

# Potential information sources on market authorisation of complementary/herbal medicine ingredients

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# Potential information sources that could assist regulators with market authorisation of complementary/ herbal medicine ingredients

## Background

This document has arisen as an action item from a side meeting to the Ninth International Summit of Heads of Medicines Regulatory Agencies, which took place on 19-21 November in Beijing, China. The side meeting was chaired by Professor John Skerritt, TGA National Manager, and was attended by 27 representatives from:

Australia  
Brazil  
Canada  
China  
European Union Directorate-General for Health and Consumers  
European Medicines Agency  
Italy  
Japan  
The Netherlands  
Singapore  
South Korea  
South Africa  
Switzerland  
United Kingdom.

The purpose of the meeting was to:

- share information on regulatory systems for herbal and other complementary medicinal products
- discuss approaches that could reduce workloads and duplication of individual regulators in evaluating products or ingredients for safety and/or quality.

There are many sources of information available on herbal and other complementary medicine ingredients. Participants agreed that an information resource on ingredients could be developed to be shared between regulators and hosted on one or more regulators' websites. It was considered that, in most cases, this would consist of safety and quality monographs but it could include public assessment reports.

Part 1 of this document provides background information on the different regulatory frameworks of countries represented at the meeting.

Part 2 is the initial draft information resource on available reports and monographs on herbal and complementary medicines and ingredients.

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## Part 1: Information on international regulatory frameworks and sources of information used for complementary/ herbal medicines

### Australia: Therapeutic Goods Administration (TGA)

#### Australia: regulatory framework

In Australia, products containing designated active ingredients such as plant or herbal material, amino acids, vitamins, minerals, essential oils, certain nutritional substances, certain non-human animal derived materials, homoeopathic preparations and essential oils are referred to as 'complementary medicines' and are regulated as medicines by the TGA under the *Therapeutic Goods Act 1989* (the Act).

Unless exempt, or otherwise approved, medicines supplied in Australia are required to be included on the Australian Register of Therapeutic Goods (ARTG). Australia has a two-tiered system for medicines based on risk. Lower risk medicines are listed on the ARTG and do not undergo individual pre-market evaluation, while higher risk medicine are registered on the ARTG and are fully evaluated by the TGA.

While some complementary medicines are registered on the ARTG, most complementary medicines are listed on the ARTG. Listed medicines must:

- only contain certain low risk ingredients that have been pre-approved
- make only lower level health claims; and
- be manufactured according to the principles of Good Manufacturing Practice.

Low risk medicines are listed on the ARTG on the basis of a certification by the applicant/sponsor that the goods meet all applicable legislative requirements, including that the sponsor holds evidence for all indications and claims made for the medicine, the medicine conforms to every standard applicable to the medicine and to every requirement relating to advertising.

#### Australia: sources of information

The default standards recognised under the Act are:

- the [British Pharmacopoeia](#)
- the European Pharmacopoeia
- the [United States Pharmacopeia – National Formulary](#)
- an order under section 10 of the Act ('Ministerial standard').

The default standards generally relate to quality aspects. The TGA does not have recognised sources of information in relation to indications. It is the responsibility of the sponsor to hold evidence that supports all indications and claims made for their medicines.

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## Brazil: National Health Surveillance Agency

### Brazil: regulatory framework

Herbal medicines for human use are regulated by the National Health Surveillance Agency (ANVISA). The Brazilian regulatory scheme separates herbal medicines into two categories:

- Traditional Herbal Products.
- Herbal Medicines.

Traditional Herbal Products have a simplified notification scheme. ANVISA recognises that some herbal species are safe and effective and accordingly, the registration of these species is simplified. A list of herbal species eligible for the simplified notification scheme is available on the ANVISA website. In addition, herbal species that have a European Community Monograph (HMPC) are also eligible for simplified registration.

Herbal Medicines may be considered a food supplement or a drug requiring registration, depending upon such things as dosage. For Herbal Medicines that require registration, safety and efficacy must be proven by clinical data or evidence of traditional use.

### Brazil: sources of information

In Brazil there are two official pharmacopoeias (available at <http://www.anvisa.gov.br/hotsite/farmacopeiabrasileira/dcb.htm>)

- The *Brazilian Pharmacopoeia*, includes the quality control tests both for synthetic and herbal medicines and has 61 herbal monographs.
- The “*Formulário de Fitoterápicos da Farmacopeia Brasileira*” includes 70 herbal medicine formulations that are recognized as safe to be prepared in pharmacies.

