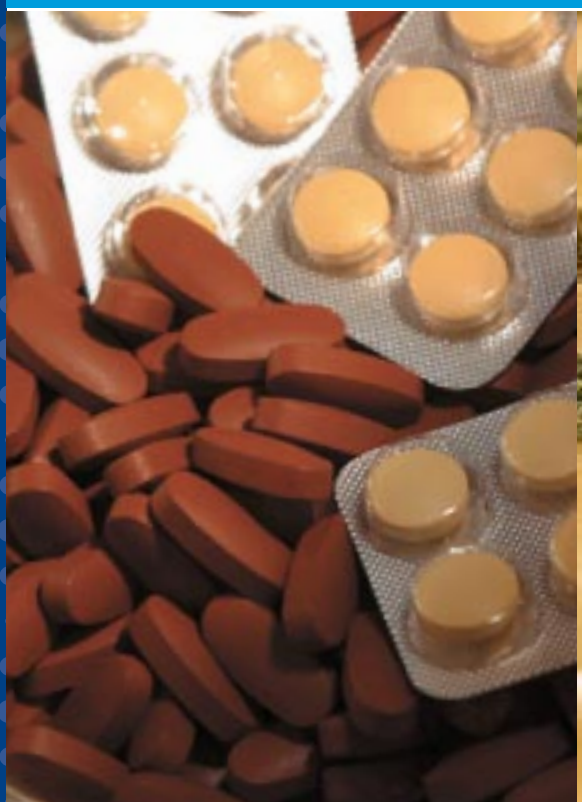
EU MARKET SURVEY 2004

Natural ingredients for pharmaceuticals



Centre for the Promotion of
Imports from developing countries

EU MARKET SURVEY 2004

NATURAL INGREDIENTS FOR PHARMACEUTICALS

Compiled for CBI by:

ProFound

in collaboration with:
Klaus Dürbeck

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Photo courtesy: Dürbeck, 2004

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REPORT SUMMARY

This market survey provides exporters of natural ingredients for pharmaceuticals with a wide range of facts, figures and information pertinent to the European Union (EU) market. The survey also includes a large number of references for additional research, primarily using the Internet. The survey is divided into two parts. Part A deals with EU market information including information about the types of products used for natural ingredients for pharmaceuticals, a description of the EU, consumption trends in the pharmaceutical industry, imports, trade structures, prices and EU market access requirements. Part B contains information about Export Marketing Guidelines including information on how to carry out a market audit, company audit and develop an export marketing strategy. A summary of part A is given below:

The natural ingredients for pharmaceuticals in this survey fall into the following groups:

- Medicinal & aromatic plants
- Medicinal and vegetable saps and extracts
- Vegetable alkaloids

Consumption and trends

There certainly is a market for natural ingredients for herbal medicines in Europe. Some 42 percent of the sales of the top 25 selling drugs world-wide are either biologicals, natural products, or entities derived from natural products. According to WHO, the industry of medicinal plants is estimated to be worth more than € 45 billion and is growing steadily. Global trade in herbal medicines is estimated at € 10 billion annually and is growing in excess of 10 percent annually. The largest EU markets for herbal medicines are found in Germany, France, Italy, the UK and Spain (Ten Kate & Laird, 1999). Herbal medicines represent a range of product types. These include products sold as raw herb (dried or fresh), and others, which are processed to varying degrees, including tinctures (an infusion of herbs in alcohol) and extracts (greater concentration of the active material of the plant with the aid of a solvent).

The leading European market is Germany, followed by France, Italy and the UK. The medicinal plant trade is largely conducted through Germany. Most importers are found in Germany and it is the leading market for exporters in developing countries. The large European markets (Germany and France) are consolidating, while smaller markets show stronger growth. New markets at a global level include Brazil, Argentina, Mexico, India, China and Indonesia.

Use of medicinal plants is expected to rise globally, both in allopathic and herbal medicine (WHO, 2002). This upward trend is predicted not only because of population explosion, but also due to increasing popularity for natural-based, environmentally friendly products. The major trends, which have an impact on demand for botanical medicines and, consequently, the demand for natural pharmaceutical ingredients, include, amongst others:

- Interest of individuals, communities and national governments in greater self-reliance in health care. Consumers seek an alternative or complement to pharmaceutical drugs and modern healthcare. The increase in demand for ‘natural’ medicine is also strongly related to the rise of the green consumption movement;
- The entry of large pharmaceutical and Over-The-Counter (OTC) companies has placed botanical medicines more strongly on the mass market;
- Increasing success in validating the safety and efficacy of herbal remedies;
- Legislation improving the status of the herbal medicine industry;
- Renewed interest of companies in isolating useful compounds from plants;
- Search for new drugs and treatments of serious and drug-resistant diseases;
- Moreover, increasingly innovative companies are requesting organically certified raw material or value-added products, especially for the development of new products. There is increasing demand for certified raw material and value-added products.

Trade structure
European-based companies, and German companies in particular, dominate the global herbal supply industry. The biggest herbal raw materials group is Martin Bauer Group, a German-based corporation with annual sales of over € 350 million.

Manufacturers of herbal medicines used to acquire their raw materials from traders, but now some have their own plantations or have direct contacts with producers. Manufacturers of herbal products are increasingly interested in having direct relationships with producers of the required materials, in order to ensure a sustained source and/or to save costs.

Exporters should realise that the Internet is an important medium in the sourcing of raw materials for herbal products. A number of users/traders of natural ingredients mentioned that they use the Internet in order to find new suppliers.

EU trade and developing countries
In 2002, the leading developing country suppliers of medicinal & aromatic plants to the EU were China, India, Morocco, Egypt, Kenya, Turkey and South Africa. About two thirds of EU imports from developing countries of medicinal and vegetable saps and extracts originated in China and Madagascar. China supplied more than a third of the total value of alkaloids originating in developing countries, followed by India (27%), Indonesia (18%), Brazil (10%) and Mexico (6%). In 2002, the value of EU imports of medicinal plants, medicinal and vegetable saps and extracts and vegetable alkaloids decreased compared to 2001 and 2000. The volume of EU imports only decreased for vegetable alkaloids.

Product group	EU imports in € million, 2001	Main EU importers and their share in EU imports	Share of developing countries in EU imports
Medicinal & aromatic plants	318	Germany (26%), France (17%), Italy (14%)	40%
Medicinal and vegetable saps & extracts	106	Germany (32%), Italy (20%), France (17%)	5%
Vegetable alkaloids	514	UK (34%), Germany (12%), Spain (11%)	6%

Source: Eurostat (2003)

Opportunities for exporters
It is not easy to present an overview of promising products for export from developing countries. There is a great transfer of natural ingredients from developing countries to the pharmaceutical industry for research purposes. Large pharmaceutical companies are engaged in bio prospecting, which refers to the exploration of biodiversity for commercially valuable genetic and biochemical resources. This type of trade in natural ingredients is research-driven. Pharmaceutical companies study the properties and effects of specific medicinal plants and the knowledge is used with the aim to develop new medicines, which can be patented.

This so-called bio prospecting is strongly dominated and controlled by large pharmaceutical companies. Exporters in developing countries will find better opportunities in the trade of ingredients with known properties and effects, which are not patented and which can be traded freely.

In Europe, some 2,000 medicinal and aromatic plants are used on a commercial basis. A number of botanical species is consistently cited by industry representatives in the USA and Europe as the most important today, and likely to be so in the next five years (Laird et al., 2002). Echinacea was cited as the top product now and in the years to come, in

both the USA and Europe. European companies continue to consider St Johns wort and Kava kava extremely important, while USA industry representatives tended to think both might be in decline due to controversial recent studies and bad press. Other important botanicals cited include: Gingko, Ginseng, Valerian, Goldenseal, and Garlic. USA companies also cited Black Cohosh and Astragalus as good performers, while European companies have had continued success with Hawthorn and Chamomile.

Most buyers in The Netherlands are not interested in plant material, but in plant extracts. There are only a few developing countries, which are able to supply extracts conforming to the requirements of western industry.

Current issues in the trade are Good Agricultural Practices / Good Manufacturing Practices, organic production and certification. A sound marketing strategy for ingredients takes into account these issues, as well as CITES regulations on certain protected species. A number of companies supplies certified organic ingredients and a new development is certification based on criteria and principles of the Forest Stewardship Council. In 2001, a Brazilian company earned FSC certification for 80 thousand ha of native forest, where extraction of raw materials for producing medicines and cosmetics takes place.

Marketing strategies still have to be adapted to national regulations, as regulations for herbal products in the EU have not yet been harmonised. However, a positive development with respect to herbal medicinal products is the proposal (COM 2002/1) of 17 January 2002 for a Directive to amend Directive 2001/83/EC, prescribing that no medicinal product may be placed on the market without having obtained a marketing authorisation on the basis of harmonised requirements. Normally, many tests are required for such an authorisation. Published scientific literature is not available for many herbal medicinal products, so that a well-established medicinal use cannot be demonstrated. The proposed Directive would provide for a special registration and, hence, the marketing of certain traditional herbal medicinal products without requiring very extensive tests.

CBI services

For information on current CBI Programmes and training & seminars, and for downloading market information and CBI News Bulletins, please refer to http://www.cbi.nl/. Currently, CBI has an export development programme for companies that manufacture natural ingredients for pharmaceuticals and/or cosmetics. Other interesting CBI publications are the EU Market Survey "*Natural Ingredients for Cosmetics"* and "*Food Ingredients for Industrial Use*".

INTRODUCTION

This document is a reference tool and the most important starting point in a reference tool is the page of contents! Although each section can be read as an individual section, we recommend that as a first step, to get an overview of the whole survey, you read pages 5-10. To supplement the information provided in this survey, we also recommend that you have access to the Internet. We welcome any feedback you have about using this survey.

This CBI survey aims to provide information about exporting to the European Union for those companies producing and selling natural ingredients for pharmaceuticals. The survey consists of two parts: EU Market Information and EU Market Access Requirements (Part A), and Export Marketing Guidelines (Part B). The layout of the survey is described below:

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<tr><th colspan="2">Market Survey</th></tr>
<tr><td colspan="2">Part A
EU Market Information and Market Access Requirements</td></tr>
<tr><td>EU Market Information (Chapters 1-8)
Product characteristics
Introduction to the EU market
Consumption and production
Imports and exports
Trade structure
Prices</td><td>EU Market Access Requirements
(Chapter 9)
Quality and grading standards
Environmental, social and health & safety issues
Packaging, marking and labelling
Tariffs and quotas</td></tr>
<tr><td colspan="2">Part B
Export Marketing Guidelines: Analysis and Strategy</td></tr>
<tr><td>External Analysis (market audit)
(Chapter 10)
Opportunities & Threats</td><td>Internal Analysis (company audit)
(Chapter 11)
Strengths & Weaknesses</td></tr>
<tr><td colspan="2">Decision Making
(Chapter 12)

SWOT and situation analysis:
Target markets and segments
Positioning and improving competitiveness
Suitable trade channels and business partners
Critical conditions and success factors (others than mentioned)
Strategic options & objectives</td></tr>
<tr><td colspan="2">Export Marketing
(Chapter 13)

Matching products and product range
Building up a trade relationship
Drawing up an offer
Handling the contract
Sales promotion</td></tr>
</table>

Chapters 1 to 8 of Part A profile the EU market for Germany, France, the UK, Spain, Italy and The Netherlands. The emphasis of the survey lies on those products, which are of importance to developing country suppliers. The major national markets within the EU for those products are highlighted. Furthermore, statistical market information on consumption, production and trade, and information on trade structure and opportunities for exporters is provided.

Chapter 9 subsequently describes the requirements, which have to be fulfilled in order to get market access for the product sector concerned. It is furthermore of vital importance that exporters comply with the requirements of the EU market in terms of product quality, packaging, labelling and social, health & safety and environmental standards.

After having read Part A, it is important for an exporter to analyse target markets, sales channels and potential customers in order to formulate export marketing and product strategies. Part B therefore aims to assist (potential) exporters from developing countries in their export-decision making process.

After having assessed the external (Chapter 10) and internal environment (Chapter 11), the (potential) exporter should be able to determine whether there are interesting export markets for his company.
In fact, by matching external opportunities and internal capabilities, the exporter should be able to identify suitable target countries, market segments and target product(s) within these countries, and possible trade channels for exporting the selected products (Chapter 12).

Chapter 13 subsequently describes marketing tools, which can be of assistance in successfully achieving the identified export objectives.

The survey is interesting for starting exporters as well as well as exporters already engaged in exporting (to the EU market). Part B is especially interesting for more experienced exporters starting to export to the EU and exporters looking for new EU markets, sales channels or customers. Starting exporters are advised to read this publication together with the CBI's Export planner, a guide that shows systematically how to set up export activities.

PART A:

EU MARKET INFORMATION AND EU MARKET ACCESS REQUIREMENTS

1 PRODUCT CHARACTERISTICS

1.1 Product groups

The natural ingredients discussed in this market survey fall under the following groups:

- Medicinal & aromatic plants
- Medicinal and vegetable saps and extracts
- Vegetable alkaloids

These natural ingredients are not only used by the pharmaceutical industry, but also find applications in other product groups such as cosmetics. The complexity of the trade in medicinal plants was already illustrated in the 1982 ITC report on Medicinal Plants and their Derivatives; from which we quote:

'It is not possible to assess the volume or value of the trade in all botanicals that are used medicinally because trade statistics do not identify all the plants individually and of those listed, the statistics do not identify medicinal and other uses separately. Products reported as medicinal plants often include gums, spices and plants used in the food industry; certain plant products include those used for teas and infusions; large volumes of plants such as pyrethrum are used in manufacture of insecticides; plants used by the cosmetic industry are also included'.

The situation in medicinal plants' trade is rather more complicated because of the levels of secrecy maintained by traders and the complexity of the trade structure itself.

There is a range of natural products, which is used as ingredients by the pharmaceutical industry, including essential oils, vegetable oils, natural gums & resins and natural colours. These ingredients, however, do not have a specific medicinal activity and only a small proportion of the total trade in these products is used by the pharmaceutical industry. For more information on these ingredients, please refer to CBI's market surveys "*Natural Ingredients for Cosmetics*" and *"Food Ingredients for Industrial Use*".

Other raw materials such as vitamins and hormones are not included in this market survey. Although these products partly include natural products or entities derived from natural products, the exact components cannot be determined. Moreover, according to EU trade data, only a few developing countries, e.g. Brazil, China and India, play a role in the trade in these products.

Please note that, since it is rather difficult to find appropriate information on natural ingredients for pharmaceuticals, the statistical information used throughout the study can be ambiguous and serve as an indication only.

1.2 Customs/statistical product classification

On January 1, 1988, a unified coding system was introduced to harmonise the trading classification systems used world-wide. This system is called the Harmonised Commodity Description System (HS) and was developed by the World Customs Organisation (WCO). The system comprises about 5,000 commodity groups, each identified by a six-digit code, arranged in a legal and logical structure and is supported by well-defined rules to achieve uniform classification. The system is used by more than 179 countries and economies as a basis for their Customs tariffs and for the collection of international trade statistics. After the six-digit code, countries are free to use further subheadings. In the trade data of Eurostat, an 8 digit system is used. Most codes, however, end with two zeros, i.e. effectively only using six digits. In some countries, even 10 digits are sometimes used.

Most of the natural ingredients used in the pharmaceutical industry do not have an exclusive HS Code and are incorporated in a broader product code. Below, a four to six-

digit list of the main product groups is presented. These product groups can be further divided into sub-groups to the extent of ten digits.

HS code	Product description
1211	Plants and parts of plants (including seeds and fruits) of a kind used primarily in perfumery, in pharmacy or for insecticide, fungicide or similar purposes, fresh or dried, whether or not cut, crushed or powdered
1302 1991	Medicinal and vegetable saps and extracts
2939	Vegetable alkaloids, natural or synthetic, and their salts, ethers, esters and other derivatives

2 INTRODUCTION TO THE EU MARKET

The European Union (EU) is the current name for the former European Community. Since 1 January 1995 the EU has consisted of 15 member states. Ten new countries joined the EU in May 2004. They are the Czech Republic, Estonia, Slovak Republic, Cyprus, Latvia, Lithuania, Malta, Slovenia, Poland and Hungary. Negotiations are in progress with a number of other candidate member states. In this survey, the former EU-15 will be referred to as EU, unless otherwise stated.

Table 2.1 Population and GDP of selected and new EU countries, 2003

Countries	**Population** *million*	**Age 15-64** *%*	**GDP (€)** *estimation 2003*
Selected EU countries			
Germany	82.4	67.0	24,407
France	60.4	65.1	24,318
UK	60.3	66.3	24,495
Italy	58.1	66.9	23,699
Spain	40.3	68.0	19,455
The Netherlands	16.3	67.8	25,291
New EU countries			
Poland	38.6	70.0	9,727
Estonia	13.4	67.5	10,877
Czech Republic	10.2	70.9	13,884
Hungary	10.0	69.0	12,292
Slovakia	5.4	70.8	11,761
Lithuania	3.6	68.4	9,904
Latvia	2.3	69.2	8,931
Slovenia	2.0	70.6	16,183
Cyprus	0.8	67.4	14,149
Malta	0.4	68.5	6,263
Currencies used in EU-15			€, UK £, DKr, SKr
Exchange (2003)			€ 1 = US$ 1.13

Source: The World Factbook 2003

Within Western Europe – covering 15 EU member countries, Iceland, Liechtenstein, Norway and Switzerland – more than 20 million enterprises are active. Small and medium-sized enterprises (SMEs) accounted for the lion's share. In 2000, the average turnover per enterprise of SMEs and large enterprises amounted to € 600,000 and € 255 million respectively.

EU Harmonisation

The most important aspect of the process of unification (of the former EC countries), which affects trade, is the harmonisation of rules in the EU countries. As the unification allows free movement of capital, goods, services and people, the internal borders have been removed. Goods produced or imported into one member state can be moved around between the other member states without restrictions. A precondition for this free movement is uniformity in the rules and regulations concerning locally produced or imported products. Although the European Union is already a fact, not all the regulations have yet been harmonised. Work is in progress in the fields of environmental pollution, health, safety, quality and education. For more information about harmonisation of the regulations, visit AccessGuide, CBI's database on non-tariff trade barriers at http://www.cbi.nl/accessguide

Monetary unit: Euro (€)
On 1 January 1999, the euro became the legal currency within twelve EU member states: Austria, Belgium, Finland, France, Germany, Greece, Italy, Ireland, Luxembourg, The Netherlands, Spain, and Portugal. In 2002, circulation of euro coins and banknotes replaced national currency in these countries. Denmark, the United Kingdom and Sweden have decided not to participate in the euro.

The most recent Eurostat trade statistics quoted in this survey are from the year 2002. The € is the basic currency unit used to indicate value in this market survey.

Trade figures quoted in this survey must be interpreted and used with extreme caution. The collection of data regarding trade flows has become more difficult since the establishment of the single market on 1 January 1993. Until that date, trade was registered by means of compulsory Customs procedures at border crossings, but, since the removal of the intra-EU borders, this is no longer the case. Statistical bodies like Eurostat can no longer depend on the automatic generation of trade figures. In the case of intra-EU trade, statistical reporting is only compulsory for exporting and importing firms whose trade exceeds a certain annual value. The threshold varies considerably from country to country, but it is typically about € 100,000. Consequently, although figures for trade between the EU and the rest of the world are accurately represented, trade within the EU is generally underestimated.

Furthermore, the information used in this market survey has been obtained from a variety of different sources. Therefore, extreme care must be taken in the qualitative use and interpretation of quantitative data, both in the summary and throughout the text, as also in comparisons of different EU countries with regard to market approach, distribution structure, etc.

Table 2.2 Exchange rates of EU currencies in US$, 1998-2004

Country	Currency	1999	2000	2001	2002	2003	April 2004
European Union	€	1.063	0.920	0.900	0.946	1.125	1.176
Denmark	Dkr	0.14	0.12	0.12	0.13	0.15	0.16
Sweden	Skr	0.12	0.10	0.10	0.10	0.12	0.13
United Kingdom	GB£	1.61	1.52	1.44	1.50	1.63	1.82

Source: CBS Statline

Selected countries
Germany, France, UK, Spain, Italy and The Netherlands are highlighted in this survey, due to their important role as importers and consumers of natural ingredients for pharmaceuticals. Besides the six selected countries, attention is paid to main developments in the accession countries (10 new EU countries i.e. Poland, Hungary, Czech Republic, Slovakia, Lithuania, Estonia, Slovenia, Malta and Cyprus).

- For more information on the EU market, please refer to the CBI manual *"Exporting to the European Union"*.

3 INDUSTRIAL DEMAND

3.1 Market size

Data regarding the trade and use of natural pharmaceutical ingredients are scattered and difficult to obtain. One of the underlying problems is that most of the ingredients are also traded for other end-users (e.g. the food and cosmetics industries). Therefore, we will first give an overview of the pharmaceutical market as an entry point to gain insight into the market for natural pharmaceutical ingredients. The pharmaceutical market is strongly dominated and controlled by large pharmaceutical companies. Exporters in developing countries will find more opportunities in the trade of ingredients with known properties and activity, which are not patented and which can be traded freely. The herbal medicine market, which is more interesting for exporters, is discussed separately.

Another reference for market information, although somewhat outdated, is "*A Guide to the European Market for Medicinal Plants and Extracts*" (2001) published by the Commonwealth Secretariat. The publication is available through several online bookstores.

Please note that the information used in this Chapter originate from several sources, most using different definitions for pharmaceuticals, medicines, etc.

Pharmaceutical market

IMS data (covering 90% of total pharmaceutical global sales) show that audited global pharmaceutical sales increased by 9 percent in 2003, reaching € 350 billion. The global pharmaceutical industry continued to grow at a solid pace in 2003, despite difficult economic conditions and continued pressure on the sector from regulators and the media. The United States continues to generate the highest growth, while Europe and Asia show solid sales results. The pace of growth in Japan has accelerated. While in 2002 sales in Latin America slumped 10 percent, in 2003 the market shows improvement. The Chinese market continues to grow significantly and represents an important strategic market for the pharmaceutical industry.

Despite economic challenges in the world's leading markets and a lower-than-normal number of new product introductions, the global pharmaceutical industry experienced solid growth in 2002. Generic drug sales strengthened in North America and Western Europe due to several patent expiries, while the Japanese market continued to show nearly flat growth. Ageing populations and the ongoing demand for innovative therapies are expected to effectively sustain pharmaceutical growth in 2004 and beyond.

Table 3.1 Global pharmaceutical sales by region, 2003

World Audited Market	Sales (€ billion)	global sales	Growth
North America	229.5	49%	+11%
European Union (EU-15)	115.4	25%	+8%
Rest of Europe	14.3	3%	+14%
Japan	52.4	11%	+3%
Asia, Africa and Australia	37.3	8%	+12%
Latin America	17.4	4%	+6%
TOTAL	**466.3**	**100%**	**+9%**

Source: IMS (2004)

Please note that IMS publications can be bought online at http://www.open.imshealth.com/, while at http://www.ims-global.com/ information on regional markets can be found (e.g. Latin American market).

The pharmaceutical market is increasingly globally in scope. Previously, companies might launch a number of products in one or two of the three major markets (USA, Europe and Japan). Today, in order to derive a satisfactory return on R&D, pharmaceutical companies generally launch products in all three markets.

Pharmaceutical products concern a very broad range of products. We will look at the self-medication category, as this includes the bulk of herbal medicine sales. Table 3.2 shows expenditures on pharmaceutical and self-medication in the six main European markets, while Table 3.3 describes the other European countries. Expenditures on self-medication are highest in Germany, followed by France. In Germany, if prescribed by doctors, patients were reimbursed by the national health services for herbal medicines. However, as of 1 January 2004, and as part of the healthcare system reform in Germany, non-prescription medicines will no longer be reimbursed under the national health insurance.

The main markets of the new accession countries are Poland, Hungary and the Czech Republic with respective expenditure of € 4,110, € 1,700 and € 1,307 mln.

Table 3.2 Total pharmaceutical and self-medication expenditure in the main EU markets, 2001-2003, in € million

	2001	2002	2003	% change 2002-2003
Germany				
Total pharmaceutical market	30,670	33,287	34,106	7.0%
Total non-prescription market	7,315	7,132	7,068	-1.0%
Self-medication market	4,269	4,205	4,257	1.0%
France				
Total pharmaceutical market	22,944	23,397	24,408	4.3%
Total non-prescription market	5,515	5,375	5,387	0.2%
Self-medication market	1,662	1,549	1,572	1.5%
Italy				
Total pharmaceutical market	17,375	17,851	18,203	1.9%
Total non-prescription market	1,801	1,867	2,037	8.9%
Self-medication market	1,293	1,351	1,510	10.3%
Spain				
Total pharmaceutical market	10,512	11,087	12,355	11.4%
Total non-prescription market	999	1,305	1,367	4.8%
Self-medication market	868	920	1,073	16.7%
United Kingdom				
Total pharmaceutical market	8,976	10,947	11,465	4.7%
Total non-prescription market	2,428	2,235	2,491	11.4%
Self-medication market	1,745	1,762	1,973	4.1%
Netherlands				
Total pharmaceutical market	4,287	4,700	4,985	6.1%
Total non-prescription market	682	629	634	-
Self-medication market	510	520	530	7.1%

Source: AESGP (2004)

Table 3.3 Total pharmaceutical and self-medication expenditure of other EU countries, 2002, in € million

Country	Pharmaceuticals	Self-medication
Belgium	5,296	488
Austria	5,127	253
Sweden	2,958	289

Portugal	2,821	235
Greece	2,659	245
Finland	1,955	237
Denmark	1,920	236
Ireland	1,234	197
EU-15	**157,974**	**17,135**

Source: AESGP (2004)

The most important characteristics of the selected individual EU consumption markets for the Over-The-Counter healthcare sector (OTC) according to Euromonitor (2004) are listed below.

Germany

- German sales of OTC healthcare amounted to € 4 billion in 2001 with low growth rates in the following years. Most sectors increased moderately in value terms, with eye-care products performing exceptionally well in value terms. However, analgesics, digestive remedies and child-specific OTC healthcare products all registered declines. The two most valuable sectors – cough, cold and allergy (hay fever) remedies and vitamins and dietary supplements – grew slightly, which contributed to the overall positive performance of the market.
- Sales increases in cough, cold and allergy remedies were mostly due to a relatively cold winter, with influenza outbreaks affecting German attitudes towards self-medication. The cold also helped sales values for vitamins and dietary supplements as did the trend “beauty from the inside”.
- Please note that changes in insurance legislation will affect consumption of prescribed OTC products and the OTC market as a whole. Although there are some exceptions, non-prescription drugs will not be reimbursed. Prescription-free drugs will probably suffer from cost avoidance, and consumption of products that used to be prescribed is likely to decrease. The health reforms (GMG) will harmonise prices for pharmaceuticals, with price increases for cheap products and vice versa.
- Prescription sales of semi-ethical herbal, homoeopathic and anthroposophic products, as well as combination products, will particularly be hurt by the health reforms. Sales of single-ingredient products are also likely to suffer. Sales of prescribed herbal products will suffer considerably. The trend favouring herbal products has weakened in recent years, and there are signs that demand for such products is suffering as a result. The predictable reduction in sales will force many herbal producers to stop producing their remedies. Therefore, for the first time in years the outlook for herbal products is a rather pessimistic one. As one industry source put it: "the big herbal hysteria is over." Herbal products are unlikely to lose their general appeal entirely, but growth is nevertheless expected to slow.
- The German OTC market is fairly fragmented. The three leading companies (Bayer Vital, Boehringer Ingelheim Pharma and Novartis Deutschland) account for 17 percent of the market. The top 25 producers have a combined market share of fewer than 60 percent. The market share of the leading producers has been increasing. The effect of the government’s reform package on companies probably lies in further consolidation, mainly through mergers and acquisitions.

France

- French sales of OTC healthcare increased by only 10.6 percent between 1998 and 2003. In 2003 the market grew by 2.4 percent to € 2.5 billion, despite de-listing of drugs and encouragement of self-medication by the French government. Still, self-medication is less significant in France that in the UK and Germany, due to a high frequency of doctor visits, a preference for prescriptions rather than self-medication and the broad reimbursement coverage by the government health system. These preferences will remain largely unchanged in the coming years.
- The largest market segment concerns semi-ethical brands, with the best performing sectors being those that are less mature, for example smoking cessation aids. Increased taxes on cigarettes fuelled this growth, with many French deciding to quit

smoking. Sales of vitamins and dietary supplements showed fast growth rates as well, due to health awareness.

- Mature sectors like analgesics, cough, cold and allergy remedies and digestive remedies showed slow rates of growth or declined. Product development, innovation and promotion in this segment were limited. The availability of generic products in the case of analgesics, and the average incidence of colds and flu did not support growth either.
- Pharmacies dominate distribution of OTC health products off all types, with an 84 percent market share. This is also because semi-ethical medicine is sold exclusively by pharmacies. However, OTC products are also becoming increasingly available through other sales channels. The market is fragmented. The top five producers account for only 25 percent of the market, due to the variety offered and the limited range of products per producer.
- Growth forecasts are modest, with 4 percent growth in constant value terms expected until 2008. The trend toward generic medicine could also drive down prices, limiting value growth.

United Kingdom

- The abolishment in 2001 of retail price maintenance, which set minimum prices on many OTC products, reduced prices in key areas and on leading products, led by grocery multiples. The UK OTC market was valued at € 2.9 billion in 2003, signifying hardly any increase in real term value. Further deregulation of the National Health Service (NHS), allowing any grocery outlet to dispense NHS medication, is to be expected. However, this will remain under supervision of a pharmacy. The British system will remain regulated and will not operate as a free market.
- The range of OTC products has grown, due to a broadening range of pharmaceuticals approved for OTC sales. The main market segments are analgesics, cough, cold and sore throat treatments, and skincare and gastro-intestinal products. New product innovations offset price pressures in analgesics, the leading market segment. Sectors experiencing higher growth are smoking cessation products, hay fever remedies and medicated mouthwashes and sprays. This increase was largely due to reclassification of these products to general sales status, which made them more widely available. Anti-smoking legislation has also fuelled growth in sales of smoking cessation products.
- The popularity of high dosage products is increasing, with consumers increasingly being drawn to quick-acting and long-lasting effect products. Producers are also introducing an increasing number of such products.
- Grocery outlets increased their market share to 30 percent in 2003, with highest growth in analgesics, cough cold and allergy remedies and digestive remedies. Grocery outlets mainly compete on prices, targeting top brands. Multiple retail outlets will continue to keep prices low and, as most markets are mature, sales growth will be limited in the future. New brand development and reclassification of more products to general sales status encourages for growth.

