

HERBAL FOOD SUPPLEMENTS

Guide for healthcare professionals



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and Pharmaceutical Care
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European Directorate for the Quality of Medicines & HealthCare (EDQM)
Council of Europe
7 allée Kastner, CS 30026
F-67081 Strasbourg Cedex
France

Internet: www.edqm.eu

FAQs & EDQM HelpDesk:
www.edqm.eu/hd

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Guide for healthcare professionals

Counselling consumers about the use of herbal food supplements¹

Background information about herbal food supplements

Definition

Food supplements are defined as “foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities” in Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements [1]. Herbal food supplements are defined as a type of food supplement that contain plants, parts of plants or plant-derived preparations, and are available as single-entity or combination products. They can be purchased from any food business operator permitted to market food, including pharmacies, non-pharmacy outlets, health food stores, supermarkets and internet sites.

Note: plants, parts of plants or plant-derived preparations can also be found in the composition of herbal medicinal products and traditional herbal medicinal products. These products are covered

¹ In this document, the term “herbal food supplement” is deemed to be interchangeable with the term “botanical food supplement” (i.e. a food supplement that contains plants, parts of plants or plant-derived preparations).

by the medicinal products regulatory framework and are outside the scope of this document.

Purpose of food supplements

According to the European Food Safety Authority (EFSA), food supplements are intended to help the consumer maintain an adequate intake of certain nutrients, supplement the normal diet or support specific physiological functions. They are not medicinal products and as such cannot exert a pharmacological, immunological or metabolic action. Therefore, their use is not intended to treat or prevent diseases in humans or to modify physiological functions [2].

According to European legislation², in the European Union (EU), any claims made for foods (including food supplements) concerning health benefits or properties related to the prevention, treatment or cure of human diseases³ must have been authorised by the European Commission (EC) after an EFSA evaluation. In addition to the above-mentioned provisions, the European Court of Justice has often ruled that “products which are presented as having therapeutic or prophylactic properties with respect to human diseases should be covered by the legislation on medicinal products.” [3].

Legislation

In the EU, food supplements are covered by the food legislation framework. They also come under Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements [1], that lays down both additional mandatory labelling requirements and other conditions, and the following:

2 This guide document is intended to refer to Council of Europe member states; however, given that most of the Council of Europe member states are also EU member states, reference is mostly made to the EU legislation.

3 Currently the assessment of health claims for herbal food supplements is suspended and “on hold” claims may be used while they are still under consideration, subject to the transition measures in Article (28)(5) of the *Nutrition and Health Claims Regulation (EC) No 1924/2006*.

- General requirements for food safety, responsibilities for producers and obligations for traceability, information provision and recall of harmful products (*Regulation (EC) No 178/2002*) [4]
- Preparation and hygiene of foodstuffs based on the principles of Hazard Analysis and Critical Control Points (HACCP) (*Regulation (EC) No 852/2004*) [5]
- Food labelling with the aim of adequately informing the consumer about the composition, properties and use of foodstuffs (*Regulation (EU) No 1169/2011*) [6]
- Use of nutrition and health claims that require prior authorisation (*Regulation (EC) No 1924/2006*) [7]
- Conditions for the use of additives (*Regulation (EC) No 1333/2008*) [8]
- Maximum levels for residues and contaminants (*Regulation (EC) No 369/2005* and *Regulation (EC) No 1881/2006*) [9-10]
- Approval of novel foods and food ingredients not on the European market before 15 May 1997 (*Regulation (EU) No 2015/2283*) [11]

Some EU member states may have national laws and regulations in addition to the EU legislation listed above. National laws may differ considerably among countries, not only in terms of design and scope, but also in terms of content (e.g. lists with ingredients that are permitted or prohibited, maximum levels of ingredients, specific labelling requirements and various other conditions of use), and the resulting variety in regional, national, European and international legal regulations makes it difficult to compare food supplement regulations and provisions [3].