As well as the official pharmacopoeias, other pharmacopoeias can be used as official codex in Brazil: USP and USP National Formulary, German, Argentinean, British, European, French, Japanese, Mexican and Portuguese Pharmacopoeias.

Several other unofficial sets of plant monographs also have been used as reference guide, for example:

- *Monografias de plantas medicinais brasileiras e aclimatadas* (Gilbert et al., 2005)
- *Farmácias Vivas* (Matos, 2000)
- WHO Monographs on selected medicinal plants, tomes 1-4 (WHO, 1999, 2004, 2007, 2009)
- European scientific cooperative on phytotherapy - Monographs on the medicinal uses of plant drugs (ESCOP, 1996)
- *American herbal pharmacopeia* (Upton; Petrone, 1999)
- British herbal compendium (Bradley, 2006)
- Expanded Commission E monographs (Blumenthal, 1999, Blumenthal et al., 2000)
- *Vademécum nacional de plantas medicinales* (Cáceres, 2006)
- Public Phytotherapy Services edited books.

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The Brazilian Health Ministry has developed a number of official monographs for well-known herbal drugs and are expanding the list. The monographs include data on safety, efficacy, quality and marketing of herbal medicines. These are available in Portuguese on the ANVISA website: <http://portalsaude.saude.gov.br/index.php/oministerio/principal/secretarias/sctie/fitoterapicos/noticias-fitoterapicos/16353-prorrogada-a-consulta-publica-sobre-especies-medicinais-da-renisus>.

## **Canada: The Natural and Non-prescription Health Products Directorate (NNHPD)**

### **Canada: regulatory framework**

Health Canada regulate Natural Health Products under the Natural Health Products Regulations, which came into force in 2004 and fall under the Canada's *Food and Drugs Act*.

Natural Health Products are evaluated for safety and efficacy before being approved for use in Canada. At the commencement of the regulations in 2004, there was a significant backlog of products requiring evaluation and market approval. To help address the backlog of products, NNHPD developed ingredient monographs as a source of pre-cleared information.

All Natural Health Products must have a product licence before they can be sold in Canada. To get a licence, applicants must give detailed information about the product to NNHPD, including medicinal ingredients, source, dose, potency, non-medicinal ingredients and recommended use.

The evaluation of Natural Health Products focuses on harm, benefit and uncertainty. There are three streams for approval of ingredients/products:

- 10 days if a Canadian monograph already exists.
- 30 days if a monograph exists but the request is for a new indication or if it's a new combination of herbals.
- Up to 180 days for products where there's a large amount of uncertainty, for example: major claims and new ingredients.

NNHPD is intending to create a new more timely regulatory approach to Over the Counter products, which is similar to the framework for natural health products. Under the new approach, evaluations will be focused on a harm, benefit and uncertainty approach rather than using the same evaluation processes as prescription medicines.

### **Canada: sources of information**

'Pre-cleared information', including monographs, is any form of information supporting the safety, efficacy or quality of a medicinal ingredient or natural health product that Health Canada has reviewed and determined to be acceptable. This information can be used to speed up the evaluation of the Natural Health Product, and serves as a reliable source of product information for consumers.

Single ingredient monographs apply to formulations containing only one medicinal ingredient. The monographs are available at: <http://webprod.hc-sc.gc.ca/nhpid-bdipsn/monosReq.do?lang=eng&monotype=single>

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## China: China Food and Drug Administration

### China: regulatory framework

Herbal medicine legislation was introduced in China in 1985. Herbal products are regulated as medicines requiring clinical trials and Good Manufacturing Practice. Many herbal medicines are initially regulated as prescription products and are then switched to Over the Counter medicines. Challenges are faced in regulating the quality of medicines in this area, especially the interface between plant and concentrate or extract.

### China: sources of information

The main information source is the *People's Republic of China Pharmacopeia* which includes herbal medicines. The 2015 version will have an English translation.

## European Union: European Medicines Agency (EMA)

### European Union regulatory framework

In the European Union, herbal medicinal products are defined as any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such preparations.

