Market Brief in the European Union
for selected natural ingredients derived from native species

*Crescentia cujete*
Calabash, Totumo

UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT
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Compiled for:

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by

ProFound
ADVISERS IN DEVELOPMENT

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The BioTrade Initiative is UNCTAD’s programme that supports sustainable development through trade and investment in biological resources in line with the Convention on Biological Diversity. The specific objectives of the BioTrade Initiative are: (i) To assist developing countries in the formulation and implementation of National BioTrade Programmes; (ii) To assist Inter-Governmental Organizations in the formulation and implementation of Regional BioTrade Programmes; (iii) To provide inputs to international policy making processes related to trade and biodiversity; (iv) To carry out technical assistance on issues related to trade and investment related to BioTrade.

The BioTrade Facilitation Programme (BTFP) for biodiversity products and services aims at assisting partners in developing countries on issues related to trade promotion of specific sectors, which have high value-adding potential and can generate local income by involving local and indigenous communities, while contributing to the biodiversity conservation. Priority product groups include edible plant products (e.g. fruits and nuts); food ingredients (e.g. natural colouring and flavouring materials); cosmetic and pharmaceutical ingredients (e.g. medicinal plants, essential, fatty and vegetable oils), fibres, latex, resins, gums and gum by-products.

The BTFP addresses specific developing countries' needs such as market information, market access strategies, development of methodological approaches, best-practices, as well as advocacy and participation in policy making processes (e.g. trade barriers, certifications, sustainable use, etc.). Selected countries from Latin America (the Andean and Amazonian regions), Africa (the eastern and southern regions) and Asia are currently part of the BTFP. The BTFP is an official partnership of the World Summit on Sustainable Development (WSSD), and counts with the financial support of the Governments of Switzerland and the Netherlands. The International Trade Centre (ITC), serves as the Programme's technical advisor. Other current BTPF partners include: BioTrade National programmes, PhytoTrade Africa, Programme Bolsa Amazonia, the Dutch Centre for the Promotion of Imports from Developing Countries (CBI), and the Swiss Import Promotion Programme (SIPPO).

This document is part of a series of market briefs on selected natural ingredients derived from native species in beneficiary countries of the BTFP. It is addressed to corporate executives, partners of the BTFP, officials of international and trade promotion agencies, representatives of nongovernmental organizations and researchers. The market brief seeks to provide balanced information and analysis of trade opportunities. Each study may be read by itself, independently of the others.

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Abstract

The market brief on Crescentia cujete, profiles the EU market for this native South American species and its derivatives, used as natural ingredients in the phyto-pharmaceutical, pharmaceutical and herbal industries. This document was developed within a series of market briefs on selected natural ingredients derived from native species in beneficiary countries of the BTFP.

The underlying market brief, on Crescentia cujete, is divided in eight sections. Sections 1 to 5 profile the EU market for Crescentia cujete. The brief starts with providing a description of the species including, botanical name, common names, trade names, HS codes, countries and regions of origin, methods of cultivation/harvesting, importance to the native biodiversity of the country of origin and traditional use. The major national markets within the EU for these products are highlighted and current trends are described. Furthermore, (statistical) market information on consumption, production and trade, and information on trade structure and opportunities for exporters is provided.

Section 6 describes the requirements, which have to be fulfilled in order to get market access. It is of vital importance that exporters meet the requirements of the EU market in terms of product quality, packaging, labeling and social, health & safety and environmental standards. Section 7 provides indicative prices and price developments for the selected products differentiated by trade channel and value added as well prices of substitutes. It also provides sources of price information.

The final Section, describes marketing and sales promotion strategies as well as recommendations on different levels: supply chain management, promotion strategies and business-to-business opportunities. This chapter was validated through interviews with buyers, consumers, market experts and other relevant actors in the EU market.

Keywords: Crescentia cujete, calabash, totumo, natural ingredients, biodiversity, sustainable use, export, BioTrade Facilitation Programme, trade, market, information
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1 Species description and product definition

<table>
<thead>
<tr>
<th>Family:</th>
<th>Bignonaceae</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genus:</td>
<td>Crescentia</td>
</tr>
<tr>
<td>Species:</td>
<td>cujete L</td>
</tr>
<tr>
<td>Common Names:</td>
<td>Calabash tree, krabasi, kalebas, huingo (totumo in Spanish)</td>
</tr>
<tr>
<td>Parts Used:</td>
<td>Fruits</td>
</tr>
</tbody>
</table>

1.1 Tree

Six wild species of this tree are known. Some of them in Central America and others in the Amazon. In Colombia, the *Crescentia cujete* is present almost all around the country in the departments of Amazonas, Antioquia, Atlántico, Bolívar, Boyacá, Caldas, Casanare, Cauca, Chocó, Cundinamarca, Huila, Guajira, Magdalena, Meta, Nariño, Putumayo, Sucre, Tolima, San Andrés and Providencia and Valle del Cauca, in altitudes within 0 to 2,000 m over the sea level.