Some non-EU member states also have national regulations in place and these may differ from the EU legislation mentioned above. For instance, North Macedonia maintains lists of plants that are either prohibited (around 250) or permitted (around 1700) in the manufacture of food supplements [12]. In Türkiye, new regulations introduced in 2023 list, among other things, health claims that may be

used in food and food supplement labelling, promotion or advertising [13]. It should also be noted that some non-EU Eastern European countries (e.g. Armenia, Georgia and Ukraine) have a different class of products which is equivalent to food supplements. These are referred to as “biologically active supplements” and have the same regulatory status as food supplements but with certain differences. For example, they are not only designed for oral administration, but can be administered parenterally (e.g. as injections), topically (e.g. ointments and creams), through inhalation, etc. The standards on which national regulations and manufacturing controls for biologically active supplements are based are much lower than in the EU. Therefore, although the legislation in these non-EU countries considers that biologically active supplements are equivalent to food supplements, higher health risks may nonetheless be associated with their use.

In conclusion, although (unlike medicinal products) food supplements and herbal food supplements do not have to undergo a marketing authorisation procedure prior to their commercialisation, they are subject to legal provisions under both food and food supplement legislation covering their composition, safety, labelling and advertisement. Indeed, the EU General Food Law [4] establishes that only safe food can be put on the market and that this safety is the responsibility of food business operators. Moreover, food supplements are controlled by national competent authorities based on risk assessment criteria, through product sampling and analysis, checking the labelling and advertising materials and inspecting manufacturing facilities. For consumer protection purposes, food supplements that do not meet all applicable requirements are taken off the market and necessary actions are taken by authorities [14].

Marketing and labelling

Directive 2002/46/EC [1] also lays down marketing and labelling requirements for (herbal) food supplements in the EU. For example, the directive establishes that member states may require the food business operator or person to notify the competent authority when

placing a product on the market in their territory, and to supply a copy of the product label. However, this notification procedure does not mean that the conformity of the product composition or labelling with the requirements set out in EU and/or national legislation is actually assessed by the competent authority.

Where labelling requirements are concerned, in addition to the conditions for food laid down in Regulation No 1169/2011, Directive 2002/46/EC makes it mandatory to state “food supplement” on the label. It also stipulates that:

- the labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties;
- the labelling must bear the following particulars:
 - (a) the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances;
 - (b) the portion of the product recommended for daily consumption;
 - (c) a warning not to exceed the stated recommended daily dose;
 - (d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;
 - (e) a statement to the effect that the products should be stored out of the reach of young children.

It should be noted that the EC authorises health claims for food, including food supplements, if the EFSA has released a positive opinion for such claims based on the scientific evidence submitted in the Authorisation Request Dossier [15]. Therefore, any food may be claimed to have a beneficial effect on human physiology if such claims have been authorised under EU law.

In addition, there is a list of so-called “on hold” claims on botanicals that may be used, provided that they comply with the Nutrition and

Health Claims Regulation (*Regulation No. 1924/2006*) and until a final decision is made by the EC.

A list of authorised and “on hold” claims can be found on the EC website [16].

Safety of herbal food supplements

Many consumers may assume that herbal food supplements are safe because they are derived from natural sources. This belief is not necessarily correct, and it is important that consumers follow the dosage and instructions for use on the label. Furthermore, in the event of a concomitant medical treatment, procedure or condition, it is essential for consumers to inform their healthcare professional that they are taking food supplements.

It is also important to note that the safety of any herbal food supplement depends on multiple factors, e.g. its composition, chemical structure and mechanism of action, the daily intake, the health status, diet and living conditions of the consumer, and storage conditions.

Moreover, some plants, or parts thereof, are prohibited from use in both food and food supplements, and may only be used in medicinal products (e.g. *Atropa belladonna L.*, *Datura spp.* and *Digitalis spp.*) [17].

