality, efficacy and safety standards with respect to the particular species. These will be used to register the species in the positive list of plants in importing countries. The Ministry of Commerce will undertake activities for branding and market development and assist exporters in sales promotion and participation in international trade fairs.

Protection of biodiversity and IP. Research and Development aimed at patenting of active molecules of medicinal plants and documentation of medicinal species and their uses, will be supported, towards ensuring protection of IP. A levy on the pharmaceutical industry has been proposed to be utilised for conservation of medicinal plants. Communities in areas rich in medicinal plants will be helped to establish herbal gardens and plantations of medicinal plants on reclaimed wastelands.

Several policy initiatives have been planned at State level towards local support for farmers and easy delivery of and access to the schemes at the grassroots. Organisations will be identified at the State level for the purpose of marketing of medicinal plant material and these will be provided financial support to in turn provide a sustainable price to cultivators of medicinal plants to cushion them from the risks in the sector, namely, market fluctuations and vagaries of climate. The States are also beginning to involve the District Forest Department officials and sensitise the State Level Drug Control units that have typically been less than supportive of the needs of this sector.

Regulatory Framework

There are more than 100 forest acts, rules and notifications governing medicinal plants trade in India, applicable in various States. Some of these are- the Indian Forest Act 1927, Forest (Conservation) Act 1980, Wild Life (Protection) Act 1972, Biological Diversity Act 2002, CITES. However most of them are not being implemented and are not understood by the various stakeholders. In the absence of clear understanding at different levels, compliance by

the interested parties is difficult. Economic and ecological concerns in this sector will need to be merged to combine adequate conservation and development.

Quality assurance is an important factor for consumer confidence, and an independent, third-party certification of medicinal plants for ecological, organic, social or quality standards is important for the development of the sector in India. To facilitate this development the Medicinal Plants Unit of the Indian Council for Medical Research has announced that it will be shortly releasing Quality Standards for 32 Indian Medicinal Plants, based on research conducted at four national research institutions. These standards will provide guidelines for herbal drugs manufacturers, practitioners, academicians, researchers as well as regulatory bodies. There are several government certification schemes focusing on product quality, environmentally friendly and organic production. The Bureau of Indian Standards has certified over 1,100 products for quality standards. ISO Certification of quality and environmental management has also been adopted. Progress in certifying products under India's only eco-labelling programme, Ecomark, has been painfully slow. An "umbrella standard", that takes into consideration all ecological, social, institutional and economic issues, and is based on international standards, might be suitable for the herbal sector.

R&D and Extension Activities

There is considerable, albeit fragmented, research in the field of medicinal plants and its integration into herbal drug preparation. The major areas of current work, are as follows:

Documentation of MAPs. The Botanical Survey of India (Govt. of India) has pursued an exhaustive inventory of the floral wealth of the country. Three government departments and agencies: the National Institute of Science, Communication and Information Resources, the Council of Scientific and Industrial Research, and the Department of Indian Systems of Medicine, have collaborated on developing a most comprehensive digital database of Ayurvedic, Unani and Siddha formulations, in the Indian Patent Application format. It is hoped that this Traditional Knowledge Digital Library (TKDL) will help protect India's codified traditional remedies. The TKDL has been registered as covering 53,000 formulations of Ayurveda and 41,000 formulations of Unani medicine. Other non-mainstream systems of medicine such as the amchi system practiced in the Himalayas and various non-codified tribal medicine systems, are however not covered in the database. Premier colleges or institutes of traditional medicine have documented the medicinal properties of key species used and the formulations of major traditional drugs in their respective systems of medicine, although these are primarily for the codified and mainstream systems such as Ayurveda and Unani. A few non-government non-academic organisations, such as Pragya, ATREE and FRLHT, are also working on medicinal plant/traditional remedies documentation. The government is supporting the development of detailed herbal monographs of most used Indian MAPs, and 600 have already been published. Eight community monographs have also been sent to the EMEA for adoption.

Technologies for cultivation and extension support for MAPs. The country has a network of Regional Research Laboratories that are working on developing cultivation technology of MAPs. They have succeeded in establishing standardised cultivation protocol of several medicinal plant species and have also carried out in depth research work in post harvest processing technologies. Research organisations such as Govinda Ballav Pant Institute for Himalayan Environment and Development (GBPIHED), and universities (YS Parmar University, Nauni, Solan (HP), Institute of Himalayan Bioresource Technology (IHBT), among others, have been engaged in extensive research work for technology development related to standardised cultivation protocol for Himalayan Medicinal plant species and the post harvest

technology with the objective of providing technological assistance to the farmers. In addition a number of premier research institutions like Indian Agricultural Research Institute (IARI), Tropical Forest Research Institute (TFRI), Tropical Botanical Garden & Research Institute, have been carrying out research on protocol development as well as post harvest processing technology focusing mainly on the tropical medicinal plant species. Research on chemical estimation in raw materials has been carried out by Central Drug Research Institute, Central Institute of Medicinal & Aromatic Plants, Central Food & Technology Research Institute. NGOs like The Energy Research Institute (TERI), ATREE, FRLHT, Pragya, CHIRAG, CEDMAP, SHER and INHERE are also engaged in development of cultivation packages of high value medicinal plants and their post harvest technology. Different Manufacturer and Traders have also established their own R&D Units for developing cultivation protocols and processing and value addition. Dabur India Ltd., Zandu Pharmaceuticals, Shree Baidyanath Ayurved Bhawan Pvt. Ltd., Lupin India, etc. are few notable names in the sector that have taken major initiatives in research and development on medicinal plants in India.

Technologies for processing of MAPs. Traditionally, herbal medicines were produced manually in small quantities by practitioners who were able to identify the correct plant species. However, with the introduction of commercial production of herbal drugs, processing efficiencies have improved considerably. Value added herbal products can be classified into following groups: extracts/concentrates (particularly in the form of retail packaging such as capsules); preparations (mixed formulations). Indian companies like Ranbaxy Labs, Parry Nutraceuticals, Dr. Morepen etc. are currently working on developing vitalisers, geriatric tonics, cycle correctives for women, growth promoters for children, digestives, liver tonics and laxatives, besides working on anti-diabetes, anti-inflammatory, anti-arthritic, cardiovascular, CNS, dermatology, respiratory and urology segments, using improved processing technologies.

QA methods/technologies. Quality control in the case of synthetic drugs is much simpler and easier than in the case of drugs prepared from medicinal plants where multiplicity of active ingredients can create difficulties in quality assurance. In spite of the modern chemical analytical procedures, phytochemical investigations cannot isolate and characterise all secondary metabolites present in a plant extract. In cases where the active principles are unknown, useful marker substances need to be established for analytical purposes. However there are enough precedents in the processes of purification, isolation and structure elucidation of naturally occurring substances to have made possible the quality assessment and standardization of herbal preparations in Europe; here the homogeneity of plant extracts is maintained, the quality of both raw material and the finished herbal drugs controlled.