*Crescentia cujete* is an evergreen tree reaching 6 to 10 m in height with a broad, irregular crown composed of long, spreading branches clothed in 5 to 15 cm long bright green leaves, which create moderate shade beneath the tree. The tree is most outstanding in the landscape for its year-round production of flowers and fruit, both of which are unusual. The 5 cm wide flowers, which bloom at night, are yellow/green with red or purple veins, cup-shaped, and appear to emerge directly from the branches. These are followed by the emergence of the large, round fruit, 12 cm to 30 cm in diameter, with a smooth, hard shell, which hang directly beneath the branches. The fruits develop after pollination by bats and has a hard green woody shell. Inside there is a pulp that has medicinal applications.

The tree grows in clayey soils with deficient drainage subject to frequent floods. It grows at elevations from sea level to 800 m, in areas with an average annual precipitation between 1,500 to 1,300 mm and an average annual temperature of 26 °C.

1.2 Main uses

The part of the tree that is used is the fruit. Its active ingredients have not yet been defined. Its uses are mainly in phytopharmaceuticals. The extract of the fruit is effective in the treatment of fever. The plant is used most frequently for the effective treatment of diseases of the respiratory tract such as: bronchitis, whooping cough, asthma and those related to illnesses caused by the cold. Good results have been seen in the treatment of otalgia (earaches). In traditional medicine Vermifuge properties are attributed to it.

*Crescentia cujete* is also frequently cultivated as an ornamental. The ripe fruits, once dry and clean inside, are used as containers to hold water. When the dry, clean fruits are cut in half, they have a variety of domestic uses, especially as containers to store salt and tortillas. They are valued in the manufacture of handicrafts and musical instruments.

Fresh seeds are ground and mixed with water to make a refreshing drink. The drink has a sweet and pleasant taste.

The wood has a specific gravity of 0.6 to 0.8. It is strong, flexible, moderately hard, and heavy. It is used for firewood and construction in rural areas and in the manufacture of handles for agricultural implements.
1.3 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. More than 179 countries and economies use the system 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. The trade data of Eurostat uses an eight-digit system. Most codes, however, end with two zeros, i.e. effectively only using 6 digits. In some countries, even 10 digits are sometimes used.

As the table below shows, *Crescentia cujete* falls under HS code 1211 90 "other plants of a kind use for perfumery, pharmacy, insecticidal purpose".

<table>
<thead>
<tr>
<th>HS code</th>
<th>Product description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1211</td>
<td>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 other plants of a kind use for perfumery, pharmacy, insecticidal purpose</td>
</tr>
<tr>
<td>1211 90</td>
<td></td>
</tr>
</tbody>
</table>
2 Market characteristics

Since *Crescentia cujete* is used as an ingredient by the pharmaceutical industry, this Section and the ones following will deal with the pharmaceutical industry.

The pharmaceutical market is strongly dominated and controlled by large pharmaceutical companies. The herbal medicine market, which is more interesting for UNCTAD exporters, is discussed separately.

2.1 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 outsource 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

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

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1 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.
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.

The herbal industry is experiencing rapid growth world-wide. Annual growth rates are between 10% and 20% 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.

2.2 Trade

The trade in medicinal plants differs widely from that: Firstly, it is a commodity trade involving some 1,600 to 2,000 species and thousands of tonnes annually, and is thus on a much larger scale than the former. Secondly, and even more importantly, this trade has strong health care implications leading to an increasing public and media awareness of these issues.

Europe plays a major role in the expanding markets for the plant raw materials. European countries act in both ways: As countries of harvest and export, like for example Bulgaria or Spain. To a much greater extent, however, many countries, especially in the EU, are centres of import and consumption.