Italy

- Changes in legislation and consumer trends caused significant market growth in 2003, mainly in the vitamin and dietary products segments, due to increased promotion and consumer trends towards well-being. Moreover, a strong flu epidemic in 2003 fuelled sales of cough, cold and allergy remedies. Increased information through media and the Internet is benefiting healthcare products in general as self-medication. The tendency towards increasing consumption of functional food also appears to be fuelling the growth in popularity of OTC products.
- Chemists and pharmacies have a near monopoly in most OTC healthcare segments, as Italian law prohibits their sales through other channels. This changed in 2003, when sales of OTC drugs were allowed from self-service shelves. Although this remains the sole providence of pharmacies, it can be seen as a first step towards further liberalisation. Vitamins, dietary products, medicated confectionery and wound treatments can already be sold through other channels. The OTC healthcare market is

very fragmented in Italy, with the top five players controlling 25 percent of the market. Examples are Roche, with its Supradyn brand, and Acraf-Gruppo Angelini.
- Further growth is expected for the period until 2008, due to government budgetary constraint favouring sales of OTC products and the trend toward well-being. Herbal and homeopathic products may claim some of this market expansion.

Spain
- In line with developments of the last years, the Spanish OTC market grew by 5 percent in 2003. Growth was limited by new laws and slack legislation. A new reference price system came into force January 2004.
- The most dynamic developments were in wound treatments, smoking cessation aids and cough, cold and allergy remedies, growing by 7 percent in 2003. OTC sales are fuelled by two factors: flu outbreaks and the heat wave of 2003, which drove sales of antifungals and antipruritics.
- Due to the emphasis on physical appearance common in Spanish culture, products that help consumers meet these images significantly increased in sales volume. Examples are medicated skin care products, vitamins and dietary supplements. Most dynamic were the “nutri-cosmetics” and “nutraceuticals”.
- Pharmacies dominate OTC sales, with a market share of 91 percent. Distribution of analgesics, adult mouth care, ear care, and smoking cessation aids and medicated skin care products can only be sold through this channel.
- Value sales of OTC healthcare products are expected to grow by 12 percent until 2008. This will depend largely on legislation, like reimbursement of smoking cessation aids, the new pricing reference system and the expected law regulating dietary supplements.

The Netherlands
- The traditionally strict Dutch regulatory system has curbed the development of the Dutch OTC market, but government efforts for the reduction of health care expenses helped the sector to reach a 7 percent growth rate in 2003. In 2002, distribution laws allowed for more freedom in product exhibition and the major drugstores have adjusted their stores to allow for a broader segment of products to be displayed. The open-shelf sale allowed customers to compare products without assistance by shop attendants.
- The fastest growing sectors are vitamins and dietary supplements, fuelled by changes in customer lifestyles and more promotion. Prevention of ailments associated with busy lifestyles, such as stress, is the main focus of Dutch consumers. Small sectors like smoking cessation aids benefited from extensive promotion efforts while the Dutch government is increasingly implementing policies to discourage smoking. Sectors such as medicated skin care products grew as well, but remained very limited in market size.
- The Dutch OTC healthcare market is still fairly fragmented, with different niches being dominated by different companies. Promotion efforts are increasing.

Accession countries
- In general, the OTC markets of Poland, Czech Republic and Hungary are increasing since customers' disposable income constantly increases. Manufacturers also benefit from the economic improvement, as growing sales encourage them to develop their range and launch new products. Due to health system reforms, sales declined in Slovakia.
- In 2002, the ***Polish*** pharmaceutical market stood at an estimated € 2.7 billion at consumer prices. Per capita spending stands at around € 70, similar to that in Hungary and Slovakia. It has been predicted that the ageing population, an increasing awareness of healthcare and the wealth effects derived from economic growth and EU accession in 2004 will result in strong market growth.
- The ***Czech*** pharmaceutical sector remains one of the better regional prospects for overseas suppliers, being relatively wealthy and largely reliant on imported medicines. The overall market has been depressed in recent years, however, by a combination of

the country's stalled economic performance, strict pricing/reimbursement policies. Rapid growth cannot be expected in the near future.

- The Hungarian pharmaceuticals market accounted for € 0.9 billion. Industry sources expect the market to grow by 5 % in the next three years. The market is dominated by imported products, as two-thirds of total sales originate in foreign countries. Major suppliers include German, Swiss, British, Israeli and French firms in addition to American companies.

- Please check http://www.wsmi.org/member_europe.htm for addresses and names of national self medication
- For more information on other markets, for example those of the new EU member countries, please refer to http://www.euromonitor.com/ industry associations.

Natural pharmaceutical products

According to WHO, the industry of medicinal plants is estimated to be worth more than € 45 billion and is growing steadily. Moreover, it estimates that 4 billion people, 80 percent of the world's population, presently use herbal medicine for some aspect of primary health care.

Some 42 percent of the sales of the top 25 selling drugs world-wide are either biologicals, natural products, or entities derived from natural products[1] (Ten Kate & Laird, 1999). Modern pharmacopoeia (official publications containing a list of drugs, formulas, doses, etc.) still contain at least 25% of drugs derived from plants (FAO, 1997). Despite the historical and current prevalence of plants in the pharmacopoeia, only between 5 and 15 percent of the approximately 250,000 - 500,000 species of higher plants have been investigated for the presence of bioactive compounds. Estimates for the overall value of natural product pharmaceuticals vary considerably. In 1995, world-wide sales of the following plant-derived pharmaceuticals were significant: opiates (€ 1.13 billion), taxanes (€ 300 million), digoxins and related compounds (€ 150 million), Ergot alkaloids (€ 113 million), and Catharanthus derivatives (€ 75 million) (Ten Kate & Laird, 1999).

Use of medicinal plants is expected to rise globally, both in allopathic and herbal medicine (WHO 2002). This upward trend is predicted not only because of population explosion, but also due to the increasing popularity of natural-based, environmentally friendly products. In general, the demand for medicinal plants and herbal remedies, and especially their renaissance in the developed countries, is driven by the following factors (FAO, 2004):

increasing costs of institutional, pharmaceutical-based health care;

- interest of individuals, communities and national governments in greater self-reliance in health care;
- interest of communities and national governments in small and large-scale industrial development based on local/national biodiversity resources;
- increasing success in validating the safety and efficacy of herbal remedies;
- legislation improving the status of herbal medicine industry;
- renewed interest of companies in isolating useful compounds from plants;
- search for new drugs and treatments of serious and drug-resistant diseases;
- marketing strategies by the companies dealing in herbal medicine.

[1] Biologicals: an entity that is a protein or polypeptide either isolated directly from the natural source or more usually made by recombinant DNA techniques followed by production using fermentation (e.g. insulin).
Natural product: an entity that though occasionally manufactured by semi-synthesis, is chemically identical to the pure natural product (e.g. Vitamin C, paclitaxel, and cyclosporine).
Derived from a natural product: an entity that starts with a natural product which is then chemically modified to produce the drug (e.g. penicillin, simivastatin).

Herbal medicine market[2]

Herbal medicines, as distinct from pharmaceuticals, are produced directly from whole plant material. As a result, they contain a large number of constituents and active ingredients working in conjunction with each other, rather than a single, isolated active compound. Because the drug approval process and patenting systems do not provide incentives for companies to conduct (expensive and time-consuming) research on the synergistic and collective function of active ingredients in whole plants or plant formulas, botanical medicines are often scientifically poorly understood (Ten Kate & Laird, 1999). However, most herbal medicines have long histories of traditional use, which confirm safety and efficacy, and as their documentation used in many regulatory systems to guide the approval of commercial products.

Herbal medicines represent a range of product types. These include products sold as raw herb (dried or fresh), and others that are processed to varying degrees, including tinctures (an infusion of herbs in alcohol) and extracts (greater concentration of the active material of the plant with the aid of a solvent). Herbal medicines are part of larger markets, referred to in the USA, for example, as the 'dietary supplement' market. Dietary supplements encompass vitamins, minerals, herbs/botanicals, and other natural medicines.

Trade in herbal medicines is estimated at € 10 billion annually and is growing in excess of 10 percent annually. Consumption of vitamins, minerals and herbs/botanicals was estimated at € 42 billion in 2000 (NBJ, 2000). The largest markets for herbal medicines are found in Germany, China, Japan, the USA, France, Italy, the UK and Spain (Ten Kate & Laird, 1999).

According to Nutrition Business Journal, global sales for herbs/botanicals accounted for € 18.5 billion of sales in 2000. The major market is Europe, accounting for some 38 percent of the world market. The leading European market is Germany, accounting for over 42 percent of the European market, followed by France (25%), Italy (9%) and the UK (8%). The medicinal plant trade is largely conducted through Germany. Most importers are found in Germany and it is the leading market for exporters in developing countries. The large European markets (Germany and France) are consolidating, while smaller markets show stronger growth. New markets at a global level include Brazil, Argentina, Mexico, India, China and Indonesia.

In August 2004, Germany's Federal Institute for Drugs and Medical Devices (BfArM) reported the total number of licensed and registered herbal medicines in the German market. There is a total of 2,269 medicinal herbal products which have marketing authorization or have completed the registration procedure, of which 1,832 (80.1%) are single-herb preparations and 437 (19.3%) are fixed combinations of more then one herb or extract. BfArM also reported the total number of licensed or registered anthroposophic- and homoeopathic medicines, many of which are also herbal-based products (MNS ITC, 2004).

Top-selling species used in commercial herbal medicine products vary by country and region. The bulk of the Japanese and Chinese markets, for example, are based on Traditional Chinese Medicine. European markets tend to follow similar species.

Regulatory frameworks set standards for proof of safety, efficacy, and quality; determine the scope of claims made about products, the information included on labels, and the content of advertisements. As a result, they help determine the nature of the industry, including the demand for 'new' materials. In most of Europe and in Japan, monographs are produced for herbal medicines in trade, and research and testing in support of claims

[2] The term herbal medicine is common in Europe, while in the USA the term botanical medicine is used. We will mostly use the term herbal medicine, but when referring to specific reports, we will use the term used in the report quoted.

to safety and efficacy is required. Materials 'new' to these markets previously took a slower route to the consumer than in the USA, where products were considered safe unless proven otherwise. This situation has changed now and standards are being developed in the USA. Over-the-counter (OTC) drugs must meet a US Pharmacopeia and National Formulary (USP-NF) existing or proposed monograph(s) for active ingredients or botanical drug substances.

Table 3.3 lists the top selling medicinal plants in Europe. A study by Laird et al. (2002) shows that a core of botanical species was consistently cited by industry representatives in the USA and Europe as the most important today, and likely in the next five years. Echinacea was cited as the top product now and in the years to come, in both the USA and Europe. European companies continue to consider St. John's Wort and Kava extremely important, while USA industry representatives tended to think both might be in decline due to controversial recent studies and bad press. The position in Europe towards Kava has changed now. In June 2002, Germany banned the supply of the herbal remedy kava-kava after reports linking it to fatal liver failure. Britain's Medicines Control Agency (MCA) has proposed to ban kava-kava and the Order has come into force on January 13, 2003. In the EU, all licensed kava-kava products have been removed from the market while in Canada, investigations have concluded that there is insufficient evidence to support the products' safety and they have also been withdrawn from the market. In Australia, products have been voluntarily removed from the market while an investigation is conducted and in the USA consumers have been warned of the risk of liver toxicity pending the outcome of an investigation by the FDA.

Other important botanicals cited by European importers and manufacturers and also visible in Table 3.4 include Gingko, Ginseng, Valerian, Goldenseal, and Garlic. USA companies also cited Black Cohosh and Astragalus as good performers, while European companies have had continued success with Hawthorn and Chamomile. Table 3.4 and Table 4.1 in the next Chapter on EU production, do no show much overlap. From this it becomes clear that European importers of medicinal plant ingredients depend on sourcing in countries outside the EU.

Table 3.4 Top selling medicinal plants in Europe

Product	€ million	Product	€ million
Gingko	338	Butcher Broom	68
Valerian	169	Evening Primrose	62
Horse Chestnut	141	Pygeum	59
Saw Palmetto	130	Melilot	56
Bitter Orange Extract	124	Grape Seed	51
Garlic	113	Milk Thistle	45
Hawthorn	79	Melissa	37
Ginseng	79	Nettle	34
Psyllium	71	Bilberry	34
Echinacea	68	Chamomile	26
		Total	**1,778**

Source: M.K. Eaves, 1998 in Commonwealth (2000)

Data charts on the global nutrition industry are available at a fee at http://www.nutritionbusiness.com/. Some interesting data charts are included under the heading "Dietary Supplement Data", "Condition Specific Healthcare Products Markets" and "Complementary and Alternative Medicine".

3.2 Market segmentation

The market for natural ingredients for pharmaceuticals can be segmented into:

- ingredients required by the pharmaceutical industry
- ingredients required by the herbal medicine industry.

Pharmaceutical industry
Pharmaceutical companies are traditionally large, vertically integrated concerns that conduct the full range of activities, from creating libraries of compounds to marketing the drugs which emerge from their pipelines. However, since the 1980s the number of small pharmaceutical biotech companies has grown rapidly. Today, there are about 1,000 of such companies in Europe (Ten Kate & Laird, 1999). There is a growing opportunity for partnerships, since large, traditional drug firms increasingly out-source research and development through alliances, collaborations, and joint ventures with smaller drug discovery companies, academia, and research institutions. With the possible exception of banking, there is probably no other sector of the economy that has been so heavily subject to mergers and acquisitions as the pharmaceutical industry.

The majority of companies does not conduct field collections, but relies instead on existing in-house collections of material, or buying in-compound or culture collections. Most companies outsource, or contract to others, the acquisition of samples for their screening programmes. They obtain samples through brokers, agents, or through specific deals with supplier organisations. The bulk of collecting activities is conducted by non-profit organisations (universities, research institutes, botanical gardens) (Ten Kate & Laird, 1999).

Herbal medicine industry
The herbal industry is experiencing rapid growth world-wide. Annual growth rates are between 10 and 20 percent in most countries.

Diversity within the industry is also apparent in the structure and nature of participating companies. The company size and function vary widely, with some companies employing only a handful of staff, and others a few thousand. Some companies emphasise a standardised, proven effective and safe products, while others are primarily in the packaging and marketing business, placing little emphasis on proven product efficacy (and sometimes quality); still others incorporate environmental and social concerns into their business practices. However, a trend exists towards uniformity in the global herbal medicine market, as a result of increased emphasis on quality control, safety and efficacy. As a result, relationships between processing and manufacturing companies and the sources of their raw material are becoming closer. Increasingly, companies seek high quality, reliable supplies of cultivated material, although wild-collected / wild-harvested material continues to play a significant role in the industry.

In this market segment, exporters in developing countries will find opportunities in the trade of ingredients with known properties and activity, which are not patented and which can be traded freely. The market segment of herbal medicines, produced directly from whole plant material, is of particular interest to exporters in developing countries. In general, the market for herbal medicines is growing at a faster rate than that for conventional chemical drugs. For an overview of the trade structure in this industry, please refer to Chapter 7.

Opportunities for developing country exporters
There certainly is a market for natural ingredients for herbal medicines in Europe. As mentioned earlier, global demand has increased dramatically during the last ten years. Trade in herbal medicines is estimated at € 10 billion annually and is growing in excess of 10 percent annually (Nutraceuticals International, January 2001). Consumption of vitamins, minerals and herbs/botanicals is estimated at € 42 billion in 2000 (NBJ, 2000). At the end of the 1990s, the market for herbal medicines was growing at a faster rate than for conventional chemical drugs. However, since 2000, the USA market slowed down significantly due to negative press on safety and efficacy. In the EU, however, sales remained strong. This is due to a number of factors, including historical differences in the marketplaces, the active role of pharmacists, doctors, and researchers in botanicals in Europe, and stricter quality control and regulation in Europe (NBJ, March 2001; Gruenwald, 2000). One of the reasons that the market in the USA grew relatively very

fast was that new materials could previously be more easily introduced in the USA than in the EU or Japan, as USA legislation considered products safe unless proven otherwise. This situation has changed now and standards are being developed in the USA. Over-the-counter (OTC) drugs must meet a US Pharmacopeia and National Formulary (USP-NF) existing or proposed monograph(s) for active ingredients or botanical drug substances.

The strongest opportunities for natural ingredients from developing countries are those that are unique to a specific region and climate (e.g. cat's claw stem bark or maca root) and, therefore, cannot be easily or feasibly produced in the EU, or, for that matter, by other leading world producers such as China and India. Manufacturers of herbal medicines used to acquire their raw materials from traders, but now some have their own plantations or have direct contacts with producers. Manufacturers of herbal products are increasingly interested in having direct relationships with producers of the required materials, in order to ensure a sustained source and/or to save costs. In some cases, these producers require a certain minimum supply of the raw material. In other cases, however, you can easily access the market with 10 kg of extract, or 100 kg of flowers. Small producers need to search for small demand, which is easier in the organic market. Salus-Haus in Germany, for example, is a medium-sized company, only buying organic certified raw material. Moreover, in Germany a number of phyto-pharmaceutical companies demonstrated their commitment to the conservation of natural medicine resources by signing a Joint Declaration for the Health of People and Nature (refer to Section 3.3). Regarding the requirements for organic products, please refer to EU Regulations EEC 2092/91 and EC 1804/1999 (refer to Legislation in Force at http://europa.eu.int/eur-lex/en/search.html), or contact Skal (see Appendix 2.6).

3.3 Consumption patterns and trends

Trends which have an impact on demand for botanical medicines and, consequently, the demand for natural pharmaceutical ingredients are the following:

The entry of large pharmaceutical and Over-The-Counter (OTC) companies has placed botanical medicines more strongly on the mass market. Increased advertising budgets and media attention for botanical medicines have contributed to rapid growth in consumer demand.

Consumers seek an alternative or complement to pharmaceutical drugs and modern healthcare. The increase in demand for 'natural' medicine is also strongly related to the rise of the green consumption movement. Herbal remedies have been a key driver, with strong growth for newer products, the majority of which are unlicensed and positioned as nutritional supplements. The entrance to the market of newer 'alternative' medicines, such as Chinese herbal remedies and Ayuvedic medicines, have positioned many herbal and homoeopathic remedies more firmly alongside conventional products, as part of the standard repertoire of effective remedies. Consumer demand remains strong, with awareness, media coverage and distribution all suggesting that the complementary remedies covered in this report are increasingly becoming part of the mainstream.

The world continues to look hopefully at the rain forest and other natural environments for new cures for old diseases. There are plenty of initiatives to help in the development of natural medicines, e.g. the Biotrade-programme of UNCTAD. However, from the side of the conventional pharmaceutical industry reactions are often sceptical and for them it is hard to say whether or when any significant contribution to the arsenal of useful medicines will come from these natural products.

Increased emphasis on safety, efficacy and quality has resulted in more research and development, a shift towards standardised products, and requirements for high-quality raw materials. This expanded research and development has improved the legitimacy of botanical medicines. Acceptance of botanical medicines by national (Germany and Japan) and commercial insurance companies (USA). However, at a global level re-imbursement is currently decreasing. Some claim that the innovation and expansion of the

pharmaceutical biotechnology sector, which is based on natural materials, has produced a scientific and financial environment open to the potential medical benefits of other natural products, including botanicals.

Opportunities for exporters in developing countries
There is a big transfer of natural ingredients from developing countries to the pharmaceutical industry for research purposes. Large pharmaceutical companies are engaged in bio-prospecting, which refers to the exploration of biodiversity for commercially valuable genetic and biochemical resources. This type of trade in natural ingredients is research driven. Pharmaceutical companies study the activities and properties of specific medicinal plants and the knowledge is used with the aim to develop new medicines, which can be patented.

Controversial examples of medicinal plants, which were patented, include ayahuasca and neem. An American citizen received a USA patent for what was commonly thought to be a variety of ayahuasca, originally cultivated by an indigenous community in Ecuador. When indigenous leaders, activists and environmental lawyers at the Centre for International Environmental Law (CIEL) learned of the patent, they mobilised an international campaign to repeal the patent. The Patent Trade Office (PTO) eventually suspended the patent in November 1999. At the same time that the ayahuasca patent was being challenged, the government of India was challenging several USA patents on a number of traditionally utilised Indian plants (P. Shanley, 2002).

This so-called bio-prospecting is strongly dominated and controlled by large pharmaceutical companies. The interest in equitable partnerships between pharmaceutical companies and indigenous communities or local universities is increasing, but still in its infancy. For a good overview see Laird (2002). Exporters in developing countries, however, will find more opportunities in the trade of ingredients with known properties and activity, which are not patented and which can be traded freely.

Current problems in the trade are the relatively slow amount of new products and the on-going price battle.

A positive development with respect to herbal medicinal products is the proposal (COM 2002/1) of 17 January 2002 for a Directive to amend Directive 2001/83/EC, prescribing that no medicinal product may be placed on the market without having obtained a marketing authorisation on the basis of harmonised requirements. This would mean that exporters would no longer have to deal with different national regulations for herbal products. The application for such an authorisation has to contain the results of tests and trials on quality, safety and efficacy of the products. However, for many herbal medicinal products, which are used for a long period, sufficient published scientific literature is not available so that a well-established medicinal use cannot be demonstrated. The proposed Directive would provide for a special registration and, hence, the marketing of certain traditional herbal medicinal products without requiring particulars and documents on tests and trials on safety and efficacy. If the pharmaceutical market becomes more easily accessible for producers of some herbal medicinal products, this would also have positive effects for producers of natural ingredients for pharmaceuticals.

Certification and conservation issues
Another trend in the phyto-pharmaceutical[3] market is that more and more innovative companies are requesting organically certified raw material and value added products, especially for the development of new products. Another indication of this trend is that more and more conventional importers and traders receive approval to deal with organically certified material.

Certification programmes related to natural resource use have mainly been developed for timber and agricultural products, but they are presently being adapted for wild harvest of

[3] Phytopharmaceuticals are plant and herb-based remedies.

non-timber plants. Various schemes focus on different areas along the supply chain: production, processing, trade, manufacturing, marketing. Four categories of certification schemes have been identified as being of relevance for medicinal and aromatic plants (FAO,2004): (i) forest management certification (e.g. Forest Stewardship Council FSC), (ii) social certification (e.g. Fair Trade Federation FTF), (iii) organic certification (e.g. International Federation of Organic Agriculture IFOAM), and (iv) product quality certification.

Regarding the requirements for organic products, please refer to EU Regulations EEC 2092/91 and EC 1804/1999 (see Legislation in Force at http://europa.eu.int/eur-lex/en/search.html), or contact Skal (see Appendix 2.6).

In October 2000, representatives from the phyto-pharmaceutical industry in Germany (e.g. Weleda, Madaus, Martin Bauer), practitioners' associations, and international organisations including the International Council on Medicinal and Aromatic Plants (ICMAP), WWF, IUCN and TRAFFIC, demonstrated their commitment to the conservation of natural medicine resources by signing a Joint Declaration for the Health of People and Nature. Working Groups have been formed to establish criteria for the use of medicinal plants, to discuss labelling and legislation and to exchange market information. The German Federal Agency for Nature Conservation (BfN), IUCN and WWF/TRAFFIC initiated a process aiming at the development of globally relevant "Practice Standards and Performance Criteria for the Sustainable Wild Collection of Medicinal and Aromatic Plants" (S&C). It will play an intermediate role between relevant general guidelines for sustainable use, particularly at the policy level, and specific management and monitoring strategies that involve local collectors and producers. A draft version of the S&C will be developed in late 2004. For more information contact honnef@wwf.de. For more information on guidelines for sustainable use, please refer to Chapter 9.

There is not only increased interest in certified organic production, but also in other forms of certification. An interesting publication on certification is "Tapping the green market" by P. Shanley et al. (2002). The purpose of the manual is to explore the feasibility of certification of non-timber forest products. It includes details on criteria for certification based on Forest Stewardship Council (FSC) principles. In 2001, a Brazilian company earned FSC certification for 80 thousand ha of native forest where extraction of raw materials for producing medicines and cosmetics takes place.

4 PRODUCTION

Medicinal and aromatic plants

Medicinal and aromatic plant material is obtained both from plants growing in the wild and from cultivated stock. Collection in the wild still plays a vital role in the use of, and trade in, medicinal and aromatic plant material in Europe, since cultivation has not proved to be profitable for the majority of plants traded. This is because: many plants are difficult to cultivate; many are required in small quantities; the quality of some wild-harvested material is supposed to be superior; the costs associated with obtaining plant material from the wild are relatively low. Moreover, collection in the wild contributes to a wider distribution of cash income in rural areas, originating in fair-trade market partnerships. However, in general, in all countries, the trend is towards a greater proportion of cultivated material. The majority of companies, the mass-market, over-the-counter pharmaceutical companies as well as the larger herb companies, prefer cultivated material, particularly since cultivated material can be certified biodynamic or organic (FAO, 2002). For more information and the publication "Impact of Cultivation and Gathering of Medicinal Plants on Biodiversity: Global Trends and Issues", please refer to http://www.fao.org/.

Lange (1998) estimates that about 2,000 medicinal and aromatic plant species are used on a commercial basis in Europe, of which two-thirds are native to Europe. In the EU, medicinal and aromatic plants are cultivated on an estimated 70,000 ha. Leading species are: lavender (*Lavandula spp.*), Opium Poppy (*Papaver somniferum*), Caraway (*Carum carvi*) and Fennel (*Foeniculum vulgare*). France and Spain are EU countries with many hectares under cultivation. However, in Spain wild-harvesting and cultivation of medicinal and aromatic plants has declined. There is some cultivation in Germany, where leading producers of herbal medicines have their own plantations for popular products. Finzelberg, for example, cultivates St. John's Wort and Echinacea in Germany. The area under cultivation, however, is small as cultivation in Eastern European countries is much cheaper.

Eastern European countries such as Bulgaria, Hungary and Albania are major EU suppliers of material from medicinal and aromatic plants. For detailed information about production of medicinal and aromatic plants in Europe, please refer to the publication "Europe's Medicinal and Aromatic Plants: Their trade use and conservation" by Lange. This publication is obtainable through Traffic (see Appendix 2.6).

The global production and processing of medicinal herbs remains concentrated in Europe, in particular France, as well as in a number of Asian countries. Other significant production areas include former Yugoslavia, Bulgaria, Germany and Hungary. Germany has a very large medicinal and aromatic plant extraction industry and the largest percentage of medicinal herbs is brokered through Germany. Similarly, Hungary developed the first research centre for medicinal herbs in the early 1900s. Strong historical ties with its former colonies have meant that the United Kingdom has become one of the major centres of research and development in the field of tropical commodities and extracts. China and Korea are the two major producers in the Asian region. They offer vast experience along with highly skilled workers using labour intensive techniques.

In 2002, the European Herb Growers Association (EHGA Europam) collected data on the production of herbs in the EU for their Inventory "Production of Aromatic and Medicinal Plants in the existing and incoming memberstates of the European Union". EHGA – Europam represents a total number of at least 13,000 growers/collectors, covering a total area of at least 90.000 hectares of which at least 2,000 hectares are organically cultivated.

"Top 20" crops (out of 168) cover at least 73,100 hectares (91%) and "Top 10" cover at least 65,600 hectares (81%). They are listed in Table 4.1 below. Table 4.2 presents the conventional and organic cultivated areas of herbs in the member countries of EHGA

Europam. Spain is not included in the statistics with more than 800 hectares, but it is assumed that it has increased the cultivated area by another 18,000 hectares.

Table 4.1 Top 20 herbal crops cultivated in Europe, in hectares

Crop	hectares	Crop	hectares
Hops	25,000	German Chamomile	1,100
Lavender	20,000	Oregano	1,000
Poppy	8,600	Peppermint	900
Squash	2,200	Saffron Crocus	800
Parsley	2,100	Coriander	700
St Mary's Thistle	1,800	Thyme	700
Borage	1,600	Basil	600
Caraway	1,600	Dill	600
Citrus	1,500	St. John's Wort	600
Sage	1,200	Gingko bilboa	500

Source: EHGA Europam (2003)

Table 4.2 Total area hectares of cultivated herbs in Europe, in hectares

Country	total area hectares	organic area hectares
France	32,200	400
Germany	27,000	500
United Kingdom	6,500	4
Austria	5,900	70
Italy	3,600	810
The Netherlands	2,000	30
Greece	1600	90
Denmark	160	100
Sweden	26	26

Source: EHGA Europam (2003)

With other countries being included and some areas not being registered, it is likely that the total cultivated area in EU-15 is around 100,000 hectares. Moreover, the entrance of new countries to the EU will at least double the total cultivation/collection area (e.g. Hungary 40,000 hect., Poland 30,000 hect., Rumania 20,000 hect., Bulgaria 15,000 hect).

For more information, please refer to http://www.europam.net/. The organisation also provides an Excell sheet with all produces medicinal plants/herbs per country.

The already mentioned report "*A Guide to the European Market for Medicinal Plants and Extracts"* by the Commonwealth Secretariat also provides some data on European production of natural ingredients.

There are two distinct trends in European medicinal plant production. Large-scale cultivation of relatively low value products such as Evening Primrose, Thyme and Milk Thistle is generally on the decline and is being replaced by imports. Production of more specialist plants is, however, increasing, especially using organic or bio-dynamic cultivation techniques (Commonwealth, 2000).

Medicinal and vegetable saps and extracts
The EU is a leading producer of extracts. Germany is among the leading pharmaceutical plant importers and big extract producers such as Finzelberg, Spreewald, General Extract Products and Gehrlicher are located in Germany. Other leading producers are Indena and Hammer Pharma in Italy.

Vegetable alkaloids
According to our information, there is no production of cinchona or ephedrine in Europe. There are, however, companies such as Buchler GmbH in Germany that process and trade these products.