Herbal medicinal products are mainly authorised by the Member States, under a harmonised EU framework. The Heads of Medicines Agencies Mutual Recognition Information (MRI) Product Index is at: <http://www.hma.eu/mriproductindex.html>.

Until 2004, herbal medicinal products were generally authorised under the 'well-established use' provisions of EU legislation (this route is still available). To reflect the fact that traditional herbal medicinal products have particular characteristics, notably their long tradition of use, Directive 2004/24/EC introduced a lighter, simpler and less costly registration procedure. A transition period of seven years was provided to register traditional herbal medicinal products that were on the market prior to 2004.

The simplified registration procedure allows the registration of herbal medicinal products without requiring documentation on safety and efficacy, provided that there is:

- sufficient evidence of the medicinal use of the product throughout a period of at least 30 years, including at least 15 years in the EU; and
- the product proves not to be harmful in the specified conditions of use.

Applications for registration of traditional herbal medicinal products have to fulfil the same requirements as applications for marketing authorisations with regard to their manufacturing and quality.

EMA's Committee on Herbal Medicinal Products Committee (HMPC) monographs have been developed mainly to address safety issues of traditional or well established herbal products. The monographs comprise the scientific opinion of the HMPC on safety and efficacy data concerning a herbal substance and its preparations intended for medicinal use.

A product which conforms to the HMPC monograph is considered safe (and effective or plausible if it complies with the well-established or traditional use requirements), but quality still needs to be demonstrated. EU Member States accept the registration of traditional herbal medicinal products when it is on the EU list, provided that the quality of the product is documented according to the EU legislation requirements (e.g. Ph. Eur. Monograph). Member States are not



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obliged to authorise or register a product which conforms to a HMPC monograph, but non-acceptance of a product would require justification.

Applications for registration of traditional herbal medicinal products can be submitted even if the substance or preparation is not included in the EU list. For more information:

[http://ec.europa.eu/health/human-use/herbal-medicines/index\\_en.htm](http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm)

Herbal products that are not authorised under the pharmaceutical legislation can still be placed on the market as food, provided that they are not presented as medicinal products and they comply with the applicable food law. Herbal products marketed in the form of food supplements must comply with Directive 2002/46/EC on food supplements and Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. There are also national laws in different member states defining food supplements, and these may differ between countries.

Many companies prefer to market their products as food supplements rather than apply for registration. The evaluation of the suitability of health claims for food supplements is under the responsibility of the European Food Safety Authority (EFSA), but the decision on whether a product can be a botanical food supplement is up to the individual Member State. This may lead to different positions among different Member States on the same product or on products containing the same herbal ingredient, which, by virtue of the free trade provisions in the EU, are marketed with different status in different Member States.

Directive 2002/46/CE (art. 2) FOOD SUPPLEMENTS means:

*Foodstuffs the purpose of which to supplement the normal diet and which are concentrated sources of nutrients (vitamins or minerals) 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*

Directive 2001/83/EC - MEDICINAL PRODUCT mean:

*Any substance or combination of substances presented as having properties for treating or preventing disease in human beings (Presentation medicinal products)*

*Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medicinal diagnosis. (Function medicinal products)*

A critical issue is thus the distinction between “restoring, correcting or modifying physiological functions” in the medicines definition and “physiological effect” in the food definition. See [www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000212.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000212.jsp)

## EMA sources of information

The European Commission’s Directorate-General for Health and Consumers (DG SANCO) is involved in maintaining the monographs of the *European Pharmacopoeia*. EMA’s Committee on Herbal Medicinal Products (HMPC) monographs are developed mainly to address safety issues of traditional or well established herbal products.

The HMPC Monograph and List Working Party (MLWP) prepares:

- HMPC documents on safety and efficacy.
- EU monographs.

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- Entries to the “EU List of herbal substances, preparations and combinations thereof for use in THMPs”.

The European Pharmacopoeia monographs are used as a reference for the quality of the herbal substance/preparation. The EU HMPC monographs are used as a reference for the safety and efficacy of Herbal Medicinal Products or Traditional Herbal Medicinal Products.

When an applicant refers to the “EU List of herbal substances, preparations and combinations thereof for use in THMPs” no further documentation on safety or on traditional medicinal use is required.

If a EU monograph reports that the test of genotoxicity and mutagenicity has not been performed or are inadequate or when a member state presented a divergent opinion at the moment of the adoption of the EU monograph, the applicant may be asked to submit further documentation to complement the EU monograph.

