



CBI
Ministry of Foreign Affairs

CBI Product Factsheet:

Natural Ingredients for Joint Health products in Europe

Introduction

Botanicals with anti-inflammatory properties have good potential to replace or complement the vast range of non-botanical solutions for joint health. Prevalence of joint conditions is growing due to an ageing, overweight and inactive European population. Often, these conditions cannot be cured and consumers and companies are interested in new ingredients, if they are safe and effective. Aromatherapy also offers solutions for this indication.

Indication & product definition

Joint health

Musculoskeletal conditions (MSCs) are the primary cause of severe long-term pain and disability in Europe. They include conditions in joints, muscles and bone structure. Many MSCs are associated with ageing, obesity and lack of physical activity. This factsheet focuses on joint health conditions. The commonest are osteoarthritis, gout and rheumatoid arthritis. These have different causes but can result in similar symptoms (joint inflammation, pain, stiffness and impaired movement) and have comparable remedies.

Box 1: How to use this Factsheet

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

The most prevalent joint disorder is osteoarthritis (OA), a condition where cartilage in joints breaks down and wears away. It is a major cause of disability among the elderly. Rheumatoid arthritis (RA) is an autoimmune disease where the immune system attacks the membrane around the joints. Patients with gout have an excessive accumulation of uric acid in the body, often as a result of kidney failure.

Joint health and natural health options

Joint health conditions are often chronic and incurable. Consequently, patients can only manage their symptoms (relieve pain or reduce inflammation) or slow down further degeneration, as in the case of rheumatoid arthritis.

The management of joint health conditions and symptoms is dominated by synthetic medicine and non-herbal supplements. Synthetic medicines include non-steroidal and anti-inflammatory drugs (NSAIDS) to reduce inflammation and/or relieve pain. These include over-the-counter drugs such as ibuprofen or stronger drugs, which are dispensed only by prescription. Corticosteroids are used to control inflammation and pain. Other medicines include topical creams, intra-articular injections and a variety of painkillers.

The supplements market for joint health is dominated by (a combination of) glucosamine and chondroitin. Other non-herbal supplements are SAME (s-adenosyl-L-methionine) and MSM (methylsulfonylmethane), as well as the emerging alternatives of Type II collagen and cetylated fatty acids.

Alternatives to these supplements are emerging in line with growth of the joint health market and a maturing glucosamine market. The plant world has options of interest to offer to this indication in terms of herbal medicinal products uses and supplements to reduce inflammation and thus decrease pain. Direct suppression of pain is beyond the herbal sphere.

Natural ingredients for joint health products

According to industry sources, various botanicals are used for joint conditions in herbal medicinal products and food supplements in Europe. These are used either topically or internally. The most commonly used plants include:

cayenne (<i>Capsicum annuum</i> L.)	nettle (<i>Urtica dioica</i>)
devil's claw (<i>Harpagophytum procumbens</i>)	ginger (<i>Zingiber officinale</i>)
turmeric (<i>Curcuma longa</i>)	eucalyptus (<i>Eucalyptus globulis</i>)
boswellia (<i>Boswellia serrata</i>)	wintergreen (<i>Gaultheria procumbens</i> , <i>G. fragrantissima</i>)
comfrey (<i>Symphytum officinale</i>)	meadowsweet (<i>Filipendula ulmaria</i>)

Aromatherapy oils are also used to help relieve joint health problems. Examples include eucalyptus, peppermint and lavender. Products of interest to developing country producers include cinnamon (*Cinnamomum verum*), wintergreen (*Gaultheria fragrantissima*), boswellia (*Boswellia serrate*), and cardamon (*Elletaria cardamomum*). 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 for medicinal use in the European Pharmacopoeia. For more information on aromatherapy, refer to the CBI's Market Intelligence on [Natural Ingredients for Cosmetics](#) regarding several essential oils and refer to relevant European and International literature available under [Forum Essenzia](#).

Exemplary species for developing country producers

Not all species are equally relevant to exporters from developing countries, because of low use in the European market (wintergreen and meadowsweet), highly competitive markets with low prices (eucalyptus), limitation in origins (wintergreen) or competitive cultivation in Europe (nettle and meadowsweet). In contrast, industry sources indicate that cayenne, devil's claw, turmeric, boswellia, and comfrey have good potential for developing country producers in areas with the right growing conditions.