Quality control and standards in medicinal and aromatic plants sector constitute an area where policy making is still 'work in progress'. The Government of India has set up pharmacopoeial committees for Ayurveda, Siddha, Unani and Homeopathy systems. The Pharmacopoeial Laboratory for Indian Medicines (PLIM) and the Homeopathy Pharmacopoeial Laboratory (HPL) are providing the technical back up to these committees. The pharmacopoeia committee has published two volumes of Ayurvedic Formularies of India consisting of 635 formulations. The Siddha Pharmacopoeia committee has brought out seven volumes containing standards of 910 drugs. The Unani Pharmacopoeia committee has published one national formulary of 441 formulations of Unani medicines. The Homeopathy Pharmacopoeia committee has brought out 7 volumes containing standards of 910 drugs. More works relating to this are in progress. There are about 7,483 drug-manufacturing units of Ayurveda, Siddha & Unani (ASU) Systems of Medicine in the country. To ensure the quality there is a need for public test houses as well as statutory State Drug Testing Laboratories for

these medicines. A network of 12 laboratories in different parts of India has been approved for drug testing.

Marketing and information support. The NMPB and SMPBs constitute the main facilitator organisation in India engaged in licensing of the farmers involved in medicinal plants cultivation, quality testing and initiating marketing of medicinal plants. A few NGOs are also playing a facilitating role in marketing: Medicinal, Aromatic and Dye Plants Stakeholders Consortium (MAPSCON), ISAP, etc. These organisations periodically conduct exhibitions and trade fairs that enable farmers to interact with buyers, traders and manufacturing companies. They also publish regularly the market rates for different species in different major markets. In particular States, State bodies (MFP Corporation, Vesaj Sangh) also facilitate marketing of medicinal plants at the state level and organise some regional markets through which the registered farmers can sell their raw material at a reasonable price.

Strategic Requirements

In spite of the policy, research and extension attention being given or being proposed for the sector, both growers and buyers of medicinal plant material, perceive gaps that could hamper their ability to access the benefits of the growth of the herbal sector in the tightening regulatory regime of the future. A recent national consultation on the issue brought out the following suggestions for interventions, apart from those already proposed in the national policy, towards adequately addressing the emerging constraints.

1) Supply side

Agro-technologies and other planting inputs. Whilst agro-techniques exist for a few species, simple cultivation technologies that can be easily adopted by farmers need to be developed for more MAP species. This will allow farmers more options and encourage multi-cropping to reduce risks from the vagaries of the market. Apart from nurseries, select wild areas (Permanent Seed Resource Areas- PSRA) should be developed as seed sources, for the purpose of producing and supplying large quantities of quality and disease-free planting material. MAP Clinics should be established at the grassroots in order to provide technical knowhow and support to the farmers with regard to GAPs including organic cultivation, integrated pest management etc.; knowledge gaps in MAP cultivation must be identified and the MAP Clinics should conduct research for effective solutions. Such developments will address the current lab to land gap.

Authentication support. Certification agencies should be specified for authentication of seeds or other propagules, prior to distribution to farmers, as adulteration is a serious concern in this sector. Proper identification is required at morphological as well as molecular level. The crude drugs (processed medicinal plants), of standard quality need to be identified and preserved as the reference standard along with herbarium specimen, chemical finger print profiles, anatomical slides, supporting literatures and a collection of living plants. This repository should then become the official certification centre (OCC) for raw materials. Certification systems should also be in place for organic cultivation and sustainable harvesting, and affordable and accessible facilities for scientific grading and quality control of plant material should be made available at the collection centres.

Information on MAPs. Regular information on market prices and demand volumes as well as buyers of different MAPs in regional, national and export markets should be disseminated regularly through regional media so that farmers might align their cropping to market demands. Available quality standards, yield specifications of different species, should similarly be made available to farmers. The NMPB and the SMPBs or premier institutions and

NGOs working in the sector could coordinate with growers and industry to collect and disseminate all information with respect to MAP demand and supply status.

Support to Institutions. Agricultural Universities and NGOs should be provided adequate financial support for promotion of MAP cultivation and extension of technical know-how developed in the field. These organisations should focus on capacity building for adoption of good practices.

Post-harvest facilities. Appropriate harvesting practices should be drawn from those prescribed in traditional medicine texts, and disseminated, towards ensuring industry-desired harvest quality. Collection centres should be established with basic infrastructure for drying, packaging, storage, etc., that ensure that there are no losses due to post-harvest deterioration. Primary processing units need to be established that help reduce the raw material volume so that transportation cost can be reduced. Infrastructure needs to be established at a village cluster level for soil testing.

Single window regulatory clearance. The SMPBs should provide the sole channel for providing clearances to MAP growers, reducing the obstacles currently faced by them in negotiating the multiple and confusing regulatory framework, and trading at the national level. The NMPB could similarly play a facilitative role with respect to handling the international regulatory framework for exports.

2) Demand side

Traceability information. It should be mandatory for every stakeholder in the sector to disclose the source of the material being traded and used. In this context, national level regulations and procedures are urgently required.

Fair trade practices. Every State should establish Herbal Mandies (rural commodity markets) for easy trade of herbs, regulated by state-designated organisations and/or cooperatives. These markets could carry out commodity auctions that would facilitate transparent grading and pricing mechanisms. Facilitation centres should be set up in each State with the active involvement of regional stakeholders like farmers/growers, industrialists, traders, R&D institutions, NGOs etc.

Quality Management. Latest techniques like Molecular Marker technology should be employed for the quality assessment of the product in testing labs, and such labs should be set up in every state with affordable service rates. Standard Quality assessment parameters, aligned to global standards, should be developed and procedures for proper labeling of the product according to its grade, should be instituted. Research institutions should also strive to develop simple, cost-effective technologies, protocols and methods for quality testing as well as low-cost quality testing facilities. The standards and specifications desired by the industry for various MAP species should be disseminated to growers, such that growers may cultivate to industry-led specifications and the process, forms for applications and list of certifying agencies should be available to the manufacturers to ensure a hassle free procedure for certification.

Validation. Plant-based drugs may be comparatively safe, but some are toxic especially when these are not properly processed and used judiciously. Although the majority of the plant-based drugs are time tested, clinical validation is also necessary for confirming the efficacy. At present there is no centre for safety evaluation of the plant-based drugs. This will be necessary to facilitate the acceptance of these drugs at a global level.

Certification. The certification procedure should be simplified and there should be a single certification agency at regional level duly authorised by the SMPBs. Certification formalities of international bodies should be managed by the SMPBs and/or specified NGOs and institutions.

Marketing and Promotion. SMPBs should be responsible for the certification and marketing of the produce from their state. Regular buyer-seller meets should be carried out and regional networks should be developed for facilitating trade. NMPB should promote the diversification of the use of MAPs, in national and international markets, into allied sectors like cosmetics, food and beverages. NMPB could also develop a brand name under which plant material of certified farmers could be marketed. Awareness of efficacy of select Indian herbs also has to be built in international markets, and this responsibility could be handled by NMPB. Various State and industry associations need to play a role in making a strong representation at WTO, WHO, and promoting a global integration of medicinal plant products with the existing mainstream healthcare system, and recognition of national systems and institutions and their certification processes. Post-2011 when the regulatory environment presents more hurdles to the smaller units and growers' co-operatives with regard to exports, State agencies may need to undertake an aggressive drive to register high sales and priority medicinal plant products in order to facilitate the industry.