A Community herbal monograph contains the view of the HMPC on all information necessary for the use of a medicinal product containing the herbal substance or preparations described in the monograph. It is comprised of the HMPC scientific opinion on safety and efficacy data for a herbal substance and its preparations intended for medicinal use. The HMPC evaluates scientifically available information including non-clinical and clinical data as well as documented long-standing use and experience in the Community. A monograph provides:

- What the herbal product is used for.
- Who the herbal product is intended for.
- Safety information such as information regarding undesirable effects and interactions with other medicines.

Monographs are published together with an assessment report containing reviews of available data relevant for the medicinal use of the herbal substance or preparations. Community monographs are divided into:

- Well-established use (marketing authorisation).
- Demonstrated with sufficient safety and efficacy data and traditional use (simplified registration).
- Accepted on the basis of sufficient safety data and plausible efficacy.

A final Community monograph can be used in application reference material by:

- A marketing-authorisation applicant (well-established-use part).
- By a traditional-use-registration applicant (traditional-use part).

## **EMA: Information sources**

- The EMA publishes a list of “Inventory of herbal substances for assessment “and updates it annually. See:  
[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2009/12/WC500017723.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017723.pdf)
- To view all European Union herbal monographs, go to the [document library](http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/landing/document_library_search.jsp&mid=WC0b01ac058009a3dc) ([http://www.ema.europa.eu/ema/index.jsp?curl=pages/document\\_library/landing/document\\_library\\_search.jsp&mid=WC0b01ac058009a3dc](http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/landing/document_library_search.jsp&mid=WC0b01ac058009a3dc)) and search using the document type, 'Herbal - European Union herbal monograph'.

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- To browse for existing European Union herbal monographs and supporting documents by herbal substance, use, status or outcome go to "Find medicine", [herbal medicines for human use](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_medicines_search_landing_page.jsp&mid=) ([http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal\\_medicines\\_search\\_landing\\_page.jsp&mid=](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_medicines_search_landing_page.jsp&mid=))

## Italy: Italian Medicines Agency

Italy operates under the EU framework. They are experiencing issues with some herbal and traditional herbal products and food supplements avoiding pre-market scrutiny.

## The Netherlands: Medicines Evaluation Board

The Netherlands also operates under the EU framework; most herbal products are not regulated as medicines, but as natural products under national licences. There are some licences for Chinese medicines.

## Japan: Pharmaceuticals and Medical Devices Agency (PMDA)

Japan does not have a category of herbal medicine per se; but rather 'quasi-drug' categories of Chinese or traditional Japanese drugs (either over the counter or pharmaceutical).

## South Korea: Ministry of Food and Drug Safety

### South Korea: regulatory framework

The regulatory scope of the Ministry of Food and Drug Safety (MFDS) regulates food, drug, cosmetics and medical devices. Herbal products are regulated as health functional foods or herbal medicines depending on the health claim or disease claim.

Individual herbal medicine products require marketing authorisation. Health functional food products require notification where the ingredients are approved by MFDS or listed on the Health Functional Food Code.

Herbal medicine is classified into:

- Traditional Korean Medicinal Products (TKMP)
- Herbal Medicinal Products (HMP)

Traditional Korean Medicinal Products are manufactured according to the TKMP combination principles, evidence is based on traditional medical books and they do not require non-clinical and clinical documents.

In contrast, Herbal Medicinal Products require approval via a safety-efficacy evaluation.

Pharmaceutical regulation covers herbal medicines and traditional medicines and marketing authorisation is required for these.

### South Korea: information sources

- *Korean Pharmacopoeia* (KP): Herbal substances and herbal preparations are listed in monographs, Part II (English) <http://www.mfds.go.kr/eng/index.do?nMenuCode=50>
- The *Korean Herbal Pharmacopoeia* (KHP) monographs (non-English) <http://www.mfds.go.kr/index.do?searchkey=title:contents&mid=1013&searchword=규격집&division=&pageNo=1&seq=8446&cmd=v>  
<http://drug.mfds.go.kr/html/search.jsp?collection=kifda>

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- 200 herbal medicine monographs on the MFDS website in English.
  - The Health Functional Foods Code monographs (English)  
<http://www.mfds.go.kr/eng/index.do?nMenuCode=65>

## **South Africa: The Medicines Control Council of South Africa's Department of Health**

In South Africa, herbal medicines are categorised as either herbal or traditional African medicines. Traditional African Medicines are not regulated if they are provided to individual patients by a practitioner.