The table below provides information on these exemplary species regarding use in joint health products, including available documentation and references, claims, origins, as well as data on traditional use, clinical trials and filed patents¹ to determine possible product development activity for specific species. The products based on these ingredients are mostly offered as pills in dosage forms, but they can also find applications in tonics or herbal teas, 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 ginger, check the Market Intelligence report on Immune system products, where ginger has been extensively covered. This factsheet also discusses turmeric from that perspective.
- 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 joint health products worldwide. Some of these can be/are already being used in Europe. Clinical evidence on efficacy in relieving joint pain and inflammation is important for new species in terms of entering the market, but it may be difficult for products which aim to prevent joint conditions.
- Link up with local universities or laboratories to conduct thorough research and product development.
- Check databases such as [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.

¹ 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 joint health

Definition	Monographs ²	Allowed usage in supplements ³	Origin	R&D
<p><i>Capsicum annuum</i> (cayenne/capsicum) Capsicum is used in products for topical, external applications, such as in joint ointments or patches.</p> <p>There is a large market for this product, especially for food. Although produced on a large scale, there are opportunities for smaller players to enter the market regarding capsicum extracts for creams (from Asia, largely exported as a finished product, such as patches for external applications).</p>	<p>No WHO Monograph available. ESCOP Monographs 2nd Edition Suppl. (<i>Capsici fructus</i>) 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 <i>Capsicum fructus</i>.</p> <p>No well-established use of capsicum in herbal medicinal products has been documented. No traditional use of capsicum in herbal medicinal products has been documented.</p>	<p>Belgium: allows use of all plant parts of <i>Capsicum annuum</i> L., allows use of fruit and sapwood of <i>Capsicum frutescens</i> L. France, Germany and Italy: allow use of fruit. Italy: also allows use of oleoresin.</p> <p>Capsicum for joint health is marketed for external use (i.e. not regulated as food supplement). A UK example of a claim made for creams containing capsicum is: "warms, soothes and eases creaky joints and stiff muscles" "...to comfort muscles, joints, backs and ease neck tension".</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 <i>Capsicum frutescens</i>): Herbmed registered 8 articles on traditional use, 13 clinical trials and 1 patent.</p> 
<p><i>Harpagophytum procumbens</i> (devil's claw) Devil's claw is used in Europe on a large scale and there is high demand.</p> <p>The species is applied in products for internal use and to relieve joint pain and inflammation.</p> <p>Given that devil's claw is used particularly in supplements, both in the form of capsules and topical gels, targeting this segment offers good opportunities.</p>	<p>WHO Monograph ESCOP Monographs 2nd Edition Suppl. (<i>Harpagophyti radix</i>). European Pharmacopoeia Monographs # 1095 Devil's claw root # 1871 Devil's claw dry extract Community Herbal Monograph</p> <p>No well-established use of devil's claw in herbal medicinal products has been documented. As a traditional herbal medicinal product, claims may include: "relief of minor articular pain" "relief of mild digestive disorders (bloating, flatulence) and loss of appetite".</p>	<p>Belgium: allows use of underground plant parts; with the label stating max. daily use of iridoidsat 40 mg. France: allows use of underground plant parts. Italy: allows use of root. Germany: allows use of roots, with maximum level recommended for food. Restricted and/or limited for use in food in Austria.</p> <p>Food supplements cannot make a medicinal claim; a UK example of a claim made for supplements containing devil's claw is: "Used for degenerative joint diseases" "Devil's claw is also known as an anti-inflammatory and arthritis treatment".</p>	<p>Cultivated in South Africa and Namibia, desert plant.</p>	<p>Herbmed registered 14 articles on traditional use, 19 clinical trials and 14 patents on devil's claw.</p> 
<p><i>Curcuma longa</i> (turmeric) According to industry experts, various studies have been conducted on its anti-inflammatory properties (relieving inflammation and pain in joints). It is used internally, in combination with other products.</p>	<p>WHO Monograph ESCOP Monographs 2nd Edition (<i>Curcuma longae rhizome</i>). European Pharmacopoeia Monograph # 2543. Turmeric rhizome Community Herbal Monograph</p>	<p>Belgium: allows use of root. Not included in French list. Italy: allows use of root, e.g. for antioxidant function. Germany: allows use of rhizome.</p>	<p>Cultivated in tropical South and South East Asia.</p>	<p>Herbmed registered 24 articles on traditional use, 36 clinical trials and 1 patent on turmeric.</p> 

² 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).