Research & Technology Development

In order to fully convert the potential of Indian medicinal plants into economic wealth, a very active R&D programme is essential. The emphasis of R&D should be on the following:

- Good agricultural practices with emphasis on organic cultivation; Germination and seed treatment protocols and certification; Variations in morphotypes, genotypes, chemotypes etc.; Good harvesting practices, post harvest handling and storage techniques
- Biological screening for optimisation of active principles followed by improvement through the selection process.
- Traceability of raw drugs from harvesting to consumption level.
- Development of technology for bulk production of medicinal products;
- Development of quality control standards for the starting materials as well as for the finished products;
- Development of new formulations and dosage forms specially suited to the prevailing climatic conditions and adapted to locally available raw materials; Bioequivalence, bioavailability and pharmacokinetic studies on the dosage forms developed;
- Assimilation of acquired technology and its continuous improvement to make the products competitive;
- Search of new plant sources for known drug and for new drugs from locally available plants; alternative species / species having similar active principles to reduce pressure on RET species.

Many organisations including governmental and non-governmental are working in the MAPs sector. They are investing a huge amount to develop the herbs sector and enhance the economic status of the community involved. However all these efforts are fragmented. There is a need to synergise the isolated efforts for better results.

Special Needs of the Himalayan Region

Cultivation-related needs

Planting inputs. Although the interest in cultivating medicinal plants is definitely growing in the Himalayan region, planting materials are severely limited and available quantities are not able to meet the demand. Nurseries are required in every administrative block in the Himalayan region and these should be supported to produce and distribute saplings to farmers who wish to cultivate medicinal plants. NGOs and farmers or women's groups can be supported to establish and operate nurseries.

Target-driven cultivation. It is necessary to determine the species most appropriate for each agro-climatic zone within the Himalayan region, and disseminate this widely. This would serve to guide farmers on what crops to take up for cultivation. Species-wise targets should be set for cultivation of medicinal plants, ensuring that the targeted acreage under cultivation of a particular species is aligned with the market demand for the species.

Dispersed facilitation units. On an average, it takes 2 days for an interested farmer from the high altitude Himalayas to reach the relevant SMPB office, mostly located in the State capital. To address the remote Himalayan villages, these service centres need to be dispersed and made available at a much lower administrative level. Local facilitation centres should be established at a strategic location in each district or even block. This would help address many of the concerns of the Himalayan farmers with respect to availability of information and easier access to governmental support for medicinal plants since materials are still limited and quantities cannot meet demand.

Grassroots level technical facilitation. Himalayan areas are at great distance from centres of R&D and technical support. Select NGOs should therefore be facilitated to provide this service in every Himalayan district/block. MAP-clinics should be set up to supply the technical advice as well as required agricultural inputs to farmers. Farmer Expert Groups should also be set up in each cluster of villages. These expert farmers should be developed as grassroots trainers and every farmer expert should be facilitated to provide regular mentoring for medicinal plants cultivation to other farmers in his/her village cluster.

Intensive training. Frequent training of farmers is necessary in cultivation techniques, and in plantation management and yield extraction for enhanced incomes, as well as on proper harvesting techniques and storage, as well as appropriate packaging. Good practices in agriculture, harvesting, storage and processing, should be disseminated and commitment built as well, through these trainings.

Marketing-related needs

Growers' cooperatives. The Himalayan farmer is usually a small farmer trading in small volumes, and distant from the market about which there is little information. This makes it difficult for an individual Himalayan farmer to reach the buyer or even attract the buyer with typical small volumes. It also makes the farmer vulnerable to unfair trade practices. Governmental and non-governmental agencies should facilitate the creation of cooperatives for medicinal plants growers in each Himalayan district that could enable a collective effort by farmers for marketing and logistics. These should also be federated into an apex structure- at the regional/national level – that could facilitate information flow and fair trade.

Produce collection and post-harvest support. For the Himalayan region, the problem of marketing is magnified due to its distance from markets and the logistical difficulties and costs involved. Dependence on middle men is high and returns to producers are lower with higher leakage to middle men; wastage and spoilage of produce and related losses are also higher. There is a need for back-end assistance - collection, storage and transportation support should be instituted by the SMPBs; value addition, namely drying, cutting and packaging, should be integrated at the local level.

Commodity markets for the Himalayan regions. Specialised medicinal plants markets based on the commodity markets format should be established at the regional level to facilitate trading in medicinal plants produce of the region. Transparent pricing could be ensured with the global bids and offers, matched electronically. As with commodity markets, both spot trading and forward contracts should be encouraged, and every commodity contract should specify: the quantity and quality of the commodity, the specific price per unit, and the date and method of delivery. An additional aspect of these specialised medicinal plants markets could be the inclusion of source specification, which would reduce illegal harvesting and promote responsible trade behaviour.

Quality and regulatory framework related needs

Documentation support. The multiple issues that trouble the MAP trade sector have necessitated various checks and greatly enhanced the need for procedural and documentation formalities for trade of medicinal plant material. Such documentation tends to confuse and deter the average Himalayan farmer from undertaking MAP cultivation; the lack of knowledge of the documentation requirements at the district level government departments compounds the issue. The proposed facilitation centres should assist the Himalayan farmers undertaking medicinal plants cultivation with the various procedural requirements, and help them get the required clearances for trade. The centres should also help the farmers deal with the documentation requirements for international trade in the medicinal plant material.

Testing and certification. Authentication and quality testing of medicinal plants material has to be made accessible to Himalayan farmers. Testing facilities need to be established in the Himalayan states and the cost of testing should be subsidised for the small and marginal farmers. It would also be wise to invest in the development of an easy field-testing method and self-certification and authentication system for farmers' cooperatives.

The development needs of the herbal sector in India have been identified and governmental, civil society, research and industry efforts, are in progress, to address them. Whether India is able to meet the challenge of stringent regulations in the sector, will depend considerably on whether these early efforts are taken through to their close, whether further interventions are designed to address remaining gaps, and also whether developments in isolated organisations/areas are leveraged for the benefit of the sector as a whole.