Commercially sold herbal medicines are regulated under a new framework which commenced in March 2014. A monograph route for herbal and OTC medicines is planned.

Vitamins and minerals are not regulated as medicines, providing they are within certain upper limits.

South Africa has commenced on reviewing claims of herbal medicines referring to HIV or malaria treatment in their indications.

## **Singapore: Health Products Regulation Group Health Sciences Authority**

Traditional medicines and health supplements are overseen by the Complementary Health Products Branch under the Health Science Authority. Complementary Health Products include Chinese Proprietary Medicines, Other Traditional Medicines and Health Supplements.

Chinese Proprietary Medicines are subjected to pre-market approval and manufacturers must be licensed. Other Traditional Medicines and health supplements (such as vitamins and minerals) are regulated under a 'listing' approach and are not subject to pre-market approval, providing they do not refer to a list of serious diseases.

## **Switzerland: Swissmedic**

In Switzerland, if specific indications are claimed for herbal medicines, efficacy data and evaluation is required.

Swissmedic is currently revising their therapeutic goods legislation to consider a new risk-based approach for registration for herbal medicines for traditional use; including a notification system for low risk products.

## **United States of America: US Food and Drug Administration**

### **USA: regulatory framework**

Under the US regulatory framework, dietary supplements include many products and ingredients such as vitamins, minerals and herbal extracts.

If a US company plans to market a dietary supplement that contains a new dietary ingredient, that has not been present in the food supply, they must submit to FDA (at least 75 days before the dietary ingredient is introduced) information that the new dietary ingredient will reasonably be expected to be safe. The proposal must include:

- The name of the new dietary ingredient.
- A description of the dietary supplement or dietary supplements that contain the new dietary ingredient, including the level of the new dietary ingredient in the product and conditions of use of the product recommended or suggested in the labelling or if no conditions of use are recommended or suggested, the ordinary conditions of use.

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- History of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labelling of the dietary supplement, will reasonably be expected to be safe. Any reference to published materials must be accompanied by reprints or photocopies. Any material in a foreign language must be accompanied by a translation.

Within 75 days after the notification, the FDA provides:

- a letter of acknowledgement without objection; or
- a letter listing deficiencies that make the notification incomplete; or
- an objection letter raising safety concerns based on information in the notification or identifying gaps in the history of use or other evidence of safety; or
- a letter raising other regulatory issues with the New Dietary Ingredient or dietary supplement (e.g., is the proposed ingredient is not defined as a dietary ingredient under FDA regulation or the product is excluded from the definition of "dietary supplement" because it is not intended for ingestion). See [www.fda.gov/Food/DietarySupplements/ucm109764.htm](http://www.fda.gov/Food/DietarySupplements/ucm109764.htm)

### **USA: information sources**

Usually detailed submissions or safety assessments are not published, however FDA do publish their responses (including some analysis of safety claims) at [www.regulations.gov/#!/home](http://www.regulations.gov/#!/home) and search under 95S-0316

## Part 2: Sources of information used for complementary/ herbal medicines

**Table 1: Official international pharmacopeia**

Country/ organisation	Official pharmacopoeia and formulary	Comments: Organisation, language
Argentina	<i>Farmacopea Argentina</i>	Language: Spanish
Brazil	<i>Farmacopéia Brasileira</i>	Language: Portuguese Includes the quality control tests both for synthetic and herbal medicines and has 61 herbal monographs.
	<i>The “Formulário de Fitoterápicos da Farmacopeia Brasileira”</i>	Includes 70 herbal medicine formulations that are recognized as safe to be prepared in pharmacies.
Croatia	<i>Hrvatska Farmakopeja</i>	
Czech Republic	<i>Césky lékopis</i>	
European Union	The <a href="#">European Pharmacopoeia</a> (Ph.Eur.)	Language: English
France	<i>Pharmacopée française</i>	Language: French, some updated texts in English
Germany	<i>Deutsches Arzneibuch – DAB</i>	Language: German
India	<i>Indian Pharmacopoeia (IP)</i>	
Indonesia	<i>Farmakope Indonesia</i>	
Italy	<i>Farmacopea Ufficiale della Repubblica Italiana</i>	Language: Italian
Japan	<i>The Japanese Pharmacopoeia (JP)</i>	Language: Japanese, English