³ Indication only. This information is unavailable in many countries, but it is expected to be comparable.

<p>For this indication, the main market opportunity can be found in the supplements market. As a herbal medicinal product, products are aimed at improving digestive health.</p>	<p>Please also note the Draft monograph on Curcuma xanthorrhiza, and European Pharmacopoeia Monograph # 1441 (Turmeric, Javanese).</p> <p>No well-established use of turmeric in herbal medicinal products has been documented. As a traditional herbal medicinal product, claims may include use to: "<i>increase the bile flow for the relief of symptoms of indigestion (sensation of fullness, flatulence and slow digestion)</i>". This being the case, there are few opportunities open to herbal medicinal products for joint health.</p>	<p>Food supplements cannot make a medicinal claim; a UK example of a claim made for supplements containing turmeric is: "<i>...to help maintain joint health</i>".</p>		
<p><i>Boswellia serrata</i> (Boswellia, also known as Indian frankincense and olibanum)</p> <p>The best market opportunities for Boswellia are in food supplements. These are for internal use. Boswellia has been used traditionally for its anti-inflammatory properties. Various studies have been conducted on the efficacy of boswellic acids.</p>	<p>WHO Monograph ESCOP Monographs 2nd Edition Suppl. (<i>Olibanum indicum</i>).</p> <p>European Pharmacopoeia Monograph # 2310 Indian frankincense (<i>Olibanum indicum</i>).</p> <p>No Community Herbal Monograph available.</p> <p>No well-established use or traditional use of Boswellia in herbal medicinal products has been documented.</p>	<p>Belgium, France and Italy: allows use of gum resin.</p> <p>Italy: allows use of gum</p> <p>Germany: allows use, with maximum level recommended for food. Restricted and/or limited for use in food in Austria</p> <p>Food supplements cannot make a medicinal claim; an example from the Netherlands of a claim made for supplements containing Boswellia is: "<i>to move smoothly</i>".</p>	<p>Wild-collected.</p> <p>Main production of the serrata variety is in India and Pakistan, but the tree also grows in North Africa and other countries in the Middle East.</p>	<p>Many patents have been registered for boswellia: Herbmed registered 13 articles on traditional use, 10 clinical trials and 16 patents.</p> 
<p><i>Symphytum officinale</i> (Comfrey)</p> <p>Comfrey is cultivated in moderate climates. At the moment, the market is dominated by large companies, but there is potential for medium-sized companies to enter the market.</p> <p>Various studies have been conducted on the anti-inflammatory effects of comfrey as well; these show good placebo control. It is used topically as an ointment in herbal medicinal products.</p>	<p>No WHO Monograph available.</p> <p>ESCOP Monographs 2nd Edition Suppl. (<i>Symphyti radix</i>).</p> <p>No European Pharmacopoeia Monograph available.</p> <p>Draft Herbal Community Monograph</p> <p>No well-established use of comfrey in herbal medicinal products has been documented. As a traditional herbal medicinal product, claims may include use for: "<i>the symptomatic treatment of minor sprains and bruises</i>".</p>	<p>Belgium: does not allow use in food.</p> <p>France and Italy: no mention of comfrey.</p> <p>Germany: restriction is recommended for use in food.</p> <p>Restricted and/or limited for use in food in Austria, Belgium, Czech Republic, Denmark, Spain, Italy, the Netherlands and Sweden.</p> <p>This being the case, outside of herbal medicinal products. Comfrey is used in creams that target extremely dry skin.</p>	<p>Moderate regions: US, Australia, Asia, (Eastern) Europe.</p>	<p>Little research has been done for comfrey: Herbmed registered 10 articles on traditional use, 1 clinical trial and 1 patent.</p> 

Source: [Herbmed](#) 2012, [ESCOP](#), [EDQM](#), [EMA](#), national food regulators

What is the demand for joint health 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.
- The global market for bone and joint health supplements is forecast to reach US\$ 9 billion (€8 billion) in 2017, according to Global Industry Analysts. However, a study of the global bone and joint ingredients market has indicated that, in Europe, bone and joint ingredients are more frequently consumed through the medium of functional foods and beverages rather than via food supplements.

Joint health products

In order to estimate the need for joint health products, statistics have been included on the main joint health conditions in Europe.