Roadmap for an MAP entrepreneur from the Himalayas

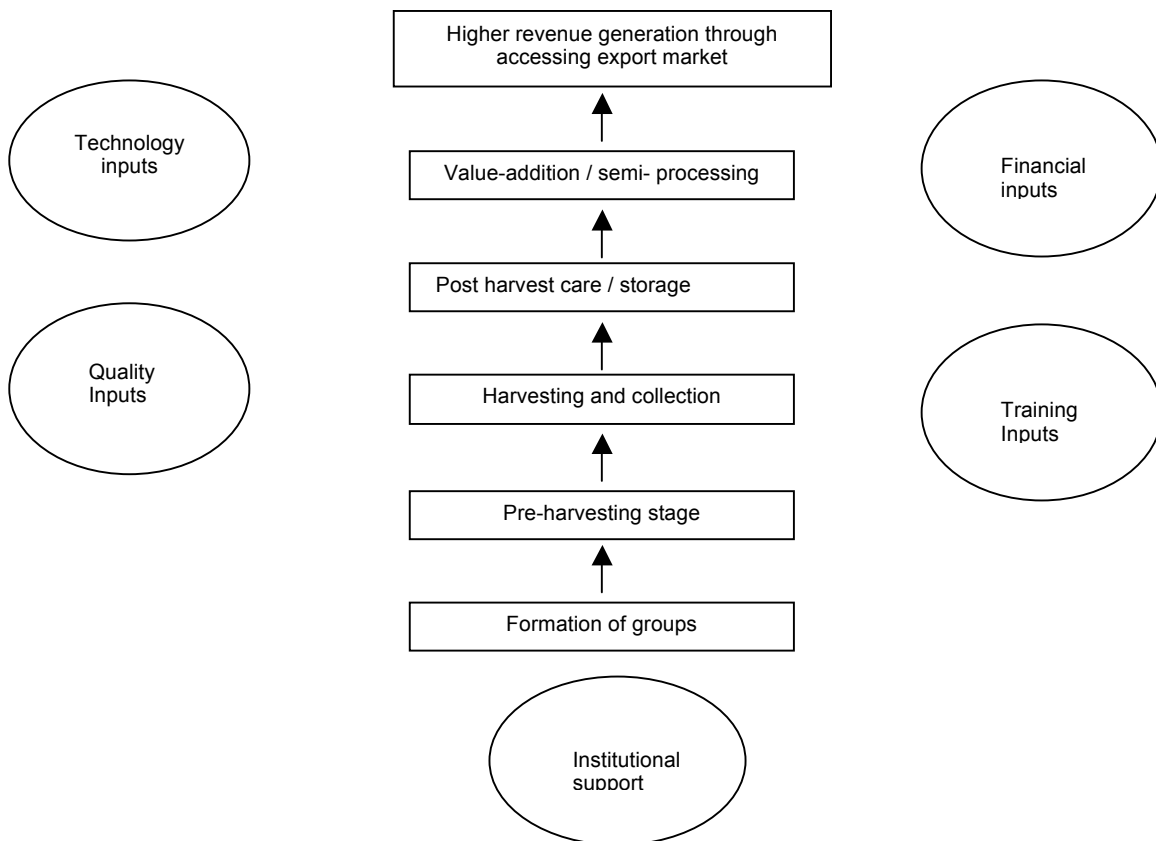
- *Define the details of operations*
 - Selection of plant species (based on market demand)
 - Selection of area of operation (state/district) based on suitability and various incentive schemes available from the Central and State level agencies.
 - Selection of local partners (land cannot be held by non-tribals; contract farming permitted) considering existing established Marketing Co-operatives with growers as members. (Registered Cooperatives are under the Control of the Registrar of Cooperatives, a statutory body, and their books of accounts are subject to Audit by Govt. agencies. This helps access funding and provides much needed transparency in the operations).

- *Firm up the financial planning and obtain Bank Closure.*
 - Cash flow projections
 - Financial approvals (detailed walk through and firming up the various incentives on offer; the incentives, typically about 30% of the project costs are interesting, they provide access to and visibility in the areas of operation.)

- *Rollout in terms of partners, species, land area etc. etc.*
 - Adequate care is needed at this stage in terms of M.O.U.'s, etc. and a clear understanding of the role and responsibilities of each of the partners is essential.

- *Tie ups for inputs in terms of*
 - Planting materials, Quality inputs, Technology inputs & Training inputs.
 - Specific teams/research Institutes under various Ministries are available to provide necessary inputs. A large number of units come under the umbrella organisation called the C.S.I.R. (Council for Scientific Research in India)
 - Testing facilities are available currently at the state level but funding for setting up cluster level laboratories is planned for the period 2007-11.

- *Logistics Planning and infrastructure.*
 - The lack of a well-developed cold chain is often cited as a major constraint and one possible way of addressing this issue would be by semi-processing some of the inputs at the point of cultivation itself.
 - The plethora of permits, forms etc. are another source of irritation and while this issue has been raised at the highest levels no immediate relief seems forthcoming. The related costs may well need to be factored in.



10. Future prospects in Europe

Summary:

The principal recommendation from this report is for suppliers of Indian MAPs to form linkages with chosen importing partners interested in good quality, sustainably cultivated niche products. Ideally such partners would have extensive market outlets across Europe and in the USA. Such partnerships will generate investment and increase long term prospects which will in turn benefit the general development of the Indian market and enable it to compete with larger farms and markets. The development of a range of high-quality transparently-sourced medicinal products from India, backed by an internationally-accepted evidence base and a vigorous educational campaign, for sale initially to health professionals or through them to the public will require significant time and investment.

MAPs as raw materials

Bulk orders for MAPs as raw materials are sometimes contracted with grower-producers but most often sourced from traders and agents. New producers will have to compete in this market against tight cost margins, reliable delivery requirements for bulk quantities, access to the trading hubs in India and an established agent-dominated sector. These are challenges for small consumers whose competitive advantage is in high-end marketing niches for transparently sourced sustainable products. The best model to study so far is the Sabinsa Corporation (page 57). This enterprise has probably most successfully crossed from India into the international market. It has identified modern priorities and produced extracts that fit; it has focused on the dietary supplement market in the USA and the cosmeceutical market in Europe. Its product range is also a strong lead for new cultivation initiatives, as almost certainly, like most companies in the business, Sabinsa has to buy most of its raw materials on the complex open market in India.

One possible outlet is to develop a range of **herbal teas** for the open market: this is however already a crowded field in Europe and it will take much marketing as well as crop production planning to make this a realistic option.

MAPs as finished products

The current market for finished Indian medicinal products in Europe is uncertain and throws up many challenges for new investment. Quality standards are not assured, are sometimes poor and when the business is direct to the consumer market there are many regulatory hurdles that have to be crossed so as not to breach the law.

Future placement on the open market of Indian plants as medicinal products will require substantial effort and investment. It is already in breach of European regulations to sell herbal medicinal products without obtaining a registration or licence, a process that none in this sector has yet attempted. Some could be sold as food supplements but in most their traditional use would be judged as 'medicinal by function' and to sustain this position will require a pharmaceutical dossier for quality and safety (see page 20). The registration process, however, is significantly less onerous than the process of obtaining a licence and could be ameliorated by partnering with an established import organisation.

The few food supplement prospects for sale to the open market would include turmeric, ginger, fenugreek, cinnamon, cardamom, and cloves. To be competitive in a crowded market these should be subjected to advanced extraction techniques to concentrate them. They could then be marketed with 'health maintenance' claims for benefits in digestion, respiratory and immunological health. However these are already widely available on the open spice market so any such initiative would benefit from focusing on partnerships with appropriate contract manufacturers and trade buyers.

In summary, the most practicable new business into UK and Europe for sustainable high-quality, fair-traded medicinal plant products from the Himalayas could have the following features

- 1) Finished products would be marketed to health professionals as the only legal route to the market for unregistered herbal medicinal products;
- 2) these practitioners could front retail operations, like apothecaries (see page 38), which however would involve investment in new retail outlets in appropriate high-street locations;
- 3) to reach practitioners outside the Indian sector, new products should be accompanied by high quality dossiers and accompanying educational materials (this could lead to a traditional herbal registration for individual products in due course);
- 4) the product range should be clearly planned in advance to combine plants with strongest evidence base prospects with sustainable sourcing, preferably cultivation;
- 5) multi-ingredient products based on traditional formulae are possible; however the need to meet non-traditional indications means that these would have to be rigorously reviewed for maximum applicability and appeal; for a number of reasons single-ingredient products will be preferred.

