



CBI  
*Ministry of Foreign Affairs*

## **CBI Product Factsheet:**

# **Natural Ingredients for Vascular System products in Europe**

## Introduction

Opportunities exist for natural ingredients aimed at supporting the vascular system and preventing vascular health problems. An ageing, overweight and inactive European population has higher risks of vascular health problems, while consumer awareness of overall health and wellbeing is growing. Food supplements offer most potential, as product development is highest in this segment and consumers are more familiar with natural health products.

## Indication & product definition

### Vascular System

The vascular system, which is also called the circulatory system, consists of arteries and veins that carry blood, oxygen and nutrients throughout the body. Common health problems in the vascular system are vascular diseases and hypertension (high blood pressure). Vascular disease affects blood flow by blocking or weakening blood vessels or by damaging valves in veins. Vascular disease and hypertension can have mild to severe consequences, including thrombosis, varicose veins, aneurysm, strokes, angina and heart attacks. The main causes of these health issues are a family history of heart disease, obesity, an unhealthy diet, lack of exercise, smoking, diabetes, stress and increasing age.

### Vascular System and natural health options

Different health options can be chosen depending on the severity of the condition. Severe conditions are commonly treated with synthetic, prescription drugs and surgery, as herbal medicinal products are unable to offer effective treatment.

#### Box 1: How to use this Factsheet

- Learn how European consumers use herbal medicinal products and food supplements for the vascular system.
- Learn about the species from developing countries that are most commonplace and of greatest interest.
- Learn about requirements you need to meet for established and non-established species.
- Learn more about vascular system market segments and receive key insights into how to enter them.

Consumers are focusing on lifestyle changes and natural health options with regard to mild vascular problems, particularly with a view to their prevention in the future. This includes a change in diet, a more active lifestyle, stopping smoking, reducing stress and adding supplements and vitamins to the diet. Furthermore, over-the-counter (OTC) medicines are also playing an important role. The type of product chosen depends on whether consumers aim to improve their overall vascular health (preventative function) or relieve specific symptoms, such as heavy legs or high blood pressure.

Natural food supplements are particularly popular, as they are seen as a safer and healthier option than synthetic alternatives. To improve vascular health, the best-selling products are food supplements containing garlic, as well as those containing fish oils with high levels of omega-3. Other popular natural food supplements are based on vegetable oils high in omega-3 and those containing high levels of antioxidants.

Herbal medicinal products exist for vascular health issues, but species used in these products offer fewer opportunities to producers in developing countries, as these species are produced in Europe to a greater extent. Moreover, innovation and product development in herbal medicinal products are much more limited than in food supplements.

### Natural ingredients for vascular system products

According to industry sources, various botanicals are used to support the vascular system in Europe. Their use is typically internal. The most commonly used plants include:

Hawthorn ( <i>Crataegus laevigata</i> )	Cardamom ( <i>Elettaria cardamomum</i> )
Butcher's broom ( <i>Ruscus aculeatus</i> )	Hibiscus/roselle ( <i>Hibiscus sabdariffa</i> )
Horse chestnut ( <i>Aesculus hippocastanum</i> )	Ginkgo biloba ( <i>Ginkgo biloba</i> )
Garlic ( <i>Allium sativum</i> )	Gotu kola ( <i>Centella asiatica</i> )
Cayenne ( <i>Capsicum annum</i> )	Hazel ( <i>Hamamelis virginiana</i> )
Green tea ( <i>Camellia sinensis</i> )	Linseed oil ( <i>Linum usitatissimum</i> )

Other natural ingredients allowed for vascular system products can be found on this [overview of herbal medicinal products for paediatric use](#) by EMA (the European Medicines Agency).

Given that both ginkgo biloba and gotu kola are covered in the [CBI Market Intelligence Report](#) on Natural Ingredients for Cognition Products, these species will not be discussed in this factsheet. Green tea is excluded from this factsheet as well, as it is covered in the Market Intelligence Reports on Natural Products for the Immune System, Energy and Stress & Anxiety.

In addition, aromatherapy oils can also be used topically to help relieve vascular health problems and to improve circulation. These include cardamom and garlic. Among the species that may be of interest to developing country producers are marjoram (*Origanum majorana*) and ginger (*Zingiber officinale*). These essential oils can be regulated as cosmetic products, unless a specific medicinal claim is made on the label. More than 30 essential oils are included in the European Pharmacopoeia for medicinal use. For more information on aromatherapy, refer to the CBI's Market Intelligence on [Natural Ingredients for Cosmetics](#) regarding several essential oils, and also refer to relevant European and International literature available under [Forum Essenzia](#).