- Around 22% of the population report long-term treatment for troubles with muscles, bones and joints, such as rheumatoid and arthritis (European survey from 2007). This also gives an indication of today's prevalence of joint health issues, as these conditions are incurable. Countries with a much higher incidence include Austria (38%), Hungary (36%), Slovakia (36%) and Spain (35%). The lowest incidence was reported in Cyprus (17%), Finland (16%) and France (11%).
- The incidence of joint conditions is difficult to quantify because of its gradual progression and problems with defining new cases. However, it is estimated that 1 in 10 Europeans aged 60 or above have significant clinical problems that can be attributed to osteoarthritis. The incidence of osteoarthritis rises steeply after 50 years of age and peaks in the 70-79 age group. Given that osteoarthritis is irreversible, prevalence of the condition increases indefinitely with age. Prevalence rates vary according to country and joint type; knee osteoarthritis is the most commonplace condition. Elaborate research in the UK found that 33% of the population aged 45 years and older has sought treatment for osteoarthritis.
- In terms of rheumatoid arthritis (RA), prevalence rates range from 0.32% in France to 0.83% in the UK and even up to 2-4% in the Netherlands. This rate tends to be higher for women than for men. There are indications that annual incidences of RA may be lower in southern European countries.
- Research into musculoskeletal disease shows that Eastern European countries, such as Poland, Slovakia, Bulgaria, Romania and Hungary, have a relatively high number of cases of rheumatoid arthritis and osteoarthritis.
- Data on gout prevalence are limited. In EU countries where data are available, this ranges from 0.3% (Czech Republic) to 3.0% (the Netherlands) of the total population.

Tips:

- Focus on markets such as the UK and Belgium, which have a higher interest in food supplements for joint health than other European countries.
- Please refer to [CBI Trade Statistics for Natural Ingredients for Health Products](#) for statistics on European markets for herbal medicinal products and food supplements.
- 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 joint health products?

An ageing, overweight and inactive population has an increasingly higher risk of joint health conditions and is increasing demand for joint health products. It is estimated that 30% of the European population will be 65 or above by 2050, compared with 17% in 2013. In addition to age, people who are overweight and do not take exercise have a higher risk of joint conditions. Given that an increasing part of the population is overweight, the prevalence of joint conditions is also increasing.

Supplement manufacturers spearheading innovation: Manufacturers of supplements are increasingly seeking out new ingredients for joint health conditions. These new ingredients will allow them to create distinct market profiles for their products. Additionally, known efficacious ingredients are being combined with new ingredients to boost formulas.

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 may relate only to function (e.g. relating to growth, development and functions of the body, psychological and behavioural functions) and risk reduction. For example, you may not claim that your ingredient prevents joint conditions, but you may stress that a certain species can help support good joint health. Also ensure you have the research results to back up your claim with any potential buyer.
- If you are targeting producers of herbal medicinal products, make sure the claims you make in your documentation are mentioned in the European Pharmacopoeia, monographs or list entries.
- Look for a partner in Europe to help build the marketing story and product dossier. Find a company which is interested and sees potential for the (new) ingredient. Please refer to the CBI Module Finding Buyers for more information and tips to find companies.
- Have a look at traditional use as a starting point for new ingredients for joint conditions, for example those with anti-inflammatory properties. Such species may form a foundation on which to build substantiation. Refer to [Market channels and segments](#) for more tips and information.

Counter indications: There is increased consumer scrutiny of contraindications from synthetic joint-health products. Some non-steroidal anti-inflammatory drugs have been linked to negative side-effects, such as increased blood pressure and gastrointestinal toxicity.

Extensive, long-term use: For chronic conditions such as joint health, there is greater potential for botanicals, as consumers are looking for health products they can use regularly and they perceive fewer side-effects from natural alternatives. This holds for all natural products, whether they be botanical or products such as fish oils, natural probiotics and eggshell membrane. As many joint health conditions are chronic, joint health products are often used extensively and over lengthy periods. Please note that natural solutions are not necessarily safer to use than chemical alternatives; this mostly relates to a public perception that natural products are safer.

Research: scientific research and clinical trials that back efficacy and safety are essential for the long-term success of supplements and traditional herbal medicinal products for joint health. Research partnerships are needed in order to develop this research. Most importantly, consumers want supplements that provide measurable benefits. For example, various studies have shown boswellia extracts to have the potential to reduce inflammation and relieve the symptoms of arthritis of the knee. Turmeric is another frequently studied ingredient that has the ability to reduce inflammation.