In a global comparison, Germany is the 4th biggest importer of medicinal plants, after Hong Kong, Japan and the USA. If we use the same UNCTAD database to combine data for the whole EU, we find that the EU imports more than 100,000 tonnes of medicinal plant raw material annually. This puts the EU on the first position as biggest importer worldwide.
3 Consumption patterns and trends

3.1 Market size

Data regarding the trade and use of natural pharmaceutical ingredients in general 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). Data on *Crescentia cujete* is even more difficult to obtain since it is not yet a familiar product in Europe. Therefore, this Section will deal with the market for natural pharmaceutical ingredients. This Section 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 Section 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% 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%, 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**

<table>
<thead>
<tr>
<th>World Audited Market</th>
<th>Sales (€ billion)</th>
<th>Global sales</th>
<th>Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>229.5</td>
<td>49%</td>
<td>+11%</td>
</tr>
<tr>
<td>EU (EU-15)</td>
<td>115.4</td>
<td>25%</td>
<td>+8%</td>
</tr>
<tr>
<td>Rest of Europe</td>
<td>14.3</td>
<td>3%</td>
<td>+14%</td>
</tr>
<tr>
<td>Japan</td>
<td>52.4</td>
<td>11%</td>
<td>+3%</td>
</tr>
<tr>
<td>Asia, Africa and Australia</td>
<td>37.3</td>
<td>8%</td>
<td>+12%</td>
</tr>
<tr>
<td>Latin America</td>
<td>17.4</td>
<td>4%</td>
<td>+6%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>466.3</strong></td>
<td><strong>100%</strong></td>
<td><strong>+9%</strong></td>
</tr>
</tbody>
</table>

Please note that IMS publications can be bought online at www.open.imshealth.com, while at 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**

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

Table 3-3 Total pharmaceutical and self-medication expenditure of other EU countries, 2002, in € million

<table>
<thead>
<tr>
<th>Country</th>
<th>Pharmaceuticals</th>
<th>Self-medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>5,296</td>
<td>488</td>
</tr>
<tr>
<td>Austria</td>
<td>5,127</td>
<td>253</td>
</tr>
<tr>
<td>Sweden</td>
<td>2,958</td>
<td>289</td>
</tr>
<tr>
<td>Portugal</td>
<td>2,821</td>
<td>235</td>
</tr>
<tr>
<td>Greece</td>
<td>2,659</td>
<td>245</td>
</tr>
<tr>
<td>Finland</td>
<td>1,955</td>
<td>237</td>
</tr>
<tr>
<td>Denmark</td>
<td>1,920</td>
<td>236</td>
</tr>
<tr>
<td>Ireland</td>
<td>1,234</td>
<td>197</td>
</tr>
<tr>
<td><strong>EU-15</strong></td>
<td><strong>157,974</strong></td>
<td><strong>17,135</strong></td>
</tr>
</tbody>
</table>


Please check [http://www.wsni.org/member_europe.htm](http://www.wsni.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 [www.euromonitor.com](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% of the world's population, presently use herbal medicine for some aspect of primary health care.

Some 42% of the sales of the top 25 selling drugs world-wide are either biologicals, natural products, or entities derived from natural products\(^2\) (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% 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.

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;

\(^2\) 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).
- 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.

Herbal medicine market

Trade in herbal medicines is estimated at € 10 billion annually and is growing in excess of 10 % 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% of the world market. The leading European market is Germany, accounting for over 42% 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 authorisation 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 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.

Data charts on the global nutrition industry are available at a fee at 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 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 Ayurvedic medicines, have positioned many herbal and homeopathic 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.

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.

It should be noted that there has been a general increase in pharmaceutical legislation over the years which resulted in the publication of directive 2001/83/EC bringing together some 25 pieces of legislation introduced over a 25 years period into one document. This has subsequently been amended by additional directives 2003/63/EC, 2004/24/EC and 2004/27/EC. A consolidated text incorporating these new directives into 2001/83/EC was published recently and is available on the European commission website. The main changes of concern were introduced on March 31st 2004 when Directive 2004/27/EC was published. This made a number of important changes to the existing European product approval systems. As well as introducing changes necessary because of EU enlargement, the centralised regulatory approval process was strengthened and a new decentralised approval procedure added. Please refer to Section 6 for more information on directive 2004/27/EC.
Certification and conservation issues

Another trend in the phyto-pharmaceutical 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 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 Section 6.

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.

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1 Phytopharmaceuticals are plant and herb-based remedies.
4 Production

As mentioned in the previous Section, information on *Crescentia cujete* is not available. Therefore, this Section focuses on the production of natural ingredients for pharmaceutical in general, which should be used as an indication for *Crescentia cujete*. Please note that since the product is unfamiliar to many European importers, this product could be seen as a product which is not being produced or processed in Europe.