### Exemplary species for developing country producers

Not all species are equally relevant to developing country producers. This is the case for hawthorn, butcher's broom, horse chestnut and hazel, which are mainly cultivated in Europe. Additionally, flax seeds are mostly crushed in Europe to produce linseed oil, e.g. in Belgium and the UK. Therefore, these species offer very limited market entry possibilities to developing country producers. Industry sources indicate that garlic, cayenne, cardamom and hibiscus have good potential for developing country producers in areas with the right growing conditions.

The table below provides information on the exemplary species used in vascular system products, including available documentation and references, claims, origins, as well as data on traditional use, clinical trials and filed patents<sup>1</sup>, to determine possible product development activity for specific species. The products based on these ingredients are mostly offered as pills in dosage form and as herbal tea or infusions, but they can also be used as tonics, for example.

#### Tips:

- Check final Community herbal monographs as provided by the [European Medicines Agency](#) (EMA) to assess product standards and possible claims.
- If you produce ginkgo biloba or gotu kola, also review the Market Intelligence Report on Natural Ingredients for Cognition products. These botanicals also have potential as vascular system products. With regard to cayenne, please refer to the [CBI Market Intelligence Reports](#) on Joint Health and Anti-Obesity products. Concerning green tea, check the Reports on Immune System, Energy and Stress & Anxiety.
- Link up with local universities or laboratories to conduct thorough research and product development. This can help in terms of claim substantiation.
- If you want to enter the European market with new or established ingredients, please refer to the [CBI Module Buyer Requirements](#) for information and tips. Many other plants are used in vascular system products worldwide. Some of these can be/are already being used in Europe. With regard to the market entry of new ingredients, you need clinical evidence on their efficacy in relieving vascular health problems.
- Check databases such as [EMA](#) or [Herbmed](#) to identify research on traditional use, clinical trials (safety and efficacy evaluation of herbal formulations on people) and patents. In Europe, you can contact relevant universities such as the [University of Vienna](#), the [University of Veterinary Medicine Vienna](#) and the [University of Graz](#). Access scientific resources, for example through [Elsevier Science Direct](#) (not for free). Also consider becoming a member of the [Society for Medicinal Plant and Natural Product Research \(GA\)](#) to access their research.

<sup>1</sup> Information on traditional use, clinical trials and filed patents should be used as an indication only. Additional research for your specific species will be required.

**Table 1: Selected key species for the vascular system**

Definition	Monographs <sup>2</sup>	Permitted usage in supplements <sup>3</sup>	Origin	R&D
<p>Allium sativum (Garlic)</p> <p>Garlic is one of the most popular supplements for the vascular system, for oral use in the form of tablets or capsules. A European herbal monograph is available, but fewer products are on the market.</p>	<p><a href="#">WHO Monograph</a>                      ESCOP Monographs 2<sup>nd</sup> Edition (Allii sativi bulbus)                      European Pharmacopoeia Monograph # 1216 (Allii sativi bulbi pulvis)                      Draft under discussion.</p> <p>No well-established use or traditional use of garlic in herbal medicinal products has been documented.</p>	<p>Italy, Belgium and France allow use of bulb and essential oil.                      Germany allows use of bulbs, with maximum level recommended for food.</p> <p>Food supplements cannot make a medicinal claim. As an example, the following claims were found on products containing garlic in Germany:                      "Garlic is used for lowering blood pressure and known to lower cholesterol".                      "Supports a healthy cardiovascular system"</p>	<p>Widely cultivated in temperate and tropical regions of Africa, Asia, Australia, North America and Europe.</p>	<p>Much research has been conducted on garlic: <a href="#">Herbmed</a> registered 95 articles on traditional use, 141 clinical trials and 20 patents.</p> 
<p>Capsicum annuum (cayenne/capsaicin, mainly from Capsicum annuum longum)</p> <p>There is a large market for this product, especially for food. Thus it is also produced on a large scale. Nevertheless, there are market-entry opportunities for smaller players.</p> <p>Cayenne is used for several indications, including the maintenance of healthy circulation. For this purpose, cayenne is sold in the form of tablets or capsules for internal use.</p>	<p>No WHO Monograph available.                      ESCOP Monographs 2<sup>nd</sup> Edition Suppl. (Capsici fructus).                      European Pharmacopoeia Monographs # 1859 Capsicum # 2336 Capsicum oleoresin, refined and standardised # 2337 Capsicum tincture, standardised # 2529 Capsicum soft extract, standardised                      Rapporteur assigned for Community Herbal Monograph for Capsicum fructus.</p> <p>No well-established use or traditional use of capsicum in herbal medicinal products has been documented.</p>	<p>Belgium: allows use of all plant parts of Capsicum annuum L., allows use of fruit and sapwood of Capsicum frutescens L.                      France: allows use of fruit.                      Italy: allows use of fruit and oleoresin.                      Germany: allows use of fruit.</p> <p>Food supplements cannot make a medicinal claim; exemplary claims from the UK made for supplements containing cayenne/capsicum are:                      "The herb is also recognised for supporting healthy circulation".                      In combination with ginger, hawthorn and lecithin:                      "Terrific for maintaining healthy circulation".</p>	<p>Cultivated in South Asia and introduced elsewhere.                      India is a very large producer.</p>	<p>Little research has been done on capsicum (as Capsicum frutescens):                      Herbmed registered 9 articles on traditional use, 15 clinical trials and 1 patent.</p> 
<p>Hibiscus sabdariffa (Hibiscus/roselle)</p> <p>Hibiscus tea is a popular drink in various countries in Africa, South America and Asia. The tea is made from hibiscus flowers, also known as roselle.</p> <p>Use of hibiscus flowers is most commonly in the form of herbal infusions. It</p>	<p>European Pharmacopoeia monograph # 1623 (Hibisci sabdariffae flos).                      No WHO, ESCOP and Community herbal monographs available.</p> <p>No well-established use or traditional use of hibiscus in herbal medicinal products has been documented.</p>	<p>Italy, Belgium and France allow use of branch, flower, leaf and seed.                      Germany allows use of seed and flowers.</p> <p>Food supplements cannot make a medicinal claim; examples from the UK of claims made for products containing hibiscus are:                      "It can decrease cholesterol..."                      "... anti-hypertensive effect".</p>	<p>China, Thailand, Sudan, other countries in Africa, tropical regions</p>	<p>Herbmed registered 14 articles on traditional use, 21 clinical trials and 9 patents.</p> <p>As Hibiscus spp. another 15 articles on traditional use, 3 clinical trials and 21 patents are registered.</p>