Enlargement EU
In 2004, some ten more countries, primarily from the Central and East European (CEE) region, have joined the European Union: Hungary, Poland, the Czech Republic, Slovakia, Slovenia, Estonia, Latvia, Lithuania, Malta and Cyprus.

As part of the integration process, these countries are adopting the common body of law in the EU. The new member countries have also entered into bilateral agreements with the EU in areas such as industrial and agricultural tariffs, and standards and certification procedures.

In this Section, the impact of the EU enlargement on exports of natural ingredients for pharmaceuticals by developing countries will be briefly discussed.

Threats from the enlargement
East-European countries (mainly Hungary, Poland, Albania and Bulgaria) cultivate and collect medicinal plants on a large scale. Many companies in CEE have a competitive advantage over their competitors in developing countries, because of their access to highly skilled, and low-cost labour.

After the enlargement, therefore, imports from developing countries may expect to be partially replaced by imports from the new member states. However, this will only be the case for product groups, which can be cultivated in Europe, such as lavender (*Lavandula spp.*), Opium Poppy (*Papaver somniferum*), Caraway (*Carum carvi*) and Fennel (*Foeniculum vulgare*). For some product groups, cultivation is not a good alternative. Collection from the wild may occur for medicinal plants, which grow slowly, are difficult to domesticate or for which only small quantities are needed. The cost of wild-collection is typically much less than that of cultivation. In these cases, the position of developing countries will not deteriorate.

Although developing countries have a dominant position in the global production of natural ingredients, the competition from industrialised countries and East-European countries remains strong. For instance, in the case of natural ingredients for the cosmetic industry, developing countries account for approximately 55 percent of total inputs, while industrial countries and East European countries supply 35 percent and 10 percent of global production respectively. Industrialised countries remain in a dominant position where high yield and full mechanisation make cultivation competitive, compared with countries that rely on low labour costs. Some industrialised countries out-source their production to East-European countries where labour costs are low.

Opportunities offered by the enlargement
The accession of the new member countries adds another 100 million consumers to the EU marketplace. This will obviously increase the overall EU buying power noticeably. Although the average income of consumers in the ten new countries is considerably lower than the average of the current 15 member countries, it is expected that this will increase rapidly. At first glance, the ten new countries which joined the European Union in May 2004 represent a comparatively small pharmaceutical market – only 8 percent of the total 15-state EU market, at € 5.3 billion in sales. Unlike the 15 EU markets, the EU accession markets have been growing -albeit from a low base- at an average 16 percent

(in local currency terms), during the past five years. The two largest markets, Poland and Hungary, have grown by almost 20 percent since 1998. That compares to an approximate 8 percent growth across the EU during the same period.

One of the greatest attributes of EU membership in terms of how it benefits exporters in developing countries is the transparency and homogeneity of the EU regulatory system. As the countries of CEE move through the accession process, they are required to adopt EU laws and regulations. Each of the new member countries already has these EU laws in place, or is in the process of adapting their laws to EU standards. As a result, transaction costs for exports from developing countries will be reduced because the harmonised rules and regulations now cover a larger area.

Accession countries' governments – like those of the 15 EU states – want to curb rising healthcare costs. Yet, despite this, IMS (2004) predicts that through to 2006, the pharmaceutical markets across the region will grow by more than 9 percent on average – almost 50 percent higher than the projections for the two largest West European markets, Germany and France.

Exporters in developing countries will find that there are new specialist ingredient trade fairs and new markets opening in the new EU countries. The following Internet site give more insight in market opportunities in these countries:

- http://www.ifeat.org/ (Warsaw conference proceedings, 2002)
- http://wayfinder.cphi.com/ (Companies from Central and Eastern Europe)

5 IMPORTS

5.1 Total imports

Table 5.1 provides an overview of the imports of the product groups falling under the category ingredients for pharmaceuticals. In general, the value of imports of these product groups decreased by more than 6 percent between 2000 and 2002. It is not particularly worthwhile to give an indication of total imports of natural pharmaceutical ingredients. Besides the medicinal & aromatic plants, the medicinal & vegetable saps & extracts, and the vegetable alkaloids, there is a range of natural products that is used as ingredients by the pharmaceutical industry, including essential oils, vegetable oils, natural gums & resins and natural colours. These ingredients, however, do not have a specific medicinal activity and only a small proportion of the total trade in these products is used by the pharmaceutical industry. For more information on these ingredients, please refer to other CBI's EU Market Surveys "*Natural Ingredients for Cosmetics"* and "*Food Ingredients for Industrial Use".* Moreover, it is important to note that most of the ingredients are not only traded for the pharmaceutical industry, but also find their way to the food and cosmetics industry.

Table 5.1 Imports by EU member countries of selected product groups falling under ingredients for pharmaceuticals, 1999-2001, € thousand / tonnes

	2000		2001		2002	
	value	volume	value	volume	value	volume
Medicinal & aromatic plants	338,808	116,964	330,426	124,783	318,271	116,920
Intra-EU	120,948	25,720	112,091	34,401	105,275	27,111
Extra-EU	217,860	91,245	218,335	90,381	212,995	89,810
Medicinal & vegetable saps & extracts	127,155	2,558	115,470	3,075	106,094	2,866
Intra-EU	93,049	1,841	85,843	2,119	76,759	2,034
Extra-EU	34,106	717	29,627	957	29,335	833
Vegetable alkaloids	531,978	10,780	548,376	9,636	513,878	8,750
Intra-EU	265,072	8,195	291,962	7,415	202,510	5,999
Extra-EU	266,906	2,585	256,413	2,221	311,368	2,751

Source: Eurostat (2003)

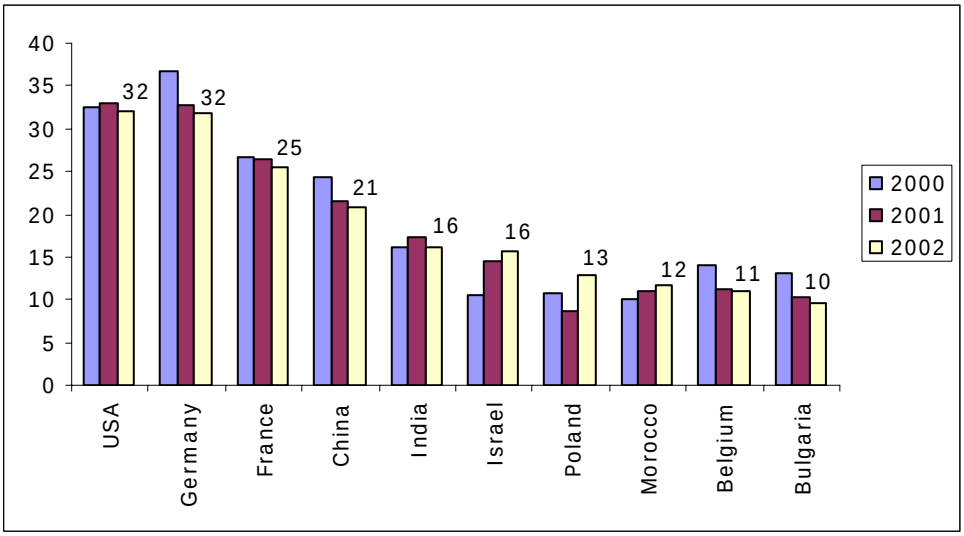
5.2 Imports by product group

Medicinal & aromatic plants

Figure 5.1 shows that, in terms of value, the leading suppliers of medicinal & aromatic plants to the EU were the USA, Germany, France and China. Between 2000 and 2002, the total value imported by EU member countries decreased, amounting to about € 318 million in the latter year. In terms of volume, imports fluctuated somewhat during the same period, reaching almost 117 thousand tonnes in 2002. Volume of EU imports of vegetable alkaloids decreased. These fluctuations and decline of imports are a result of broadening of EU regulations on more products falling under natural ingredients of pharmaceuticals.

Two thirds of the imports (in value) was supplied from extra-EU sources, of which 60 percent represented developing countries.

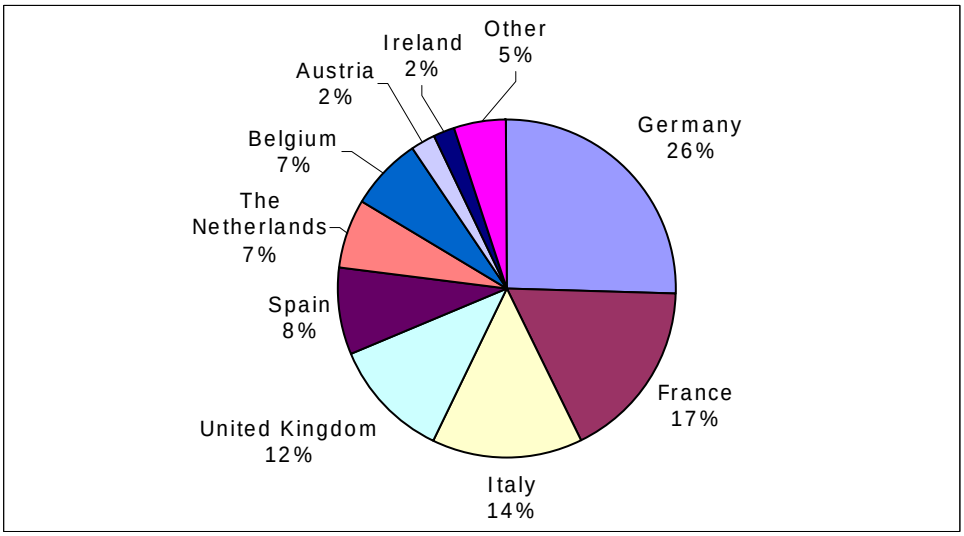
Figure 5.1 Leading suppliers of medicinal and aromatic plants to the EU, 2000-2002, € million



Source: Eurostat (2003)

Figure 5.2 shows that in 2002, Germany was, by far, the leading EU importer of medicinal & aromatic plants, accounting for more than a quarter of total imports (in value). Between 2000 and 2002, however, Germany saw its imports decrease in terms of value, while The Netherlands experienced a considerable increase in imports by the factor 12 during the same period. Please refer to Appendix 1 for more detailed statistics.

Figure 5.2 Leading EU importers of medicinal & aromatic plants, 2002, % of total EU import (in value)



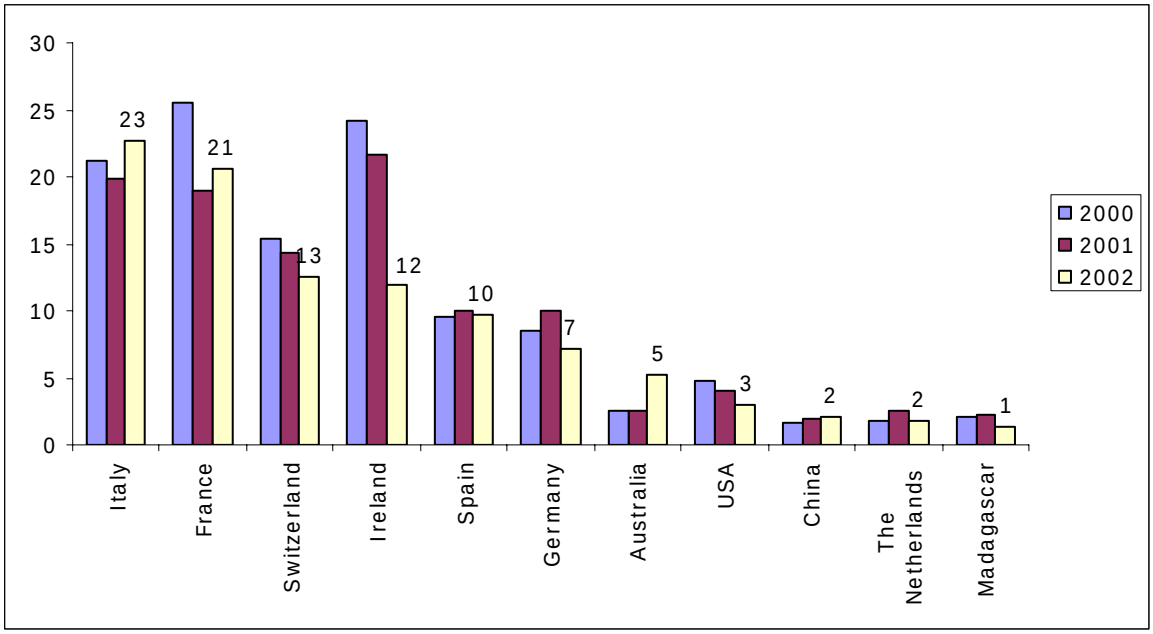
Source: Eurostat (2003)

Medicinal & vegetable saps & extracts

As from 2000, imports by EU member countries of medicinal & vegetable plants & extracts decreased by a quarter in terms of value, reaching € 106 million in 2002. In terms of volume, imports fluctuated from 2.5 thousand tonnes in 2000 to 3 thousand tonnes in 2001 and back to 2.8 thousand tonnes in 2002.

The leading suppliers to the EU were Italy, France, Switzerland, Ireland, Spain and Germany, together supplying almost 80 percent of the imported value of medicinal & vegetable saps & extracts by EU member countries in 2002. More than a quarter of the imported value was supplied by countries outside the EU, of which 16 percent by developing countries.

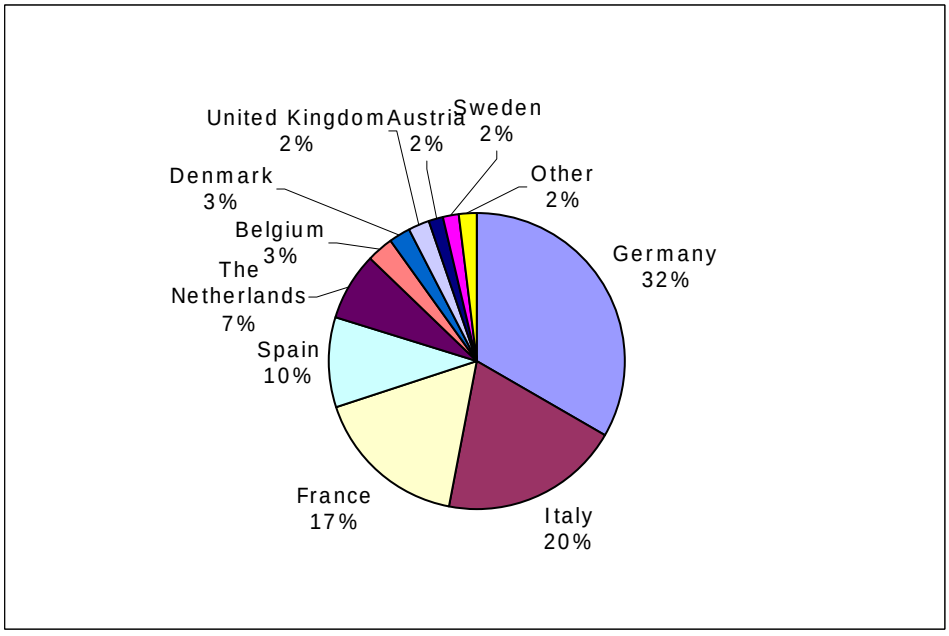
Figure 5.3 Leading suppliers of medicinal & vegetable saps & extracts to the EU, 2000-2002, € million



Source: Eurostat (2003)

Figure 5.4 shows that Germany is, by far, the leading importer of medicinal & vegetable saps & extracts, followed by Italy and France. Particularly the first two countries mentioned, saw their imports decrease between 2000 and 2002. Imports by relatively smaller importers increased (The Netherlands, Belgium) or fluctuated somewhat (Denmark, the United Kingdom). Please refer to Appendix 1 for more detailed statistics.

Figure 5.4 Leading EU importers of medicinal & vegetable saps & extracts, 2002, % of total EU import (in value)



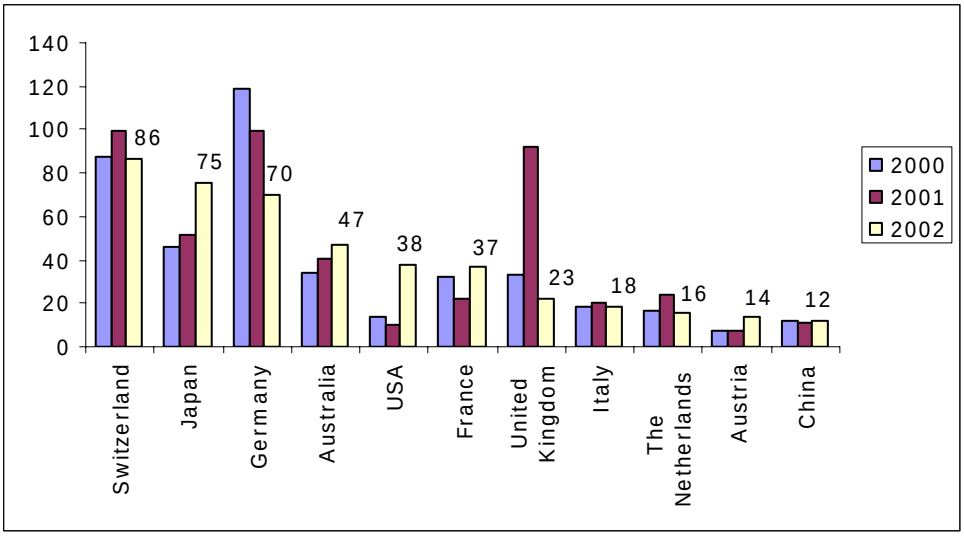
Source: Eurostat (2003)

Vegetable alkaloids

Between 2000 and 2002, imports by EU member countries of vegetable alkaloids, decreased by 3.5 percent in value and by 19 percent in volume, amounting to € 514 million / 8.6 thousand tonnes in the latter year. In 2002, the leading EU suppliers were

the United Kingdom, Spain, Germany and France, together accounting for two thirds of total imports (in value). More than 60 percent of the imported value was supplied from extra-EU sources, of which only 11 percent represented developing countries.

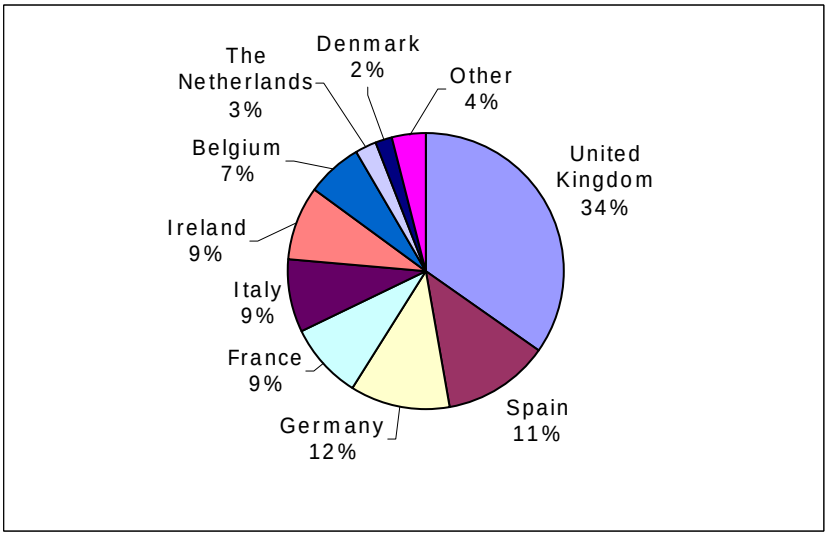
Figure 5.5 Leading suppliers of vegetable alkaloids to the EU, 2000-2002, € million



Source: Eurostat (2003)

Figure 5.6 shows that the United Kingdom was the leading EU importer of vegetable alkaloids, followed by Spain, Germany and France. The first three countries increased their imports during the survey period. The remarkable growth of Netherlands imports, which increased to € 73 million in 2001, decreased to € 14 million in 2002. Please refer to Appendix 1 for more detailed statistics.

Figure 5.6 Leading EU importers of vegetable alkaloids, 2002, % of total EU import (in value)



Source: Eurostat (2003)

Under the group HS 2939, vegetable alkaloids, some derivatives from medicinal plants have a specific HS code (including quinine, alkaloids of cinchona and ephedrine(s)).

Table 5.2 Imports by EU member countries of selected vegetable alkaloids, 2002, € thousand

HS Code	EU imports	DCs	Leading suppliers
HS 293921	13,668	6,181	Indonesia (5,287), Germany (4,373), The Netherlands (1,793)
HS 293929	9,435	97	New Zealand (9,317), Germany (1,664), The Netherlands (1,081)
HS 293941	2,306	289	Japan (2,250), Germany (411), India (260)
HS 293949	6,493	6	United Kingdom (6,496), Germany (1,153), Japan (487)

DCs: Developing countries
HS 293921: Quinine and its salts (from medicinal plant Cinchona sp)
HS 293929: Alkaloids of cinchona (excl. Quinine and its salts) and their derivatives and salts
HS 293941: Ephedrine and its salts (from Ephedra sp)
HS 293949: Ephedrines and their salts (from Ephedra sp).

Source: Eurostat (2002)

EU accession countries

Table 5.3 provides an overview of the imports in 2002 of Central and Eastern Europe (CEE) countries of the product groups falling under ingredients for pharmaceuticals. CEE countries form together the greater part of the accessing or candidate countries. The main importing country is the Czech Republic, importing 68 percent of total CEE imports of natural ingredients for pharmaceuticals.

Table 5.3 Imports by CEE countries of selected product groups falling under ingredients for pharmaceuticals, 2002, € thousand

	1211 (plants and part of plants)	**13021991** (medicinal and vegetable saps and extracts)	**2939** (vegetable alkaloids)
CEE countries total	*22,001*	*11,338*	*37,323*
Czech Republic	8,345	2,718	12,573
Poland	2,703	1,534	7,776
Hungary	5,730	5,151	6,707
Slovenia	1,972	3,330	1,602
Ukraine	968	97	2,394

Central and Eastern Europe (CEE) countries are: Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Ukraine.
Source: ITC TradeMap

In 2002, Germany and Poland are the main suppliers for plants and part of plants, respectively exporting 16 and 15 percent of this product group to CEE countries. For the product group medicinal and vegetable saps and extracts the USA (representing 15% of total imports), France (14%), Germany (13%) and China (11%) are the main exporting countries. China (21%), the United Kingdom (17%) and Germany (15%) represent the major suppliers of vegetable alkaloids for the CEE countries.

5.3 The role of the developing countries

Medicinal & aromatic plants

In 2002, developing countries were particularly strong in the supply of medicinal & aromatic plants, accounting for more than 40 percent of imports by EU member countries in terms of value and more than 50 percent of imports by EU member countries in terms of volume. During the past few years, the share of developing countries in EU imports has fluctuated closely around these levels.

Table 5.4 EU imports of medicinal & aromatic plants from selected developing countries, 2002, € million

Country	€ million	Country	€ million
China	20.8	Iran	1.5
India	16.2	Sudan	1.4
Morocco	11.7	Peru	1.4
Egypt	8.4	Madagascar	1.3
Kenya	7.4	Tunisia	1.3
Turkey	6.9	Congo	1.0
South Africa	6.0	Togo	1.0
Chile	5.4	Cameroon	0.9
Brazil	4.6	Pakistan	0.9
Thailand	3.0	Congo Dem. Rep.	0.8
Namibia	2.1	Syria	0.7
Argentina	2.1	Guatemala	0.7
Mexico	1.8	Indonesia	0.6
Paraguay	1.6	Azerbaijan	0.5

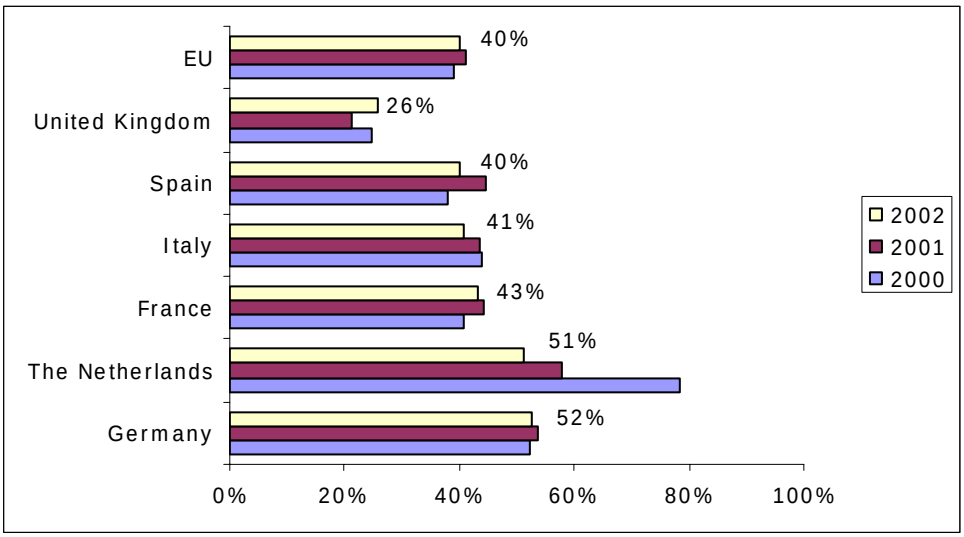
Source: Eurostat (2003)

China and India, as a result of their long tradition in the field of natural medicine and their vast land area, comprising all climatic zones, are leading producers of natural ingredients for pharmaceuticals.

Fiji increased its exports of medicinal & aromatic plants to the EU from just over € 1.5 million in 1997 to € 9 million in 1998. This was the result of the exploding international demand for kava kava, which is endemic to the South Pacific. Vanuatu is another Pacific Island, which profited from the increased demand. After 1998, EU imports from Fiji decreased again to their previous level. In June 2002, Germany banned the supply of the herbal remedy kava kava after reports linking it to fatal liver failure. Britain's Medicines Control Agency (MCA) proposed to ban kava kava in 2002 and the Order came into force from January 2003. However, it is said that members of the ACP/EU parliamentary assembly adopted a resolution calling on EU states "to urgently initiate measures to secure reversal of the bans".

Although The Netherlands was a relatively small European importer of medicinal & aromatic plants in 2002, relatively it obtained, together with Germany, the biggest share of its imports from developing countries. Kenya and South Africa together supplied almost 40 percent of The Netherlands' imports (in value) in 2002.

Figure 5.7 Share of developing countries in imports of medicinal & aromatic plants into selected EU countries, 2000-2002, % of imported value



Source: Eurostat (2003)

For CEE countries the main suppliers in developing countries in 2002 are Sudan (representing 10% of total imports) and South Africa, Egypt, China and India.

Medicinal and vegetable saps and extracts

In 2002, developing countries accounted for 5 percent of the imported value by EU member countries of medicinal and vegetable saps and extracts. Almost three-quarters of the supplies from developing countries originated in two countries, i.e. China and Madagascar. Other important developing country suppliers were India (11%), Morocco (5%), Mexico (4%) and South Africa (2%). In 2002, Italy accounted for 28 percent of the imports (in value) by EU member countries originating in developing countries, France for 25 percent and the UK for 11 percent.
Apart from China, India was the major supplier of medicinal and vegetable saps and extracts for CEE countries in 2002.

Vegetable alkaloids

In 2002, developing countries supplied 6 percent of the imports (in value) by EU member countries of the product group vegetable alkaloids. China supplied more than a third of the total value originating in developing countries, followed by India (27%), Indonesia (18%), Brazil (10%) and Mexico (6%). In 2002, Germany was the EU member state which accounted for 28 percent of imports (in value) originating in developing countries, Ireland for 17 percent, The Netherlands and France each for 16 percent and the United Kingdom for 13 percent. Please also refer to Table 5.2.

Although they do not feature in Eurostat figures, other countries of origin and of value-added production of quinine products, next to Indonesia and India, are Ecuador, Bolivia, Brazil, Tanzania, Rwanda and Congo (Dürbeck, p.c.). There is forestry containing cinchona varieties in these countries and in most of them value-added processing has been conducted through local companies. European companies from Germany and The Netherlands do the cultivation and processing in Rwanda and Congo. Tanzania and Ecuador are traditional exporters of the dried bark of cinchona varieties. In Bolivia, Brazil, Indonesia and India, the extraction is done by local companies primarily for the local markets, but also for the export of extracts. The products from cinchona varieties in the international market are Quinine hydrochloride and Quinine sulphate.

Ephedra has been used in China for over 4,000 years. Several companies in Europe use the extract for herbal medicines. Extraction of Ephedra alkaloids is carried out in China and in Europe.

Apart from China, India was the major supplier of medicinal and vegetable saps and extracts for CEE countries in 2002.

Opportunities for developing countries

It is not easy to present an overview of promising products for exporters in developing countries. In Europe, some 2,000 medicinal and aromatic plants are used on a commercial basis. A number of botanical species is consistently cited by industry representatives in the USA and Europe as the most important today, and likely in the next five years (Laird et al., 2002). Echinacea was cited as the top product now and in the years to come, in both the USA and Europe. European companies continue to consider St Johns Wort and Kava Kava extremely important, while USA industry representatives tended to think both might be in decline due to controversial recent studies and bad press. Other important botanicals cited include: Gingko, Ginseng, Valerian, Goldenseal, and Garlic. USA companies also cited Black Cohosh and Astragalus as good performers, while European companies have had continued success with Hawthorn and Chamomile.

Most buyers in The Netherlands are not interested in plant material, but in plant extracts. There are only a few developing countries able to supply extracts which conform to the requirements of western industry.

Exporters should focus on ingredients with known activity. The box below gives a selected overview of top selling herbal medicines and their claimed activity.