There are two good precedents for this model.

- 1) the Australian company Mediherb (www.mediherb.com.au). It has built an appreciable worldwide business among health professionals based on a range of products made to pharmaceutical GMP and an impressive educational and information campaign. Their current product range includes the Indian herbs listed on page 51 as well as *Inula racemosa* and *Picrorrhiza kurroa* from the Pragma sample. Mediherb is a potential buyer or even partner.
- 2) The retail business Napiers (www.napiers.net). In the UK this has built a profitable business on the high street by having practitioners on site and practicing in clinics out the back. This model will be the only legal way in which unlicensed herbal medicinal products can be provided to the public.

An enterprise for sustainably grown Himalayan MAPs that seeks to benefit local communities in the region should:

- 1) Implement a programme of propagation and cultivation of medicinal plants agreed as suitable and environmentally sustainable;
- 2) Provide continued support for infrastructure investment by grower/producers;
- 3) Create dedicated new co-operative marketing channels to assure reliable deliveries of product while also assuring transparent sourcing, fair returns to grower/producers and meeting international standards of Good Agricultural and Collecting Practice;

- 4) Connect with partners in India to manufacture products to international standards of Good Manufacturing Practice;
- 5) Establish partnership with National and State governments, perhaps through newly augmented National and State Medicinal Plant Boards, to negotiate appropriate licences and permits;
- 6) Institute a verifiable certification system, whether in cooperation with National or State government or independently.
- 7) Target markets in Europe with a good range of products to practitioners and a linked 'apothecary' retail operation, extending it in time, to local distribution outlets in Italy, Germany, the Netherlands, Spain, Ireland and other European Member States.
- 8) Undertake strong education-based marketing.
- 9) Further pay-offs may involve a step up to new medicine registrations in Europe and more immediately a related launch of OTC versions of these products in the USA with promotion based on the assured quality standards, sustainable and verified sourcing, and the professional endorsement of practitioners.

Such preparations are long-term objectives that require significant planning and work, particularly in securing new propagations and cultivations. Inevitably progress in this area will rest of the nature of any investments. It would be useful to look at companies that are already in the field with a view to building productive partnerships rather than creating new markets from scratch.

It may be that the development of such opportunities could be enhanced by association with other initiatives to build sustainable production and marketing of the Indian medicinal heritage, for example through the Fair Deal project (www.plant-medicine.com/fairdeal.htm)

Further prospects for this market and details of the above are available from the authors of this report.

Appendix: Future prospects in the USA

Summary:

The USA market is the largest for the international medicinal plant sector. Regulatory barriers to entry are low making the wide scope for permitted labelling and promotional claims attractive to manufacturers of finished products for the supplement market, but also raising concerns about quality. This may act as a deterrent to entrants from India focused on delivering a high quality and sustainably cultivated product. Whilst the USA may be the most attractive market in the short term, the requirements for transparency and quality in the UK may help to develop a more sustainable Indian market that benefits marginalised Himalayan communities in the longer term, albeit at a price. For access to the USA, because of the competitive pricing, growers will benefit from partnering with retailers with the necessary muscle. Such a partnership would require bulk production at competitive prices and in the language and conventions of the USA public.

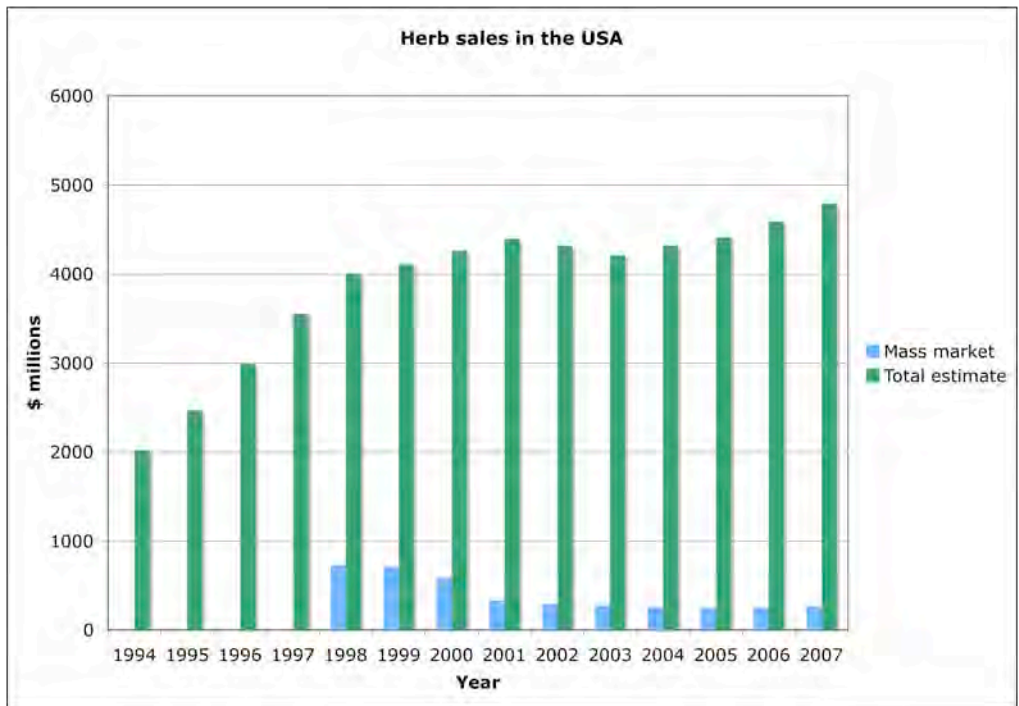
The market

Use of 'botanical' remedies in the United States increased dramatically during the 1990s (by a factor of 10). Growth slowed and occasionally reversed since the millennium but has shown signs of new increase in year 2006-7.¹²

Exact market data are elusive as botanical products are available from many sources, including health food stores, supermarkets and most recently, Internet suppliers. The only firm data are for mass-market outlets (supermarkets and stores), those that are monitored by barcode records. These are shown in blue in Figure 10.1, page 82. The sharp dip in 2001 reflected the loss of Walmart figures from data but it is generally agreed that this sector has been in decline since the late 1990's with last year being the first to show a significant rise - 7.6% - for 10 years. It has been explained that this is the sector used by 'peripheral' herb buyers, those least committed to the choice, most likely to be attracted by claims for short-term effect, and those both more disappointed in lack of short-term effect and more put off by negative media. The rest of the market estimates below are derived from ongoing reviews and surveys by Nutrition Business Journal.

12 Cavaliere C, Rea P, Blumenthal M. Herbal supplements in United States show growth in all channels. Herbalgram 78: 60-63

Fig 10.1



The total figures of sales from all quarters, including the Internet, are said to be stable, now rising again. However there is no reliable way of calculating this figure and any conclusions must be contentious, possibly self-serving. Some calculations are based on likely individual spend and on surveys of supplement use like the Boston report below and what is known of the herbal proportion of the total supplement market.