<sup>2</sup> Only European Pharmacopoeia monographs (legally binding), Community Monographs (non-binding) and entries (binding) are valid in the EU. WHO monographs provide information on the uses to which herbs are put in medicine systems outside of Europe, including information on growing conditions, purity tests, chemical constituents and an overview of the botanical's specific action. ESCOP monographs provide a basis for EMA dossiers on herbal medicinal products. They are a reference standard (not legally binding).

<sup>3</sup> Indication only. This information is unavailable in many countries, but it is expected to be comparable. Italy, France and Belgium have created a common positive list for plants and derivatives allowed in food supplements, and this may be subject to updates. Italy is the first country to adopt this list; individual country lists still apply to France and Belgium.

<p>is also available as a supplement in the form of tablets and capsules for internal use.</p>				
<p>Elettaria cardamomum (Cardamom)</p> <p>Cardamom is used as a spice in food. Additionally, the spice is used for a wide range of health benefits, which includes the reduction of blood pressure.</p> <p>Cardamom is not allowed for use in herbal medicinal products, but has applications as a food supplement, where it is used in the form of tablets or capsules.</p>	<p><a href="#">WHO monograph</a> (Semen Cardamomi). No ESCOP, European Pharmacopoeia and Community herbal monographs available.</p> <p>No well-established use or traditional use of cardamom in herbal medicinal products has been documented.</p>	<p>Italy, Belgium and France allow use of seed and oil. Germany allows use of fruits with maximum level recommended for food.</p> <p>Food supplements cannot make a medicinal claim; examples from the UK of claims made for supplements containing cardamom are:          "Cardamom pods contain ... compounds that are known to have been antioxidant, disease preventing and health promoting"          "... a good source of minerals like potassium, calcium and magnesium".</p>	<p>Cultivated in East Africa, China, South America, India and Asia tropical.</p>	<p>Very little research has been done on cardamom; Herbmed registered 6 articles on traditional use, no clinical trials and 1 patent.</p> 

Source: Herbmed, 2014

## What is the demand for vascular system products in Europe?

- Demand for food supplements and herbal medicinal products is strongest in Germany, France, Italy and the UK. The strongest growth in these segments stems from Eastern European countries, such as Poland, Romania and Slovakia.

### Vascular System

In order to estimate the need for vascular health products, statistics have been included on the main vascular health conditions in Europe, as well as prevalence of risk factors and related conditions.