Kazakhstan (Ph. Eur. Obs.)	<i>The State Pharmacopoeia of the Republic of Kazakhstan</i>	
Mexico	<i>Farmacopea de los Estados Unidos Mexicanos</i>	Language: Spanish
	<i>Mexican Herbal Pharmacopoeia</i>	Language: Spanish
Portugal	<i>Farmacopeia Portuguesa</i>	Language: Portuguese
People's Republic of China	<i>People's Republic of China Pharmacopeia</i>	Language: Chinese, English
Russian Federation (Ph. Eur. Obs.)	<i>State Pharmacopoeia of the Russian Federation</i>	
Serbia	Yugoslav Pharmacopoeia	
South Korea	<i>The Korean Pharmacopoeia (KP) monographs ( English)</i> <a href="http://www.mfds.go.kr/eng/index.do?nMenuCode=50">http://www.mfds.go.kr/eng/index.do?nMenuCode=50</a>	Language: English
	<i>The Korean Herbal Pharmacopoeia (KHP) monographs (non-English)</i> <a href="http://www.mfds.go.kr/index.do?searchkey=title:contents&amp;mid=1013&amp;searchword=한약집&amp;division=&amp;pageNo=1&amp;seq=8446&amp;cmd=v">http://www.mfds.go.kr/index.do?searchkey=title:contents&amp;mid=1013&amp;searchword=한약집&amp;division=&amp;pageNo=1&amp;seq=8446&amp;cmd=v</a> <a href="http://drug.mfds.go.kr/html/search.jsp?collection=kifda">http://drug.mfds.go.kr/html/search.jsp?collection=kifda</a>	Language: Korean Herbal substances and herbal preparations are listed in monographs, Part II.
Switzerland	<i>Pharmacopoea Helvetica</i>	Language: French, German, Italian
United Kingdom	The <a href="#"><i>British Pharmacopoeia</i></a>	Language: English
United States of America	The <a href="#"><i>United States Pharmacopeia – National Formulary</i></a>	Language: English
Ukraine (Ph. Eur. Obs.)	<i>The State Pharmacopoeia of Ukraine</i>	
World Health Organization	<a href="#"><i>The International Pharmacopoeia (Ph. Int.)</i></a>	Language: English

**Table 2: International monographs**

Country/organisation	Monographs	Comments
American Botanical Council	<a href="http://abc.herbalgram.org/site/PageServer?pagename=Monographs">http://abc.herbalgram.org/site/PageServer?pagename=Monographs</a>	ABC is a non-government organisation. To date, the ABC has published four books of monographs.  Currently, ABC is developing a series of product-specific and proprietary botanical ingredient monographs.
Brazil	<i>Monografias de plantas medicinais brasileiras e aclimatadas</i> ( <a href="#">Gilbert et al., 2005</a> );  <i>Vademécum nacional de plantas medicinales</i> ( <a href="#">Cáceres, 2006</a> )  <i>Farmácias Vivas</i> ( <a href="#">Matos, 2000</a> ),	
Brazilian Health Ministry of official monographs	<a href="http://portalsaude.saude.gov.br/index.php/oministerio/principal/secretarias/sctie/fitoterapicos/noticias-fitoterapicos/16353-prorrogada-a-consulta-publica-sobre-especies-medicinais-da-renisus">http://portalsaude.saude.gov.br/index.php/oministerio/principal/secretarias/sctie/fitoterapicos/noticias-fitoterapicos/16353-prorrogada-a-consulta-publica-sobre-especies-medicinais-da-renisus</a> .	The monographs include data on safety, efficacy, quality and marketing of herbal medicines. They are now on public consultation and can be obtained on the website.  The list of monographs that are usually accepted is published in the resolution RDC 26/2014.
Canada	Health Canada monographs are available at:  <a href="http://webprod.hc-sc.gc.ca/nhp/bdipsn/monosReq.do?lang=eng&amp;monotype=single">http://webprod.hc-sc.gc.ca/nhp/bdipsn/monosReq.do?lang=eng&amp;monotype=single</a>	'Pre-cleared information', including monographs, is any form of information supporting the safety, efficacy or quality of a medicinal ingredient or natural health product that Health Canada has reviewed and determined to be acceptable. This information can be used to speed up the evaluation of the Natural Health Product, and serves as a reliable source of product information for consumers.  Single ingredient monographs apply to formulations containing only one medicinal ingredient.