**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 [www.fao.org](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 Annex).

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 UK 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 EU". 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.

**Table 4-1 Total area hectares of cultivated herbs in Europe, in hectares**

<table>
<thead>
<tr>
<th>Country</th>
<th>total area</th>
<th>organic area</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>32,200</td>
<td>400</td>
</tr>
<tr>
<td>Germany</td>
<td>27,000</td>
<td>500</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>6,500</td>
<td>4</td>
</tr>
<tr>
<td>Austria</td>
<td>5,900</td>
<td>70</td>
</tr>
<tr>
<td>Italy</td>
<td>3,600</td>
<td>810</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>2,000</td>
<td>30</td>
</tr>
<tr>
<td>Greece</td>
<td>1600</td>
<td>90</td>
</tr>
<tr>
<td>Denmark</td>
<td>160</td>
<td>100</td>
</tr>
<tr>
<td>Sweden</td>
<td>26</td>
<td>26</td>
</tr>
</tbody>
</table>


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 ha, Poland 30,000 ha, Romania 20,000 ha, Bulgaria 15,000 ha).

For more information, please refer to www.europam.net. The organisation also provides an Excel sheet with all produces of 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).

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.
5 Trade Structure

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.
Figure 5-1 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 %, 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.

**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.

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

**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
6 Market Access

6.1 Relevant trade-related issues and measures

6.1.1 Legislative requirements

Procedures have been laid down in the EU 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.

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.

<table>
<thead>
<tr>
<th>The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and the ICH Global Cooperation Group</th>
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<tbody>
<tr>
<td>Other important organisations are ICH and the ICH Global Cooperation Group (GCG).</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>For more information: <a href="http://www.ich.org">http://www.ich.org</a></td>
</tr>
</tbody>
</table>

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 EU 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: emearequests@emea.eu.int

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.

As mentioned in Section 3, **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 3e).
- 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 EU 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 6.1.2, for more information on this issue.

If a medicinal ingredient or 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.

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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](http://www.escop.com)
- An important resource regarding up-to-date legislation for pharmaceutical ingredients is [http://dg3.eudra.org](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://europa.eu.int/comm/enterprise/)
- [http://www.emea.eu.int](http://www.emea.eu.int)
Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

Known as CITES, the Convention on International Trade 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 plant species have been added to CITES appendices. 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.

At the moment, *Crescentia cujete* is not listed as one of the species that is controlled by CITES regulation.

The lists of species are available through CITES Internet-site at 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 www.cites.org.

### 6.1.2 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. Consistent supply and reliability are important requirements when products are being exported.

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 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 EU. 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 final 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) and final products. 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 of final herbal medicinal products; 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 6-1 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.
WHO has established detailed guidelines for GMP for herbal medicinal products in the context of traditional medicine. 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 EU 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.

### 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.

6.1.3 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% 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 6.1.1).

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.

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://www.codexalimentarius.net/)

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.

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**6.2 Requirements for 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)” ([www.who.int/medicines/library/trm/medicinalplants/agricultural.pdf](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:
Market Brief in the European Union for selected natural ingredients derived from native species: Crescentia Cujete

- 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.

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**


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.
6.3 Tariffs and quota

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.

<table>
<thead>
<tr>
<th>Product group</th>
<th>General tariff</th>
<th>Tariff for DC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicinal and aromatic plants</td>
<td>0-3</td>
<td>0'</td>
</tr>
<tr>
<td>Medicinal and vegetable saps and extracts</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* Excluding China, Ukraine, Myanmar and Syria.
Source: Internet site of the Dutch Customs: www.douane.nl/taric-nl

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.
7 Prices

7.1 Price developments

As *Crescentia cujete* is a specialty product and in fact a novelty product on the European market, there is no world market price. If negotiations start with a prospective buyer, it could be the case that also the buyer does not have a clue what the price of the products is. The exporter will have to set his own export price depending on production costs, exporting costs, etc. and in some cases on local market prices. In the end, it is important to agree on a justified price in such a way that it is profitable for the exporter as well as the buyer.

An exporter should also keep in mind that different natural ingredients can be used as substitutes. This has of course a major impact on price settings. In the case of *Crescentia cujete*, however, there is not really a substitute.

In general, one should also consider the fact that prices of natural ingredients can be 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.