- According to the WHO, cardiovascular diseases cause more than half of all deaths across Europe. Important risk factors for cardiovascular diseases are increased blood pressure, high blood cholesterol and obesity. Herbal medicinal products and food supplements have the greatest potential for preventing vascular problems and treating symptoms of minor vascular health issues.
- According to the WHO Global Health Observatory data, the prevalence of raised blood pressure in adults aged 18 and above is highest in Eastern European countries: 20-30% for women and 30-40% for men. The countries with the lowest prevalence of raised blood pressure are the UK, Belgium, Switzerland, Norway and the Netherlands. In these countries, around 20% of men had raised blood pressure and 12-14% of women.
- In 2008, the prevalence of raised blood cholesterol was highest in northern and western European countries, most notably in Iceland, Luxembourg and Denmark. In these countries, 25-30% of men and 20-25% of women had high levels of cholesterol.
- On average, 17% of the adult population in the EU is obese (when taking the population classed as overweight into consideration, this number rises to over half the EU population). The level of obesity has doubled over the past 20 years in many European countries, varying significantly from country to country (ranging from 8% in Romania to more than 25% in the UK, Hungary and the Czech Republic).
- Although data on the prevalence of vascular diseases are limited, data on the levels of conditions caused by vascular diseases are available. One example is peripheral arterial disease (PAD), which is a condition where veins in the abdomen or lower extremities are clogged and hardened, leading to pain in the muscles while walking. In Europe, 40.5 million cases of PAD were reported in 2010 ([Medpagetoday, 2013](#)). In Western Europe, it is estimated that 4% to 8% of the population have PAD.

**Tips:**

- Please refer to [CBI Trade Statistics for Natural Ingredients for Health Products](#) for statistics on European markets for herbal medicinal products and food supplements.
- Consider your potential for exporting to Eastern Europe; the fast growth and the prevalence of cardiovascular health issues offer opportunities. These herbal medicinal product and food supplements markets are smaller than in Western Europe
- For more statistics and information, please refer to the [European Cardiovascular Disease Statistics \(2012\)](#) published by the [European Society of Cardiology](#).
- For more information on sector associations in various European countries, please refer to the sources and promising countries (France, Germany, Italy and the UK) on the [CBI Natural Ingredients for Health Products website](#).

## What trends offer opportunities on the European market for vascular system products?

**Need in society:** There is an increasing need among Europeans to prevent and treat vascular system problems, given the growing prevalence of disease risk factors. The relevant risk factors relate to a population that is ageing and increasingly overweight.

- An *ageing population* is increasing the demand for natural health options (and their ingredients), particularly with regard to age-related conditions such as many vascular conditions. It is estimated that 30% of Europeans will be 65 or above by 2050, compared with 17% in 2013. This consumer group uses herbal medicinal products and supplements more extensively than younger populations. Note that the elderly favour well-established, traditional products.
- Vascular conditions are projected to rise continually because of rising *obesity* figures. Projections of obesity are gloomy in terms of the numbers of Europeans who will be affected by this condition in the years to come.

**Consumer awareness of health:** natural health products correspond better to the notion that they will improve overall health and prevent health problems, such as vascular health conditions. An increasing consumer awareness of general health and wellbeing is increasing the demand for food supplements that prevent vascular diseases or improve blood circulation. Healthy diets and lifestyles are increasingly seen as important in supporting the vascular system. Given that many consumers believe products deriving from botanicals have fewer side-effects than conventional medications, consumers consider their long-term use to be safer than that of conventional medications.

**From curing to preventing illness:** Consumers believe that maintaining good health prevents illnesses. Given that problems in the vascular system may be difficult to cure, the prevention of such problems may be more effective. Healthy lifestyles are increasingly important, including daily dietary supplements. It is this in particular that is increasing the demand for supplements.

#### Tips:

- Do not make medicinal claims for your ingredient in your product documentation or marketing materials if you are targeting the food supplements market. Claims in food supplements can relate only to function (e.g. relating to functions of the vascular system, blood pressure) and risk reduction. For example, you may not claim that your ingredient can prevent/cure specific vascular issues, but you may stress that a certain species can help maintain good vascular health. Also ensure that you have the research results to back up your claim with any potential buyer.
- If you target producers of herbal medicinal products, make sure the claims you mention in your documentation are mentioned in the European Pharmacopoeia, monographs or list entries.
- Communicate that long-term use of your species does not have negative health effects; this is an important marketing argument. You always need to be able to substantiate product safety based on scientific research. Although European manufacturers are responsible for product safety, providing such information supports your marketing effort.
- Have a look at traditional use as a starting point for new ingredients for the vascular system. Such species may form a foundation on which to build substantiation. Refer to [Market channels and segments](#) for more tips and information.
- In your marketing, focus on the prevention of vascular health problems. This is key in these health problems: according to the [WHO](#), 80% of premature heart disease and strokes can be prevented. Also focus on promoting increased overall health.
- Determine your botanical product's potential in terms of treating mild vascular problems, aside from preventing vascular health problems. Do not attempt to treat serious vascular health issues; these are beyond the scope of herbal medicinal products or food supplements.
- Please refer to [CBI Trends](#) for more market trends.

## What requirements should natural ingredients for vascular system products comply with to be allowed on the European market?

This factsheet considers two industries: herbal medicinal products and food supplements. Both have a distinct legislative framework and route to market, which are elaborately explained in the [Module Buyer Requirements](#).