Claimed activity of selected top selling herbal medicines

Product	***Plant part***	***Activity***
Ginseng	*Root*	*Increases energy and sex drive*
Siberian ginseng	*Root*	*Defuses nervous tension and fights fatigue*
Kava kava	*Root*	*Combats anxiety and stress*
Green tea	*Leaves*	*A powerful anti-oxidant and cholesterol reducer*
St. John's wort	*Herb*	*Anti-depressant*
Psyllium	*Seeds*	*Anti-constipation; helps weight loss*
Hawthorn	*Fruit*	*Lowers blood pressure*
Saw palmetto	*Seeds*	*Treats prostate problems*
Valerian	*Root*	*Relieves insomnia, anxiety, menstrual cramps, headache*
Liquorice	*Root*	*Treats ulcers and stomach disorders*
Wild yarn	*Roots*	*Alleviates PMS and menopausal symptoms*
Aloe	*Leaves*	*Treats wounds and skin problems*
Chamomile	*Flowers*	*Alleviates moods and skin problems, calming*
Garlic	*Bulb*	*Boosts the immune system; lowers cholesterol*
Calendula	*Flowers*	*Soothes skin; fights bacterial, viral and fungal infections*
Echinacea	*Root, flowers*	*Boosts immune system; prevents colds*
Ginger	*Rhizomes*	*Treats nausea; inflamed joints*
Gingko	*Leaves*	*Improves energy, mood and brain function*

Source: Ten Kate & Laird (1999)

Product profiles of Echinacea and Cat's Claw are included in Part B, Chapter 10 of this survey.

Although farmers in developing countries have no knowledge of plants not native to the tropics, a number of medicinal plants, which are not day-length sensitive (i.e. requiring many hours of sun-light), have been successfully moved into sub-tropics. Argentina, for example, has substantial cultivation areas of Chamomile and St. Johns Wort. Top-selling species such as Echinacea are now also supplied by developing countries such as Bolivia, Costa Rica and Malawi.

6 EXPORTS

Table 6.1 provides an overview of the exports of the product groups falling under ingredients for pharmaceuticals. These export data should be interpreted with caution, since a substantial amount of these products is traded, further processed and re-exported at a higher value. Moreover, the exported products may be used for multiple purposes and not only for the production of pharmaceuticals.

Table 6.1 Exports by EU member countries of selected product groups falling under ingredients for pharmaceuticals, 2000-2002, € 1,000 / tonnes

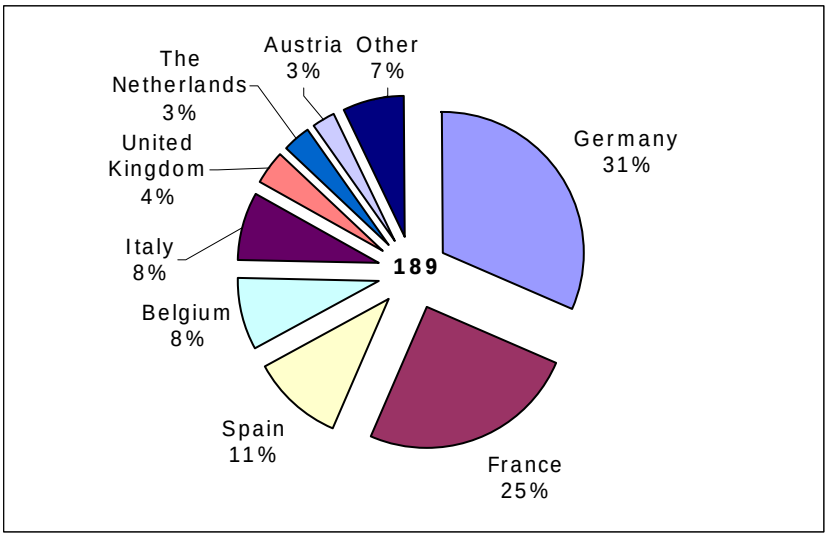
	2000		2001		2002	
	value	volume	value	volume	value	volume
Medicinal & aromatic plants	202,032	43,218	194,768	41,644	189,197	44,862
Intra-EU	128,093	29,611	128,185	28,083	123,685	29,865
Extra-EU	73,939	13,607	66,583	13,561	65,512	14,997
Medicinal & vegetable saps & extracts	127,155	2,558	115,470	3,075	106,094	2,866
Intra-EU	93,049	1,841	85,843	2,119	76,759	2,034
Extra-EU	34,106	717	29,627	957	29,335	833
Vegetable alkaloids	531,978	10,780	548,376	9,636	513,878	8,750
Intra-EU	265,072	8,195	291,962	7,415	202,510	5,999
Extra-EU	266,906	2,585	256,413	2,221	311,368	2,751

Source: Eurostat (2003)

Medicinal & aromatic plants

In 2002, EU member countries together exported € 189 million worth of medicinal & aromatic plants, representing a volume of 45 thousand tonnes. In the same year, the leading destination was France, importing 15 percent of exports (in value) by EU member countries, followed by Switzerland (10%), the United Kingdom (9%), Germany (9%), Italy (7%), USA (6%), Spain (5%) and Belgium (5%). Figure 6.1 shows the leading EU exporters.

Figure 6.1 Leading EU exporters of medicinal and aromatic plants, 2002 % of total value, value in € million

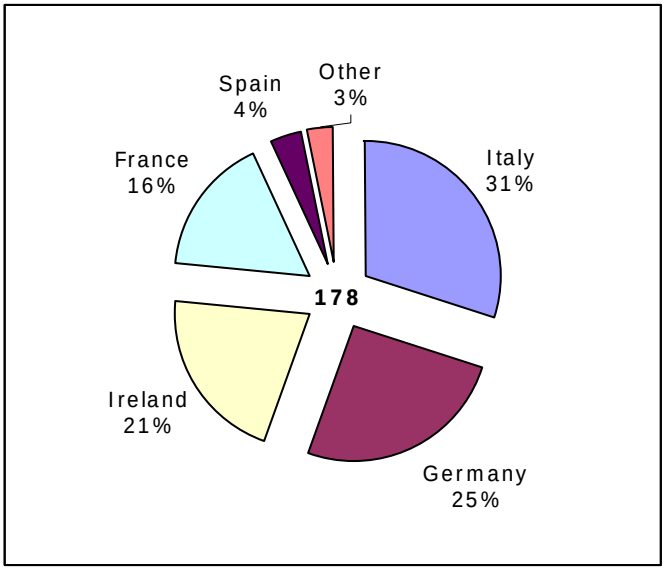


Source: Eurostat (2003)

Medicinal & vegetable saps & extracts

Between 2000 and 2002, exports by EU member countries of medicinal & vegetable saps & extracts decreased by about 4 percent in value and more than 40 percent in volume, amounting to € 178 million / 2.9 thousand tonnes in the latter year. The leading destination was France, receiving 22 percent of the exported value in 2002, followed by Germany (13%), the USA (12%), Italy (7%) and Turkey (5%). Figure 6.2 shows the leading EU exporters.

Figure 6.2 Leading EU exporters of medicinal & vegetable saps & extracts, 2002, % of total value, value in € million

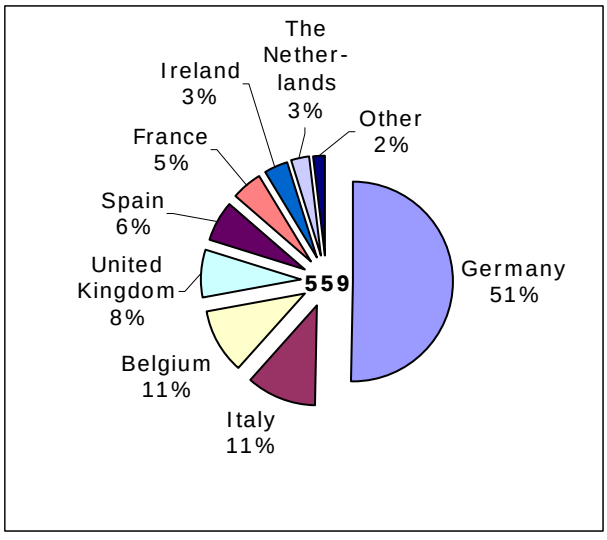


Source: Eurostat (2003)

Vegetable alkaloids

In 2002, EU member countries together exported € 559 million worth of vegetable alkaloids, representing a volume of 11.9 thousand tonnes. The leading destination was the USA, receiving 23 percent of the total exported value in 2002, followed by Italy (10%), the UK (7%), Japan (6%) and France (5%). Figure 6.3 shows the leading EU exporters.

Figure 6.3 Leading EU exporters of vegetable alkaloids, 2002 % of total value, value in € million



Source: Eurostat (2003)

7 TRADE STRUCTURE

7.1 EU trade channels

Pharmaceutical industry

Advances in research techniques have allowed the pharmaceutical industry to conduct large-scale natural products screening programmes, which over the past decade have increased demand for natural product samples, many collected from the biologically-rich tropical countries. The bulk of these samples is collected by sub-contracted collectors, most of whom are based in developed countries.

The collection of biological samples for industry (biodiversity prospecting) generally involves two or sometimes three direct relationships:

- that between the company and the contracted collector (usually described in a contract which is legally binding under the law of the country in which the company is situated);
- that between an outside collector and in-country collaborators (usually more informally defined, although increasingly detailed in agreements of some kind, and regulated by national legislation);
- that between an ethno botanical collector and local communities that provide traditional knowledge on collected samples, which will subsequently be supplied to commercial companies.

The transfer of samples from a collector to a company is the most direct path by which biological and cultural diversity travels to commercial interests, and generally the most direct path upon which benefits return. However, there are many other groups which are indirectly involved in and affected by this exchange although they are not written into two-party arrangements, but are increasingly addressed in international and national law and policy such as: communities which live in biodiversity-rich areas where samples are collected; national governments which, as written into the Convention on Biological Diversity (CBD), now claim national sovereignty over their country's genetic and biochemical resources; the international community which, through documents and agreements such as the CBD, have expressed interest in the conservation and sustainable and equitable use of biodiversity.

Herbal medicine industry

European-based companies, and German in particular, dominate the global herbal medicine supply industry. The biggest herbal raw materials group is Martin Bauer Group, a German-based corporation with annual sales of over € 350 million. The Martin Bauer Group has been repositioned as the nature network. Under the roof of MB-Holding, 25 companies (under which Finzelberg, Plant Extract, Phytolab and Phytocon) and 40 representative offices are active. Other leading companies include the German Madaus (of which the turnover in 2002 increased by € 330 million) and the Italian Indena (turnover of € 150 million in 2003).

Lewington (1993) reported that between 500 and 600 medicinal plants are traded via Hamburg, which made it the world's leading trading centre in plants. However, the position of Hamburg has decreased in recent years.

The boxes in which the structure of the industry and trade are presented are relevant for the product group Medicinal and aromatic plants. Processed products falling under the product group Vegetable saps and extracts, in which developing countries do not have an important stake, are directly traded with manufacturers of finished products (e.g. bark extract of *Prunus africana* to Indena in Italy). Quinine, a vegetable alkaloid, is traded via trading houses. Internationally, there are more than 60 trading houses trading quinine, of which 15 in Germany and 12 in the United Kingdom. Trading houses in Germany include Buchler GmbH and Henry Lamotte, in the United Kingdom they include StanChem International.

Structure of the botanical/herbal medicines industry

Cultivation or wild-collection of plants
Plants are cultivated or wild-collected. Plant material is cleaned and dried. The majority of plant material in trade is in dried form. Drying methods must bring moisture content down to <14 percent, while retaining the chemical composition of the plant. A minority of material is traded fresh, or preserved in alcohol.

↓

Exporters/importers/wholesalers/brokers/traders
Plant material is purchased either directly from wild-crafters or cultivators, or after it has passed through a number of traders (e.g. local dealers, village co-operatives, district traders). Brokers and agents act on behalf of purchasing companies. Wholesalers, importers and exporters may specialise in a few raw materials, or in a few thousand, which they sell as commodities to a number of different companies. Wholesalers/traders may also process plant material. Some companies apply testing, or use voucher specimens at this stage, to ensure correct species identification and quality.

↓

Bulk ingredient suppliers and processing companies
Plant material is tested for contamination (e.g. pesticides). It is formed into bulk ingredient, either coarsely cut, rasped, or ground into powdered form (for use in crude herbal products and in the preparation of extract). Due to consolidation in the industry, the production of bulk ingredients is often undertaken by wholesalers/traders. Further processing in the form of extraction, particularly standardised extracts, is undertaken by processing companies, many of which also produce branded lines, which they sell directly to distributors or retail outlets.

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Manufacturers of finished products
Bulk and processed ingredients are supplied to companies which manufacture (e.g. might add excipients to extracts to make tablets and capsule products, based on in-house formulae), label, and package products for retail sales. Some sell lines directly to health professionals, others sell directly to consumers through multi-level marketing and mail order. Some companies use brokers or distributors to supply their products to retail outlets, others market directly to mass and specialty outlets.

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Distributors
Some manufacturers (usually smaller companies) use distributors to sell finished products to retail outlets.

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Retail/consumer sales
The bulk of finished products is sold through retail outlets, either mass market (e.g. chain pharmacies, supermarkets, grocery stores) or speciality (e.g. health food stores, pharmacies), although direct sales command a significant proportion of the market.

Source: Ten Kate & Laird, 1999

Structure of the botanicals trade in Germany

Drug brokers

Seven brokers or agents are involved in the trade in Germany. Most are active on a global scale, although some specialise in specific countries. Brokers represent foreign import-export companies, traders, farmers and manufacturers. They deal mostly for wholesalers, and to a lesser extent for pharmaceutical companies or herbal tea companies. Most brokers also trade in spices.

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Wholesalers (traders in bulk material)

In Germany, the mainstream bulk trade in botanicals is dominated by about 20 wholesalers, with further consolidation of the trade in the past few years. 95 percent of plants sold by German wholesalers are sold as dried plants and plant parts, with the remaining 5 percent comprised of plants preserved in alcohol, mainly for use in homeopathy. Traders deal with a range of customers including the food industry, pharmaceutical companies, cosmetics, liqueur, extract-producing companies, and colouring agent companies. Overall volumes imported by individual traders range from 1,000 tonnes to 30,000 tonnes annually. On average, each company trades in 400-500 botanical species.

↓

Processing

Wholesalers are often responsible for processing the plant material before sale, including cleaning, cutting and grinding it into a powder. Some wholesalers are also involved in producing extracts, herbal teas, or herbal mixtures.

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Manufacturing

Processed material is supplied to manufacturers of pharmaceuticals, plant extracts, cosmetics, liqueurs, dyes, etc., as well as to second-level retail suppliers, and to other wholesalers and tea-packing companies. Bulk extract producers and pharmaceutical companies often manufacture intermediary products, which are then sold to cosmetics, pharmaceuticals, or food companies which manufacture finished products.

Source: Ten Kate & Laird, 1999

With respect to TCM, research by TRAFFIC Europe revealed that twelve major distributors of Chinese drugs and patented medicines in Germany import their products from Hong Kong and China or obtain them from one of the few large European importers.

7.2 Distribution channels for developing country exporters

Exporters should realise that the Internet is an important medium in the sourcing of raw materials for herbal products. Several users/traders of natural ingredients mentioned that the Internet is an important source for finding suppliers.

A very interesting link for exporters is http://www.herbworld.com/cropshop/, where growers and buyers of botanicals can get together. Growers can list which crops they have available, date of availability, price, quantity, etc. Buyers can also list what they are looking for.
The site http://www.ingridnet.com/ is a marketing instrument for companies, which supply ingredients. The database includes contact details of 10,000 ingredient suppliers and is used by the food, cosmetic and pharmaceutical industries to source ingredients.

Many of the importers have an Internet site, where interested parties can find more information on the field in which these importers are active. Most of the interesting

contacts can be found in Germany. Agrimedia has published the Business Guide 2000: Medicinal and Spice Plants including over 1,500 addresses of organisations and companies active in this field.

Interesting contacts in the market for medicinal and aromatic plants are for example Alfred Galke, Cealo and Madaus in Germany. There are only a few companies importing extracts directly. Indena (Italy), for example, imports bark extract of *Prunus africana*.

Organisations working with pharmaceutical companies in bio-prospecting arrangements are referred to the Earthscan publication "Biodiversity and Traditional Knowledge" (for contact details see Appendix 2.6). This practical manual demonstrates how to arrive at equitable and successful arrangements on access to, and commercial development of, genetic resources.

Exporters should realise that the Internet is an important medium in the sourcing of raw materials for herbal products. A number of users/traders of natural ingredients mentioned that they use the Internet in order to find new suppliers.

8 PRICES

8.1 Prices developments

The prices of natural ingredients for pharmaceuticals can fluctuate widely depending on the raw material. The price level of natural ingredients is influenced by:

- **Quality factors:** Determined by the country of origin, the climate, the crop, the concentration of the ingredients and the extraction method.
- **Economic factors:** Based on supply and demand. The supply depends on the size of the current crop, the carry-over from previous crops and the existence of synthetic substitutes.

The following table should be considered purely indicative and reflects the price of a specific phytochemical characteristic from a specified origin. The level of marker compounds (for chemical standardisation of extracts) referred to in quotes are those commonly found in the industry. They do not imply any sort of "trading standard". Moreover, as the products are bought by bulk, these prices vary according to negotiation with the companies.

Table 8.1 Indicative prices of botanical extracts, September 2004 US$/€ per Kg

Product	%	Price (US$)	Price (€)
Bilberry fruit (*Anthocyanins)*	25	225	183
Devil's claw root tuber (*Harpagoside)*	1.5	50-70	41-57
Echinacea purpurea root (*Phenols/Alkamides)*	4.0/0.025	40-50	32-41
Ginkgo leaf (*Flavonglycosides)**	24/6	200-300	162-243
Milk thistle fruit (*Silymarin)*	80	75-125	61-102
St John's wort herb (*Hypericins/Hyperforin)*	0.3/3.0	46	37
Valerian root (*Valerenic acids)*	0.25-0.35	60-70	49-57

* Signifying an extreme price increase since 2003
Source: ITC (September 2004) exchange rate 1 euro=1.23 dollar (24 September 04)

Just ahead of the 2004 harvest season, Hurricane Charley followed by Hurricane Frances have caused considerable damage to this year's crop of saw palmetto fruit (*Serenoa repens)* causing raw material prices at the supplier level to approximately double in recent weeks with large daily price fluctuations. Last year's prices fluctuated between € 83 and € 113.

Great care should be taken when comparing prices of medicinal plants and extracts from differing origins as form structure and biochemical activity may differ considerably between very similar products.

For information on price setting, please refer to Section 13.3.

8.2 Sources of price information

Internet can be a good source for obtaining an idea of retail prices for raw materials. Please refer to Appendix 2.2 for addresses. At some sites, professional users can request samples and offers for ingredients. However, Internet is not always a reliable source for obtaining commercials prices for natural ingredients. In general, Internet marketers often publish only consumer and retail pricing schedules, for example, for less than 1 kg quantities.

Useful sources are:

- Green Trade; online market place for organic natural ingredients: http://www.greentrade.net/. Here, buyers and sellers can register for online services.
- The Internet site of the Herb Growing and Marketing Network includes a herb crop shop, where growers and buyers of botanicals can come together (http://www.herbworld.com/cropshop/).
- Prices for the following raw materials are published weekly in the Public Ledger (see Appendix 2.2):
  - crude drugs including balsam, bayberry root bark, cochineal, echinacea and valerian;
  - herbs and spices including cloves, ginger, black pepper and turmeric;
  - waxes and gums;
  - 38 essential oils including amyris, geranium, lemongrass and vetiver;
  - oilseeds, oils and fats including soya oil, sunflower seed oil, groundnut/peanut oil, palm oil and castor oil.
- The Market News Service (MNS) for Medicinal Plants and Extracts is a quarterly publication available from the International Trade Centre (ITC), that provides indicative ton pricing of selected high-demand medicinal herbs and extracts from several major world markets including North America, Western Europe, Eastern Europe, Northern Africa, China and India. Many natural ingredients are also classified, in some cases, as “spices” (e.g. ginger, garlic or poppy) and therefore indicative ton pricing for such natural ingredients may also be obtained from the ITC’s MNS Spices World Report, a weekly publication.
- AESGP (The Association of the European Self-Medication Industry) provides individual Country Profiles from its study “Economic and Legal Framework for Non-Prescription Medicines”. The building up of prices is described in these reports. For more information: http://www.aesgp.be/.

9 EU MARKET ACCESS REQUIREMENTS

This chapter will only deal briefly with the relevant issues within this subject. References to relevant information sources will be made. Since CBI's AccessGuide is an important instrument providing the larger part of the information described below, references to AccessGuide will be made.

AccessGuide
AccessGuide is CBI's database on European non-tariff trade barriers, specially developed for companies and business support organisations in developing countries. Registered companies and organisations have unlimited access to AccessGuide information.

Exporters in developing countries wishing to penetrate the European Union should be aware of the many requirements of their trading partners and EU governments. Standards that are being developed through legislation, codes, markings, labels and certificates with respect to environment, safety, health, labour conditions and business ethics are gaining importance. Exporters need to comply with legislation in the EU and also have to be aware of the many market requirements. AccessGuide provides clear information on these standards and their implications.

For more information please refer to http://www.cbi.nl/accessguide*. As an introduction, go to the Information Scan of Natural ingredients for cosmetics and pharmaceuticals.*

9.1 Non-tariff trade barriers

9.1.1 Legislative requirements

Procedures have been laid down in the European Union in order to ensure the production and marketing of safe and effective pharmaceutical products and parts of products. EU product legislation on environmental and consumer health and safety issues is compulsory and, therefore, of utmost importance. Therefore, if you export your products, they must comply with EU requirements. Pharmaceutical products and ingredients have to comply with several legal EU requirements on safety, marketing and Good Manufacturing Practices. Moreover, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) is relevant. In AccessGuide, you will find an analysis of all EU requirements that are applicable in the EU member states. In addition, more strict legislation in The Netherlands, Germany and the United Kingdom is included in the database. You should note however, that the scope of the database is now limited to these countries, although this does not imply that in other EU member states there is no additional legislation.

EU product legislation

In this section, an overview of the legislation concerning pharmaceutical end-products will be presented. This overview serves as background information, before we discuss the standards for ingredients.

In order to enter the EU market with pharmaceutical products, companies must apply for registration of their products. This application must be accompanied by documents, which provide the results of tests and trials carried out on the product concerned. The application and quality requirements are such that they represent an actual regulatory and technical barrier to entering the EU market.

Since science is progressing radically and new therapies are on the horizon, the existing legislation must be adapted and thought must be given to a basic outline for the procedures for authorising the products which will be placed on tomorrow's market. For up-to-date information on Pharmaceuticals, please refer to: pharmacos.eudra.org (or dg3.eudra.org).

On January 1995, an authorisation system for registration (Council Regulation 2309/93) became operational for all EU-member countries. This system offers two routes for authorisation of medicinal products:

- *Centralised procedure:* Applications are made directly to the European Agency for the Evaluation of Medicinal Products (EMEA), leading to the granting of a European marketing authorisation. Use of this procedure is compulsory for products derived from biotechnology, and optional for other innovative medicinal products.

- *Decentralised procedure:* Is applicable to the majority of conventional medicinal products. Applications are made to EU Member States selected by the applicant and the procedure operates by mutual recognition of national marketing authorisations. Where this is not possible, the EMEA is called on to arbitrate.

The European Agency for the Evaluation of Medicinal Products

EMEA plays a central role in the above-mentioned system for registration (Council Regulation 2309/93). It is a decentralised body of the European Union and its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. The EMEA functions as a network, bringing together the scientific resources of the Member States to ensure the highest level of evaluation and supervision of medicines in Europe. The Agency cooperates closely with international partners on a wide range of regulatory issues. The scientific opinions of the Agency are prepared by three committees responsible for medicines for human use (CHMP), for veterinary medicines (CVMP) and for the designation of 'orphan' medicines for rare diseases (COMP). A network of over 3,000 European experts underpins the scientific work of the EMEA and its committees.

For more information on EMEA please refer to www.emea.eu.int or for an information request by e-mail: mailto:emearequests@emea.eu.int

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and the ICH Global Cooperation Group

Other important organisations are ICH and the ICH Global Cooperation Group (GCG).

ICH brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry, to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration, in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. The objective of such harmonisation is a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines, whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health.

The purpose of GCG is to make available on ICH, ICH activities and ICH guidelines to any country or company that requests the information. The GCG will respond to regulatory authorities or pharmaceutical companies that request information.

For more information: http://www.ich.org

Moreover, harmonised legislation on pharmaceutical products and parts of it was first published in 1965, in the form of Directive 65/65/EEC. This Directive had been amended very frequently and substantially, so that in the year 2001 a new text repealing all former legislation was published.

Directive 2001/83/EC on the Community code relating to medicinal products for human use applies to all industrially produced medicinal products for human use intended to be placed on the European market.

- A medicinal product is defined in the Directive as: any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medicinal diagnosis.

Please note that also homeopathic products fall under the scope of the Directive and, since an amendment in 2004, also herbal medicinal products, substances and preparations are included (Directive 2004/24/EC). In addition, amendment 2004/27/EC introduced legislation on Manufacture and Importation that also applies to intermediate products (medicinal ingredients).

Directive 2001/83/EC consists of several Chapters all focusing on specific issues:

- *Placing on the market*
  - *Chapter 1:Marketing authorisation*
  - *Chapter 2:Specific provisions for homeopathic medicinal products*
  - *Chapter 2a:Specific provisions applicable to traditional herbal medicinal products*
  - *Chapter 3:Procedures relevant to the marketing authorisation*
  - *Chapter 4:Mutual recognition of authorisations*
- *Manufacture and importation*
- *Labelling and package leaflet*
- *Classification of medicinal products*
- *Advertising*
- *Information and advertising*
- *Pharmacovigilance*
- *Special provisions on medicinal products derived from human blood and blood plasma*
- *Supervision and sanctions*
- *General provisions*

Placing on the market

Chapter 1 of Directive 2001/83/EC lays down that, in the EU, it is not permissible to place medicinal products on the market, unless a marketing authorisation has been issued by the authority of that Member State. In order to be granted such an authorisation, an application has to be made to the competent authority of the Member State concerned. Please note that a marketing authorisation can only be granted to an applicant established in the Community. This makes the importer responsible for the application on behalf of producers/exporters in developing countries. Article 8 of the Directive describes the information that should be submitted with the application. Please refer to the text itself for the complete list. Note that some of the points have been either updated or added in Directive 2004/27/EC.

The following points are included:

- The qualitative and quantitative particulars of all constituents of the medicinal product (article 8, sub 3c, as amended by 2004/27/EC).
- Therapeutic indications, contra-indications and adverse reactions (article 8, sub 3 e).
- Results of pharmaceutical (physico-chemical, biological or microbiological) tests; pre-clinical (toxicological and pharmacological) tests, and clinical trials (article 8, sub 3i, as amended by 2004/27/EC)).
- A summary of the product characteristics (article 8, sub 3j), the content of which is specified in detail in article 11 (Directive 2004/27/EC).

- A copy that the manufacturer is authorised in its own country to produce medicinal products (article 8, sub 3k).

Homeopathic medicinal products
Chapter 2 of Directive 2001/83/EC deals specifically with homeopathic medicinal products. Since homeopathic products contain only a very low level of active principles and because the conventional statistical methods relating to clinical trials are difficult to apply, a special and simplified procedure for homeopathic products was developed.

The following homeopathic products are subject to this simplified procedure (2001/83/EC, Article 14):

- They are administered orally or externally,
- No specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto, and
- There is a sufficient degree of dilution to guarantee the safety of the medicinal products.

Article 15 specifies what information should be included with the application for a marketing authorisation for the above-mentioned homeopathic products. All homeopathic medicinal products not complying with characteristics specified above shall be authorised in compliance with the procedure for “conventional” medicinal products. In principle, the Member States shall ensure that the procedure for marketing authorisation is completed within 210 days after the application was submitted.
Authorisations can be refused if not all-necessary information is included and if a) the medicinal product is harmful under normal conditions of use; b) its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant and/or c) its qualitative and quantitative composition is not as declared. An authorisation is valid for 5 years, and is renewable for five-year periods.

Traditional herbal medicinal products
Directive 2004/24/EC amends Directive 2001/83/EC and extends the coverage to include traditional herbal medicinal products (Chapter 2a). Just as for homeopathic products, a special and simplified procedure has been developed for these products.

The following traditional herbal medicinal products are subject to a simplified procedure (2004/24/EC, Article 16a):
- They have indications exclusively appropriate to traditional herbal medicinal products,
- They are exclusively for administration in accordance with a specified strength and posology,
- They are an oral, external and/or inhalation preparation,
- The period of traditional use has elapsed and the information on the traditional use is sufficient. (By “the period of traditional use” is meant that the product in question has been in use for at least 30 years, of which 15 within the EU. That this is the case must be backed up by bibliographical or expert evidence.)

Manufacture and importation into the EU
Manufacturers of medicinal products in the European Union must be authorised to manufacture. Please note that such an authorisation is necessary for both total and partial manufacture, and for the various processes of dividing up, packaging or presentation. Also note that import into the EU of “an active substance used as a starting material”, i.e. medicinal ingredient, falls under this part of the Directive (2004/27/EC, Article 46a).
Such an authorisation is also required for imports coming from third countries into a member state. A manufacturing authorisation can be obtained if the manufacturer meets the requirements as laid down in Article 41 and 46. These include administrative provisions, technical requirements qualified personnel, as well as other requirements. Article 47 moreover lays down that the principles and guidelines of Good Manufacturing Practice should be adopted. See Section 9.1.2, for more information on this issue.

If a medicinal product is imported from a third country (non-EU country), each production batch must have undergone a full qualitative analysis in the importing Member State. This should be an analysis of at least all the active ingredients and all the other tests or checks necessary to ensure the quality of medicinal products, in accordance with the requirements for the marketing authorisation.
However, such checks do not need to be performed under the responsibility of the holder of the marketing authorisation, if the Community has arranged with the exporting country:

a) to ensure that the manufacturer of the medicinal product applies the standards of Good Manufacturing Practice at least equivalent to those laid down by the Community, and
b) to ensure that the checks mentioned in the paragraph above have already been carried out in the exporting country.