Fig 10.2

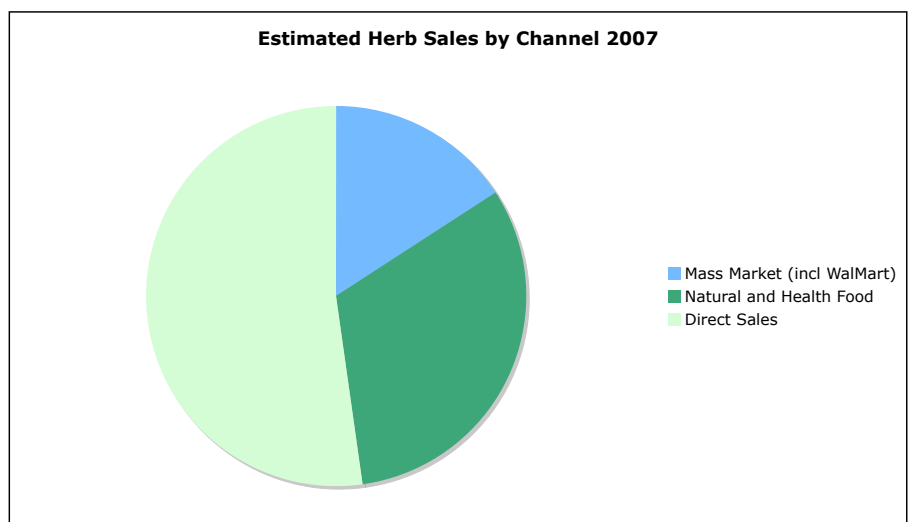
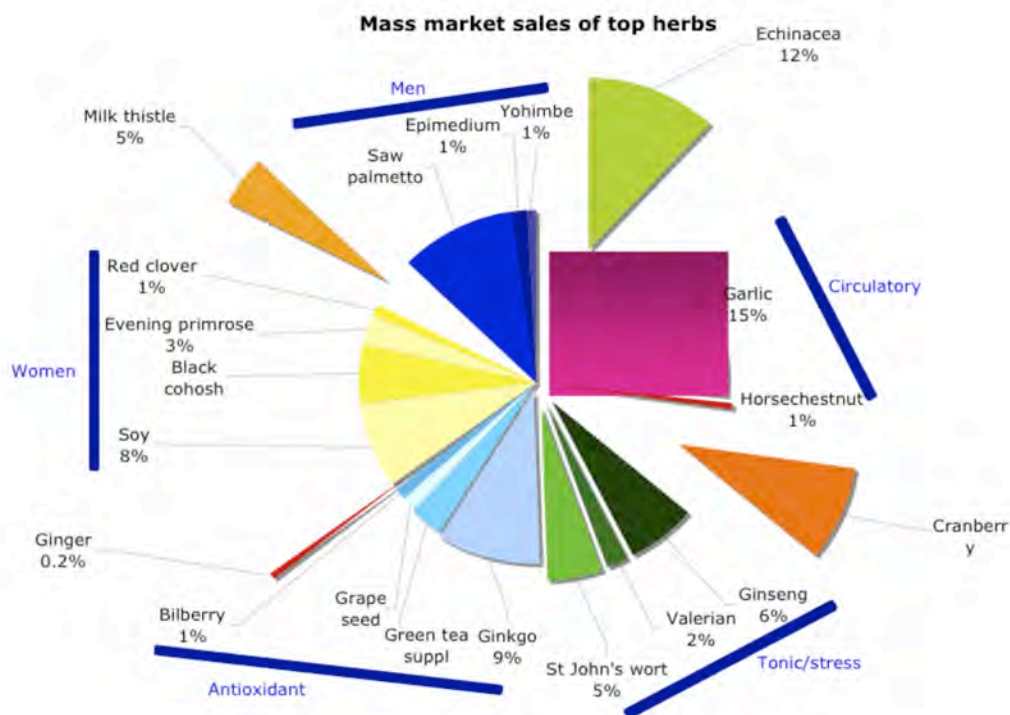


Figure 10.2 is a breakdown of herbal sales for 2007 by outlet, as estimated by the Nutrition Business Journal. They have included an estimate of WalMart sales and added them to the confirmed barcode data of the Mass Market. The sector that has grown the most in the previous year, not surprisingly has been Direct Sales, including those via the Internet.

Fig 10.3



The figures in Figure 10.3 are derived from the Mass Market outlets in the first chart. It effectively shows the market interest of the 'peripheral' herb buyers described above. There is a strong market for male remedies, two of which are Viagra substitutes. Another large sector is the preventative antioxidants, which are best considered as caution remedies – their effects are rarely seen. The largest single sector is in women's health.

Demand for dietary supplements generally is maintained in part by an ageing population, more limited access to physicians (due to the private healthcare system), and a generally greater awareness of personal health and nutritional issues. Demand for dietary supplements (including non-herbal) was particularly strong in categories that address age-related complaints including:

- | | |
|-----------------------|---------------------------|
| Joint pain/arthritis | Prostate health |
| Digestive health | Osteoporosis |
| Menopause | Mental clarity |
| Energy level/vitality | Heart disease/cholesterol |
| Ocular health | |

US consumers tend to be fickle with regards to their vitamins and dietary supplement consumption. Though consumers may take a product such as echinacea to support immune function and both prevent and treat the common cold and flu, their interest wanes over time. This is partly a result of consumers' difficulty, even aversion, to maintaining a specific dosage in the long term. Another explanation for rapidly shifting consumer interest is that most US consumers do not know precisely what they are purchasing when they buy a dietary supplement. Because of this, consumers frequently listen to manufacturer product hype as they look for the 'next big thing' quick-fix, miracle cure. It is much easier to notice when

health problems occur than when products have been contributing to an overall level of good health. Echinacea sales fell by 27.6% between 1998 and 2003, to US\$178 million.

Demand is often influenced by media coverage often cited by the trade press and the industry. In the late 1990s, media coverage was predominantly favourable, and amounted in many ways to free advertising. National news programmes covered the growing use of certain supplements types as news, prompting further experimentation by consumers, and leading to triple-digit growth rates for some supplement types in mass-market distribution channels. However, in later years media coverage has developed a negative bias, depressing demand for many supplements as coverage of substandard quality products eroded consumer trust. A frequently employed media strategy was to decry the lack of actual clinical research done to support manufactures' claims.

The hardest hit overall were the initially prominent herbal products, herbal supplements such as ginkgo, echinacea, and St John's wort, which peaked as category leaders in 1999, continued to suffer significant current value declines, by over 50% in the next four years. In general, strong initial trials of such products by consumers did not lead to repeat purchases in many instances, with many consumers becoming increasingly disillusioned regarding product efficacy. Other products to suffer significant decline in recent years include ginseng and garlic (see also below).