## What requirements do I need to comply with to export natural ingredients?

- You need to comply with the **Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)**. CITES regulates the trade in (for example) wild-collected endangered plants and provides guidance on the species for which trade is prohibited or restricted.
- Your ingredient might require you to establish **Access and Benefit Sharing (ABS)** agreements. These 'mutually agreed terms' detail the terms and conditions of access and use of genetic resources and/or traditional knowledge and supply of raw materials.
- You need to ensure **sustainable sourcing** of your ingredients. This is important to buyers, as they are facing supply shortages for an ever-increasing number of cultivated, but especially wild-collected species. You do not always have to certify sustainable sourcing; have a look at these value-addition opportunities in the section [Competition](#).

#### Tips:

- Conduct a resource assessment and implement a resource management system.
- If you are an exporter of wild-collected botanicals or their derivatives, take into account the provisions of [CITES](#) in order to guarantee the EU entry of your products. Check [Annex A and B of Regulation \(EC\) No 338/97](#) to ascertain whether import and export permits are required for your product. You can also contact the [local CITES authority](#).
- Read more about [CITES](#) in the EU Export Helpdesk.
- Put a procedure in place to check whether ABS applies. Contact the competent authorities in your country as a starting point. [UEBT](#) and [FairWild](#) provide thorough information on the practical implications of ABS, as established by the [Convention on Biological Diversity](#).

## What requirements do I need to comply with to enter the EU market for herbal medicinal products?

If you want to enter the European herbal medicinal products market, you need to comply with the relevant [EU legislation](#) (Directive 2004/24/EC). This procedure provides a specific, simplified regime for traditional herbal medicinal products which can meet certain requirements. Compliance is still required with the detailed quality, documentation, labelling, packaging, certification and traceability standards as established in [the rules governing medicinal products in the European Union](#). This set of rules also governs [marketing authorisation](#) of medicinal products to be sold in the EU market.

### Tips:

- Read more about [marketing authorisation for pharmaceutical products](#) in the EU Export Helpdesk.
- Read more about the simplified procedure for homeopathic and herbal products on the [website of the European Commission](#).
- Consult the [EU Export Helpdesk](#) and the [CBI Module Buyer requirements: natural ingredients for health products](#) for a full list of requirements for natural ingredients in health products.

**GACP and GMP for natural ingredients:** If your ingredients are used in medicinal products for human use, you need to follow Good Agricultural and Collection Practices (GACP) and Good Manufacturing Practices (GMP), established specifically for the industry to ensure your product meets all identity, quality, efficacy and safety requirements. You can support the implementation of these Good Practices by developing Standard Operating Procedures (SOP) and work instructions (WIN). SOPs should be developed for your specific processes and products, but some institutions are developing SOPs, such as Europam, the European Herb Growers Association.

### Tip:

- Which guidelines you need to comply with depends on your product:
  - Raw plant materials: [Guideline on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin](#) (GACP). GMP starting material needs to comply with [Part II - Basic Requirements for Active Substances used as Starting Materials](#).
  - Extracts: GACP or GMP requirements depend on stage of product (in extraction process) and intended use. For extracts, comply with requirements on page 3 of the [EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, Annex 7: Manufacture of Herbal Medicinal Products and for Active Pharmaceutical Ingredients \(API\)](#), follow [requirements on page 7 of Part II - Basic Requirements for Active Substances used as Starting Materials](#).
  - [Develop company specific SOPs and WINs to implement the Good Practices](#)

## What requirements do I need to comply with to enter the EU market for food supplements?

**EU Legislation specific to food supplements:** In addition to general requirements for food, as established under General Food law, food supplements are subject to specific legislation. This legislation lays down compositional and labelling requirements, but still leaves composition beyond minerals and vitamins (e.g. essential fatty acids, fibre, and various plants and herbal extracts) at the discretion of national authorities.

### Tips:

- Familiarise yourself with the legislation on food supplements, which is listed on the [website of the European Commission](#).
- Make sure that your ingredients comply with [general requirements for food](#) and food labelling. Buyers usually demand compliance with guidelines for herbs according to [Codex Alimentarius](#). Standards have not been established for extracts.
- Check the positive lists of European countries to determine whether your ingredient is already allowed in those markets or whether there are species that you could potentially produce in your country. You can find such lists at:
  - [German Federal Ministry of Food and Agriculture](#)
  - [Italian Ministry of Health](#) (BELFRIT list for Belgium, France and Italy).

**Food safety:** Ingredients for food supplements need to comply with requirements for food safety. You can read more about food safety and Novel Food requirements on the websites of the [EU Export Helpdesk](#) and the [European Commission](#).