Tips:

- Communicate how the long-term use of your species will not have a negative impact on health. However, you need to be able to substantiate product safety based on scientific research.
- Create marketing stories for supplements that help joint conditions. These stories need to be clearly communicated to end-users, explaining long-term use options for such supplements, e.g. by means of traditional usage.
- Focus on your botanical's potential in terms of relieving (minor) chronic pain and inflammation, as serious clinical problems relating to joint conditions are beyond the scope of herbal medicinal products or food supplements. Your data should also indicate whether the product is safe for continued use. Although European manufacturers are responsible for product safety, providing such information supports your marketing effort.
- Please refer to [CBI Trends](#) for more market trends.

What requirements should natural ingredients for joint health 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 [HACCEUROPA websites](#).

What competition do I face on the European market for joint health products?

Synthetic alternatives

Synthetic drugs play an important role in treating joint health problems and thus compete with herbal solutions. Herbal medicinal products or food supplements cannot substitute for the *conventional medicines* and treatments used to delay the development of joint conditions (e.g. corticosteroid injections into the joint). Moreover, when managing joint inflammation and pain, synthetic medicinal alternatives (e.g. NSAIDs and, in particular, narcotics) are often effective more quickly than natural solutions.

The *food supplements* segment is especially vibrant in terms of ingredient introductions, and demand for existing natural ingredients also remains strong.

Tips:

- Look for leads to interesting new ingredients in literature on traditional uses research at local universities. Bear in mind that new ingredients need to be researched in terms of their effectiveness and safety. The continuing search for long-term natural solutions to chronic joint problems makes it relatively easy to introduce new ingredients and stories to the food supplements segment.
- Consider whether your ingredient offers anti-inflammatory properties which might be of interest to this segment. Also consider whether your ingredient is already used in this segment. To find species allowed for use in Europe, please refer to the [CBI Module Buyer Requirements](#). 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

There are good opportunities for new ingredients and products in the *food supplements* segment. Most current alternatives to herbal products are natural, non-botanical supplements (e.g. supplements containing glucosamine and chondroitin). Since these markets are reaching maturity, companies are interested in alternative ingredients aimed at joint health that have more potential for growth. In addition, the EFSA has rejected the health claims of glucosamine and chondroitin, because a cause and effect relationship has not been proven between glucosamine and the maintenance of normal joint cartilage.

Various products have emerged in the course of seeking alternatives to glucosamine and chondroitin. Examples of botanical alternatives include seaweed and pine bark extracts. Non-botanical alternatives have emerged as well, such as extracts of eggshell membranes, involving a process largely performed in Western countries.

Tips:

- If your product is already used for joint health, demonstrate in your communication and promotional materials your insights into developments within the competitive environment.
- 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 of 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 to create a distinct market profile and to make 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 both 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 the case of many herbal extracts. With that in mind, many EU buyers prefer to import raw materials, even if their suppliers would prefer to export extracts (to other markets).
- **Finished products** for joint conditions on the EU market are beyond the scope of most companies in developing countries, taking into consideration product development, market authorisation and marketing costs. Ready-to-use capsicum patches and ointments for joint conditions are exported from Asia. New entrants will find it difficult to compete with these players.

Tips:

- Help manufacturers build their story by documenting and visualising your product and company's unique value proposition (e.g. sustainable wild collection, supporting communities, traditional uses of interest, etc.). 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 the potential exists for getting an adequate return on investment.

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 joint health products?

Market segments

Herbal medicinal products on offer in Europe include various products for joint health conditions. Given Europe's ageing population, most producers of herbal medicinal products have products for this indication in their portfolio. Although product development in Europe is limited, the increasing demand for joint health products makes product innovation more viable than for herbal medicinal products for other conditions. Moreover, existing supplier-buyer relations make it difficult for new producers to enter this market segment.

The marketing of a vast number of **food supplements** in Europe targets the relief of inflammation and pain in joint conditions. The segment is dominated by non-herbal supplements, but there is a growing interest in herbal solutions.

Many manufacturers have joint health products in their portfolio, mostly based on established recipes. However, 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 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 joint health in your local language? What do local people use to support joint health or fight inflammation? 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, and to attract their interest.
- 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

Trade fairs

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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