

The Regulation of herbal medicines in the EU



This document reflects the position of EUROCAM, the alliance of European umbrella organisations of patients, physicians and practitioners in the field of Complementary and Alternative Medicine.

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Association for Natural Medicine in Europe – ANME

European Ayurveda Association – EUAA

European Central Council of Homeopaths – ECCH

European Committee for Homeopathy – ECH

European Council of Doctors for Plurality in Medicine – ECPM

European Federation of Homeopathic Patients' Associations – EFHPA

European Federation of Osteopaths – EFO

European Federation of Patients' Associations for Anthroposophic Medicine – EFPAM

European Herbal & Traditional Medicine Practitioners Association – EHTPA

European Traditional Chinese Medicine Associations – ETCMA

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The objective of EUROCAM is to promote and facilitate CAM's role in maintaining citizens' health, highlight the health promotion and illness prevention aspects of CAM for EU public health policy and programmes, to advance the accessibility, affordability and availability of CAM, and generally promote CAM at European level.

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EUROCAM

Rue du Trône 194

1050 Brussels

Belgium

T: +32 2 644 00 20

E: info@cam-europe.eu

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1. Background and introduction

1.1. What are herbal products?

A herbal product is made from any part of a plant (including trees, fungi and seaweeds) of which the leaves, seeds, flowers, fruits or roots can be used for their therapeutic or cosmetic properties. Such products may be marketed as herbal medicines under Directive 2001/83/EC or food supplements under Directive 2002/46/EC or used in cosmetic products under Regulation (EC) N° 1223/2009. Cosmetic products lie outside the scope of this paper. Herbal medicinal products are marketed as medicines to maintain health and treat disease. Herbal food supplements are available to enable consumers to exercise their choice to supplement their intake of nutrients for salutogenic purposes to maintain health.

The use of herbs can legitimately claim to be the oldest of medicines being used to treat disease and maintain health since the dawn of history by all cultures and peoples of the world. The Chinese *Shen Nong Ben Cao (Divine Farmer's Materia Medica)* attributed to the mythical Chinese emperor, Shen Nong, was compiled in the first century BCE. The ancient Egyptian *Ebers Papyrus*, containing references to more than 700 herbal remedies was written circa 1550 BCE. The *Charaka Samhita*, the oldest extant treatise on Ayurveda, dates back to the 1st century CE; the original text lost centuries earlier is thought to have been compiled around 600 BCE.

1.2. How do herbal medicinal products work?

Since *Homo sapiens* evolved some 200,000 years ago, human physiology has adapted to benefit from a plant-based diet rich in phytochemical compounds naturally present in fruits, grains, nuts, seeds, vegetables and in herbal medicines too. Evidence suggests that consuming foods rich in phytochemicals reduces the risk of contracting illnesses as well as helping to alleviate many chronic diseases including cardiovascular disease, cancer, Alzheimer's disease and type 2 diabetes as well as playing a vital role in healthy aging.^{1,2} It is for this reason that diets like the Mediterranean and Palaeolithic diets, rich in these phytochemicals, are thought to be so beneficial for health.³ Scientific analysis of herbal medicinal products reveal them to contain a gamut of active phytochemicals e.g. polyphenols, saponins, alkaloids, tannins, essential oils, fatty acids, vitamins and trace elements and it is through the agency of these naturally occurring compounds that they take effect. The discovery and isolation of active plant compounds that gave birth to modern drug discovery and development only began in the 19th century. Despite the current preoccupation with synthetic chemistry as a vehicle to discover and manufacture drugs, the contribution of plants to disease treatment and prevention is still vast. At the start of 21st century, 11% of the 252 drugs considered as basic and essential by the WHO were exclusively of flowering plant origin.⁴ Researchers Fabricant

¹ Murugaiyah V, Mattson MP. Neurohormetic phytochemicals: An evolutionary-bioenergetic perspective. *Neurochem Int.* 2015 Oct;89:271-80.

² Howes MJ, Simmonds MS. The role of phytochemicals as micronutrients in health and disease. *Curr Opin Clin Nutr Metab Care.* 2014 Nov;17(6):558-66.

³ Whalen KA, McCullough ML, Flanders WD, Hartman TJ, Judd S, Bostick RM. Paleolithic and Mediterranean Diet Pattern Scores Are Inversely Associated with Biomarkers of Inflammation and Oxidative Balance in Adults. *J Nutr.* 2016 Jun;146(6):1217-26.