**Tips:**

- [Novel Food Regulation](#): Consumer safety of ingredients that were not consumed within the EU before 15 May 1997 needs to be assured to comply with this regulation. Consult experts and internet research for insights into whether there is historical use in Europe. The (non-exhaustive) [Novel Food Catalogue](#) lists plants subject to the Novel Food Regulation and provides their current status.
- [Maximum Residue Levels \(MRLs\)](#): strict control of pesticide use must be a focal point in your production system. These controls are increasingly strict, as improving laboratories can detect more residues.
- Criteria and maximum levels of [contaminants in food](#) and [microbiological contamination of food](#): Apply GACP/GAP and GMP to minimise and document contamination.
- [Hygiene of food \(HACCP\)](#): legally binding for food processors (including ingredients) and recommended for farmers (primary production).
- Find out which [extraction solvents for food](#) you can use and under which conditions.
- [Irradiation of food](#) is only permitted in specific cases for spices and herbs, including supplements.
- [Traceability is based on the](#) "one step back-one step forward" principle; you need to trace food that is used for consumption through the value chain.
- Be ready to demonstrate traceability by documenting your value chain. If you want to have your product certified (e.g. FairWild, Fairtrade or organic), traceability will be important as well.
- Moreover, have a look at common causes for border rejection and product withdrawals on the [Rapid Alert System for Food and Feed \(RASFF\)](#). Examples include contaminants and unauthorised food ingredients.
- Check and adhere to the food safety legislation in your country.

**What additional requirements do buyers often have?**

**Buyer specifications and requirements:** Many buyers have additional quality requirements which can go beyond legislation and standards (active ingredient content, moisture content, contaminants, residues, etc.). These are established in buyer specifications. To show that you meet their specifications, they also require well-structured company and product information, including detailed technical data sheets.

**Tips:**

- Make sure you meet international product standards and buyer specifications.
- Include plant identification through a national and/or a company herbarium in your product specifications, this is important as a reference.
- Prevent (un-)intended adulteration and contamination by other foreign materials by keeping facilities and equipment clean, and by ensuring full documentation and traceability.
- If you produce extracts, you need to meet buyer requirements in terms of extraction methods, solvent use, preservatives, etc. Validate and document extraction conditions: processing aids, temperature, pressure/vacuum, flow rate, etc.
- If you use preservatives, make sure you have the HR capacity to tailor their use to buyer specifications and for their proper documentation. You also need specialist staff to monitor process quality and microbiology.
- Make sure your documentation and labelling comply with respective legislation and buyer requirements. Information on possible dangerous characteristics of chemical substances must be provided on Material Safety Data Sheets. Furthermore, it is likely that your buyer requires test reports.
- Implementing and documenting Standard Operating Procedures can provide a lot of trust on the part of buyers that you will keep up quality standards.

## What are the standards and requirements for niche markets?

### Social and environmental sustainability:

- If you want to market **organic ingredients** in the EU, you need to comply with EU requirements on the production and labelling of organic products of agricultural origin. Herbal medicinal products cannot be labelled as organic or fair trade.
- Verifying and/or certifying **sustainable production** represents a niche market, but can add value to your product. For more information on such value addition, please refer to value-addition opportunities in the section [Competition](#). Better-known sustainability standards include:
  - The [UNCTAD BioTrade Initiative BioTrade Principles and Criteria](#) or [FairWild Principles and Criteria](#)
  - Social: Fair Trade certification, such as [FLO Fairtrade](#) or [FairForLife](#).
- Some EU buyers may expect you to comply with their supplier **codes of conduct** regarding **social responsibility**, which are often based on ILO labour standards or on UN Global Compact reporting.

#### Tips:

- Discuss with (potential) buyers whether they would be interested in certified sustainable natural ingredients of the above standards.
- If you choose to obtain a certificate for organic production, find out more about [Organic production and labelling](#).
- Dedicate the processing plant to the exclusive production of organic ingredients. If this is not possible, ensure thorough cleansing of machinery and equipment at all times.
- Consult the [Standards Map database](#) for different sustainability and organic standards.
- For more information on responsible business practices, refer to the [UN Global Compact](#) and ISO 26000 as guidance, and use the [SEDEX](#) online database, where members can share information on ethical and responsible practices. You can also use SEDEX to prepare for possible audits/questions from your buyers.

**Quality and food safety management:** In addition to the mandatory HACCP standard, EU food industries increasingly demand compliance with more comprehensive food safety standards (food safety management systems), as well as quality safety management as specified in [ISO 9001:2008](#) (required for health ingredients). This mostly concerns large retailers and (private label) manufacturers, most notably for food supplements. Examples include the [International Food Standard \(IFS\)](#), [ISO 22000](#) (food safety) and [ISO 31.000](#) (risk management).