Regulation in the USA

Most use of herbal ('botanical') remedies is self-directed and not under the direction supervision of either a conventional or alternative provider. Botanical products are considered to be food supplements, and are not regulated as prescription or over-the-counter drugs. Their supply is instead regulated by the Dietary Supplement and Health Education Act (DSHEA) - an amendment to the Federal Food, Drug and Cosmetic Act, enforced by the Food and Drug Agency (FDA). Under the terms of DSHEA manufacturers are permitted to make claims for effects on the "structure and function of the body or on general wellbeing" as long as such claims can be substantiated and cannot be construed as "therapeutic claims" (i.e. treating symptoms or diseases). As long as they comply with these rules they cannot be prevented from putting botanicals on the market unless evidence exists to prove the supplement is unsafe. The law allows the FDA to 'prohibit sales of a dietary supplement if it presents a significant or unreasonable risk of injury'. This legal standard requires a rather vague risk-benefit calculation based on the best available scientific evidence. The FDA must determine whether a supplement's known or supposed health risks outweigh any known or suspected benefits. However they are prevented from reviewing products for safety and effectiveness before they are marketed. Manufacturers also are not required to monitor the safety of their products nor to report any adverse effects to the FDA.

Importantly in addition to there being no effective safety regulations of botanical products there are no mandatory manufacturing standards of quality beyond those required to avoid harm.

This regulatory policy has raised many concerns over product quality and safety of botanical remedies in the US. Without mandatory quality controls, there can be no guarantee of product content or purity, and contamination with heavy metals and conventional medicines also occurs.^{13,14} Matters may have worsened in recent years: closer examination of the falling

13 Ko RJ: Adulterants in Asian patent medicines. N Engl J Med 1998;339:847.

14 Slifman NR, et al: Brief report: contamination of botanical dietary supplements by *Digitalis lanata*. N Engl J Med 1998;339:806-811

sales data referred to above suggests that in some cases the total dollar turnover has been eroded by discounted and lower priced units and that total consumption may still be rising.¹⁵ This would imply that quality standards are further eroded.¹⁶ A report to an international conference from the WHO Collaborating Centre at the University of Illinois estimated that 75% of herbal products on the US market were of "poor quality".¹⁷

In late 2003, the FDA proposed a new set of regulations for the dietary supplement sector. The new regulations are designed to ensure accuracy in labelling and in the quality of ingredients and manufacturing procedures involved in the sales of supplements products and include the requirement for (food-standard) Good Manufacturing Practices for all dietary supplements sold in the US. These regulations would, for the first time, hold companies accountable for ensuring that dosages were reflected correctly on product labels and that contaminants or impurities would not seep into supplement products. Final regulations for Good Manufacturing Practices ('GMP rules') were announced in 2007. It is clear that these still lack the rigour of the most basic European requirements, allowing for example companies to determine their own tests to verify the identity, purity, strength and composition and to avoid testing every batch. Nevertheless such is the laxity in the current industry that it is estimated that 30% of botanical supplement manufacturers will go out of business as the new GMP rules apply. The opportunities for a manufacturer with basic international standards to enter the market clearly look good.

The challenges

Drawing on articles co-authored by Utah Natural Products Alliance director Loren Israelson and Nutrition Business Journal editor Tom Aarts¹⁸ and on his own experience and perspective, American Botanical Council founder and Executive Director Mark Blumenthal discusses reasons for slumping herbal supplement sales and charts a path to a more successful future.¹⁹ While some negative media stories continue, and a significant minority of industry executives at an earlier summit seemed to blame negative coverage for their woes, others acknowledge that such stories "do not occur in a vacuum," but "reflect real and legitimate concerns about supplement quality, safety and claims." Effective self-policing and high manufacturing standards will do more to deflate negative media than "creating" positive stories or exposing critics' anti-supplement bias.

The over-availability of controversial products points to a problem underlying others which Blumenthal discusses more directly: lack of effective consumer education. In order to survive as a big business, the supplements industry should heed scientific evidence. Ethical conduct, ongoing commitments to clinical research, and voluntary or mandatory state-of-the-art GMPs from field to lab to retail sale are the coming reality. The industry also needs to convince consumers to support high standards with their pocketbooks.

In a report 'US Herbal Market At A Crossroads' for Functional Foods by Grant Ferrier in 2002 Michael McGuffin, president of the American Herbal Products Association (AHPA) is reported saying that there are many who believe false expectations among consumers may have contributed to a lack of satisfaction with herbal products. "Some mass-market shoppers want herbal products to work just like aspirin, and they don't." Unlike health-food store users, who tend to know a little more about natural products, mass-market shoppers are more likely to hold unrealistic expectations about what herbal supplements can and cannot

15 Blumenthal M. Herb market levels after 5 years of boom. *Herbalgram* 1999;47:64-65

16 Fugh-Berman A: Herb-drug interactions. *Lancet* 2000;355:134-8

17 Mahady, G. British Toxicology Society meeting London June 23, 2002

18 Israelson LD, Aarts TD. Industry needs to rethink DSHEA; Leaders must address the reality of a post-DSHEA world by looking in the mirror. *Nutrition Business Journal* 2002 Dec.

19 Blumenthal M. Improving herb sales. *Whole Foods*. 2003;September:54-58.

do. This may explain why herbs such as (the now banned) ephedra, which produce immediate reactions, gained popularity among mass-market shoppers. The industry has arguably perpetuated unrealistic expectations about herbs or simply not managed the expectations of their newest consumers, doing what is necessary to convert them into faithful users. Insiders agree the failure of retailers and manufacturers to educate mass-market consumers has contributed significantly to the problem.

Ferrier reports that suppliers of botanical raw materials and extracts intent on weathering the downturn were focusing efforts on eliminating supply backlogs and streamlining operations. To sustain business for the long term, they were also focusing on product innovation, value-added services and partnerships with key distributors and retailers. Both raw materials suppliers and finished-product manufacturers agreed the focus should be on quality and efficacy, not cost alone. Greg Ris of Indena (USA). "Some marketers are realising the only way to win back consumer confidence is to offer a legitimate product and offer the safety and efficacy reported in the literature."

Market trends

Researchers from Boston University School of Public Health²⁰ conducted a study to determine which dietary supplements adults in the United States use. For the purpose of this study, the authors defined a supplement as a herb (plant or algae substance or their extract) or other natural product (substance derived from other natural sources). Vitamins or minerals were not included.

From 1998 through 2002, 10,470 subjects from the 48 contiguous states and the District of Columbia were interviewed by telephone to determine their demographic information and details of their use of all conventional medicines and dietary supplements in the preceding week. The authors report their results based on the 8,470 subjects who were at least 18 years of age.

The median age of the subjects was 43 years; the proportion of female subjects varied from 54% to 58.3%. Overall, **15.9%** of subjects had used one or more supplements during the previous week; prevalence of use varied, with a low of 12.3% in 2000 and a high of 19.8% in 2001. Supplement users were **older** (median age, 49 versus 42 years) and more likely to be **female** (59.9% versus 55.5%) and **white** (80.7% versus 75.6%) than nonusers. Users also included a higher proportion of subjects from the Mountain Pacific states than nonusers (27% versus 21.2%). Annual household **income and educational level were higher** among users.