Herbal food supplements may be contaminated with microorganisms, fungal toxins, pesticides and heavy metals, and this may pose a threat to the health of consumers [18].

In some cases, herbal food supplements may even be adulterated (e.g. undeclared presence of controlled drugs and active pharmaceutical ingredients in their composition) leading to serious health risks such as acute or chronic toxicity, severe adverse reactions and drug interactions [19].

It is therefore important that consumers buy food supplements from reputable food business operators and suppliers that comply with EU obligations and/or national food safety legislation and via trustworthy channels (e.g. pharmacies and non-pharmacy outlets, company websites).

Consumers taking other medication concurrently may be potentially at risk for a drug-herbal food supplement interaction [20-21]. For instance, according to a study by Sood *et al.*, the most common prescription medication classes with a potential for interaction are antithrombotic medications, sedatives, antidepressants and antidiabetic agents [22]. In their research, the authors found that concomitant use of these classes of prescription medications and herbal food supplements accounted for 94% of all potential clinically significant interactions between these two types of products. The same study found that the five most common herbal food supplements associated with potential drug interactions were *Allium sativum* (garlic), *Valeriana L.*, *Piper methysticum* (kava), *Ginkgo biloba L.*, and *Hypericum perforatum L.* (St. John's wort).

Some harmful – even life-threatening – consequences may also be experienced if herbal food supplements are used instead of medicines, are not taken as recommended, are combined with each other, are misidentified or are taken by consumers with preexisting medical conditions (e.g. cardiovascular, kidney or liver disease).

In addition, as stated above, if herbal food supplements are bought online from dubious or unfamiliar websites, the risks of obtaining poorly manufactured, substandard, adulterated, contaminated or incorrectly stored products are increased and this may result in acute health problems or severe poisoning, for instance [23-24].

Finally, it is important to note that many herbal food supplements have not been tested in vulnerable populations, such as pregnant or breastfeeding women, children or older people; it is therefore essential for consumers to read the label carefully and, if necessary, to consult a healthcare professional before using these food supplements.

Procurement of herbal food supplements to be sold in pharmacies and non-pharmacy outlets

Pharmacists (and, if applicable, other professionals, e.g. herbalists) should ensure that the herbal food supplements they procure and supply are of good quality and that they satisfy relevant legislative requirements. To this end, they must take all reasonable steps to ensure that the criteria listed above (see *Legislation* and *Marketing and labelling*) are met and to obtain evidence of the safety and suitability of the food supplements they intend to supply.

In particular, as far as possible, herbal food supplement vendors are advised to ensure that:

- reputable food business operators offering high quality products are selected, in order to avoid entry of substandard, adulterated and falsified herbal food supplements into the system. These food business operators must comply with European and national rules, e.g. maximum levels for residues and contaminants, labelling requirements. If applicable, they must also have implemented a quality management system (e.g. International Organization for Standardization (ISO), Good Manufacturing Practice (GMP), Good Agricultural and Collection Practice (GACP), Hazard Analysis Critical Control Point (HACCP));
- the suppliers/manufacturers they select are authorised, registered as food business operators with the national competent authority and operate in compliance with the applicable regulations;
- the procurement process is supported by strong quality assurance principles;
- all products sold in the pharmacy or non-pharmacy outlet are stored under appropriate conditions;
- comprehensive and up-to-date information is provided with the labelling (e.g. qualitative and quantitative composition);

claims; information for consumers providing details such as composition, dose, frequency of use and duration of use; any warning statements aimed at specific groups of people);

- an effective traceability system is in place allowing prompt product withdrawal in the event of a safety or quality issue with a food supplement on the market, etc.