#### Tips:

- Consider carefully whether to comply with the above standards and certifications. Verify whether your buyer truly demands compliance, whether compliance will facilitate market access or offer you a better price, or whether compliance will benefit your company's supply security or internal processes. In the case of food safety standards, it is also important to ascertain whether you can gain your buyer's trust in another way.
- Stay up to date with information on food safety standards by checking news items published on the [Codex Alimentarius](#) and [HACPEUROPA websites](#).

## What competition do I face on the European market for vascular system products?

### Synthetic alternatives

Most vascular health issues are treated with *conventional medicine* and in some cases surgery. The health issues included in this factsheet, most notably vascular diseases and mild hypertension, can be treated with a wide range of conventional medicines and treatments. Examples include cholesterol-lowering drugs, blood pressure-lowering drugs, blood-thinning drugs and diuretics.

In terms of *food supplements*, synthetic alternatives encompass both synthetic vitamins and minerals. Popular supplements are folic acid, potassium, magnesium, iron, vitamins C, D and E, and other antioxidants.

#### Tips:

- Consider whether your ingredient offers blood pressure-lowering or cholesterol-lowering properties which might be of interest to this segment. Also consider whether your ingredient is already used in this segment. Online resources to assist with this include herbal medicinal product manufacturers' websites, [EMA monographs](#), [Pharmacopoeia](#) and websites such as the [European Medicines Agency](#), [MedlinePlus](#) or [Herbmed](#).
- Please refer to [CBI Competition](#) and CBI Top 10 Tips for doing business for more information.

#### Existing natural alternatives

The vascular system is supported by a wide range of natural alternatives. Many of the alternatives for the vascular system are marketed in other indication areas as well, such as immune support, anti-obesity and digestive health.

- Omega-3 oils or supplements are the most frequently used natural alternatives. Given that the most typical source for these supplements is fish waste, they can be offered at low prices. Botanical examples include rapeseed/canola oil and evening primrose oil.
- Botanical sources grown in Europe are traditionally used in herbal medicinal products or food supplements aimed at improving or treating health issues affecting the vascular system. These include horse chestnut, hawthorn berries and hazel.
- Soluble dietary fibres are used to help lower blood cholesterol and blood pressure. Moreover, dietary fibres may help to reduce weight, which can help support vascular health. Examples of sources include fruits and vegetables (e.g. apples, avocados, figs and Brussels sprouts), nuts and pulses (e.g. flaxseeds, beans, dried peas and lentils), and grains (e.g. oatmeal and oat bran).
- Natural antioxidants may also be marketed in terms of supporting or improving heart health and overall health. Examples of sources include green tea, and various fruits and vegetables.

#### Tips:

- Create a strong marketing story, backed up by research, concerning how your product can prevent vascular system problems. It may be of interest to link products to other indication areas, such as weight control, immune support or improving overall health.
- Carefully consider whether you would be able to meet the high legislative and buyer requirements for herbal medicinal products, and whether your offer would improve to such an extent on offers made by current suppliers (in terms of price, delivery and services) that it would enable you to entice buyers to work with you.
- Traceability is not available for many ingredients for herbal medicinal products. Your offer will be of greater interest to buyers if you can show traceability and sustainable future access to raw materials, particularly with regard to scarce ingredients.

#### Value-adding opportunities when competing in the market

Adding value can be a way of creating your own distinct market profile and making your product more attractive to buyers. You can add value with further processing (e.g. from raw material to extract to final product):

- Opportunities to **add value to raw materials** are often not fully exploited; proper post-harvest processing (sorting, grading) and proper documentation can lead to you obtaining a higher price.
- Developing country producers are moving **beyond raw material** towards the export of extracts. Processing raw materials into essential oils is guided by the existence of standards, and buyer demands are well understood. In contrast, it is more difficult to come to a common understanding on quality in terms of herbal extracts. Therefore, many EU buyers prefer to import raw materials, even if their suppliers would prefer to export extracts (to other markets).
- **Finished products** on the EU market aimed at relieving vascular system problems are beyond the scope of most companies in developing countries, taking into consideration product development, market authorisation and marketing costs.

**Tips:**

- Help manufacturers build their story, e.g. by documenting and visualising your product and company's unique value proposition. This will also contribute considerably towards your own marketing effort. Final manufacturers can use this information to market the end-product in Europe.
- Align quality improvements to your product with buyer requirements (specifications) and their willingness to pay for them. Quality improvements can be costly, and you need to ensure that the potential exists for getting an adequate return on investment.
- Determine your option to market simple finished products such as herbal teas. Although these hold a smaller market share in this indication area when compared to food supplements, some botanicals, such as hibiscus, are more commonly marketed as herbal tea.

You can also add value by certifying your company according to social and environmental sustainability principles:

- Producers with a company image focused on sustainability (ethical/ environmental) place more value on certification of the ingredients in their food supplements.
- In **food supplements** the value of certification depends on the positioning of the producer and product. Opportunities for certification increase if the product is positioned more as a food-type product, rather than as a medicinal-type product.
- Even though certifications cannot be used on labels for **herbal medicinal products**, sustainable certification will add value when approaching manufacturers adhering to a philosophy that calls for such certification.