Country/organisation	Monographs	Comments
European scientific cooperative on phytotherapy	<p>Monographs on the medicinal uses of plant drugs ESCOP monographs(<a href="#">ESCOP, 1996</a>);</p> <p>Monographs. The Scientific Foundation for Herbal Medicinal Products. Second Edition Supplement 2009; Thieme Publisher: Stuttgart, New York; ESCOP 2009, ISBN 978-1-901964-08-0 (ECOP), ISBN 978-3-13-149981-3 (GTV). These are purchased through <a href="http://www.thieme.com">www.thieme.com</a></p> <p>Alternatively individual monographs can be downloaded for a fee from <a href="http://escop.com/individual-monographs">http://escop.com/individual-monographs</a></p>	<p>The European Scientific Cooperative on Phytotherapy (ESCOP) was founded in June 1989 as an umbrella organisation representing national herbal medicine or phytotherapy associations across Europe, especially in their discussions with European medicines regulators. In particular it produces state-of-the-art reviews of the therapeutic use of leading herbal medicinal products, based on the latest evidence and on leading expertise across Europe. Preparation of the monographs by the ESCOP Scientific Committee has involved delegates from 15 countries with the assistance of numerous external experts on herbal medicine and a Board of Supervising Editors.</p> <p>The European Medicines Agency can formally receive ESCOP monographs as a basis for core dossiers on herbal medicines. Initial funding for the enterprise was provided by the European Commission.</p>

Country/organisation	Monographs	Comments
EMA	<p>Herbal Medicinal Products (HMPC)</p> <p>To view all European Union herbal monographs, go to the <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/landing/document_library_search.jsp&amp;mid=WC0b01ac058009a3dc">document library</a> (<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/landing/document_library_search.jsp&amp;mid=WC0b01ac058009a3dc">http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/landing/document_library_search.jsp&amp;mid=WC0b01ac058009a3dc</a>) and search using the document type, 'Herbal - European Union herbal monograph'.</p> <p>To browse for existing European Union herbal monographs and supporting documents by herbal substance, use, status or outcome go to "Find medicine", <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_medicines_search_landing_page.jsp&amp;mid=">herbal medicines for human use</a> (<a "="" href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_medicines_search_landing_page.jsp&amp;mid=">http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_medicines_search_landing_page.jsp&amp;mid=</a>)</p>	<p>A Community herbal monograph contains the view of the HMPC on all information necessary for the use of a medicinal product containing the herbal substance or preparations described in the monograph. It is comprised of the HMPC scientific opinion on safety and efficacy data for a herbal substance and its preparations intended for medicinal use. The HMPC evaluates scientifically available information including non-clinical and clinical data as well as documented long-standing use and experience in the Community. A monograph provides:</p> <ul style="list-style-type: none"> <li>• what the herbal product is used for</li> <li>• who the herbal product is intended for</li> <li>• safety information such as information regarding undesirable effects and interactions with other medicines.</li> </ul> <p>Monographs are published together with an assessment report containing reviews of available data relevant for the medicinal use of the herbal substance or preparations. Community monographs are divided into:</p> <ul style="list-style-type: none"> <li>• well-established use (marketing authorisation)</li> <li>• demonstrated with sufficient safety and efficacy data and traditional use (simplified registration)</li> <li>• accepted on the basis of sufficient safety data and plausible efficacy.</li> </ul> <p>A final Community monograph can be used in application reference material by:</p> <ul style="list-style-type: none"> <li>• a marketing-authorisation applicant (well-established-use part); and</li> <li>• by a traditional-use-registration applicant (traditional-use part).</li> </ul>