Consumer counselling and education around the use of herbal food supplements

General considerations [25-30]

When advising consumers, after checking the composition of the product (as specified on the label) and evaluating potential issues, healthcare and other professionals should take the following elements into consideration and discuss:

- why a herbal food supplement may be appropriate;
- whether the consumer belongs to a special population (e.g. pregnant or breastfeeding women, older people, children, patients with liver or kidney disease);
- the consumer's pre-existing conditions and health status, since some herbal food supplements may not be appropriate (e.g. *Ginkgo biloba L.* in patients with a pathologically increased bleeding tendency (haemorrhagic diathesis));
- the other medicines and products the consumer is taking, as interactions with prescription and non-prescription medications (e.g. *Ginkgo biloba L.* and concomitant use of warfarin) and/or other food supplements (e.g. St. John's wort and 5-hydroxytryptophan) are possible;
- any scheduled laboratory tests and medical examinations and/or surgical interventions: consumers should be reminded of the need to inform their healthcare professionals if they are taking any supplements because some may affect laboratory tests (e.g. some herbal products such as *Panax ginseng* (Asian ginseng) and *Eleutherococcus senticosus* (Siberian ginseng) are structurally similar to digoxin and may interfere with the digoxin immunoassay, potentially leading to falsely elevated or decreased digoxin levels depending on the type of assay used in the laboratory) or interfere with surgery (e.g. *Ginkgo biloba L.* may cause bleeding problems, whereas *Valeriana L.* may interfere with the effects of surgical anaesthesia);

- the intended effects of the herbal food supplements as well as the main differences between medicines and food supplements: it is important to ensure that consumers are aware that herbal food supplements are considered as food and not medicinal products and as such cannot exert a pharmacological, immunological or metabolic action. Therefore, their use is not intended to treat or prevent diseases or to modify physiological functions, and they should not be used instead of a medical treatment or conventional medicines to treat acute/chronic conditions or diseases;
- safety and awareness of possible risks for the consumer: it is crucial to remind consumers that the term “natural” does not always mean “safe” and, even if many herbal food supplements are considered safe, others may have the potential to be harmful, especially if they are used incorrectly, concomitantly with prescription or over-the-counter medications, instead of medications, or not bought from reputable suppliers in which case they may not contain what is declared (see *Safety of herbal food supplements*);
- the importance of reading the product label carefully, following the instructions closely, storing herbal food supplements appropriately and using them for short periods only;
- surveillance of adverse reactions: while many products are safe to use, some herbal food supplements may cause adverse reactions. These reactions may occur immediately or can happen sometime later and can range from minor events to life-threatening reactions, resulting in emergency room visits or hospitalisation. Adverse reactions to herbal food supplements may also be under-reported due to information asymmetry, i.e. consumers might fail to inform healthcare professionals that they are taking food supplements or do not consider this information important. It is therefore essential for healthcare professionals to both inform consumers that adverse effects or allergic reactions may occur when using herbal food supplements and to instruct them on what to do if they experience such

undesired effects (e.g. stop taking the product, seek medical care). In addition, healthcare professionals and consumers are encouraged to report any reactions to a food supplement or even the suspicion of a problem to their national competent authorities (see below: *Adverse event reporting*).

In general, healthcare (and other) professionals should consult reputable sources of information and make sure they are informed about recent updates on plants that can be used in herbal food supplements. It may also be useful to consult available lists of plants that could be relevant to the healthcare professional's practice (e.g. because they are kept in stock or questions about them are frequently asked) to be able to advise consumers in a meaningful and comprehensive manner.

Healthcare professionals⁴ - Possible questions to ask consumers

Before recommending a given herbal food supplement, it is important to discuss the consumer's medical and medication history to make sure that the supplement is suitable.

Questions that can be asked include:

- Is this food supplement for you or for someone else?
- Did a healthcare professional (e.g. your general practitioner) advise you to use this product and, if yes, for what reasons?
- Have you informed other healthcare professionals (e.g. your general practitioner) that you intend to take this product?
- Why do you want to use this food supplement?
- Do you have any ongoing health conditions?
- Are you allergic to any herbal products?
- Are you taking any other medication or food supplements?