The prevalence of use in men aged 45 to 74 years increased by about half between 1998-2000 and 2001-2002. **Supplement use increased each year among the oldest men**; by 2002, men aged 65 years and older had the highest prevalence (22.7%). The youngest women had the lowest use, with the highest prevalence of this group (16.3%) occurring in 2001. Supplement use was greatest among **women aged 45 to 64 years**.

The authors report numerous changes in use for each of the most commonly reported supplements. Among younger men, Asian **ginseng** had the highest prevalence (4.1%) in 1998-1999 but was used by only 2.1% in 2002. The next most often reported supplements for this group in 1998-1999 -- creatine (an amino acid) and saw palmetto -- were not among the

20 Kelly J, Kaufman D, Kelley K, Rosenberg L, Anderson T, Mitchell A. Recent trends in use of herbal and other natural products. Arch Intern Med. February 14, 2005;165:281-286.

top supplements in 2002. Over time, in middle-age men, use of garlic did not differ; use of **ginkgo, Asian ginseng, and St. John's wort decreased**; and use of **saw palmetto increased**.

For women aged 18 to 44 years, none of the top six supplements in 1998-1999 were in the top five in 2002. Although the ranking of glucosamine (for arthritis) fell to second in 2002 among middle-age women, its prevalence increased to 8.6. Chondroitin (for arthritis) gained in popularity, while use of **ginkgo, Asian ginseng, and garlic declined**. Among women aged 65 years or older, use of glucosamine almost doubled from 1998-1999 to 2002, with use rising from 5.2% to 9.8%.

The **overall prevalence is relatively unchanged during those four years**, causing the authors to suggest "the use of dietary supplements in the form of individual herbs or herbal mixtures has reached a **plateau**."

Indian medicine in the USA

There is increasing interest in the medicine and culture of India within the USA. Although the proportion of citizens originating from India is low (0.3% of the population) and there is a much lower cultural profile (for example in the number of Indian restaurants) than in the UK, fascination with the subcontinent appears to be rising.

In terms of raw material medicinal plant imports into the USA India's overall export performance with respect to the US Market has been very encouraging. In 1998, India's share in US imports of pharmaceutical preparations was less than 20% of that China (Table 10.1). However, by year 2002 India has increased its exports five fold to be almost at par with China. Even the specific case of medicinal plants India has overtaken China as the leading supplier to USA.

Table 10.1. US Imports of Pharmaceuticals (US \$ million)

Year	Total	India	China
1998	16,980	60	306
1999	22,510	78	376
2000	27,810	96	387
2001	32,700	214	296
2002	40,550	331	332

Source: US Census Bureau

Table 10.2. US Imports of Medicinal Plants (US \$ million)

Year	Total	India	China
1999	133	20	45
2000	132	29	39
2001	137	38	35

Source: US Census Bureau

Indian corporations are already active in the USA supplement market. In 2003 Indian-owned Vitabiotics Ltd., a leading vitamin and dietary supplement supplier that has moved to be one of the largest in the UK, launched three of its top branded products in the United States. In 2007 an Indian corporation Plethico Pharmaceuticals, which specialises in herbal and nutritional products, acquired the US-based nutritional products specialist Natrol (turnover \$65.6 million) for US\$80.7 million. Shashikant Patel, chairman and Managing Director of Plethico said the deal would make the company a “truly global player”. In 2006 Plethico reported sales of US\$82 million. Himalaya Herb Company has also moved some of its range of teas and herbal supplements into the USA. As seen earlier, the Sabinsa Corporation (pages 57 and 77) has focused its high quality manufacturing on the dietary supplement market in the USA.

Moves announced in 2007 by the Government of India to spend about US\$40m, on what is known as the Golden Triangle Partnership, to assess the country's herbs scientifically, and select those suitable for serious investigation are a welcome boost to prospects in markets like the USA. (http://www.economist.com/science/displaystory.cfm?story_id=9644701)

There are signs of an emerging professional interest as well. With the direct support of Prime Minister Manmohan Singh the Government of India in January 2006 cleared a proposal to send experts to teach Ayurveda in 10 American medical colleges. An official view of Ayurvedic medicine in the USA can be found on the website of the National Center for Complementary and Alternative Medicine at the US National Institutes of Health: http://nccam.nih.gov/news/newsletter/2006_winter/ayurveda.htm.

The curiosity about this rich tradition of medicine in the USA is however tempered by persistent negative reports on product quality. For example, a recent publication in a leading medical journal²¹ reported that analysis of some Ayurvedic herbal preparations imported directly from India and sold in Boston-area ethnic grocery stores showed that out of 70 remedies 14 (one-fifth) contained lead, mercury, and/or arsenic at levels that could be harmful. There have been reports of heavy metal contamination in Ayurvedic products and herbal materials for over 25 years.

There is another example of the mixed profile for Indian medicine in the USA. A non-profit organisation that offers health services to Ground Zero rescuers (Serving Those Who Serve Inc.), headed by two Ayurvedic physicians, has developed herbal supplements to treat the toxic effects of the smoke that surrounded Ground Zero following the attack. They have been offering the supplements free of charge to 9/11 emergency personnel, and thus far over 400 fire-fighters have participated in the Ayurvedic program. Unfortunately for the two physicians, the city of New York “isn’t sold on treatments that lack sufficient scientific and clinical evidence of the herbs’ effectiveness” and they did not receive the grant they sought for this work. Charles Kim, MD, director of medical acupuncture in the anesthesiology department at Mount Sinai Medical Center, raised concerns over the city’s potential backing of the herbal treatments. “There’s really little evidence to support it. Most clinical trials of Ayurvedic approaches have been small, had problems with research designs, lacked appropriate control groups, or had other issues that affected how meaningful the results were,” he said.

21 Saper RB, Kales SN, Paquin J, Burns MJ, David M, Eisenberg DM. Heavy metal content of Ayurvedic herbal medicine products. JAMA. 2004;292:2868-2873

Assessment

The evidence suggests that the USA is currently the most attractive international market for medicinal plants from a sales perspective. The wide scope for permitted labelling and promotional claims are very attractive to manufacturers of finished products for the supplement market. The USA is a single market (unlike the 25 Member States of Europe). India already has a relatively strong manufacturing and importing infrastructure there. Regulatory barriers to entry are among the lowest in the developed world, however this has an impact on both the quality of products and their sustainability.

What would be required however for any entrepreneurial grower/producer would to find a partner with the muscle to move in to what is also a very competitive market. Although there is increasing awareness of fairtrade and other ethical standards, there have been persistent concerns about quality and the USA consumer still buys overwhelmingly on price. There are possible niche and premium markets to aim for but in most cases the manufacturing partner will have to strike a hard bargain on the cost of his goods and will require relatively high quantities for usual bulk discounting activities. This may act as a deterrent to entrants from India focused on delivering a high quality and sustainably cultivated product. Whilst the USA may be the most attractive market in the short term, the requirements for transparency and quality in the UK may help to develop a more sustainable Indian market that benefits marginalised Himalayan communities in the longer term, albeit at a price.

Importantly, because there is still little awareness of Indian culture and traditions, any product range being marketed here will have to be clearly pitched in the language and culture of the USA public. Practices familiar within India are unlikely to transfer successfully to the US market at present.



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