For up-to-date information on EU legislation (for example other, not here described issues of Directive 2001/83/EC), please refer to the following Internet sites:

- The European Scientific Cooperation on Phytotherapy: http://www.escop.com
- Besides the AccessGuide, another important resource regarding up-to-date legislation for pharmaceutical ingredients is http://dg3.eudra.org, the Internet site of the Unit F3 of Biotechnology, Competitiveness in Pharmaceuticals and Cosmetics. The Unit's overall policy objective is to promote completion of the Single Market and competitiveness within the context of meeting the EU's health and consumer protection objectives. The history of natural ingredients as active pharmaceutical ingredients is found in the EU legislation at this Internet site.
- EU Internet site: http://europa.eu.int/comm/enterprise/
- http://www.emea.eu.int
- http://www.ich.org

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

Known as CITES, the Convention on International Trad e in Endangered Species of Wild Fauna and Flora, entered into force on 1 July 1975 and now has a membership of 160 countries. These countries act by banning commercial international trade in an agreed list (Appendix I) of endangered species (including plants) and by regulating and monitoring trade in others (Appendix II) which might become endangered. More than 230 medicinal plants species have been added to CITES appendices. Medicinal species on CITES Appendix II include: False hellebore *(Adonis vernalis),* desert cistanche *(Cistanche deserticola),* Asian ginseng *(Panax ginseng),* Himalayan may-apple *(Podophyllum hexandrum),* Himalayan yew *(Taxus wallichiana)* and snake-root *(Rauvolfia serpentina).* Under this listing, commercial trade is permissible, provided specimens of listed species are legally harvested without detriment to wild populations, and valid CITES documentation is obtained prior to shipping.

The lists of species are available through CITES Internet-site at http://www.cites.org/. Council Regulation EC/338/97, Commission Regulation EC/938/97 and EC/2307/97 are the legislative instruments regulating the trade in wild fauna and flora at EU level. These regulations fully implement the provisions of CITES and include a number of stricter measures.

- For up-to-date information on species included in CITES Appendix I and II, please refer to http://www.cites.org/.

9.1.2 Quality and grading standards

Quality requirements in the pharmaceutical industry are extremely high. Quality of raw material can vary considerably, so suppliers of natural ingredients should be able to submit detailed information about their products. If a company is interested in a particular plant, it will ask for samples, which will be tested in its laboratory on quality and content of active material. If an exporter wants to offer plant extracts, there are stringent requirements regarding content and purity. The percentage of the plant material in the extract has to be indicated and should not vary between different batches.

The most important requirements mentioned by company representatives interviewed are quality (consistent supply) and reliability.

The Ad hoc Working Group on Herbal Medicinal Products was established in 1997 at EMEA. It has carried out a comprehensive review of existing guidelines and updated/adapted them to the particular needs of herbal medicinal products. The aim is to further develop and update guidelines to clarify the situation for herbal medicinal products, with the final objective of allowing their free circulation throughout Europe. The group's work is meant to include the verification of monographs proposed by the European Scientific Co-operative on Phytotherapy (ESCOP) and the World Health Organisation (WHO) in order to come to generally accepted European summaries of Product Characteristics for widely-used medicinal plants. At http://www.escop.com/ one can find a list of available European Scientific Co-operative (ESCOP) Monographs, currently consisting of 60 leading herbs, and order them.

It is advisable that medicinal herbs and separate medicinal herbs present in the herbal medicines should meet the requirements of the European Pharmacopoeia (if there is a monograph present), or the requirements of specific countries. If medicinal herbs and herbal medicine are imported as medicines, they have to meet the requirements of the European Pharmacopoeia as mentioned above.

GACP and GMP

Government and the trade both recognised that quality control and quality assurance for herbal medicines must begin at the farm. Therefore ,the guidelines for "Good Agricultural and Collection Practice of Medicinal and Aromatic Plants" (GACP). GACP is a modified version of Good Agricultural Practice (GAP) and the guidelines are intended to apply to the growing and primary processing of all such plants as traded and used in the European Union. Hence, they apply to the production of all plant materials used in the food, feed, medicinal, flavouring and perfumery industries. They also apply to all methods of production including organic production in accordance with the EU regulations. The main aim of GACP guidelines is to ensure that the plant raw material meets the demands of the consumer and thus fulfils high quality standards. It is therefore important that the plants:

- are produced hygienically, in order to reduce microbiological load to a minimum,
- are produced with care, so that negative effect on plants in the course of cultivation, processing and storage is limited.

Since medicinal and aromatic plants and their products are exposed to a large number of microbiological and other contaminants in the course of the production process, the main aim of the present guidelines is to provide guidance for producers to reduce contamination in the raw plant material to the lowest possible minimum.

"Good manufacturing practice" (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. In contrast to GACP, which aims on raw material, GMP focuses on processed raw material (ingredients). European Directive 2003/94/EC lays down the principles and guidelines of GMP.

GMP designed to minimise the risks involved in any pharmaceutical or cosmeceutical production that cannot be eliminated through testing the final product. The main risks are:

- unexpected contamination of products, causing damage to health or even death;
- incorrect labels on containers, which could mean that patients receive the wrong medicine;
- insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects.

GMP covers all aspects of production; from the starting materials, premises and equipment, to the training and personal hygiene of staff. Detailed, written procedures are essential for each process that could affect the quality of the finished product. There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made.

The Regulatory applicability of GMP may vary as to the legal classification of an active pharmaceutical ingredient (API). When a material is classified as an API in the region or country in which it is manufactured or used in drug products, it should be manufactured according to this guide.

An “API Starting Material” is a raw material, intermediate, or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. The company should designate and document the rationale for the point at which production of the API begins. Regarding extraction and purification, etc. this rationale should be established on a case-by-case basis. Figure 9.1 gives guidance on the point at which the API Starting Material is normally introduced in the process. It implies that all steps shown should be completed. The stringency of GMP in API manufacturing should increase as the process proceeds from early API steps to final steps, purification, and packaging. Physical processing of APIs should be conducted at least to the standard of this guide.

Figure 9.1 New WHO Guidelines 2004 on GACP

„Increasing GMP requirements“

„Annex 18 **Good manufacturing practice for API (July 2001)**

Type of Manufacturing	Application of GMP Guide of API Manufacturing (shown in yellow) to steps used in this type of manufacturing				
API extracted from plant sources	collection of plants	cutting and initial extraction(s)	Introduction of API Starting Material into process	Isolation and purification	Physical processing and packaging
Herbal extracts used as API	collection of plants	cutting and initial extraction(s)		Further extraction	Physical processing and packaging
API consisting of comminuted or powdered herbs	collection of plants and/or cultivation and harvesting	cutting and comminution			Physical processing and packaging
Status/ Nomenclature	**plant raw material**	**natural ingredients**	**natural ingredients**	**natural ingredients**	**final products**

New WHO guidelines 2004 on GOOD AGRICULTURAL AND WILD COLLECTION PRACTICES (GACP)

Expansion of GMP through GACP

Source: K. Duerbeck (p.c, 2004)

WHO has established detailed guidelines for GMP. Many countries have formulated their own requirements for GMP based on WHO GMP. Others have harmonised their requirements, for example in the Association of South-East Asian Nations (ASEAN), in the European Union and through the Pharmaceutical Inspection Convention.

- More detailed information on the international WHO guidelines can be found at its Internet site: http://www.who.int and http://www.who.int/medicines/library/trm/medicinalplants/agricultural.pdf

Guidelines and standards for sustainable medicinal and aromatic plant use
Rapidly growing demand for herbal products is raising concerns on the sustainability of medicinal and aromatic plant use. Appropriate guidelines and standards, taking environmental and social sustainability into account, are needed. Unfortunately, most of the existing efforts are deficient as a recent review of standards and guidelines and WWF-UK's comments on two respective European- and global-level efforts show.

At a recent meeting, organised by the WWF-UK International Plants Conservation Unit and the WWF-Germany Species Unit, representatives from WHO, IUCN, TRAFFIC and WWF discussed the need to revise the 1993 “Guidelines on the Conservation of Medicinal Plants”. These are global guidelines that were published by WHO, IUCN and WWF following the historic 1988 Chiang Mai Declaration “Saving Lives by Saving Plants”.

All participants recommended the revision of the 1993 guidelines in light of significant new developments in the field of medicinal plant conservation and use over the past decade (e.g., community involvement in conservation, incentive-based approaches/certification). The usefulness of an up-to-date global framework document was highlighted strongly. Apart from governments and NGOs a new key audience for the revised guidelines will be the commercial sector (e.g., herbal medicine industry, traders). This sector can contribute significantly to conservation and sustainable use of medicinal plants through socially and environmentally sound sourcing practices.

9.1.2 Trade related environment, social and health & safety issues

Despite their importance, medicinal plants are, for the moment at least, seldom handled within an organised, regulated sector; most are still exploited with little or no regard for the future. Escalating demand is resulting in indiscriminate harvesting of wild plants, this damaging both ecosystems and their precious biodiversity. The damage is especially serious when bark, roots, seeds and flowers - all essentials for the species’ survival - are removed.

Concern is growing that many medicinal plants are on the verge of extinction. The need to protect rare medicinal plants seems to be urgent. China’s situation gives some sense of the scope of this problem. There, more than 80 percent of the 700,000 tonnes of plant material harvested each year comes from wild sources. The destruction of forests, overgrazing of meadows, expansion of industry and increasing urbanisation, as well as the excessive collection of wild plants, all means that the natural sources of medicinal products for a billion people are being rapidly reduced.

However, protection without any utilisation schemes has proved not be very effective. Examples are the plants *Pterocarpus santalinus* (red sandalwood) and *Saussurea costus*. These plants were strongly protected when the plant came to the brink of extinction. Currently, there is commercial interest for these plants, leading to sustainable management schemes. The whole chain, from collection to manufacturing, should be encouraged, while keeping in mind sustainable practices.

Despite the problem of unsustainable harvesting, there is a limited number of measures for controlling international trade in medicinal plants. Currently, the main form of regulation is through CITES (see Section 9.1.1).

A few governments are trying to protect some local species. Their efforts include improving the methods of collection as well as the deliberate cultivation of the plants. The goal is normally to ensure proper quality control and to regulate commerce for the protection of both consumer and producer. These few governments are also involved in educating their populations and in creating greater awareness of the importance of medicinal plants as a whole.

The World Bank proposes that policies should be developed to regulate medicinal plant conservation, cultivation, processing, and marketing. Among the points, which need to be addressed by each nation, according to the World Bank are the following:

- Is the use of medicinal plants encouraged in healthcare programmes?
- Are there policies for conserving medicinal plants and incentives to encourage local community participation?
- Is there a policy for restoring plants harvested in the wild?
- Are there incentives for collectors and farmers to keep the production of medicinal plants sustainable?
- Does the government support research into medicinal plants
- What are the policies regarding the export of medicinal plants?
- Are only raw materials exported?
- Is 'in-country' processing (which may further help the trade in medicinal plants) being promoted?

Many factors have often failed to provide central governments, the private sector, or local and indigenous populations with sufficient incentives to preserve biological resources. Such factors are for example: uncertain property rights, the lack of entrepreneurial, technical and financial resources, and high political, economic and technological risks.

Most of the current conservation efforts seem to be led by non-governmental organisations and privately funded international agencies, such as Worldwide Fund for Nature (WWF), Conservation International, International Union for the Conservation of Nature, and several botanical gardens, mainly Kew, Edinburgh, Missouri and New York.

The fact that there is little or no legislation restricting the use of wild-harvested materials in finished products, or for assuring the sustainable utilisation of medicinal plants, is a serious concern.
There needs to be greater awareness amongst the end users, e.g. the pharmaceutical, phytopharmaceutical and health products companies, as to the consequences of their trade on the future availability of medicinal plant resources.

Efforts are underway on a number of fronts to create guidelines for sustainable harvesting and codes of conduct for collectors. Within industry, some companies are involved in monitoring the trade in raw materials. East West Biotics, for example, has entered into a partnership with the Royal Botanic Gardens, Kew, and the Institute for Medicinal Plants in Beijing to establish research links, and monitor Traditional Chinese Medicinal (TCM) plants in the UK trade for correct identification, as well as to ensure CITES species are not marketed (Ten Kate & Laird, 1999).

Manufacturers of botanical medicines used to acquire their raw materials from traders, but now some have their own plantations or have direct contacts with producers. Manufacturers of botanical products are increasingly interested in having direct relationships with producers of required materials, in order to ensure a sustained source and/or to improve transparency of the supply chain, meaning to save costs for the establishment of the product documentation as GMP requirement (Dürbeck, p.c). These producers, however, require a certain minimum supply of the raw material.

Organic certified raw material
Another trend in the market is that more and more innovative companies are requesting organically certified raw material and value added products, especially for the development of new products. There is, therefore, increasing demand for certified raw material and value added products. Another indication of this trend is that more and more conventional importers and traders receive approval to deal with organically certified material.

Guidelines for the production, processing, labelling and marketing of medicinal plants and products from organic farming has been established within the work of the CODEX ALIMENTARIUS of FAO/WHO and the EU organic products regulations EC 1804/1999 supplementing Regulation EEC 2092/91.
Please refer to the following Internet sites:

- http://www.codexalimentarius.net/
- http://europa.eu.int/eur-lex/pri/en/oj/dat/1999/l_222/l_22219990824en00010028.pdf
- http://europa.eu.int/eur-lex/en/search.html

A new development, besides organic certification, is certification based on criteria and principles of the Forest Stewardship Council. In 2001, a Brazilian company earned FSC certification for 80 thousand ha of native forest, where extraction of raw materials for producing medicines and cosmetics takes place.

For more information on organic products, please refer to CBI's EU Market Survey "*Organic Food Products*".

Environmental and consumer health and safety are important for this product group, since the use of cosmetics and pharmaceuticals has to be very safe for the final consumer. Therefore, compliance with additional market requirements might give an added value to the product on EU markets. Like the trend in the food sector, European consumers wish to purchase safe products. As for natural products, product safety is also partly related to the environmental aspects of production (e.g. the use of pesticides). Environmental labels that are gaining importance are the organic production label mainly used in the UK and the international label FSC for (non-timber) products from sustainable forestry. The internationally accepted environmental management system is ISO 14000. Finally, increasing attention is given to the impact of production processes on local environments. In order to encourage 'environmentally sound production', producers made aware of on either 'end-of-pipe' measures or, preferably, preventive pollution measures. AccessGuide contains several documents on this topic.

9.1.3 Packaging, marking and labelling

Packaging, marking and labelling of herbal raw material is principally carried out according to the requirements of the buyer. At present, general requirements are part of the "Good Agricultural and Collection Practices for Medicinal and Aromatic Plants (GACP)" (http://www.who.int/medicines/library/trm/medicinalplants/agricultural.pdf).

Packaging and labelling

After the repeated control and eventual elimination of low-quality materials and any foreign bodies, the product should be preferably packaged in new, clean and dry sacks, bags or chests. The label must be clear, permanently affixed and be made of non-toxic material.

In general, legal requirements for raw materials specify that the following aspects must be indicated on the label:

- of which material it is; and
- from which batch the material comes.

Further, it is highly recommendable to include the following aspects on the label:

- name and address of the producer/exporter;
- net weight; and
- recommended storage conditions.

The overall trend in Europe is towards facilitating re-use and recycling of packaging, through incentives. In order to harmonise the different forms of legislation, the EU has issued a directive for packaging and packaging materials (Directive 94/62/EC) in which minimum standards are regulated. The maximum sum of concentrations of lead, cadmium, mercury and chromium allowed in packaging is 100 ppm.

Most of the time, packaging policy does not affect 'foreign' manufacturers because importers will be held responsible for the packaging. However, sensible marketing requires taking the obligations for the importer into consideration. That means that packaging materials should be limited and re-useable or recyclable. Otherwise the importer will be confronted with additional costs, thus reducing the competitiveness of the exporter.

Re-usable packaging materials should be well cleaned and perfectly dried prior to their usage. It must be guaranteed that no contamination takes place by re-using bags.

Storage
In the period before transportation, packaged dried materials should be stored in a dry, well-aerated building, in which the daily temperature fluctuations are limited and good aeration is guaranteed. Fresh products (except basil) should be stored between 1°C and 5°C, while frozen products should be stored below –18°C.

As a protection against pests, birds, rodents and domestic animals, the window and door openings should be protected, e.g. by wire netting.

It is recommended that the packaged dry crop be stored as follows:
- in buildings with concrete or similar easily cleanable floors,
- on pallets,
- with sufficient distance from the wall,
- with thorough separation from other crops to avoid cross-contamination,
- and organic products must be stored separately.

Organic certified raw material
As mentioned in the previous Section, guidelines for the production, processing, labelling and marketing of medicinal plants and products from organic farming has been established within the work of the CODEX ALIMENTARIUS of FAO/WHO and the EU organic products regulations EC 1804/1999 supplementing Regulation EEC 2092/91.

Extracts
Regarding the trade in value-added medicinal plant products, the principles and guidelines of good manufacturing practice for medicinal products for human use (Commission Directive 91/356/EEC) are applicable, reflected in the National Legislation of the EU Member States Annex *7 "Manufacture of Herbal Medicinal Products*" explains in detail the specific requirements for packaging, marking and labelling. Council Directive 92/27/EEC, on the labelling of medicinal products for human use and on package leaflets, applies in this context as well.

At http://europa.eu.int/eur-lex/en/search.html, one can find the exact content of these Directives, by searching for Legislation in Force.

9.2 Tariffs and quota

In general, all goods entering the EU are subject to import duties. External trade conditions in the European Union are mostly determined by EU regulations. The level of the tariffs depends on:
- country of origin
- product

In order to support exports from developing countries, the EU operates the Generalised System of Preferences (GSP). Under the GSP scheme of the EU, imports from a number of developing countries are admitted at a reduced tariff and imports from a group of least developed countries at a zero tariff.

Based on the outcome of the Uruguay Round, and the general trend towards liberalisation of world trade, it was felt necessary to reconsider the GSP. A general

lowering of trade barriers would mean an erosion of the relative advantage of the preferences received by developing countries. A renewed GSP was therefore required. The renewed preferential scheme was introduced on 1 January 1995.

The EU Commission has established a new scheme of preferential rights since 1 January 1997. This new scheme was formally published under Regulation EC 1256/96. It also applies to natural ingredients for pharmaceuticals.

Product group	General tariff	Tariff for DC
Medicinal and aromatic plants	0-3	0
Medicinal and vegetable saps and extracts	0	0
Vegetable alkaloids	0	0

Source: http://europa.eu.int/comm/taxation_customs/dds/en/tarhome.htm (September 2004)

Import duties specified are applicable for a number of developing. A "form A" or "EUR I form" has to be provided, in case a tariff is applicable and the exporter in a developing country wants to take advantage of the GSP tariff.

Regarding natural ingredients for pharmaceuticals, no quotas are applied.

Value Added Tax (VAT)
All fiscal borders disappeared in the EU on 1 January 1993. The EU decided at that moment that all VAT (tax levied at the consumption level) rates for pharmaceutical products should be harmonised at a low level.

Table 9.1 VAT rates on pharmaceutical products, October 2003

Country	Percentage	Country	Percentage
Belgium	6, 12 or 21	Luxembourg	3 or 15
Czech Republic	5	Hungary	-
Denmark	25	Malta	0
Germany	16	The Netherlands	6 or 19
Estonia	5	Austria	20
Greece	8 or 18	Poland	-
Spain	4 or 16	Portugal	5 or 19
France	5.5 or 19.6	Slovenia	8.5
Ireland	0	Slovak Republica	19
Italy	10 or 20	Finland	8
Cyprus	0	Sweden	25 or 0
Latvia	9	United Kingdom	0 or 17.5
Lithuania	5		

Note: * the reduced tariff rate depends on the product, which is imported. For a number of products the standard rate is applied while, for a number of product groups, the reduced tariff is applied.
Source: European Commission, Directorate-General Taxation and Customs Union (2003)

For information on VAT rates applied in the member states to natural ingredients for cosmetics, please refer to CBI's EU Survey "*Natural Ingredients for Cosmetics*".

Useful Internet sites	
Netherlands Custom Services Directorate General XXI	http://europa.eu.int/comm/taxation_customs/dds/en/tarhome.htm http://europa.eu.int/comm/taxation_customs/publications/info_doc/taxation/tva/taux_tva-2003-5-1_en.pdf

Thus far, the previous part of this market survey – Part A – provided market information on the EU market for natural ingredients for pharmaceuticals and on the requirements for market access. The next part – Part B – aims at assisting (potential) exporters in developing countries in their decision-making process as to whether to export or not.

PART B:

EXPORT MARKETING GUIDELINES: ANALYSIS AND STRATEGY

How do you get involved in the international marketplace? How much time and money will it take? Should you make exporting part of your business plan? These are common concerns of producers who realise the importance of international trade, but are not sure if exporting is for them. That is what Part B is all about: to help you to evaluate whether to get involved in international business, and learn how to go about exporting.

The first Chapters 10, 11 and 12 aim at assisting potential exporters in the **decision-making process** whether or not to export. By matching external opportunities and internal capabilities, the exporter will be able to identify suitable export products, target countries, market segments, and possible trade channels.

Subsequently, Chapter 13 provides sector specific knowledge and sources to enable the exporter to further investigate what to export, to which markets, through which channels, and at what prices. In other words, which **marketing tools** can be used to build a successful business relationship?

Keep in mind that the export marketing process is integrated; each individual part is inter-linked.

The information provided in the previous parts of this survey is an essential ingredient in conducting the analysis and formulating a clearly targeted export strategy. Where applicable, reference will be made to the concerning sections in Part A.

For general information on export marketing and how to conduct market research, please refer to CBI's "*Export Planner"* and CBI's new manual on market research.

10 EXTERNAL ANALYSIS: MARKET AUDIT

The external analysis assists the exporter to identify market opportunities, suitable sales channels and other relevant external factors.

10.1 Market developments and opportunities

As a first step towards the identification of the most suitable export markets, the exporter needs to research the importance of potential markets and understand the ongoing developments that shape the market structure. This should be done by means of a systematic method of market research, involving a preliminary screening of potential markets followed by a more detailed assessment of the targeted markets.

Markets may be researched using primary or secondary data sources. Primary market research means collecting data directly from the foreign marketplace through interviews, surveys, and other direct contact with market participants. Primary research has the advantage of being tailor fit to meet your company's needs and provide answers to specific questions, but this data collection can be very time-consuming and expensive.

For a global scan of the market, most companies make use of secondary data sources such as trade statistics, to focus its marketing efforts. This type of research is a valuable and relatively easy first step for a company to take. Specific market developments as described in Chapters 3, 4, 5 and 6 of this market survey, for instance, can be used as a starting point for your export market research.

Results of the research inform the company of the largest markets for its product, the fastest growing markets, market trends and outlook, market conditions and practices, and competitive firms and products. Based on all the information, a company must decide which markets are the most promising.

☞ Besides the European market, exporters in developing countries should keep an eye on developments on other national, regional and international markets. First of all, because of international developments in the industry and secondly so as not to be solely dependent on one market sector. In this way, fluctuations in the international market can be buffered by demand in the national and regional market. However, in general, when starting with exporting it is better to focus on one market and one market segment.

Questions that need to be answered:

- Market size: What is the (estimated) market size for your potential export products? Try to first focus on your product group, then on your specific products.
- Market developments: How has the total market volume developed during the last 3-5 years? If there is no information on the specific natural ingredient itself, then try to obtain information on the development of the market for finished products. It is for instance not possible to obtain exact figures on sales of Asian Ginseng root. Still, from the stagnating sales of finished Ginseng tablets, you can determine that the market for them in all probability is also sluggish. It must be noted that, for some products, this kind of determination is difficult since those products are not used solely by the pharmaceutical industry, but also by the cosmetic and food industry.
- Imports: How have imports developed during the last 3-5 years? Again, there probably is no information on all specific products available.
- Are importers and potential business partners in the EU interested in new suppliers of your particular products?
- Price development: How have the prices of your product developed during the last few years? Again, there probably is no information on all specific products available.

Where to find information?

ⓘ The market information described in **Part A of this market survey** can be very useful as a starting point for your export market research. Where applicable, also the sources for this market information are mentioned in the specific chapters.
ⓘ Moreover, CBI provides some useful manuals: "Your Guide to Market Research" and "Digging for Gold, EU marketing information".
ⓘ For more general information, you can use the EU statistics bureau **Eurostat**: http://europa.eu.int/comm/eurostat
ⓘ **Trade press**
Useful sources for information on market developments are (international) trade magazines, which can be relevant for exporters who want to develop a better insight into the EU markets. Some of the most interesting magazines for exporters of natural ingredients for pharmaceuticals are:

- Drogenreport (English, German)
- Pharma marketing service (English)
- Zeitschrift für Arznei- und Gewürzpflanzen (German)
- Fitoterapia (Italian)
- European Journal of Herbal Medicine (English)
- Herbalgram (English)
- Journal of Herbs, Spices & Medicinal Plants (English)

ⓘ Last but not least, **Internet** provides you easily more and more direct market information. In this survey several examples of useful Internet sites are given.

Please refer to Appendix 2.4 for a more extensive list of names and addresses of publishers.

Market access requirements

Quality standards and other non-tariff barriers
Section 9.1 of this survey described a wide array of non-tariff barriers, which are applicable to exporters natural ingredients for pharmaceuticals. It is important to determine which standards and regulations apply to your situation. Not all standards are compulsory or widely recognised by your potential customers.

For exporters of natural ingredients for pharmaceuticals, a compulsory regulation like Directives 2001/83/EC or 2004/27/EC can embody a major obstacle to export to the European Union.

It is advisable that medicinal herbs and separate medicinal herbs present in the herbal medicines should meet the requirements of the European Pharmacopoeia (if there is a monograph present), or the requirements of specific countries. If medicinal herbs and herbal medicine are imported as medicines, they have to meet the requirements of the European Pharmacopoeia as mentioned above.

What is more, many European importers entering into a co-operation agreement with an African, Asian or Latin-American company introduce their own quality system. Regarding quality standards, an exporter should distinguish between product quality standards (i.e. GMP, GACP) and processing or management quality standards (ISO 9000 and ISO 14000). In general, legislative requirements are more important than ISO, since those requirements often determine whether or not the European importer decides to enter into a relationship. In some cases, the importer will assist the exporter with product adaptations, so that traded products comply with European requirements.

Since importers face an additional cost factor in establishing the GMP documentation in Europe, they prefer ingredients accompanied by the necessary documentation. Therefore, exporters in developing countries need to develop or acquire technologies necessary to improve quality control in cultivation, harvest, post-harvest and transport. In other words, the implementation of the appropriate GMP will be necessary in order to better compete in the international market.

Exporters in developing countries will find more opportunities in the trade of ingredients with known properties and activity, which are not patented and which can be traded freely.

Keep in mind that regulations and standards can change from time to time. Therefore, it is recommended to check the up-to-date situations with importers or the relevant organisations.

Questions that an exporter should answer are:
- What standards are set on the quality of products?
- What standards apply to the quality of your company (ISO)?
- To what degree do GAP/GMP apply to the products?
- Especially in the case of medicinal plants collected in the wild, it is important to check if CITES regulations apply.
- What is the importance of environmentally and sustainably sound production methods?

Where to find information?
ⓘ In Sections 9.1 of this survey, you can find information on quality standards; trade-related environmental, social and health & safety issues; and packaging, marking and labelling. This section also provides Internet-Sites like CBI's AccessGuide and dg3.eudra.org, which can be of assistance in obtaining product specific information.
ⓘ Other potentially useful information sources are colleague exporters and European importers.

Tariff barriers
Section 9.2 dealt with current tariffs on imports of ingredients for pharmaceuticals. In general, tariff barriers are important for bulk replacement products. Exporters should not only look at the current tariff, but also consider whether the tariff will remain the same for the coming years. It is also important to bear in mind that changes in the level of import tariffs applicable to other countries may influence your competitive position. However, in general, a lower tariff applies to developing countries.

Questions that an exporter should answer are:
- Are there import restrictions that limit sales opportunities?
- Which import tariffs apply to your export products?

Where to find information?
Refer to Section 9.2, for information on applied import tariffs. This section also provides Internet sites that are helpful to find product specific information.

10.2 Competitive analysis

Generally, competitors and their pricing will have a direct effect on the potential of your trade opportunities. It is, therefore, important to learn more about your competitive environment, companies as well as countries.

In many cases, suppliers of ingredients for pharmaceuticals in developing countries benefit from their climatic conditions, labour costs, costs of raw material, costs of land etc. This is often one of the most important factors that positively distinguishes your company from competitors in other countries, particularly from competitors in Europe. Other positive factors already mentioned in the previous section are low or zero import duties.

Other factors can weaken your competitive position. European companies for instance have the advantage of being, both in a geographical and cultural context, close to their customers, which in general makes marketing of products and communication easier.

Another important difference is the fact that processing technology and input is readily available to European companies (see Chapter 4 of part A).

Suppliers of ingredients for pharmaceuticals in other developing countries also represent an important group of potential competitors. You can find useful information in Chapter 5 of Part A on product streams originating in these countries. Furthermore, several weak points of ingredient producing companies in developing countries, that have to compete with better organised companies in the world are given in the internal analysis of Chapter 11.

Below a step-wise approach to learning more about your competitive environment is lined up:

Step 1: Key competitors.
Prepare a broad list of all competition and then pick out your main competitors. Those who have most overlap with your product range and, moreover, can supply under better conditions (regarding price, quality, delivery conditions, extra services etc.) are your main competitors. To learn more about competition you can do a secondary research study of your industry and ask customers and suppliers for their opinions.

Step 2: Main competitors analyse.
If possible, visit competitors' companies to learn how products are priced and distributed. You can prepare a list of your main competitors' strengths and weaknesses.

Step 3: Where and how does the competition sell their products?
You need to find out which trade channels are used by your competitors, and why. For instance, do your competitors supply directly to European importers (and are they thus able to produce required quality), or do they use the expertise of a European counterpart?

Step 4: Trade show activity.
Of course, trade shows can be helpful for making contact with new customers and learning about market developments. It is, however, also an excellent opportunity to find out more about competition. Take the time to attend trade shows to see what your competition is like.

Step 5: Where to expect new competition?
The pharmaceutical ingredient sector is a very dynamic sector. Constantly check with trade news, customers, suppliers and your competitors to see if they have heard of any new businesses.

☞ Please note that, although it is always good to observe your competitors, in case of ingredients for pharmaceutical often a partnership between exporters is recommended. Because demand is larger than supply, exporters can together keep the prices high. Moreover, a partnership can lead to better logistic systems, better purchasing conditions for packaging, combined promotion actions, lobbying etc.