⁴ Veeresham C. Natural products derived from plants as a source of drugs. *J Adv Pharm Technol Res.* 2012 Oct;3(4):200-1.

and Farnsworth noted (2001) that, 80% of 122 plant derived drugs had a traditional medicine use identical or related to the current use by the pharmaceutical sector of the active elements of the plant.⁵

1.3. Chemical synergy

The orchestra of chemical compounds naturally present in plants act in concert to make active constituents safely and easily available. This is a major reason why herbal medicinal products are ideal tools to restore health and treat disease acting to restore disrupted physiological processes. The therapeutic effect of the whole plant tends to be significantly more effective than the particular action of any of its perceived active constituents. In this context, two and two turns out to add up to rather more than four.⁶ Using this synergistic principle, herbal practitioners, from all traditions, customarily combine herbs together to take further advantage of the subtle but potent healing potential of mixtures of traditional herbal medicines.

2. Definitions and descriptions

2.1. Herbal medicinal products

Herbal medicinal products are defined in EU legislation 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 herbal preparations.⁷ The Traditional Herbal Medicinal Products Directive (formally named the Directive 2004/24/EC amending, as regards traditional herbal medicinal products, Directive 2001/83/EC) permits such herbal medicinal products to be marketed with combinations of certain specified minerals and vitamins. Such herbal products are available over-the-counter (OTC) direct to the public in standard formulations either as simples (containing one herb at a time) or in mixtures. The availability of such products is discussed in detail in Section 3 below.

2.2. Herbal food supplements

Under EU law (see discussion Section 4 below) a wide range of nutrients and other ingredients are permitted in food supplements including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plant and herbal extracts.

2.3. Herbal medicine practice

Herbal medicine practice provides herbal treatment based on a holistic or ‘whole person’ approach, i.e. the perception that the physical, mental, emotional, and spiritual elements of an individual are dynamically interconnected to maintain or regain vitality and health. Such a

⁵ Fabricant D S, Farnsworth N R. The value of plants used in traditional medicine for drug discovery. *Environ Health Perspect.* 2001 Mar; 109(Suppl 1): 69–75.

⁶ Williamson E. (2001). Synergy and other interactions in phytomedicines. *Phytomedicine* 8, 401–409. 10.1078/0944-7113-00060

⁷ http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm

holistic approach focuses on the whole person rather than just treating the illness or symptoms and signs of disease. Herbal practitioners carry out in-depth consultations, make independent diagnostic judgements and treat patients using herbal prescriptions which are flexibly adjusted in the light of the patient's changing condition. Each tradition, Ayurvedic, Chinese, Unani Tibb, Tibetan and Western has developed its own diagnostic framework which requires years of study and clinical training.

2.4. Using herbal medicinal products to support the innate healing capacity

Herbal treatment is primarily directed towards reinforcing the resilience, resistance and immune status of the individual concerned. When confronted with physiological and/or mental and emotional stress, a healthy person's system is able to mount a protective response to restore equilibrium – a process known as homeostasis which maintains health and stability within a constantly shifting environment. If this coping mechanism is inadequate, illness due to allostatic load (wear and tear on the body/mind) may result. The herbal approach uses herbal medicines to support natural resilience or the capacity to cope to maintain and restore a person's health. This reduces the susceptibility to illness and disease as well as specifically addressing any existing disease process. Herbal medicines may directly invigorate poor circulation, allay inflammation, reduce pain, relax muscular and psychological tension, improve sleep, regulate hormone imbalance, combat infection etc. Herbal medicine can be used as a stand-alone treatment or as complementary treatment alongside conventional medicine intervention that is more disease focused.

3. Regulation of herbal medicinal products in the EU

In the EU medicines are regulated by Directive 2001/83/EC. The following specifics apply to herbal medicinal products.



3.1. Full market authorisation

Currently herbal medicines, like conventional pharmaceuticals, may in theory apply for a full EU market authorisation when the application concerns a new active ingredient (i.e. in the case of herbal medicines – a plant that has not previously been authorised to be placed on the market as a herbal medicinal product). To obtain this authorisation, an application consisting of a dossier supporting the medicinal product's quality, safety, and efficacy needs to be submitted to regulatory authorities. The dossier requires delivery of the results of the studies (clinical and preclinical as well as quality) conducted by the prospective marketing authorisation holder. In practice, this route is effectively barred to most botanical medicines since, as discussed previously, plant medicines contain a large number of phytochemicals and their precise mode of action is hard to determine. This is not the case for chemical drugs containing a single active chemical principle. Another major stumbling block debarring herbal medicines from obtaining a full marketing authorisation is that as they are natural products they cannot be patented. For this reason their drug development via a full marketing authorisation is of no commercial interest to pharmaceutical companies.