7.2 Sources of price information

As *Crescentia cujete* is a new product to the European market, there is no information on prices available. However, we already described that having insight in prices of related raw materials can be helpful when determining your export price.

In general, 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: [www.greentrade.net](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 ([www.herbworld.com/cropshop/](http://www.herbworld.com/cropshop/)).

- Prices for the following raw materials are published weekly in the Public Ledger (see Annex):
  - 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: www.aesgp.be.
8 Marketing strategies/prospects and sales promotion

8.1 Marketing and sales promotion strategies

Exporting *Crescentia cujete* to the European market starts with distinguishing different markets and market segments and identifying the most interesting to target. From the previous Sections and from discussions with importers and specialists in the branch, it could be said that market opportunities for *Crescentia cujete* can be found in the ingredients for pharmaceutical market.

To be able to supply the product to these market it is critical that you satisfy the following requirements:

Critical requirements for supplying the selected markets:
(for information on these issues, please refer to Section 6)

- CITES
- EU directives as mentioned in Section 6
- Technical Data Sheets (TDS)

Compliance with the above mentioned requirements gives you a 'license to supply' the European market. However, you will need to compete with other suppliers and substitutes of your product.

From our research and discussions with European importers and specialists, we have found that *Crescentia cujete* is new to the European market. Most interviewees did not recognise the name of the product. This means that to be able to market the product in Europe many efforts must be taken on to gain success.

Value addition

It is therefore critical that the exporter verify if there are any other possibilities to add value to the product in order to make the product more interesting for European buyers. In this way the exporter will be able to obtain the competitive edge he will need to get a foothold on the European market.

There are a number of important issues to be covered under achieving value addition, which can be summarised by:

- Every aspect of the product:
  - Supply and value chain analysis
  - Good business planning and cost calculation
  - Product and processing: reviewing and purchasing/upgrading equipment, training etc.
  - Good practices, with proper information and documentation, leading to traceability;
  - Market entry strategy and market differentiation (requiring market segment analysis at national/regional and international/export level).

- Information, documentation and registration:
  - Information and documentation for each step of the supply chain, forming a manual to meet various market requirements and registration procedures:
  - Regulatory requirements concerning quality, safety and efficacy, product development (pre-clinical and clinical investigation, including toxicological studies, registration documents).

- Certification of management and processing systems, and of product quality (ISO, GACP/GMP):
- Supplier or self-audit
3rd party audit.

Based on these principles and on the discussions with importers and sector specialists, the roadmap for value addition with respect to *Crescentia cujete* is to work in particular on:

**Organic certification**

- Although still a small segment, the market for organic ingredients is expected to keep on growing in the coming years. Growers and exporters in developing countries can distinguish themselves from the mainstream products by offering organic ingredients to EU importers.
- This is particularly important for small specialty products like *Crescentia cujete*. Smaller quantities can be more easily marketed in the organic market than in the regular market, where larger quantities are required by traders.

**GMP and GAPC**

- Also suppliers who have quality systems like GMP and GAPC in place have a major competitive advantage, as standards state minimum quality and hygiene requirements for the production processes in the pharmaceutical industry.

**Niche marketing**

- *Crescentia cujete* is a new product to the EU market, therefore it should be considered a specialty good. Most importers and end users are not familiar with the product, therefore, more information on the product, such as a technical data sheet, is required.
- Nevertheless, opportunities exist for this kind of specialty products if the producer is able to show the added value of the extract. The exporter should point out the specific properties of the extract which makes it interesting for the end user to pay the higher price.
- Exporters 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.
- Nutraceuticals and phytopharmaceuticals show large annual growth and the future trend is also towards increased demand. Also in these market segments opportunities for *Crescentia cujete* can be found.

**Co-operation**

- Although it will not be easy to find a partner in Europe who will be willing to invest in marketing and promotion of the product, to go directly to the end-industry is not recommendable. Try to find a European partner. These partners can help with vital legislation and also with product design, distribution and marketing. For over the counter medicine legislation is different across Europe. European partners can help with the specific aspects.
- Since *Crescentia cujete* is largely unknown among European buyers, European buyers need to be enticed by providing tests on attributes of the products to start with partnerships. European partners can assist in finding an European partner for product development.
- Due to required tests, it is stated that exporting raw material is easier than exporting finished products. It is recommended to export raw material or semi-processed materials to European processors who are interested. Finding end-users for an unknown ingredient will be very difficult.
- In case of a co-operation, an European partner can also help the exporter to design a new product and market the product. The European importer then can take care of legislation and registration.
For the producers, in case there are several, it is recommended to look into co-operatives as a way to cut on costs of quality control, market entry etc.