Important questions to be answered are:
- How many suppliers are currently active in the market?
- Who are your main competitors? What are their strengths and weaknesses compared to your company?
- To what degree is the sector in the target market supported by the local government?

10.3 Sales channel assessment

☞ *The information provided in Chapter 7 of Part A should be used as a starting point.*

Having assessed the prospective markets and market segments, it is now also important to understand the trade structure and supply chains supplying these market segments. After the assessment of the exporter's capabilities (next chapter), the exporter is able to determine the most suitable sales channel.

The majority of large pharmaceutical companies does not conduct field collections, but relies instead on existing in-house collections of material, or buying in-compound or culture collections. Most companies outsource, or contract to others, the acquisition of samples for their screening programmes. They obtain samples through brokers, agents, or through specific deals with supplier organisations. The bulk of collecting activities is conducted by non-profit organisations (universities, research institutes, botanical gardens) (Ten Kate & Laird, 1999).

B2B: advantages for suppliers

- Long-term and more stable commercial ties
- Fair prices and revenues
- Potential for expanding/ entering into new markets
- Social responsibility
- Risk mitigation
- Skills and technology transfer from larger business
- Best practices related with biotrade activities
- Improving natural resources' management

B2B: advantages for buyers

- Strengthened and stable supply chains and sustainable development creation
- Cost efficiency and stability
- Product innovation
- Enhanced public image through better corporate social responsibility
- Quality improvement and tracing
- Support sustainable value chains with adequate use of natural resources

Source: BTFP Technical Up-dates, July 2004

People in the medicinal industry feel that long-term relationships with raw material suppliers benefit the product quality, the growers and the environment (Ten Kate & Laird, 1999). Manufacturers of botanical products increasingly become interested in having direct relationships with producers of required materials, in order to ensure a sustained source and/or to save costs. Therefore, a trend towards long term partnerships and business-to-business (B2B) activities can be distinguished.

Important questions to be answered are:

- Which potential sales channels exist?
- Which products are traded in the different sales channels?
- What are the most important requirements of the identified sales channels? What are the conditions for an exporter to take part in a specific supply chain?
- What quality standards do the sales channels demand?
- What kind of packaging is used in the various sales channels?
- What are the requirements concerning production process (environmental, ISO, GAP, GMP, etc.)?

ⓘ Refer to Chapter 7, and Section 7.2 in particular, for information on potential sales channels.

ⓘ To get in touch with an European partner (for a joint venture for example) it is recommended to contact a local embassy of the country you want to export, the local European delegation, a local Chamber of Commerce or Export Development Board. These organisations can also give you information on when trade delegations from the EU are visiting your country. Direct match-making is also possible through for example the CBI News Bulletin, in which you can offer products and proposals.

ⓘ Again, customers, importers or colleague exporters are useful information sources!

10.4 Logistics

When transporting products overseas, the exporter ideally looks for the fastest and most efficient mode(s) of transportation that will deliver the product in perfect condition at the lowest possible costs. The actual selection will be a compromise among these factors.

Transport

In the case of bulk delivery, it is important to ensure that the transportation conditions are dry. Furthermore, it is highly advisable to use aerated containers in order to reduce the risk of mould formation or fermentation. As a supplement, the use of other sufficiently aerated transport vehicles and other aerated facilities is recommended.

In the case of natural ingredients for pharmaceuticals, three types of international transportation can be recognised: ocean cargo, air cargo and truck cargo.

- Ocean transportation takes longer than airfreight, but the costs of transportation are usually lower. This kind of transportation is most suitable for dried raw materials and for a number of oils.
- The cost for moving products by air tends to be higher than the cost of ocean transportation. This type of transportation is used for value added products, such as essential oils and extracts.
- Truck cargo in the EU can only be used for imports from nearby located countries such as Turkey, Balkan and other countries in Eastern Europe, and Morocco. Different options of formats etc. exist for this method of cargo.

Freight rates also vary depending on the product being shipped, its value, level of service provided, destination, weight, and seasonal variations in demand for cargo space. Please pay attention to which system is being used: the metric system (used in most EU countries) or Anglo-American (used in the United Kingdom).

Freight forwarders

It is a good idea to use a freight forwarder to arrange transportation services on your behalf. They can simplify the shipping process because they are familiar with import and export regulations. It is important to use a forwarder that is experienced in handling natural ingredients or other perishables, as well as one that is experienced in the destination country. Freight forwarders can also assist you in handling all the documents. Freight forwarders are cost effective to use, because they can negotiate the best rates with airlines. They usually operate on a fee basis paid by the exporter, and these are part of the cost price.

Cold chain

Cold chain is required for a limited number of products (fresh plant material or special plant extracts, mostly used for intermediate products of Aloe vera). Critical point of interest regarding transport, just as during storage, is proper refrigeration. In handling perishable products, maintaining a cold chain is a major logistical issue. It determines for a large part the quality of the product as it arrives at the destination. The saying is "one hour lost in departure to being refrigerated will be one day less for the sale in the destination". Check whether you and your freight forwarders are able to manage the cold chain. Make use of temperature recorders to check whether your products travel in optimal climatic conditions during their entire voyage. A reliable freight forwarder with a cold store at the airport or good management of the temperature in the containers is recommended to keep the cold chain in control.

Packaging

Packaging is used for hygienically purposes and to protect against mechanical damage. It is an essential factor in determining the product's quality. However, according to the way in which packaging sometimes is applied in developing countries, it can also be a risk to quality, due to bruising and less than optimum conditions of temperature.

The packaging has to satisfy conditions in the field of handling. The transportation volume must be as efficient as possible and a high level of uniformity is desirable. Packaging design should take the following into account:

- Proper storage and transport;
- Standard packaging sizes;
- Recyclable materials or two-way systems.

Points of interest when choosing the right packaging:

Have your customers ever complained about the quality of your products?

Look for possible causes:

- □ Unsuitable packaging material (avoid unnecessary re-packing by the customer)
- □ Insufficient cooling during transport
- □ Too many damaged boxes on arrival
- □ Differences in weight mentioned and real weight
- □ Other causes

In the case of marine transport, different kinds of products shipped together in one container should have compatible:

- □ Temperature needs
- □ Relative humidity needs
- □ Airflow characteristics

Does your importer use special transport packaging?

→ Perhaps you could use this special transport packaging as well? Using the wrong packaging size can have a negative effect on your business.

→ Maybe you could make use of the importer's packaging know-how.

Fully recyclable packages must be used when trading with certain business partners.

→ Colouring materials, used for printing, should not be harmful to the environment.

→ Do not use metal clips for the cartons.

→ Avoid waxed boxes or any combined packaging materials

Documentation

Producers, traders and processors of medicinal and aromatic plants, should comply with the GMP guidelines. They should document their products by a waybill (batch documentation) and demand that their partners also adhere to these requirements. Minimal information included in the waybill should cover the geographical definition of growth place, the country of origin and the responsible producer.

☞ In Chapter 9 several methods of packaging for different natural ingredients are described. The exporter should always discuss the preferred type of packaging with his European trading partner or organisation.

Important logistic questions to be answered are:

- How often does the sales channel require delivery? What cycles of delivery does this channel require? Are you able to deliver this often?
- What lot sizes does this sales channel demand? What lot sizes are you able to produce?
- What formalities does the sales channel require to be handled by the exporter?
- What are the typical costs of logistics? (Check with freight forwarders)
- Is it profitable to co-operate with other exporters?

ⓘ Airfreight forwarders and air carriers are the best sources for obtaining freight rates. There are also companies that specialise in publishing air cargo tariffs. These publishing companies charge a fee for their services.

ⓘ International Federation of Freight Forwarders Association (FIATA): http://www.fiata.com

ⓘ Directory of Freight Forwarding Services: http://www.forwarders.com

ⓘ International Air Transport Association (IATA): http://www.iata.org
ⓘ Extensive lists of freight forwarders can be found at: http://www.cargoweb.nl and http://www.shipguide.com

10.5 Value chains

The value chain covers the full range of activities required to bring a product from its conception to its end use and beyond, such as research and development, raw material supply and all activities of production, marketing and sales to international buyers, and beyond that to disposal and recycling. Activities that comprise a value chain can be contained within a single company or divided over different companies, and can cover a single geographical location or be spread over wider areas.

The value chain approach is a systematic approach for designing strategy with respect to buyer requirements and market conditions (market access regulations, standards and consumer preferences) that a company has to conform to, in order to gain access to a market and be competitive.

The value chain approach builds upon sustainable supply chain management, by providing a framework to:

- improve efficiencies within the existing supply chain (thereby enhancing sector competitiveness);
- capture and retain a higher proportion of the product's final market value within the existing value chain;
- increase the sector's added-value by establishing new value chains within the sector;
- improve the sector's contribution to development objectives.

From a company perspective, the value chain approach offers more than a theoretical concept. It is a very practical tool for analysing linkages in the supply chain and for accessing potential for capturing, retaining and adding value to the company's product, keeping in mind its final user.

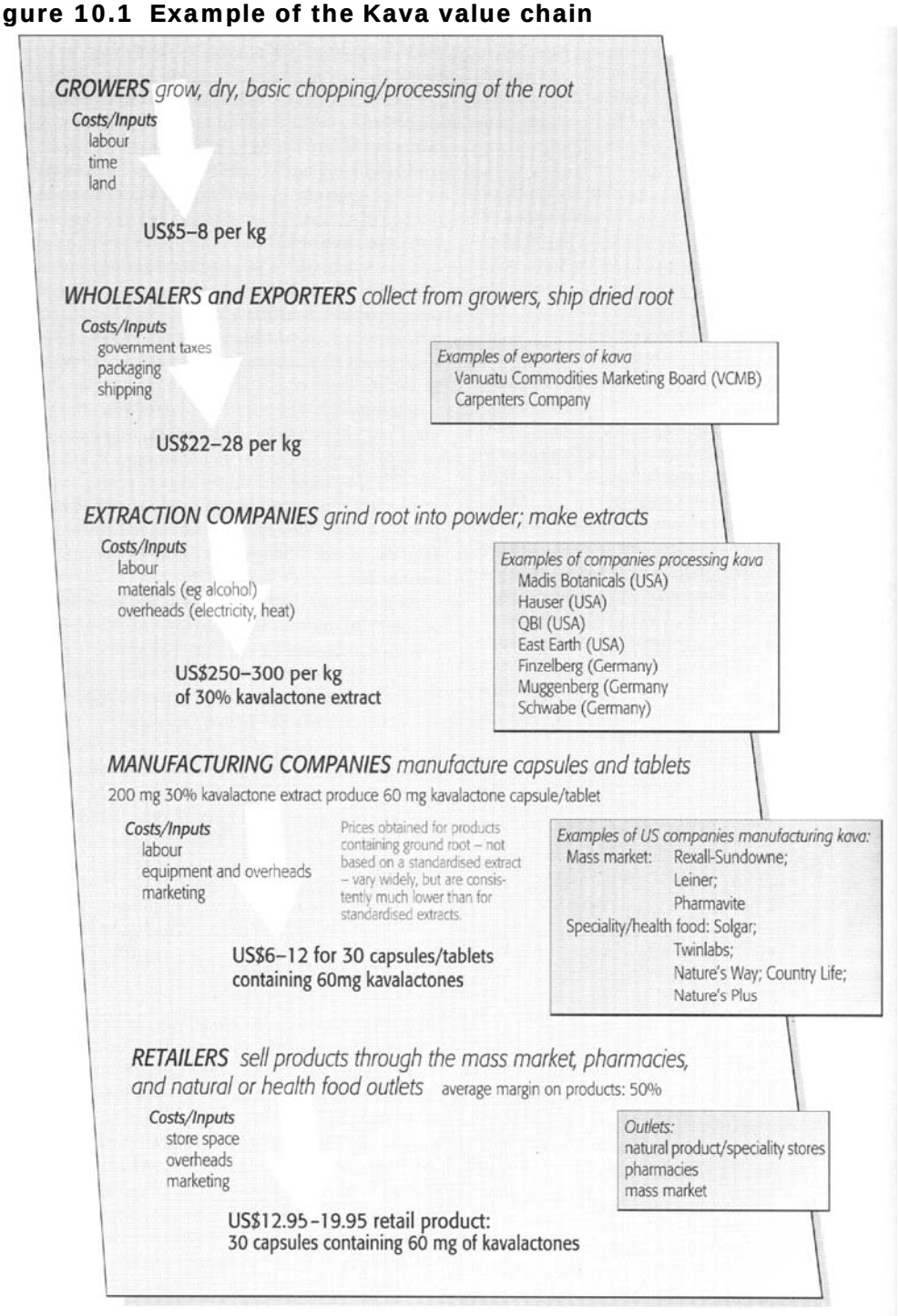
Guiding value chain analysis at company level

a. Try to note all the steps required to progress from raw materials to end-users.
b. Make this list as detailed as possible since one of the objectives of value chain analysis is to understand where, when and how to simplify or adjust the chain.
c. Determine the value each step adds to the final product from the point of view of the end user.
d. Once this chain is clear you can explore avenues to increase your profitability as well as increase the benefits to the end user; for example:
   - identify which steps can be combined to more efficiently add value;
   - determine which steps are not adding any value but just adding costs;
   - determine better communication flows in both directions to assist rapid change to market factors;
   - determine your own "value niche" along this chain.

It is important to understand where you, as a processor, fit into the supply chain, to ensure that the value you add continues to be important both for your direct customers as well as you customers' customers. The value chain can be a useful tool to help in this process.

As an example, Figure 10.1 shows the value chain for Kava (Piper methysticum).

Figure 10.1 Example of the Kava value chain



Source: Ten Kate and Laird (1999)
Note: Import and trade of Kava is currently under review by EU authorities.

Value addition in the supply chain

The first level of the supply chain is the collection or cultivating of the medicinal plants. Value addition at the collector's level is often limited, due to a lack of technical knowledge and equipment, and limited market knowledge. The potential for value addition by collectors/growers usually comprises cleaning, drying, and sorting of raw materials, which is otherwise usually captured by traders.

Collectors/growers then sell the products to local traders as cleaned, dried, and mould-free raw material, or directly to processors for value addition. Some traders dry natural ingredients and sort them into larger bales and sacks. At this level, potential for value addition is determined by capacity to comply with national/regional (e.g. ASEAN or

Andean Pact) legislation, and with industrial buyers' quality standards (GMP, including good agricultural and collection practices, as defined by WHO; see http://www.who.int).

Usually, local traders subsequently interact with three potential buyers: larger regional dealers, industrial buyers, and foreign buyers.

Generally, large dealers have greater capital investment in storage facilities, packing, and transport machinery. These dealers are capable of handling a much larger volume.

Local traders sometimes sell directly to industrial manufacturers, who process the ingredients into their final form.

Foreign buyers come from all parts of the world, mostly selling onwards to the next level in the supply chain: manufacturers of final products. These final manufacturers include pharmaceutical, cosmetic, and health food/dietary supplement industries (which have to conform to GMP for pharmaceuticals and cosmetics), processing natural ingredients into their final form (capsules, pills, cosmetics, teas, lotions, etc.), to be distributed throughout Europe, North America, Australia and Asia. Products are sold in retail or wholesale sales centres including over-the-counter drug stores, prescription drug pharmacies, cosmetic stores, health food stores, and catalogue sales. Products are then sold to the final level in the supply chain, the consumer.

Costing and pricing in the value chain

Also shown in Figure 10.1 is the value addition at the various stages of the supply chain. Growers or collectors sell their products at a price of € 3.75-6 per kg to exporters. Exporters, after partly processing the products, ask € 16.5-21 per kg, indicating a price increase of minimum € 12.75 per kg. The added value could be analysed by deducting all costs from the market prices. As is also clear from the Figure, prices paid for materials increase significantly along the value chain. This analysis requires involvement of all stakeholders in the supply chain, in order to be able to identify proper cost and price calculation. Only if there is transparency at the different levels, will it be possible to determine fair costing and pricing, which in turn will enhance awareness and importance of the potential for value addition in the supply chain, and thus the potential for sector development in a national context.

Critical factors for building a competitive advantage

The presentation of success stories by entrepreneurs in developing countries highlighted the following as **critical factors** for building a competitive advantage:

- Increasing the range of products and identifying market demands.
- Cost and price calculation on the basis of a business plan.
- Putting the emphasis on the quality of the product, and exercising strong control on the tracking and tracing of products.
- Introducing the use of new technologies.
- Promoting involvement and loyalty of staff, as well as integration into the life of the local community.
- Co-operating with buyers, in order to obtain necessary pre-financing, technologies or packaging.
- Reducing the number of middlemen.

☞ Factors that contribute to **success** are: niche products for niche markets, moving up the value chain through R&D and processing, responding to the ever-rising demand from consumers for higher quality standards, or shortening the distribution chain to capture a greater market share.

Please also refer to Chapter 8 and Section 13.3 for information on developments of prices and price setting.

For more information about the value chain approach, see e.g. http://www.tradeforum.org/news/fullstory.php/aid/529.

10.6 Product profiles

In the Herbal Education Catalog at http://www.herbalgram.org/, exporters can find and order publications on a range of herbs, including two of the products described in these product profiles, i.e. Echinacea, and Cat's Claw.

Furthermore, the British Pharmacopoeia can be ordered at this site. This Pharmacopoeia contains 169 monographs on definition, identification, and standards for plant materials commonly used in herbal products on the market. The Pharmacopoeia includes, amongst others, Devil's Claw, Echinacea root, Kava kava, Cinchona bark, Cola, Jamaica Dogwood, and Liquorice root.

At http://www.escop.com/publications.htm, one can find a list of available European Scientific Cooperative (ESCOP) Monographs, currently consisting of 60 leading herbs, and order them. The Monographs include, amongst others, Devil's Claw and *Echinaceae pallidae radix*, *Echinaceae purpureae herba*, and *Echinaceae purpureae radix*, Java tea, and Cape Aloes.

The (in Chapter 3) mentioned publication of the Commonwealth Secretariat "A Guide to the European Market for Medicinal Plants and Extracts"(2001) provides eleven product profiles: Aloe, Senna, Chamomile, Echinacea, Ginger, Ginseng, Hypericum, Milk Thistle, Pygeum, Rauwolfia and Valerian.

WHO has published two series of volumes (1999, 2001 and one in edition), the WHO monographs on selected medicinal plants. The monographs aim to provide scientific information on the safety, efficacy, and quality control of widely used medicinal plants; provide models to assist countries in developing their own monographs or formularies for these and other herbal medicines; and facilitate information exchange. They are comprehensive scientific references for drug regulatory authorities, physicians, traditional health practitioners, pharmacists, manufacturers, research scientists and the general public. For more information on the WHO Monographs of medicinal plants and other publications on i.e. quality control, please refer to:
http://www.who.int/medicines/library/trm/medicinalplants/monographs.html

The following tables list the product profiles of 2 important natural ingredients for pharmaceuticals: Echinacea and Cat's Claw.

PRODUCT PROFILE ECHINACEA

1. Product name: Echinacea

Interesting links for this product:

http://www.herbs.org/
http://www.geocities.com/chadrx/echin.html
http://www.forthrt.com/~roland/herbfarm.html
http://www.hcrc.org/faqs/echinac.html

Use: Echinacea is best known for its reputation for shortening the duration of colds or flu.

Main species: *Echinacea purpurea, Echinacea angustifolia*
other species: *E. pallida*, *E. paradoxa, E. simulata*, *E. atrorubens, E. sanguinea*, *E. leevigata*, *E. tennesseensis.*

Three species, Echinacea angustifolia, Echinacea pallida and Echinacea purpurea, are grown for the medicinal herb industry.

2. Market requirements:

Quality standards: ESCOP Monograph for whole, cut, and pulverised Echinacea.
Importers/manufacturers will first request a sample and test it for active ingredient content. Demand and price are determined on the basis of this test. Please refer also to information on Good Agricultural and Collection Practices in Section 9.1 and at http://www.who.int/.

Minimum labelling:
Legal requirements for raw materials specify that the following aspects must be indicated on the label:

- product name
- of which material it is, and
- from which batch the material comes.

Further, it is highly recommendable to include the following aspects on the label:

- name and address of the producer/exporter;
- net weight; and
- recommended storage conditions.

Packaging:
For 10-30 kg of raw material paper bags, poly bags covered by paper bags, or jute bags are used.

Import documentation
It should be documented in a waybill (batch documentation) that cultivation, harvesting and production have been performed in accordance with the Good Agricultural and Collection Practices (GACP) guidelines. Minimal information included in the waybill should cover the geographical definition of growth place, the country of origin and the responsible producer.

3. Market structure:

Prices:
Echinacea Angust Root, Spot: 28.58 £/kg
Echinacea Purpurea Root, Spok UK: 5.75 £/kg
(Public Ledger, Februay 2004)

Main markets:
The main European market for Echinacea is Germany. The top retail product is Echinacin of Madaus.

Market trends:
The consumption of echinacea products is linked to the trend towards healthier diets and the consumption of natural medicinals. Due to stricter regulations for herbal medicines internationally, cultivation (instead of wild-crafting) of Echinacea has increased strongly.

4. Main suppliers:

Echinacea can be found in the USA and also in Germany, where leading producers of botanicals have own plantations for popular products.

Known sources for Echinacea in developing countries are Bolivia, Costa Rica, Malawi and South Africa.

5. How to improve the quality:

Quality can be improved through harvesting of the proper plant part (root), prevention of adulteration, and appropriate drying procedures.

PRODUCT PROFILE CAT'S CLAW

1. Product name: Cat's claw (Uña de gato)

Interesting links for this product:
http://www.geocities.com/chadrx/catsclaw.html
http://www.austriantrade.org/AustrianTrade/bulletin/us/immodal.htm
http://www.cats-claw.com/piu/thirdparty/herbqfr.htm
http://www.kcweb.com/herb/catsclaw.htm

main species of interest: *Uncaria tomentosa* and *Uncaria guianensis*

Use: The bark of the root of this plant is reputed to be a remarkably powerful immune system booster and effective in treating a wide array of maladies including cancer, systemic candidiasis, genital herpes, and AIDS. Stem bark is the most commonly used commercial product.

2. Market requirements:

Quality standards: Importers/manufacturers will first request a sample and test it for active ingredient content. Demand and price are determined on the basis of this test. Please refer also to information on Good Agricultural and Collection Practices in Section 9.1 and at http://www.who.int/.

Minimum labelling:
Legal requirements for raw materials specify that the following aspects must be indicated on the label:

- Product name
- of which material it is, and
- from which batch the material comes.

Further, it is highly recommendable to include the following aspects on the label:

- name and address of the producer/exporter;
- net weight; and
- recommended storage conditions.

Packaging: containers (glass/aluminium/steel/plastic), depending on the specification of the buyer.

Import documentation
It should be documented in a waybill (batch documentation) that cultivation, harvesting and production have been performed in accordance with the Good Agricultural and Collection Practices (GACP) guidelines. Minimal information included in the waybill should cover the geographical definition of growth place, the country of origin and the responsible producer.

Export regulation: Officially no raw material can be exported from Peru. Only extracts, capsules and other processed Cat's claw products can be exported.

3. Market structure:

Prices:
Prices in for raw material in Peru were reported at €0.38 per kilo from local communities and between €0.75 and €9 per kilo in Lima depending upon the amount being bought. The price of extracts, ready for capsulation, is around FOB € 150/kg (depending on quality).

Main markets:
The leading EU manufacturer and importer is located in Austria. Most research work is conducted by Austrian companies, which also own of all major patents. The leading EU consuming markets is probably Germany.

Market trends:
Uncaria tomentosa, reputedly the most effective of several Cat's claw species, is endemic to the Peruvian Amazon and is gaining international attention for its documented curative qualities. Peruvian production of Cat's claw showed an upward trend between 1992 and 1996, amounting to 694 tonnes in 1996. In recent years, however, the market has declined a bit.

4. Main suppliers:

Peru is the leading supplier of *Uncaria tomentosa*.
Ecuador and Colombia only supply *Uncaria guianensis*.

5. How to improve the quality:
A major problem for quality assurance is that, in producer countries, there is hardly any infrastructure to execute a proper quality control.
A more open market scenario would contribute to the quality of the raw material. Currently, the trade is very price orientated. Buyers do not pay much attention to what part of the plant is presented, bark of the root (which is high in active principal) or bark of the vine. There is a high incidence of adulteration and no proper identification of plant parts.

Source used: Plantas Amazonicas de Uso Medicinal, CIFOR, Walter Nalvarte et al. (1999).

11 INTERNAL ANALYSIS: COMPANY AUDIT

The internal analysis or company audit is a review of the company's strength and weaknesses in terms of all company resources such as export marketing capabilities, finance, personnel, internal organisation, management, infrastructure, etc. As a result of this internal analysis, you will be able to assess to which extent your company is able to take advantage of the opportunities identified in the former chapter. Furthermore, with a thorough understanding of your company's unique capabilities, you are able to invest in opportunities that exploit your strengths.

11.1 Product range

A product range can consist of several product groups (range width), each with several different products (range depth). Again, one product can consist of several varieties (see example).

A supplier can only select a suitable business partner when armed with correct information about the range that he or she is able to offer. A precise review of the product range, therefore, aims at matching products on offer with market opportunities. Keep in mind that varieties are sometimes known under different trade names overseas.

Example of a company's product range

Product range (range width)	Products (range depth)	Varieties
Medicinal & aromatic plants	Cat's claw (*Uncaria*)	• Uncaria tomentosa • Encaria guinaensis
Vegetable alkaloids	Quinine (*Cinchona*)	• Cinchona officinalis • Cinchona calisaya • Cinchona succirubra

The next step is to review product characteristics of the products and varieties on offer.

Example of product characteristics

Product	Variety	Chemical properties	Use	Packaging	Availability
Cat's claw	Uncaria tomentosa	This herb contains mainly pentacylic alkaloids, substances responsible for the most well-researched effect of cat's claw, namely immune stimulation.	Effective in treating a wide array of maladies including cancer, systemic candidiasis, genital herpes and AIDS.	Containers (glass/aluminium/steel/plastic) depending on the specification on the buyer.	Cat's claw is already being radically over harvested in the wild, and therefore, rare.
etc.					

Questions an exporter needs to answer:

- Which products are you currently producing? How comprehensive is your product range?
- Which products do you consider to be the main products you are specialised in?
- What new products would you be able to collect / cultivate / produce / process?

11.2 Product standards, quality, USP and production capacity

In understanding your own company, it could be very helpful to develop a *Unique Selling Proposition*, or USP. Your USP is what differentiates your product or service from your competitors. Your chances in the market greatly increase when you have a USP!

There are two major benefits in developing the USP. First, it clearly differentiates your business in the eyes of your current and potential customers or clients. Second, it focuses your staff on delivering the promise of the USP, thus helping to improve your internal performance.

What a USP could look like:
- One sentence.
- Clearly written, so that anyone can understand it.
- It should be believable.
- Composed of one benefit that is unique solely to your company or product.

How to develop your USP? Sit down with a notebook and:
- ☐ Brainstorm.
- ☐ List all the benefits your company or product can offer.
- ☐ Prioritise those benefits in order of what is the strongest, and most unique to your business.
- ☐ Write one sentence that conveys the first benefit on the list.

☞ Thinking about what happens with your export product, after the importer has received it, can help you bring to new ideas.

Quality

Quality is probably the main competitive factor in every business. It is an absolute requirement for European importers to receive natural ingredients for pharmaceuticals that comply totally with EU regulations. It is therefore obvious that it is also the key issue when looking for suppliers in developing countries.

☞ Products originating in developing countries should be produced hygienically and with care. Microbiological load should be minimised and the negative effect on plants in the course of cultivation, processing and storage should be limited.

Also mentioned in Section 10.1, quality refers not only to product quality, because management quality is just as important. Documentation according to GMP and ISO 9000.2000 is a must, because importers of natural ingredients will have to channel the ingredients into their GMP systems. Notably, documentation reflects costs and addition of value.

Check your current quality standards with the voluntary and compulsory standards described in Section 9.1. Also refer to Chapters 9 and 10 for information on the importance of the various quality standards for your product-market combinations.

Questions an exporter needs to answer:
- What quality standards does your product and production process comply with?
- What is the general level of your product quality compared to other products in the identified market?
- In the case that environmental labelling could significantly improve the competitiveness of your export product, which one is the most interesting for your situation?

Production capacity
The foreign buyer is seldom looking for a 'spot' purchase. Instead, he is looking for a quality product at a fair price with continued availability. If you are merely seeking to market your sporadic surplus capacity, then the entry into the foreign trade market will probably be a disappointment. On the other hand, if the company is willing to devote even 10 percent of its production capacity to foreign markets and the servicing of these accounts, it can reasonably expect to build substantial and permanent trade in those markets suited to its products.

☞ However, keep in mind that often, the volume of the product marketed is not as important as a consistent and reliable supply of the actual product.

Questions that need to be answered:
- How efficiently is the present capacity being used?
- Will new export activity hurt domestic sales?
- Is it possible to expand your production capacity if necessary?
- What will be the cost of setting up additional production capacity?
- What cycles of production apply to your products and how does this match up to the demand in the target market?

11.3 Logistics

It is a good idea to use a freight forwarder to arrange transportation services on your behalf. They can simplify the shipping process because they are familiar with import and export regulations. It is important to use a forwarder who is experienced in handling natural ingredients, as well as one that is experienced in the destination country.

Freight forwarders are cost effective to use, because they can negotiate the best rates with airlines. They usually operate on a fee basis paid by the exporter, and these are part of the cost price.

Questions that need to be answered:
- How often are you able to deliver?
- What lot sizes do you generally produce or are you able to produce?
- Are there cold-room facilities at your production base?
- Are you able to maintain a cold chain during the transportation of the products (air-conditioned domestic transport, cold-room facilities at the airport)?
- What are the typical costs of logistics? (Check with freight forwarders)

11.4 Marketing and sales

How do you sell to current export markets? What works in one European market is likely to work in another, subject to refinement based on market intelligence and knowledge about specific trade channel requirements.

What existing contacts does the company have in the target markets - relatives, friends, suppliers, etc? It is an advantage to have some local presence in the target market that can gather information, monitor progress and follow up leads.