**Tip:**

- Verify your buyers' interest in certified ingredients:
  - Organic certification also acts as a quality control system and can help to improve your quality image.
  - Fair Trade and FairWild certification can help indicate to your buyer that the production of ingredients is generating rural income and does not harm local communities (this could jeopardise the buyer's image).
  - Certification demonstrating sustainable sourcing (e.g. FairWild) can help show potential buyers that you could be a reliable future partner.

## What do the trade channels and interesting market segments look like in Europe for vascular system products?

### Market segments

Both herbal medicinal products and food supplements to relieve or prevent vascular health issues are based on traditional recipes in Western herbal medicinal products and well-known, established species. Most producers of **herbal medicinal products** will have some products to relieve vascular health issues in their portfolio. Examples include bilberry/horse chestnut food supplements ([Solgar](#)) and Crataegutt®, based on hawthorn extract ([Schwabe Pharma](#)). Although their use as medicinal products is well documented, fewer products are marketed as herbal medicinal products when compared with food supplements. One reason for this is that legislative hurdles offer limited product innovation and introductions to Europe. Existing supplier-buyer relations make it difficult for new producers to enter this market segment.

Botanical-based **food supplements** are commonplace and are marketed either as preventing vascular health problems or as supporting healthy circulation and blood pressure. Among consumers, such food supplements are more popular than herbal medicinal products that aim to relieve vascular health issues. These food supplements are mainly single-herb products.

Products for the vascular system are not as common as in other indication areas. Some companies are being (increasingly) innovative in adding new ingredients unfamiliar as supplements in Europe. In general, the UK and France are more vibrant in terms of product introductions than are Germany or Italy.

### Market channels

Regarding established species for food supplements, trade relations focus on maximising supply security and reducing costs. By contrast, new ingredients call more strongly for collaboration. With regard to herbal medicinal products, trade relations offer more room for collaboration owing to the paramount importance of supply security.

**Tips:**

- Look at local practice: what is the term for vascular system in your local language? What do local people use to improve the vascular system's health? Build up files on traditional use, and support this with clinical tests. Such information can be used to approach European traders, ingredient processors and manufacturers.
- Seek a partner in Europe to help research the effectiveness of new ingredients, to build product documentation and to assist with the marketing story. Find a company that shows interest and sees potential for the (new) ingredient.
- Consider whether you would be able to become a preferred supplier for larger players (larger volumes, very high expectations in terms of service delivery).
- For tips on finding buyers, have a look at the CBI Module Finding Buyers. Use your knowledge of product development activity and potential for marketing your product more specifically to the right buyer.
- Please refer to [CBI Market Channels and Segments](#), where the various players at the various levels of the value chain are discussed in more depth. You are also provided with an overview of the key market characteristics and trends for both segments: herbal medicinal products and food supplements.

## Useful sources

Visiting and, above all, participating in trade fairs are highly recommended as among the most efficient methods of testing market receptiveness, obtaining market information and finding prospective business partners. The most relevant trade fairs in Europe for exporters of natural health ingredients are:

- [SANA](#) in Bologna, Italy.
- [Hi/Ni](#) (Health ingredients/Natural ingredients): Travelling trade fair.
- [Fi/Ni](#): Food ingredients/Natural ingredients travelling trade fair.
- [Biofach](#) in Nuremberg, Germany (for organic producers).
- [Vitafoods](#) in Geneva, Switzerland.
- [CPHI](#) is more focused on pharmaceuticals, but larger natural extract companies also exhibit at this fair in a dedicated natural extracts zone.
- [Anuga](#) in Cologne, Germany, is a food and beverages fair with a dedicated "Wellfood" department (supplements, functional food and medicine).

## Trade press/news

- [Nutra Ingredients](#): News on supplements and nutrition in Europe.
- [Foodnavigator](#): Science and nutrition research, product news, newsletter, health and nutritional ingredients.
- [Nutraceuticals World](#): News, buyers' guide on various herbs and botanicals, knowledge centre and market, peer-reviewed and supplier research.
- [Nutraceuticals Now](#) ([spring issue 2015](#)): technical review on functional products and ingredients which are defined as disease preventing and/or health promoting in addition to nutritional value.

## More information:

CBI market information: Promising EU export markets.

EU Expanding Exports Helpdesk - <http://exporthelp.europa.eu>.

Eurostat - <http://epp.eurostat.ec.europa.eu/newxtweb> - statistical database of the EU. Several queries are possible. For trade, choose 'EU27 Trade Since 1995 By CN8'.

International Trade Statistics - <http://www.trademap.org> - you have to register.



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