Country/organisation	Monographs	Comments
	<p>"Inventory of herbal substances for assessment See <a href="http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017723.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017723.pdf</a></p> <p>EU List of herbal substances, preparations and combinations thereof for use in THMPs".</p> <p>Herbal Medicinal Products or Traditional Herbal Medicinal Products.</p>	
German Commission E	<p><a href="#">The Complete German Commission E Monographs</a>,  <a href="#">Herbal Medicine: Expanded Commission E Monographs</a>,  <a href="#">The ABC Clinical Guide to Herbs</a>, and  <a href="#">The Identification of Medicinal Plants</a>.</p>	English
South Korea	<p>The Health Functional Foods Code monographs  <a href="http://www.mfds.go.kr/eng/index.do?nMenuCode=65">http://www.mfds.go.kr/eng/index.do?nMenuCode=65</a></p>	English
United Kingdom	British herbal compendium ( <a href="#">Bradley, 2006</a> )	English
USA	American herbal pharmacopeia( <a href="#">Upton; Petrone, 1999</a> )	
US National Institutes for Health (NIH)	There are several sources with detailed information on ingredients.	

Country/organisation	Monographs	Comments
World Health Organization	<p>WHO Monographs on selected medicinal plants tomes 1-4 and Abstract</p> <p><a href="#">Volume 1</a> contains 28 monographs published in 1999.</p> <p><a href="#">Volume 2</a>, published in 2003 includes 30 monographs.</p> <p><a href="#">Volume 3</a> in this series was published in 2007 and includes 31 monographs.</p> <p><a href="#">Volume 4</a>, which was published in 2009, includes 28 monographs.</p> <p><a href="#">WHO Monographs on Medicinal Plants Commonly Used in the Newly Independent States</a> (NIS) (2010 in Russian).</p>	<p>A series of volumes, the <i>WHO monographs on selected medicinal plants</i> aims to provide scientific information on the safety, efficacy, and quality control of widely used medicinal plants; provide models to assist Member States in developing their own monographs or formularies for these and other herbal medicines; and facilitate information exchange among Member States. WHO monographs, however, are not pharmacopoeial monographs, rather they are comprehensive scientific references for drug regulatory authorities, physicians, traditional health practitioners, pharmacists, manufacturers, research scientists and the general public.</p> <p>Each monograph follows a standard format with information presented in two parts followed by a reference list. The first part presents pharmacopoeia summaries for quality assurance. The second part includes sections on medicinal uses, pharmacology, safety issues, and dosage forms. The descriptions under the medicinal uses section merely represent, for purposes of information exchange, the systematic collection of scientific information available at the time of each volume's preparation and should not be taken as having WHO's official endorsement or approval.</p>

**Table 3: Other sources of information**

Country/organisation		Comments
Cochrane summaries for alternative and complementary medicine	<a href="http://summaries.cochrane.org/search/site/?f[0]=im_field_terms_archie_topics%3A948&amp;f[1]=im_field_stag_e%3A3&amp;f[2]=im_field_terms_cochrane_library%3A49909">http://summaries.cochrane.org/search/site/?f[0]=im_field_terms_archie_topics%3A948&amp;f[1]=im_field_stag_e%3A3&amp;f[2]=im_field_terms_cochrane_library%3A49909</a>	
The National Centre for Complementary and Alternative Medicine	Reference: <a href="http://nccam.nih.gov/health/herbsataglance.htm">http://nccam.nih.gov/health/herbsataglance.htm</a>	The National Centre for Complementary and Alternative Medicine (NCCAM) is the US Federal Government's lead agency for scientific research on complementary and alternative medicine. Herbs at a Glance is a series of brief fact sheets that provides basic information about specific herbs or botanicals—common names, what the science says, potential side effects and cautions, and resources for more information.
The NIH Office of Dietary Supplements	Reference: <a href="http://ods.od.nih.gov/factsheets/list-Botanicals/">http://ods.od.nih.gov/factsheets/list-Botanicals/</a>	The NIH Office of Dietary Supplements publish factsheets on complementary medicines. Some of the ones on vitamins and minerals are quite detailed reviews of the safety and evidence literature
PubMed	CAM on PubMed Reference: <a href="http://nccam.nih.gov/research/camonpubmed">http://nccam.nih.gov/research/camonpubmed</a>	CAM on PubMed provides literature searches that will be automatically limited to the complementary and alternative medicine (CAM) subset of PubMed. Searches are free. NCCAM and the National Library of Medicine (NLM) have partnered to create CAM on PubMed®, a subset of NLM's PubMed. PubMed provides access to citations from the MEDLINE database and additional life science journals. It also includes links to many full-text articles at journal Web sites and other related Web resources.