A serious export marketing campaign requires substantial management time to execute it properly. Therefore, the company needs to be realistic as to how much time can be devoted to export marketing.

More information on how to make use of your marketing tools to foster your export activities will be described in Chapter 13.

Questions that need to be answered:

- Does your company have people specifically assigned to marketing and sales activities?
- Which persons do you know in the target markets?
- What sales support material is available?

A proper marketing strategy for natural ingredients takes into account current issues in the trade such as Good Agricultural and Collection Practices or Good Manufacturing Practices (providing guidelines for cultivation, harvest, processing, packaging and storage) and CITES regulations on certain protected species.
Since Directive 2001/83/EC has been amended, a special registration (marketing authorisation) applies to herbal medicinal products and, hence, the marketing of these products no longer requires extensive tests.

Although a clear focus on one, i.e. European, market is a very useful marketing strategies developing country exporters should draw up a marketing strategy aiming at markets at national, regional, and international level. In this way, developing country exporters will not be solely dependent on one market sector. Moreover, fluctuations in the international market can be buffered by demand in the national and regional market. In its June 2001 edition, The Natural Foods Merchandiser published the article "Latin America: Emerging Markets For Botanicals, Organics". The article specifically discussed the following countries: Argentina, Brazil, Chile, Costa Rica, Ecuador, Honduras, Mexico and Peru. Moreover, the exhibition organiser Penton launched its first Natural Products Expo Asia in Hong Kong in May 2002. It included 5 concurrent events: Traditional Chinese Medicine Asia, Herbal Asia, Nutraceuticals Asia, Functional Foods Asia and Organics Asia. Target countries included Hong Kong, China, Taiwan, Japan, Korea, Australia, India, Malaysia, Thailand and Indonesia.

11.5 Financing

Export marketing is expensive. If financial resources are limited, then marketing plans will have to be modest. It is not sound to develop five new markets if the company only has the money to develop one.

Financing is often necessary for product and process adaptation to EU standards. Often domestic products cannot be exported unchanged. The extent to which the exporter will modify products sold in export markets is a key policy issue to be addressed by management. If the exporter produces more than one product he should choose one that is nearest to the target market requirements and progress from there.

Sometimes local banking systems in developing countries are insufficient for exporting. It is therefore recommended to use an international bank that is also located in the importing country. Moreover, this will also simplify the payments between you and your business partner. Each country has a list of their local banks with their correspondent banks in other countries or special relationships with financial institutes outside their country. Choosing the right bank can facilitate and speed up money transfers considerable.

For methods and terms of payments please refer to Section 13.4.

Questions that need to be answered:
- What amount of money can be allocated to setting up new export activities?
- What level of export operating costs can be supported?
- How should the initial expenses of export effort be allocated?
- What other new development plans are in the works that may compete with export plans?
- Is outside capital necessary to support efforts?

11.6 Capabilities

Commitment to export

It is important to consider whether or not the company has staff who are able to sell and develop an international business. The company should be able to generate the physical and administrative infrastructure to deal with increased activities related to exporting - not only in dealing with orders but also with processing Customs and shipping documentation. If this type of infrastructure is limited, then it is a weakness in developing sustained export activities.

Questions that should be answered are:

- What kind of commitment is the top-level management willing to contribute to an export effort? How much senior management time should be allocated? How much could be allocated?
- What organisational structure is required to ensure that export sales are adequately serviced? Who will be responsible for the export activities (export department's organisation and staff)?
- What are the management's expectations of the effort?

Export experiences

It is important to learn from past experience. If the company has tried and failed to penetrate an export market previously, this can be analysed to determine where things went wrong.

Questions that should be answered are:

- In which countries has business already been conducted?
- From which countries have inquiries already been received?
- What general and specific lessons have been learned from past export experience?

Language skills

When dealing with European trade partners in the natural ingredients for pharmaceuticals business, English is the most used language. Although most European trade partners will not be native speakers themselves, the vast majority speaks English fluently. In almost all cases, foreign language skills, particularly English, are essential when entering the European market. When dealing with France, knowledge of the French language is a distinct advantage. If you can communicate in Spanish, you have a competitive advantage if you address the Spanish market.

On the few occasions when correspondence and documents in English will not suffice, exporters can usually find sources of translation capabilities for the more popular European languages. Language capability can be advantageous since it facilitates cultural and social relationships.

Questions that should be answered are:

- Which language skills are necessary when dealing with your selected markets?
- Which language capabilities are available within the export company?

12 DECISION MAKING

Answers to the questions mentioned in Chapters 10 and 11 can help an exporter not only to decide whether or not to export but also determine what methods of exporting should be initially used. A SWOT analysis can be used as a tool to analyse the identified opportunities and threats and the company's identified relative strengths and weaknesses.

12.1 SWOT and situation analysis

A SWOT (Strengths, Weaknesses, Opportunities and Threat) analysis is recommended while you are planning your business. The SWOT will help you in structuring your thoughts, analysing your risks and setting-up your strategy. It is one of many good techniques that can help an exporter to build a strong competitive position for his organisation.

Specifically, the SWOT will be of value in helping you to:
a) Build on your strengths
b) Eliminate your weaknesses
c) Exploit opportunities
d) Develop strategies to deal with threats

- Strengths and weaknesses are internal factors over which you have some influence
- Opportunities and threats are external issues that you cannot control (UNCTAD, Businessplan SOFI Manual).

Carrying out an analysis using the SWOT framework helps an exporter to focus his activities into areas where he is strong and where the greatest opportunities lie.

☞ Simple rules for successful SWOT analysis

- Be realistic about the strengths and weaknesses of your organisation.
- Analysis should distinguish between where your organisation is today, and where it could be in the futures.
- Be specific. Avoid grey areas.
- Always analyse in context to your competition i.e. better than or worse than your competition.
- Keep your SWOT short and simple.

Useful sources for SWOT analysis are, for example:

- Organisations such as ITC, UNCTAD and CBI provide (free) information on writing your business plan. Please check their Internet sites for more information: http://www.intracen.org/, http://www.unctad.org/ and http://www.cbi.nl/.
- http://www.quickmba.com/strategy/swot/ and http://www.mindtools.com/ are examples of commercial services offering information on management strategy, decision making etc.

An example of a SWOT analysis for an exporter of natural ingredients for pharmaceuticals in developing country is given in Table 12.1. It should be noted that this matrix should be treated as an example and that it should be adapted to the exporter's own situation.

Table 12.1 Example of a SWOT analysis for exporters of natural ingredients for pharmaceuticals in developing countries

INTERNAL FACTORS	
Strengths	***Weaknesses***
• *Exclusive access to natural resources* • *Low raw material prices* • *Low labour costs* • *Low or zero import duty* • *Long tradition in using ingredients* • *Sustainable supply chain management* • *Established legal framework for GMP* • *Important contribution to the supply of national and regional consumer products*	• *Entrepreneurial capacity* • *Language and communication* • *Certification* • *Lack of marketing knowledge* • *Limited knowledge of properties of medicinal plants beyond traditional knowledge and belief* • *Limited knowledge of intellectual property rights* • *Lack of information on regulations, prices etc* • *Limited access to finance*
EXTERNAL FACTORS	
Opportunities	***Threats***
• *Active Business Support Organisations* • *Markets open to limited natural resources* • *Rural income generation through sustainable sourcing including wild collection, cultivation and forest management* • *UN guidelines for cosmetics and pharmaceuticals are implemented through national and regional laws* • *The same global rules for production and processing on the basis of WHO guidelines* • *Value addition at the origin*	• *Technical trade barriers* • *High investments needed* • *Over-collection* • *Sustainable use of the raw materials (biodiversity)* • *Globally applied guidelines are promoting strong competitive development of national and regional markets regarding export to Europe.*

Within the SWOT figure, a distinction can be made in the SWOT figure between internal factors (strengths and weaknesses) and external factors (opportunities and threats). Nevertheless, factors of sectoral and of company level are both found under the internal factors in this figure. For example, “exclusive access to natural resources” and “active business support organisations” are both internal factors, although the first is at company level and the latter at sectoral level.

Such an analysis should be adapted to your personal circumstances since the factors differ for each exporter in the world. While for one exporter of natural ingredients for pharmaceuticals “language and communication” is a weakness, for another exporter this problem does not exist.

Please note that also within a company a threat or weakness can change into an opportunity or strength. A good example concerning this matter is “technical trade barriers and new regulations imposed by the EU”. The regulations can be a threshold for exporting to the EU. However, when an exporter has adapted the export product to EU standards, he will have access to the EU market. In this way, the factor of technical trade barriers can be seen as an opportunity instead of a threat.

Be aware that success in export is by no means guaranteed by taking into account all the factors mentioned so far. Your environment consists of other critical conditions and success factors, that are often more difficult to influence as an individual company, than changing for example internal factors. Some of the critical conditions such as low level of

organisation in the industry and financing have already been included in the figure above. However, other factors (sector-specific) should also be included in the SWOT analysis are:

- sector policies;
- availability of sector/branch organisations;
- clustering/co-operation within the sector, organisation of supply and production, value chain management (please also refer to Section 10.5);
- know-how and technical assistance;
- foreign trade assistance;
- financing.

☞ Inquiring of local business support organisations or colleague exporters can be a good starting point in being aware of other critical conditions for successful exporting.

12.2 Strategic options and objectives

Through of conducting the external analysis (market audit) and internal analysis (company audit) (Chapters 10 and 11), you will be able to come to a decision whether or not to export.

- ☑ You have identified products suitable for export development. Also, you know what modifications, if any, must be made to adapt them to overseas markets.
- ☑ You know what countries and market segments you are going to target for sales development and/or co-operation agreements.
- ☑ You have identified the best sales channel (direct exporting or co-operation agreements).
- ☑ You know what special challenges pertain to the selected markets (competition, import controls etc.) and what strategies you will use to address them.

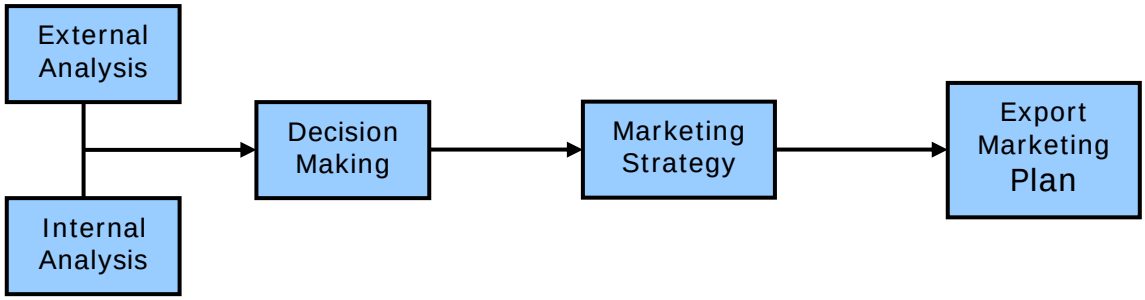
Once a company has determined that it has exportable products, it must still consider whether the development of an export business adheres to the company objectives. In order to arrive at this conclusion the management should ask itself the following questions:

- What does the company want to gain from exporting?
- Is the goal of exporting consistent with other company goals?
- Are the benefits worth the costs or would company resources be better spent developing new domestic business?

☞ **Advantages and disadvantages of exporting**	
Advantages:	**Disadvantages**
• Enhance domestic competitiveness • Increase sales and profits • Gain global market share • Reduce dependence on existing markets • Exploit corporate technology and know-how • Extend the sales potential of existing products • Stabilise seasonal market fluctuations • Enhance potential for corporate expansion • Sell excess production capacity • Gain information on foreign competition	• Develop new promotional material • Subordinate short-term profits to long-term gains • Incur added administrative costs • Allocate personnel for travel • Wait longer for payments • Modify your product or packaging • Apply for additional financing • Obtain special export licenses

Companies can waste a lot of time and money attempting to enter markets which do not have potential or for which their product is not suitable. To be successful in export marketing, exporters need to

focus on specific products and markets and be prepared to deal with all foreseeable situations. Therefore, several possible strategies have to be considered.



The above figure could be summarised in the following strategic steps:

- External analysis (market audit, Chapter 10) and internal analysis (company audit, Chapter 11)
- SWOT (Chapter 12)
- Decision making & formulation objectives (Chapter 12)
- Elements which can be used as inputs for the Market Entry Strategy and Export Marketing Plan (Chapter 13).

If you have come to the decision to export, the next phase of the export marketing process is to draw up an Export Marketing Plan (EMP) which defines a marketing strategy stating how the company is going to penetrate the identified market. The marketing strategy is designed around the information collected in the internal and external analysis and the marketing tools will be described in the following chapter.

☞ **An international business plan should define your company's:**

- readiness to export
- export pricing strategy
- reason for exporting
- potential export markets and customers
- methods of foreign market entry
- exporting costs and projected revenues
- export financing alternatives
- legal requirements
- transportation method
- overseas partnership and foreign investment capabilities
- corporate commitment to the exporting process

Formulating an export marketing strategy based upon sound information and its proper assessment increases the chances that the best options will be selected, resources will be utilised effectively, and efforts will consequently be carried through to completion.

For assistance in writing an EMP and formulate answer on the questions asked in this chapter, please refer to the CBI's "*Export Planner*".

13 EXPORT MARKETING

Which marketing tools are available to you to help build up your export business? This Chapter will provide you with insights and give tips on how to make use of your marketing tools to promote the sales of your products and to build a favourable trade relationship.

13.1 Matching products and the product range

In the company audit (see Section 11.1), the exporter reviewed the company's product range and product characteristics. The aim of this review was to enable the exporter to match market opportunities with the company's products on offer. This review can also be used as a starting point for considering opportunities for improving the exporter's product range.

In most cases, exporters will find out that the current product range does not match the demand of the identified market segments and sales channels. The cause of this mismatch can, for example, lie in the fact that currently produced varieties are outdated.

In the case of exporters who are looking for varieties to improve their product range, a couple of possible sources exist:
- ⓘ **Trade magazines**
- ⓘ Visiting **trade fairs** is also a good way of becoming informed about potentially interesting varieties.
- ⓘ From more **detailed trade statistics** (for instance auction sales), you can often determine which varieties are most popular in the target markets.

Note that one of the most important issues in selecting new varieties is the question whether or not the variety can be successfully produced under your production circumstances.

13.2 Building up a relationship with a suitable trading partner

One of the most ominous obstacles for exporters can be the search to contact, attract and secure a good importer or trade partner. Many avenues are available for locating trade partners. You should employ any and all, which seem appropriate for your product-market combination.

How to find a potential trading partner

The main ways European importers use to look for new suppliers from developing countries are the following:
- Visiting the country in which one intends to set up/expand production capacity;
- Recommendation by someone he knows; and
- International trade fairs.

The best ways for exporters in developing countries to approach potential European customers are:
- Direct mail: You can write a letter (post, fax or e-mail) directly to a European company. Most companies will respond that they are not interested or that they already carry a competitive line. However, only a few positive replies are needed to continue your search and evaluation of prospective distributors.
- Personal visits: Once you have received a number of interested replies, plan a trip to that market. Additionally while travelling, stop in other potential markets to assess the situation as well as attempt to make contacts. Many times a personal visit will pay for itself in terms of the benefits gained.
- Invite EU importers or potential business partners to visit your company;
- Build a network in order to extend your contacts;
- Visit international trade fairs.

Also refer to the recently published CBI manual "*Your Image Builder*".

In the case of natural ingredients for pharmaceuticals, a number of European importers mentioned that a good way to approach the market is by establishing direct contact with them. Note that this should not be organised through trade fairs. Importers are not always positive about trade fairs as an instrument to promote the access of exporters in developing countries. This opinion may be obvious as, at the fair, exporters gain direct contact with European growers, while big importers prefer to maintain in control of the trade.

For European manufacturers, however, importing via large importers may be the most effective way to come in contact with suppliers of natural ingredients for pharmaceuticals. Large importers know the language of the region, they know all about logistics and transport tariffs (by sea and air) and they are familiar with the payment methods. Furthermore, they are constantly in contact with the producers in developing countries and they generally have their own personnel overseas or regular travel to suppliers, in order to guarantee constant quality and to coach local staff wherever necessary.

How to identify the most suitable trade partner?
Evaluate the potential trade partners on which you have obtained information, using the following criteria:

- Is the information complete? (full address, telephone / fax number, e-mail address, contact person)
- Is the importer active in the country you selected?
- What kind of trade relation is the potential trade partner interested in (arm's-length, co-operative agreement, joint-venture)? Does this correspond with your preferred type of relations?
- What is the position of the potential trade partner in the market?
- What is the financial status and credibility of the company?

Using these criteria, draw up a priority list of the contacts you have received.

Going by the priority list, you must identify the trade partners best matching your own company profile, product range and export strategy. Particularly in the case of future long-term close co-operation, it is important to gain a clear picture of the company you are dealing with and understand their business activities.

Cultural differences
The single most common reason for export failure is inattention to cultural factors, a maxim frequently repeated in international business literature. People choose service providers and strategic business partners with whom they feel at ease, and this comfort level is dictated initially by cultural factors. National cultures are numerous, and subcultures are even more so. Increased travel has resulted in a large group of people socialised in more than one culture, and widespread television access gives exposure to different cultural values.

The factors that can affect cross-cultural business include:

- *who speaks first*
- *attitude to God and nature*
- *decision-making time*
- *thought patterns*
- *personal space*
- *social behaviour*
- *material possessions*
- *family relationships*
- *risk avoidance*
- *competitiveness*
- *short- and long-term planning*

For example in Germany, first names are reserved for family members and close friends.

Moreover, in German business culture, it's not uncommon for colleagues who have worked together for years not to know of each other's first names.

☞ It is important to be aware of and deepen yourself in cultural differences between your country of origin and European countries. By the way, even great varieties in cultural behaviour exist between the EU countries themselves!

13.3 Drawing up an offer

There are two different kinds of offers:
1. general offer or company introduction; and
2. specific offers.

(a) Drawing a general offer

- The purpose of a general offer is to make the first contact with potential trading partners who the supplier does not yet know personally.
- A general offer consists of sending a short profile of your own company and a summary of your product range.
- In a personal letter, briefly introduce your company and what you have to offer.

(b) Drawing up a specific offer

A specific offer is legally binding for a certain period of time. You must therefore be capable of fulfilling the terms of your offer. You should make up a specific offer only when you know the business partner personally or after you have made the initial contact.

When sending a specific offer, it should include:

- Name of the person responsible in your company;
- Exact description of the products offered;
- Price of the products offered in accordance with the Incoterms 2000 (if applicable, split up by delivery quantities or quality); and
- Possible delivery date.

In case a sample of the product is required:

- Product samples must correspond to the goods available for delivery (if they do not, this can have a lasting negative effect on business relations).

Other tips:

- It is important to ask (by telephone or e-mail) whether the offer (and the samples, if applicable) has arrived in good shape.
- It is a good idea to invite your customer to visit your company.
- Possibly propose a visit to the country of destination.
- In that case:
  - If necessary, hire an interpreter.
  - Ask your own consulate, trade promotion organisation, or other intermediary for assistance.
- First time exporters should start with small samples, rather than large high-value commercial shipments. An exporter should be testing whether his products meet the legislative requirements of the destination country, transportation routing, airline handling and packing methods.

Price setting

To establish an overseas price natural ingredients for pharmaceuticals, you need to consider many of the same factors involved in pricing for the domestic market. These factors include competition; costs such as production, packaging, transportation and handling, promotion and selling expenses; the demand for your product or service and the maximum price which the market is willing to pay.

In most cases, an exporter will have to follow market prices. However, in case of some products, like novelty products, you will be able to set your own export price. There are two common methods of calculating your price for exports:

- Domestic Pricing is a common but not necessarily accurate method of calculating prices for exports. This type of pricing uses the domestic price of the product as a base and adds export costs, including packaging, shipping and insurance. Because the domestic price already includes an allocation of domestic marketing costs, prices determined using this method might be too high to be competitive.
- Incremental Cost Pricing determines a basic unit cost that takes into account the costs of producing and selling products for export, and then adds a mark-up to arrive at the desired profit margin. To determine a price using this method, first, establish the "export base cost" by stripping profit mark-up and the cost of domestic selling. In addition to the base cost, include genuine export expenses (export overheads, special packing, shipping, port charges, insurance, overseas commissions, and allowance for sales promotion and advertising) and the unit price necessary to yield the desired profit margin.

How you price your product is worth a good deal of thought and effort since it directly affects your ability to make a profit. Take some time to research the following management questions:

Questions to ask when setting your price

How much does it cost to grow your product?

→ Production costs not only include costs for cultivating/collection, but also for packaging, distribution and promoting your products.
→ The costs of unsold products also should be included.

What are your profit goals?

→ A profit goal states how much a business should earn.
→ You can set the profit goal as a percentage (margin) above the product costs or set the total profit figure for the entire business.
→ A profit goal can guide decisions on the amount of produce you will grow and the price you will charge.

How will you market your product?

→ Are you producing natural ingredients for pharmaceuticals on a contract basis for a European manufacturer?
→ Do you sell your products on an arms-length basis to customers in Europe?

What price do competitors charge?

→ Try to gain an industry focus on your pricing by researching your competitor's price levels.
→ By walking through the steps indicated in Section 10.2 you will know the prices competitors charge and why they charge what they do. Use the competitive analysis to develop the upper limit of your price range. Be sure you compare your products to competitors.
→ If competition is intense, you should price at the lower end of the price range unless you can distinguish your product through quality or a unique selling feature.

What is the customer demand for my product?

→ How unique is your product (or production location in the case you offer propagation capacity)?
→ To price according to demand you have to know more about the size and nature of your customer base and their feelings about pricing.
→ You will need to keep an eye on general market trends, particularly if your product range has many substitutions. See also Chapter 3.

Understanding how to price your product is an essential step in developing your business. You must continually monitor your price including your costs of production, your competition and your customers and be prepared to make adjustments.

Below you find an overview of the way you can calculate the price of your export product (for information on Incoterms refer to the Internet site http://www.iccwbo.org/incoterms/preambles.asp).

Export price calculation
Total costs per unit
+ Profit
+ Commissions
+ Domestic banking fees
+ Palletisation / export packing
+ Freight forwarding and documentation fees
+ Other direct expenses related to special shipping requirements such as temperature recorder charges
= EXW price (Ex Works)
+ Inland transportation
= FAS price (Free Alongside Ship)
+ Terminal handling charges
= FOB price (Free On Board)
+ Ocean freight charges
+ Ancillary charges
= CFR price (Cost & Freight)
+ Insurance
= CIF price (Cost, Insurance, Freight)

13.4 Handling the contract

When handling the contract, you should consider the terms and the fulfilment:

Contract terms

Terms of payment

There are various methods of receiving payment for your exports. The most commonly used terms in the natural ingredients for pharmaceuticals are documents against payments (D/P) and payments in advance.

- **Documents against payments**
  Also known as cash against documents (CAD). The buyer takes possession of the goods only after payment. Although this method is not very popular, it is very safe and the costs amount to one pro mille. One can also make use of a 'documents against acceptance of a bill of exchange'. However, the bill of exchange is not commonly used in the European Union and it does not guarantee that the bill will be paid; it is less secure than the D/P.
- **Payment in advance**
  This method is the most desirable from the seller's standpoint, because all risk is eliminated. While cash in advance may seem most advantageous to you, insisting on these terms may cost you sales. Just like domestic buyers, foreign buyers prefer greater security and better cash utilisation. Some buyers may also find this requirement insulting, especially if they are considered credit worthy in the eyes of the rest of the world. Advance (partial) payments and progressive payments may be more acceptable to a buyer, but even these terms can result in a loss of sales in a highly competitive market.

Most export shipments are partly pre-paid before the natural ingredients are shipped. Because collections from customers are more difficult overseas, it is recommended to get

a minimum of 50 percent in advance. Once on-going business and trust is established, exporters should grant their foreign customers standard payment terms. Because of the possible complications and costs, letters of credit are often avoided in the ingredient trade.

In the case of co-operation agreements with overseas companies, payment terms could also include periodical payments.

Terms of sale
Export terms of sale determine what costs are covered in the price of the cargo. They also indicate at what point ownership transfers to the buyer and at what point responsibility for the cargo is transferred. International commercial terms (Incoterms) provide "the international rules for the interpretation of trade terms."

The most commonly used trade term is:
- **FOB (Free on Board)**
  Under this term, the seller quotes a price for goods that includes the cost of loading at the port of departure. The buyer arranges for transportation and insurance.

Other trade terms less frequently encountered are:
- **CFR (Cost and Freight)**
  For shipments to designated overseas port of import, the seller quotes a price for the goods that includes the cost of transportation to the named point of debarkation. The buyer is responsible for the cost of insurance. This is referred to as C&F in the old Incoterms. The seller pays for the cost of unloading cargo at the port of destination, to the extent that they are included in the freight charges. If the charges are separate, they fall to the account of the buyer.
- **CIF (Cost, Insurance, Freight)**
  Under this term, for shipments to designated overseas port of import, the seller quotes a price for the goods, including insurance costs and all transportation and miscellaneous charges, to the point of debarkation from the vessel or aircraft. The seller pays for the cost of unloading cargo at the port of destination, to the extent that they are included in the freight charges. If the charges are separate, they fall to the account of the buyer.

Contract fulfilment
It is important that an exporter discusses the 'what ifs' with his trade partner: what if there is a problem with inspection, what if a claim is necessary because the airline mishandles the natural ingredients, and what if your customer has a problem with product quality after arrival.

Important issues are:
- ❑ Procure the delivery documents in good time.
- ❑ If there is a supply agreement, comply strictly with all parts. If you cannot comply with any part of the agreement (e.g. delivery delays or quality problems), inform the customer clearly and in good time.
- ❑ Co-operate on a partnership basis and seek a common solution even if conflicts arise.
- ❑ Fulfilling the contract should have a high priority, particularly when delivering for the first time.

Other more practical questions that should be asked are:
- When is the shipment needed?
- Does the customer have a preferred freight carrier?
- Which airport (or ocean port) is most convenient?
- Does he have an agent to clear the shipment through Customs?
- Does the customer want to pay for the shipment to be insured?

13.5 Sales promotion

One of the major critical success factors for exporters of natural ingredients for pharmaceuticals to the European Union is attention to customer requirements and the ability to maintain good relationships with their European business partners. Sales promotion revolves around developing and expanding these customer relations and thereby maintaining and increasing sales volume.

Some tips for developing customer relations:

- Take good care of existing contacts. This includes for example expressions of thanks to business partners, regular information on the company developments like product range, quality improvements, etc.
- Always reply to a letter of inquiry. If you cannot supply this contact, say so, explaining that you will get in touch with him for the next campaign.

Communication

It is advisable to commence with communication measures, which only require a small amount of planning and co-ordinating, such as revising the company's standard printed matter:

- Standardise all printed paper used outside the company (letterheads, visiting cards, fax form, etc.)
- A brochure of your company (including photos of production sites and produce) can be useful for promoting new contacts and sales.

Constant, prompt and reliable communication is a vital prerequisite for maintaining a long-term business relationship with your customers. If possible, smaller firms should also try to be reachable by (mobile) phone at office hours.

Sales organisation

The term “sales organisation” refers to the organisational system that carries out the sales of the company's products. A sales organisation usually consists of back office and sales force.

As most sales are conducted by telephone, fax or e-mail, having well-functioning sales staff is an absolute precondition for successful market participation. This also applies to smaller company where one person has to take up different (sales) functions.

An essential tool used in sales is a detailed and up-to-date customer database. This database can vary from a simple collection of customer data sheets to an advanced customer relation management system. However, the customer database should at least contain the following information:

- Basic information on the customer: name, address, telephone numbers, etc.
- Changing data on the customer: data resulting from business activities with the customer, such as telephone calls, offers, sales information, etc.

The customer database should give the sales person a quick review of the most important customer information when making or answering a telephone call or planning a visit.

If possible, the database should be computerised, because this simplifies changes, updating, sorting and selection procedures, etc. If computerisation is not possible, the customer database should be on file cards (see example).

Example customer data sheet		
General information		
Company name: Postal address: Street address Country: Telephone: Fax: E-mail: Contact name:	Customer no.: First contact date: _ _ / _ _ / _ _ _ _ Customer class*: □ A □ B □ C □ D Customer type: *(manufacturer, importer, agent)* Other info:	
Sales information		
Sales realised: *(last year)* Sales planned: *(this year)* etc..		
Contact record		
No. 1	Contact date: _ _ / _ _ / _ _ Contact type: *(telephone, visit, fax, etc.)* Information:	
No. 2	Contact date: _ _ / _ _ / _ _ Contact type: *(telephone, visit, fax, etc.)* Information:	
No. 3	Contact date: _ _ / _ _ / _ _ Contact type: *(telephone, visit, fax, etc.)* Information:	

** Classify your customers by importance to your company (sales, quality of relation, etc.)*

Internet

As a source of information and means of communication, Internet is generally considered to have many opportunities for companies in developing countries. The main advantages of the Internet are:

- Low cost of communication;
- Fast delivery of information;
- Independence of distance and timeline;
- Multimedia possibilities.

Besides one-to-one communication through the use of E-mail, Internet offers opportunities for presentations, (market) research, distribution, sales and logistical improvements. If your target group consists of importers/growers in overseas countries, you can advertise for (new) customers on your Internet site, showing your company, product range and indicating the production circumstances.

☞ Exporters should realise that the Internet is an important medium in sourcing of raw materials for herbal products. A number of users/traders of natural ingredients mentioned that they use the Internet in order to find new suppliers.

☞ *CBI provides the manual "Website promotion". For more information please contact CBI through e-mail: mailto:cbi@cbi.nl.*

Trade fairs

We have stated earlier in this survey that, in the case of ingredients for pharmaceuticals, European importers are not in favour of trade fairs as a means to promote suppliers from developing countries.

However, visiting or even participating in a trade fair abroad can be an efficient tool for communicating with prospective customers. It provides more facilities for bringing across the message than any other trade promotional tool. It can also be an important source of information on market developments, production techniques and interesting varieties.