3.2. Well-established use

The EU's pharmaceutical legislative framework also allows for a reduced application for medicines that are no longer bound by their data exclusivity. One such type of application is the well-established use (WEU) medicinal product application requiring a complete quality documentation dossier, but a reduced clinical and preclinical program. The WEU route of obtaining a marketing authorisation in the EU is established by Article 10a of Directive 2001/83/EC with terms of the conditions set out in Annex I of Directive. This decrees that WEU medicinal product dossiers should demonstrate that the medicinal product to be placed on the market is safe and effective as well as of good quality. Some herbal medicinal products have obtained WEU authorisations in cases where an applicant can demonstrate by detailed references to published scientific literature that the constituent or the constituents of the herbal medicinal product has a well-established medicinal use with recognised efficacy and level of safety. However, providing proof of efficacy sufficient for WEU authorisation is frequently too expensive for herbal medicines because, as explained, they cannot be patented and unlike most conventional pharmaceuticals they are chemically complex. The required level of research to validate such WEU market authorisations is lacking for most herbal medicines

3.3. Directive 2004/24/EC - The Traditional Herbal Products Directive (THMPD)

In view of the difficulties of authorising herbal medicines under these two legislative processes and lack of any agreement between Member States about how such products should be marketed, a simplified procedure was introduced by Directive 2004/24/EC  of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC  relating to medicinal products for human use. Directive 2004/24/EC is also known as The Traditional Herbal Products Directive (THMPD) was fully implemented 30 April 2011. The THMPD was intended to remove the differences and uncertainties about the status of traditional herbal medicinal products that existed in the past in the Member States and facilitate the free movement of such products by introducing harmonised rules in this area.

3.4. A simplified registration process

The THMPD provides a simplified registration mechanism for herbal medicinal products with a long tradition, which do not fulfil the requirements for a full marketing authorisation or WEU. This simplified procedure allows traditional use registration (TUR) of herbal medicinal products without requiring particulars and documents on tests and trials 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. However, with regard to the manufacturing of these products and their quality, applications for registration of traditional herbal medicinal products have to fulfil the same requirements as applications for a full marketing authorisation.

The Directive defines traditional herbal medicinal products as fulfilling the following criteria:

- They have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use

without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;

- They are exclusively for administration in accordance with a specified strength and posology;
- They are an oral, external and/or inhalation preparation;
- The data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience.

3.5. The HMPC

Alongside these new provisions a Committee for Herbal Medicinal Products (HMPC) has been established at the European Medicines Agency (EMA). The HMPC is tasked with establishing Community monographs for traditional herbal medicinal products, and, with the objective of further facilitating registration and harmonisation in the field of traditional herbal medicinal products, is compiling a list of herbal substances which have been in medicinal use for a sufficiently long time, and hence are considered not to be harmful under normal conditions of use.

3.6. Report from Commission to Council and European Parliament

In 2008 the EU Commission reported to the Council and the European Parliament on “the experience acquired as a result of the application of the provisions of... Directive 2004/24/EC ... applicable to traditional herbal medicinal products.”⁸ This pointed out a significant shortcoming in the THMPD legislation. The Commission said:

“Directive 2004/24/EC was intended to address the specific situation of traditional herbal medicinal products. In order to gain experience, the scope of the Directive was deliberately limited to these products. However, other products may face a similar situation and have a long tradition as medicinal products but do not fulfil the requirements for a full marketing authorisation or a well-established use authorisation. This applies to several traditional forms of medicine...”

The Commission said that it was prepared to consider a possible extension to the THMPD which:

“would enable certain medicinal products from specific European or non-European medicine systems (such as — in alphabetical order — anthroposophic, Ayurvedic, Chinese, Kampo Korean, Mongolian, Thai, Tibetan, Unani, or Vietnamese medicine), as well as traditional products with a long-standing tradition in the European Union (such as honey, royal jelly, propolis, fish oils, minerals, micro-organisms and other substances) to be eligible for the simplified registration procedure with a view to placing them on the market as traditional medicinal products.”