⁴ This section refers to questions that can be asked by healthcare providers working in pharmacies/outlets but similar questions can also be asked by other healthcare providers who may be in a position to discuss the use of food supplements with consumers (e.g. general practitioners, nurses).

- Are you pregnant or breastfeeding?
- Do you have any laboratory tests, surgical operations or other invasive procedures planned in the near future?
- Are you aware that food supplements should not be used to prevent or treat a health condition?
- Are you aware that herbal food supplements may cause side effects?

Adverse event reporting

Consumers should be informed that if they experience any adverse reactions, they should contact the food business operator mentioned on the product label and, if applicable (or deemed necessary), their doctor or pharmacist who, in turn, should notify the competent food authority. When reporting adverse reactions, it is important to include as much detail as possible, in particular all the information available about the consumer, together with the name of the product, the batch number, the food business operator, details relating to the herbal food supplement (including the intake and duration of use) and any other food supplements or medicines used concomitantly (including, if available, any remaining product in order to perform a lab analysis).

Consumers should also be encouraged to stop using a food supplement if they suspect that its quality is impaired (e.g. change in its colour or smell), to contact the food business operator and send it back as food operators may be interested in receiving the product to test it to determine the root cause of the issue.

Information sources

Additional information on herbal food supplements (including individual herbs, their use, and risks) can be found in the resources listed below.

American Herbal Products Association – <https://www.ahpa.org/>

Cochrane database – <https://www.cochrane.org/>

European Commission – Food supplements – https://food.ec.europa.eu/safety/labelling-and-nutrition/food-supplements_en

European Food Safety Authority (EFSA) – Botanicals: <https://www.efsa.europa.eu/en/topics/topic/botanicals>

EFSA: Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements – <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2012.2663>

Mayo Clinic - <https://www.mayoclinic.org/drugs-supplements/>

Memorial Sloan Kettering Cancer Center – <https://www.mskcc.org/cancer-care/diagnosis-treatment/symptom-management/integrative-medicine/herbs/search>

National Center for Complementary and Integrative Health – <https://www.nccih.nih.gov/health/herbsataglance>

National Institutes of Health – <https://ods.od.nih.gov/factsheets/list-all/>

NatMed database for food, herbs and supplements – <https://naturalmedicines.therapeuticresearch.com/databases/food,-herbs-supplements.aspx>

PubMed database (for medical and scientific studies on specific herbal supplement ingredients) – <https://pubmed.ncbi.nlm.nih.gov/>

US Food and Drug Administration – <https://www.fda.gov/food/healthcare-professionals/dietary-supplement-continuing-medical-education-program>

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List of authors

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Author names and affiliations (in alphabetical order)

Dr Anna Bryndís Blöndal

University of Iceland and The Primary Health Care of the Capital Area – Iceland

Dr Zaza Chapichadze

Ministry of Labour, Health and Social Activities – Georgia

Dr Marcello Chiavoni

Italian Medicines Agency – Italy

Ms Elona Cilku

Agency for Medicines and Medical Devices in Northern Macedonia – North Macedonia

Dr Valeria D. di Giorgi Gerevini

Ministry of Health – Italy

Dr Denis Gjika

Agency of Health and Social Care Quality Assurance – Albania

Ms Eva Mendes (Project Rapporteur)

National Authority of Medicines and Health Products – Portugal

Dr Tijana Micovic

Institute for Medicines and Medical Devices – Montenegro

Dr Silvia Ravera

EDQM Secretariat

Council of Europe – France

The growing availability and use of herbal food supplements have raised concerns about their safe and appropriate use, quality, potential interactions with medication and/or other food supplements, and misleading claims.

The aim of this guide is to provide healthcare professionals with a structured approach to help them advise consumers on the appropriate use, potential risks and high-level regulatory framework of herbal food supplements. It includes key counselling points, common misconceptions and some practical recommendations to minimise misuse and potential interactions with medicines and/or other food supplements.



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