Important motives for companies visiting European trade fairs are:

- Establishing contacts with potential customers;
- Orientation on the European market;
- Gathering information on specific subjects;

Although significant costs are involved, actually participating in a trade fair could be interesting for a number of companies to meet, for example, European companies interested in setting up natural ingredients production facilities in tropical regions. One of the major advantages of participating yourself in a trade fair is the ability to present your company and products in a more extensive way (3-D presentation, company video, and product displays).

Trade fairs are organised in many European Union countries. The most relevant fairs for exporters of natural ingredients are listed in the box below. The contact addresses of these and other trade fairs are listed in Appendix 2.3.

Main European trade fairs 2004-2005				
Trade fair	**Where?**	**When?**	**What?**	**Internet**
SANA	Bologna, Italy	September 9 -12, 2004	Natural nutrition, health, and the environment.	http://www.sana.it/
Health Ingredients Europe	Amsterdam, The Netherlands	November 16 - 18, 2004	Ingredients for health, functional and organic foods.	http://www.hi-events.com/
CphI Worldwide & CSE 2004	Brussels, Belgium	December 7-9, 2004	Pharmaceutical ingredients and intermediates.	http://www.icsexpo.com/
BioFach	Nürnberg, Germany	February 24-27, 2005	Organic Trade Show.	http://www.biofach.de/
PCI Europe 2005	Paris, France	April 12 - 14, 2005	Personal Care Ingredients trade fair	http://www.pcie.info
In-Cosmetics 2005	Berlin, Germany	April 12 - 14, 2005	Trade fair for suppliers of raw materials/ ingredients for cosmetics, toiletries and personal care.	http://www.in-cosmetics.com/2005

VItafoods	Geneva, Switzerland	May 10-12, 2005	Technology + marketing of ingredients, dietary & herbal supplements and foods for vitality.	http://www.vitafoods.eu.com/
Natural Products Expo Europe	Amsterdam, The Netherlands	June 15-16, 2005	Natural products, including raw materials.	http://www.expoeurope.com/
Food Ingredients Europe	Paris, France	November 29 - December 1, 2005	Food ingredients and semi-finished food products.	http://europe2005.fi-events.com/

For other meetings and trade shows please refer also to the MNS (Market News Service) Medicinal Plants and Extracts of ITC.

☞ For additional information on trade fair participation, please refer to CBI's *Handbook "Your show master - a guide for selection, preparation and participation in trade fairs*".

Assistance with market entry

Local business support organisations

Before approaching organisations abroad, an exporter should first check with local business support organisations (trade promotion organisations, Chambers of Commerce, etc.) and foreign representatives in his or her country.

Import Promotion Organisations

In most EU countries, there are organisations that promote imports from developing countries through specific export promotion activities:

- They supply information on: statistics and other information on national markets, regular news bulletins, importer databases, and market opportunities;
- Individual assistance is offered: management training, testing products by display and adaptation services; and
- They can establish contacts: collective trade fair participation and selling missions.

☞ CBI export development programmes (EDP)

On the basis of the results achieved in previous programmes and on the basis of expected market opportunities, CBI has initiated a new export promotion programme for companies that manufacture or produce natural ingredients for pharmaceuticals and/or cosmetics. Only companies in a number of selected countries in Latin America, Asia and Africa are eligible for participation.

A step-by-step approach provides intensive support for selected exporters in developing countries, so that they can secure a firm footing on the EU market. Programmes are made to measure, demand-driven and flexible, combined with fixed elements such as:

- pre-selection of candidates based on kick-off workshops;
- technical assistance during company visits and distance guidance by CBI branch experts;
- export marketing training (for instance through the EXPRO seminars);
- market entry (for instance via participation in European trade fairs);
- market consolidation by way of follow-up support, further technical assistance and/or repeat market entry activities.

To date, CBI has organised kick-off workshops in Colombia, Ecuador, Bolivia, Indonesia

and Sri Lanka for representatives from companies and institutions involved in the conservation, development, certification and export promotion of natural ingredients for pharmaceuticals and/or cosmetics. April 2003, a number of EDP participants took part in the trade fair In-Cosmetics in Paris (for more information please contact mailto: pgilst@cbi.nl).

Development organisations increasingly promote the cultivation of local and indigenous medicinal plants, as the return is higher than for traditional crops. In Europe, there are also activities in terms policy towards traditional medicine. The European Commission, for example, is working on a possible directive on traditional medicinal products. For more information please refer to: http://www.mca.gov.uk/.

Branch organisations

As is probably the case in your own country, in most European countries, producers, wholesalers and often retailers are also organised in so-called branch organisations. These organisations can be of use to new exporters to the EU.

Information how to reach these organisations can be found in Appendix 2.5.

APPENDIX 1 DETAILED IMPORT/EXPORT STATISTICS

The source of the data presented below is Eurostat COMEXT 2003.

IMPORTS

Table 1 EU imports of medicinal & aromatic plants, by supplying country, 2000-2002, € thousand / tonnes

	2000		2001		2002	
	value	volume	value	volume	value	volume
Total	338,808	116,964	330,426	124,783	318,271	116,920
Intra EU	120,948	25,720	112,091	34,401	105,275	27,111
Extra EU	217,860	91,245	218,335	90,381	212,995	89,810
Developing countries	132,298	63,904	135,411	65,285	127,519	60,231
USA	32,498	4,884	32,948	4,308	32,031	5,475
Germany	36,786	8,450	32,791	16,841	31,767	9,095
France	26,779	5,343	26,380	4,850	25,452	7,461
China	24,330	6,570	21,635	6,120	20,768	6,914
India	16,212	6,962	17,272	6,493	16,201	6,796
Israel	10,625	1,414	14,484	1,826	15,602	2,042
Poland	10,718	6,657	8,567	6,158	12,917	8,744
Morocco	10,107	7,451	10,952	7,726	11,691	7,044
Belgium	13,970	1,890	11,341	1,851	11,020	1,608
Bulgaria	13,163	8,406	10,281	7,678	9,705	8,466
Spain	8,764	1,979	10,595	2,981	8,772	2,571
The Netherlands	6,684	1,513	8,773	2,674	8,439	1,387
Egypt	11,170	6,470	8,151	4,889	8,432	5,708
Italy	6,761	1,733	8,422	1,764	7,634	1,482
Kenya	1,241	580	7,644	777	7,413	592
Turkey	7,897	4,197	7,810	4,676	6,915	4,697
South Africa	2,404	1,142	5,215	2,027	5,969	2,041
Chile	8,224	3,102	7,352	3,200	5,441	2,733
Brazil	5,507	1,041	4,341	858	4,639	948
Austria	5,731	2,538	3,802	1,940	4,313	2,109
Hungary	4,275	2,567	4,535	2,266	4,291	2,012
Albania	5,577	3,403	4,217	2,800	4,150	2,594

Table 2 EU imports of medicinal & vegetable saps & extracts, by supplying country, 2000-2002, € thousand / tonnes

	2000		2001		2002	
	value	volume	value	volume	value	volume
Total	127,155	2,558	115,470	3,075	106,094	2,866
Intra EU	93,049	1,841	85,843	2,119	76,759	2,034
Extra EU	34,106	717	29,627	957	29,335	833
Developing countries	6,537	226	6,247	263	4,817	322
Italy	21,123	242	19,857	326	22,760	403
France	25,495	607	18,928	523	20,637	447
Switzerland	15,446	265	14,294	204	12,604	114

Ireland	24,233	55	21,599	213	11,904	298
Spain	9,509	423	10,009	651	9,689	514
Germany	8,555	294	9,973	254	7,183	226
Australia	2,582	5	2,569	9	5,237	24
USA	4,726	72	3,991	354	3,049	233
China	1,681	121	2,013	98	2,153	113
The Netherlands	1,769	81	2,569	55	1,804	40
Madagascar	2,037	25	2,225	37	1,344	15
United Kingdom	243	34	494	29	810	42
New Zealand	1	0	19	1	719	9
Denmark	87	4	1,450	26	666	19
Czech Rep.	198	12	223	18	654	19
Sweden	806	7	322	2	653	16
Poland	555	40	1,017	64	593	60
India	156	12	423	20	541	26
Slovenia	675	2	15	1	416	1
Belgium	770	49	346	20	366	26

Table 3 EU imports of vegetable alkaloids, by supplying country, 2000-2002, € thousand / tonnes

	2000		2001		2002	
	value	volume	value	volume	value	volume
Total	531,978	10,780	548,376	9,636	513,878	8,750
Intra EU	265,072	8,195	291,962	7,415	202,510	5,999
Extra EU	266,906	2,585	256,413	2,221	311,368	2,751
Developing countries	71,409	2,059	32,914	1,725	33,151	2,021
Switzerland	87,237	124	99,285	115	86,227	170
Japan	45,810	121	51,695	115	75,378	155
Germany	118,463	2,789	99,680	3,849	69,926	2,856
Australia	34,061	82	40,889	86	46,675	98
USA	14,189	109	10,556	73	37,549	150
France	32,583	1,399	21,936	1,178	36,821	1,386
United Kingdom	32,856	799	92,143	1,063	22,516	721
Italy	18,790	416	19,938	692	18,470	614
The Netherlands	16,214	2,208	23,978	178	15,741	107
Austria	7,648	14	7,632	32	14,241	23
China	12,186	1,324	11,089	1,413	11,780	1,701
Spain	4,548	109	8,158	225	10,703	199
New Zealand	3	0	0	0	9,317	1
India	3,990	113	6,726	120	9,088	178
Hungary	2,998	5	7,922	16	8,930	43
Czech Rep.	3,911	4	6,142	7	7,106	6
Indonesia	4,441	95	5,056	96	5,914	99
Sweden	3,907	13	4,824	67	5,646	21
Ireland	12,695	351	7,091	45	3,978	12
Belgium	16,332	46	5,152	41	3,607	37
Brazil	11,070	6	3,559	2	3,447	22
Slovakia	3,076	35	2,692	50	2,325	52

Table 4 **EU imports of medicinal & aromatic plants, by importing country, 2000-2002, € thousand / tonnes**

	2000		2001		2002	
	value	volume	value	volume	value	volume
Total	338,808	116,964	330,426	124,783	318,271	116,920
Germany	97,393	44,527	84,168	39,022	81,631	42,155
France	56,890	23,643	60,075	26,821	55,004	23,450
Italy	49,064	12,819	45,342	12,964	45,336	12,872
United Kingdom	39,746	8,575	38,483	7,045	37,530	7,751
Spain	27,384	11,506	25,369	11,585	26,230	11,527
The Netherlands	1,681	871	20,993	4,462	21,802	4,291
Belgium	21,483	5,361	23,444	5,776	21,756	6,899
Austria	6,351	1,785	8,372	2,277	7,943	2,229
Ireland	12,100	3,109	10,607	2,963	6,321	1,901
Sweden	3,646	457	3,273	443	3,812	435
Denmark	15,738	2,030	3,872	740	3,809	691
Portugal	2,439	558	2,435	486	2,643	396
Luxembourg	1,756	105	1,244	73	2,031	113
Greece	2,251	1,295	1,893	9,702	1,452	1,563
Finland	887	325	857	424	969	649

Table 5 **EU imports of medicinal & vegetable saps & extracts, by importing country, 2000-2002, € thousand / tonnes**

	2000		2001		2002	
	value	volume	value	volume	value	volume
Total	127,155	2,558	115,470	3,075	106,094	2,866
Germany	51,087	927	43,185	1,188	35,220	1,202
Italy	26,188	584	20,091	488	20,930	296
France	18,806	395	18,388	424	18,057	427
Spain	11,199	175	8,786	105	10,236	137
The Netherlands	5,121	125	4,560	79	7,911	183
Belgium	2,013	75	2,345	120	2,870	155
Denmark	4,625	41	5,723	41	2,717	32
United Kingdom	3,087	121	4,479	463	2,202	229
Austria	1,263	36	1,558	38	1,889	47
Sweden	1,088	45	1,671	56	1,716	88
Portugal	2,169	17	2,803	14	1,283	22
Finland	329	10	1,715	37	918	23
Greece	165	5	115	21	98	24
Ireland	16	1	45	3	42	3
Luxembourg	0	0	5	0	5	1

Table 6 **EU imports of vegetable alkaloids, by importing country, 2000-2002, € thousand / tonnes**

	2000		2001		2002	
	value	volume	value	volume	value	volume
Total	531,978	10,780	548,376	9,636	513,878	8,750

United Kingdom	153,746	475	125,917	778	179,027	835
Spain	45,088	1,089	68,663	1,207	63,309	403
Germany	61,327	745	66,448	975	60,228	963
France	72,447	731	57,235	673	45,586	614
Italy	64,619	1,638	56,857	1,299	44,631	1,442
Ireland	31,321	1,963	43,255	3,065	44,226	3,326
Belgium	27,923	2,669	27,941	163	33,698	197
The Netherlands	47,360	942	72,972	977	13,565	363
Denmark	6,794	149	7,698	130	9,334	137
Austria	7,105	216	6,952	200	6,370	232
Sweden	3,627	61	4,163	47	4,904	46
Portugal	3,788	66	4,941	102	3,898	166
Greece	5,449	19	3,702	9	3,821	13
Finland	1,286	14	1,595	11	953	12
Luxembourg	98	2	38	1	328	3

EXPORTS

Table 7 EU exports of medicinal & aromatic plants, by exporting country, 2000-2002, € thousand / tonnes

	2000		2001		2002	
	value	volume	value	volume	value	volume
Total	202,032	43,218	194,768	41,644	189,197	44,862
Intra-EU	128,093	29,611	128,185	28,083	123,685	29,865
Extra-EU	73,939	13,607	66,583	13,561	65,512	14,997
Germany	62,022	14,607	59,253	13,654	60,339	14,197
France	58,770	10,257	51,207	8,140	46,991	10,676
Spain	19,172	5,820	20,693	7,914	20,098	7,434
Belgium	13,184	1,882	17,055	2,470	15,589	2,087
Italy	16,055	3,710	15,799	3,586	14,939	3,135
United Kingdom	6,410	579	5,993	487	7,104	1,299
The Netherlands	3,738	1,117	4,724	1,597	6,599	1,617
Austria	9,622	3,937	5,004	2,410	5,100	2,623
Ireland	6,239	629	8,501	738	4,640	616
Sweden	4,506	44	3,194	27	3,485	48
Greece	1,343	439	2,331	467	2,045	395
Portugal	251	98	375	98	911	648
Luxembourg	282	11	257	21	886	35
Denmark	425	87	374	35	463	54
Finland	13	0	9	0	9	0

Table 8 EU exports of medicinal & vegetable saps & extracts, by exporting country, 2000-2002, € thousand / tonnes

	2000		2001		2002	
	value	volume	value	volume	value	volume
Total	186,583	5,012	189,224	4,288	178,234	2,859
Intra-EU	108,972	3,926	99,823	3,034	97,172	1,585
Extra-EU	77,611	1,086	89,402	1,253	81,062	1,274
Italy	59,279	712	52,796	687	53,096	676

Germany	41,920	879	46,017	806	45,165	692
Ireland	50,341	978	39,034	92	37,490	90
France	25,259	393	25,321	456	29,222	499
Spain	3,068	192	6,455	442	7,168	470
Belgium	1,348	49	1,898	68	2,122	98
The Netherlands	2,223	113	13,910	420	2,116	223
United Kingdom	451	57	910	146	808	72
Finland	49	3	222	17	503	27
Sweden	55	1	835	10	260	1
Denmark	227	2	190	1	193	7
Austria	2,313	1,628	1,628	1,141	88	5
Portugal	50	5	7	1	3	0
Greece	0	0	1	0	0	0
Luxembourg	0	0	0	0	0	0

Table 9 EU exports of vegetable alkaloids, by exporting country, 2000-2002, € thousand / tonnes

	2000		2001		2002	
	value	volume	value	volume	value	volume
Total	551,669	11,586	618,320	12,100	559,448	11,896
Intra-EU	207,377	4,044	266,064	5,168	211,193	4,119
Extra-EU	344,293	7,542	352,256	6,932	348,255	7,777
Germany	298,545	8,564	311,994	8,275	280,988	8,762
Italy	74,456	833	71,341	924	63,893	957
Belgium	26,688	70	71,819	78	58,978	37
United Kingdom	56,025	197	69,149	266	43,726	133
Spain	30,938	1,048	30,983	996	35,254	990
France	30,808	248	16,378	391	28,279	549
Ireland	5,954	58	5,646	27	19,030	112
The Netherlands	19,131	328	25,347	818	17,384	170
Sweden	1,175	6	4,564	16	5,561	26
Austria	4,659	30	7,452	28	4,095	51
Denmark	3,046	111	2,615	115	1,828	101
Portugal	146	1	336	4	389	2
Finland	96	93	683	162	43	6
Greece	0	0	13	1	0	0
Luxembourg	0	0	0	0	0	0

APPENDIX 2 USEFUL ADDRESSES

2.1 Standards organisations

INTERNATIONAL
The World Health Organization
E-mail: mailto:info@who.int
Internet: http://www.who.org/

EUROPEAN UNION
European Medicines Agency (for the Evaluation of Medicinal Products) **(EMEA)**
E-mail: mailto:mail@emea.eu.int
Internet: http://www.emea.eu.int/

Comité Européen de Normalisation (CEN)
European Committee of Standardization
E-mail: mailto:infodesk@cenorm.be
Internet: http://www.cenorm.be/

FRANCE
Association Française de Normalisation
E-mail: mailto:communication@afnor.fr
Internet: http://www.afnor.fr/

GERMANY
Deutsches Institut für Normung eV (DIN)
E-mail: mailto:zentrale@dincertco.de
Internet: http://www.din.de/
ITALY
Ente Nazionale Italiano di Unificazione (UNI)
E-mail: mailto:uni@uni.com
Internet: http://www.uni.com/it

THE NETHERLANDS
Nederlands Normalisatie Instituut (NEN)
E-mail: mailto:info@nen.nl
Internet: http://www.nen.nl/

SPAIN
Asociación Española de Normalización y Certificación (AENOR)
E-mail: mailto:info@aenor.es
Internet: http://www.aenor.es/

UNITED KINGDOM
British Standards Institution (BSI)
E-mail: mailto:cservices@bsi-global.com
Internet: http://www.bsi-global.com/

2.2 Sources of price information

INTERNATIONAL
FAO (Food and Agriculture Organisation)
Publisher of *'Monthly Bulletin of Statistics'*, *'Commodity and Market Review'*, and *'Food Outlook'*
E-mail: mailto:FAO-HQ@fao.org
Internet: http://www.fao.org/
International Trade Centre (ITC)
MNS Medicinal Plants & Extracts

E-mail: mailto:mns@intracen.org
Internet: http://www.intracen.org/

UNITED KINGDOM
Agra Europe Ltd.
Publisher of '*The Public Ledger*'
E-mail: mailto:marketing@public-ledger.com
Internet: http://www.public-ledger.com/

INTERNET
Herb crop shop
(at Herb Growing and Marketing Network)
http://www.herbworld.com/cropshop

Sites for retail prices for herbal materials include:
- http://www.herbmarket.com/
- http://www.libertynatural.com/

2.3 Trade associations

AESGP Association of the European Self-Medication Industry
(Here, also a list of national self-medication associations can be found.)
E-mail: mailto:info@aesgp.be
Internet: http://www.aesgp.be/

European Federation of Pharmaceucial Industries and Associations
E-mail: mailto:info@efpia.org
Internet: http://www.efpia.org/

The European Pharmaceutical Wholesaler Association (GIRP)
E-mail: mailto:euro.keys@euro-keys.com
Internet: http://www.girp.org/ or http://www.euro-keys.com/
(A source of useful addresses is the Internet site: http://www.girp.org/)

European Scientific Cooperative On Phytotherapy (ESCOP)
E-mail: mailto:secretariat@escop.com
Internet: http://www.escop.com/

The Association of European Producers of Medicinal and Aromatic Plants (EUROPAM)
E-mail: mailto:ottens.bart@hetnet.nl
Internet: http://www.europam.net/

2.4 Trade fair organisers

➢ Please refer also to more detailed information on trade fairs provided in Section 13.5

BioFach (certified organic products)
NürnbergMesse GmbH
Frequency: annual (Nuremberg)
Internet: http://www.biofach.de/

CphI
Frequency: annual
E-mail: mailto:jekelschot@cmpinformation.com
Internet: http://www.cphi.com/

Fi

Expoconsult B.V. trading as CMP Information
Frequency: annual
E-mail: mailto:fi@cmpinformation.com
Internet: http://www.fi-events.com/

Health Ingredients Europe
Expoconsult B.V. trading as CMP Information
Frequency: annual
E-mail: mailto:fi@cmpinformation.com
Internet: http://www.hi-events.com/

Natural Products Expo Europe
New Hope Natural Media
Frequency: annual
Internet: http://www.expoeurope.com/

IN-COSMETICS
Reed Exhibitions
Frequency: annual
Internet: http://www.in-cosmetics.com/

SANA
Exhibition of Health Food, Health and Environment
Frequency : biennial
E-mail: mailto:info@sana.it
Internet: http://www.sana.it/

Vitafoods International Ltd.
Frequency: annual
Email: mailto:vitafoods@iirx.co.uk
Internet: http://www.vitafoods.co.uk/

PCIE
Personal Care Ingredients Europe
E-mail: mailto:pcie@stepex.com
Internet: http://www.stepex.com/

2.5 Trade press

GERMANY
Drogenreport
E-mail: mailto:info@drogenreport.com
Internet: http://www.drogenreport.com/

Pharma Marketing Service
E-mail: mailto:vertrieb@aerztezeitung.de
Internet: http://www.fachzeitung.com/content/detailinfo.php?id_fz=13563&id_verlag=61025060

Zeitschrift für Arznei- und Gewürzpflanzen
E-mail: mailto:order@agrimedia.com
Internet: http://www.agrimedia.com/

ITALY
Agro Food
E-mail: mailto:info@teknoscienze.com
Internet: http://www.teknoscienze.com/

Fitoterapia
Internet: http://www.indena.com/fitoterapia_profile.asp

UNITED KINGDOM

Nutraceuticals International
Telephone: +44 (0)20 7828 7272
Fax: +44 (0)20 7828 0415
E-mail: mailto:editorial@marketletter.com

Review of Aromatic and Medicinal Plants
E-mail: mailto:enquiris@cabi.org
Internet: http://www.cabi-publishing.org/AbstractDatabases.asp?SubjectArea=&PID=51

INTERNATIONAL
Herbalgram American Botanical Council
E-mail: mailto:abc@herbalgram.org
Internet: http://www.herbalgram.org/

Journal of Herbs, Spices & Medicinal Plants
E-mail: mailto:getinfo@haworthpressinc.com
Internet: http://www.haworthpress.com/store/product.asp?sku=J044

Nutrition Business Journal
E-mail: mailto:info@nutritionbusiness.com
Internet: http://www.nutritionbusiness.com/

An interesting source of magazines in the field of medicinal herbs is http://www.herbnet.com/press_p5.htm

2.6 Other useful addresses

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)
E-mail: mailto:cites@unep.ch
Internet: http://www.cites.org/

FI Data Services
Internet: http://www.ingridnet.com/

CBI / Accesguide
(CBI's database on European non-tariff trade barriers
Email: mailto:cbi@accessguide.nl
Internet: http://www.cbi.nl/accessguide

GTZ Deutsche Gesellschaft für Technische Zusammenarbeit GmbH
Internet: http://www.gtz.de/

International Chamber of Commerce
E-mail: mailto:webmster@iccwbo.org
Internet: http://www.iccwbo.org/

Netherlands Association for Phytotherapy
E-mail: mailto:nvf@fyto.nl
Internet: http://www.fyto.nl/

Skal
(Internationally operating organisation, inspecting and certifying sustainable agricultural production methods and products)
E-mail: mailto:info@skal.com
Internet: http://www.skal.nl/

Traffic Europe
(Joint wildlife trade monitoring programme of WWF and IUCN)
E-mail: mailto:traffic@trafficint.org
Internet: http://www.traffic.org/

International Council for Medicinal And Aromatic Plants
E-mail: mailto:info@icmap.org
Internet: http://www.icmap.org/

European Advisory Services (EAS)
Avisory company specialising in European and international food and nutrition policy (incl. herbal supplements).
E-mail: mailto:info@eas.be
Internet: http://www.eas.be/

Earthscan Publication Ltd.
E-mail: mailto:earthinfo@earthscan.co.uk
Internet: http://www.earthscan.co.uk/

APPENDIX 3 LIST OF DEVELOPING COUNTRIES

The list of developing countries as applied in this market survey, is the OECD DAC list of countries receiving Official Development Assistance (Part I). The list used is the one as at 1/1/2004.

Afghanistan
Albania
Algeria
Angola
Anguilla
Antigua and Barbuda
Argentina
Armenia
Azerbaijan
Bahrain
Bangladesh
Barbados
Belize
Benin
Bhutan
Bolivia
Bosnia & Herzegovina
Botswana
Brazil
Burkina Faso
Burundi
Cambodia
Cameroon
Cape Verde
Central African rep.
Chad
Chile
China
Colombia
Comoros
Congo Dem. Rep.
Congo Rep.
Cook Islands
Costa Rica
Côte d'Ivoire
Croatia
Cuba
Djibouti
Dominica
Dominican republic
Ecuador
East Timor
Egypt
El Salvador
Equatorial Guinea
Eritrea
Ethiopia
Fiji
Gabon
Gambia
Georgia
Ghana
Grenada
Guatemala
Guinea
Guinea-Bissau
Guyana
Haiti
Honduras
India
Indonesia
Iran
Iraq
Jamaica
Jordan
Kazakhstan
Kenya
Kiribati
Korea, rep of
Kyrghyz Rep.
Laos
Lebanon
Lesotho
Liberia
Macedonia
Madagascar
Malawi
Malaysia
Maldives
Mali
Marshall Islands
Mauritania
Mauritius
Mayotte
Mexico
Micronesia, Fed. States
Moldova
Mongolia
Montserrat
Morocco
Mozambique
Myanmar
Namibia
Nauru
Nepal
Nicaragua
Niger
Nigeria
Niue
Oman
Pakistan
Palau Islands
Palestinian Admin. Areas
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Rwanda
Samoa
São Tomé & Principe
Saudi Arabia
Senegal
Serbia and Montenegro
Seychelles
Sierra Leone
Solomon Islands
Somalia
South Africa
Sri Lanka
St. Helena
St. Kitts-Nevis
St. Lucia
St. Vincent and Grenadines
Sudan
Surinam
Swaziland
Syria
Tajikistan
Tanzania
Thailand
Togo
Tokelau
Tonga
Trinidad & Tobago
Tunisia
Turkey
Turkmenistan
Turks & Caicos Islands
Tuvalu
Uganda
Uruguay
Uzbekistan
Vanuatu
Venezuela
Vietnam
Wallis & Futuna
Yemen
Zambia
Zimbabwe

APPENDIX 4 USEFUL INTERNET SITES

http://www.cites.org/
CITES has a membership of 163 countries. These countries act by banning commercial international trade in an agreed list (Appendix I) of endangered species (including plants) and by regulating and monitoring trade in others (Appendix II) which might become endangered. Around 200 medicinal plants species have been added to CITES appendices. At this site, one can find an up-to-date overview of the Appendices I and II.

http://www.wisia.de/
WISIA-online helps to identify the protection status of a given plant or animal species. The site presents a general view of the diverse field of species conservation legislation. The Internet site is only available in the German language.

http://dg3.eudra.org/
This site is operated by the European Commission -DG III-E-3 on Pharmaceuticals and Cosmetics. The site includes information on the rules governing pharmaceuticals in the European Union, addresses of those involved in the EU pharmaceutical sectors and documents released for consultation or for information.

http://www.europages.com/
This site includes contact details of companies in the sector Chemicals and Pharmaceuticals. Interesting subcategories include: Herbs for medicines and cosmetics, and Import-export – chemicals and pharmaceuticals.

http://www.naturalfoodsmerchandiser.com/
The Natural Foods Merchandiser's Directory is a resource guide for the natural products industry. You can search our database of thousands of companies and organizations for those that offer you the products or services you need.

http://www.herbalgram.org/
This site contains information about herbal education research, literature (e.g. The Herbal Education Catalog containing some 400 items available with additional titles added on a regular basis), and German Commission E Monographs.

http://www.herbs.org/
A comprehensive site for herb information, featuring the latest scientific, political, business and international news from the world of herbs. You can browse to recommended links, view herbs in the photo gallery, speak out on herbal topics and ask herb questions online. Herb "Greenpapers" highlight specific herbs and their medicinal uses.

http://www.herbnet.com/
The home page of the Herb Growing and Marketing Network. The site includes a herb crop shop, which is a message board where growers and buyers of botanicals can come together (www.herbworld.com/cropshop/).

http://www.escop.com/
The site provides an information resource (e.g. legislative issues and useful contacts) for those involved in the development, manufacture, regulation and surveillance of phytomedicines and herbal drugs.

http://www.fao.org/forestry/fop/fopw/nwfp/nwfp-e.stm
This site is operated by FAO's Forest Products Division and includes information about Non-wood Forest Products (NWFP), a database with organisations active in the field of NWFPs, information about relevant publications and projects. At the site, one can read the Non-wood News, which is an annual newsletter.

http://www.inaro.de/
This site contains information in German and French on raw materials, including Medicinal and aromatic plants. It includes a detailed overview of 'Good Agricultural and Collection Practice of Medicinal and Aromatic Plants' and a marketplace where buyers and sellers of raw material can meet.

http://www.europam.net/
Europam EHGA is the European Herb Growers Association. The Internet site provides the "EHGA Inventory Production of Herbs in the existing and incoming member-states of the EU", a European Seeds Suppliers list and other interesting documents.

http://www.who.int/
The Internet site of the World Health Organisation provides a section on Essential Drugs and Medicines under which WHO documents on Medicinal Plants can be found. For example, GACP and WHO Monographs on Medicinal Plants (http://www.who.int/medicines/library/trm/medicinalplants/medplantsdocs.shtml).

http://wayfinder.cphi.com
At this Internet site of the CPHi trade fair, exhibiting companies can be found according to the products they offer.

http://www.actahort.org/
On this Internet site scientific publications on horticulture of the International Society of Horticultural Science can be found.

APPENDIX 5 REFERENCES

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