**Language and communication**

- When dealing with European importers, English is the most frequently 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. For Latin American companies, an exception of course is the competitive advantage they have if communicating with Spanish importers.
- All documentation (company profiles, technical data sheets, etc.) should be made available in English.
- It is advisable to commence with some communication measures which only require a small amount of planning and co-ordinating. A company brochure (including photos of production sites and produce) can be useful for promoting new contacts and sales.

The most important bottlenecks that have to be overcome are:

- **Demonstrating the functionality** of the product through clinical research.
- **Meeting European requirements.** Although European legislation is being standardised there are still important differences. Especially novel food regulation could seriously impede exports to Europe. 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.
- **Competitive price.** *Crescentia cujete* can be used by the self-medication sector. In this sector, consumers are usually not prepared to pay a high price for a product. Therefore, if the price of the ingredient is high, then it will not be attractive to buyers.
- **Creating a need in the market.** Since *Crescentia cujete* is used as a treatment also for fever, it has to compete with other existing medicines (substitutes) such as paracetamol, which are relatively inexpensive. It will be difficult to create a market need for a new ingredient to treat an existing illness for which already inexpensive treatments exist. To make the new ingredient interesting, some form of exclusivity should be introduced.
Annexes

Annex 1: Sources of price information

INTERNATIONAL
FAO (Food and Agriculture Organisation)
E-mail: FAO-HQ@fao.org
Internet: www.fao.org

International Trade Centre (ITC)
MNS Medicinal Plants & Extracts
E-mail: mns@intracen.org
Internet: www.intracen.org

UNITED KINGDOM
Agra Europe Ltd.
Publisher of ‘The Public Ledger’
E-mail: marketing@public-ledger.com
Internet: www.public-ledger.com

INTERNET
Herb crop shop
(at Herb Growing and Marketing Network)
www.herbworld.com/cropshop
Sites for retail prices for herbal materials include:
www.herbmarket.com
http://libertynatural.com

Annex 2: Trade associations

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

European Federation of Pharmaceutical Industries and Associations
E-mail: info@efpia.org
Internet: www.efpia.org

The European Pharmaceutical Wholesaler Association (Girp)
E-mail: euro.keys@euro-keys.com
Internet: www.girp.org or 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: secretariat@escop.com
Internet: www.escop.com

The Association of European Producers of Medicinal and Aromatic Plants (EUROPAM)
E-mail: ottens.bart@hetnet.nl
Internet: www.europam.net
Annex 3: Trade fair organisers

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

Cphi
Frequency: annual
E-mail: jekelschot@cmpinformation.com
Internet: www.cphi.com

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

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

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

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

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

Annex 4: Standards organisations

INTERNATIONAL

**World Health Organization (WHO)**
E-mail: info@who.int
Internet: http://www.who.org/

**International Standardisation Institute (ISO)**
E-mail: central@iso.org
Internet: www.iso.org
Annex 5: Trade press

GERMANY
Drogenreport
E-mail: info@drogenreport.com
Internet: www.drogenreport.com
Pharma Marketing Service
E-mail: vertrieb@aerztezeitung.de
Internet: www.fachzeitung.com/content/detailinfo.php?id_fz=13563&id_verlag=61025060
Zeitschrift für Arznei- und Gewürzpflanzen
E-mail: order@agrimedia.com
Internet: www.agrimedia.com

ITALY
Agro Food
E-mail: info@teknoscienze.com
Internet: 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: editorial@marketletter.com
Review of Aromatic and Medicinal Plants
E-mail: enquiris@cabi.org
Internet: http://www.cabi-publishing.org/AbstractDatabases.asp?SubjectArea=&PID=51

INTERNATIONAL
Herbalgram American Botanical Council
E-mail: abc@herbalgram.org
Internet: www.herbalgram.org
Journal of Herbs, Spices & Medicinal Plants
E-mail: getinfo@haworthpressinc.com
Nutrition Business Journal
E-mail: info@nutritionbusiness.com
Internet: www.nutritionbusiness.com

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

Annex 6: Other useful addresses

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)
E-mail: cites@unep.ch
Internet: www.cites.org
FI Data Services
Internet:  www.ingridnet.com

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

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

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

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

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

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

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

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