⁸COM(2008) 584 final; Communication from the commission to the Council and the European Parliament concerning the Report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to traditional herbal medicinal products 29/9/2008. Available from <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0584:FIN:en:PDF>.

The Commission went on to say:

“During the public consultation, proponents of three traditional medical systems using products with a long-standing tradition expressed support for the global regulation of their traditions within the EU: anthroposophic, Ayurvedic and traditional Chinese medicine. It was suggested that proof of the plausibility of efficacy should not be by medicinal product, but by therapeutic approach. Medical traditions such as those mentioned above are based on a holistic approach, and the set of requirements for the simplified registration procedure under Directive 2004/24/EC is not appropriate for a global regulation of such medical practices. The regulation of such traditions would demand a different approach from that introduced by Directive 2004/24/EC. Therefore, the Commission does not envisage extending the scope of the simplified registration procedure to cover traditional medical systems as such. Nevertheless, independently of this report, the suitability of a separate legal framework for products of certain traditions should be assessed.”

3.7. WHO Traditional Medicine Strategy

To date no such assessment of a separate legal framework has occurred and the majority herbal medicinal products used by practitioners of these traditions lie outside the scope of this Directive. Introducing *The WHO Traditional Medicine Strategy 2014-2023*, WHO Director General, Dr Margaret Chan, observed:

“Much has changed since the previous global strategy was published in 2002. More countries have gradually come to accept the contribution that T&CM (traditional and complementary medicine) can make to the health and well-being of individuals and to the comprehensiveness of their health-care systems. Governments and consumers are interested in more than herbal medicines, and are now beginning to consider aspects of T&CM practices and practitioners and whether they should be integrated into health service delivery... The strategy has two key goals: to support Member States in harnessing the potential contribution of T&CM to health, wellness and people centred health care and to promote the safe and effective use of T&CM through the regulation of products, practices and practitioners.”⁹

It is to be hoped that the Commission will heed its own 2008 report (quoted above) and the advice of WHO to create a legislative framework that allows for the authorisation of herbal and traditional medicinal products used by practitioners of traditional medicine systems to be available throughout the EU (see recommendations below).

3.8. Matrix Insight Report

Matrix Insight, an independent company specialising in health research, produced a *Study on the Availability of Medicinal Products for Human Use* (access the full report [here](#)) on behalf of the European Pharmaceutical Committee. The report was produced in 2012 but only publically released late in 2014. The study investigated the availability of medicinal products for human use in the EU and European Economic Area (EEA), focussing on the authorisation

⁹ http://www.who.int/medicines/publications/traditional/trm_strategy14_23/en/

procedures for medicinal products including herbal medicine. On this subject, page 23 of the report comments...

"consulted industry stakeholders pointed out that the process of authorising products can take a long time (up to five years) and the approach to authorising such products can differ substantially between Member States. This makes it difficult for producers to bring such products to the market as medicinal products, potentially resulting in unavailability. Since the coming to force of Directive 2004/24/EC on Traditional Herbal Medicinal Products (THMPD), 572 products have been registered, with significant discrepancies across Member States (only seven Member States saw more than 20 products registered, and over 150 of all registrations were in Poland)."

The Matrix Study also noted (table page 7) that there is *"divergence in national procedures and approach to herbal medicinal products."* This *"incomplete and ineffective implementation in Member States seems to result in relatively few products becoming registered as medicinal products."* It recommended (page 9) there should be *"Work to improve the national implementation of simplified procedures for herbal medicinal products."*

In summary, the Matrix Study highlighted the fact that despite the common regulatory framework laid down in Directive 2004/24/EC, the registration of herbal medicinal products by the Member States remained heterogeneous and haphazard eight years after the Directive had come into force

3.9. The current situation in 2017

Regrettably, this unfortunate state of affairs prevails in 2017. Data supplied by the EMA in 2015¹⁰ shows surprisingly few THMPs are registered in the EU with only 983 THMP registrations for mono-component products and only 594 for combination products (see EMA table in the Appendix below). These total registrations in no way represent that same number of different herbal products. As the graphs from the EMA reproduced in the Appendix below show, 975 recorded registrations accounted for just 158 herbal substances and of these a mere 20 herbal medicines accounted for practically half the total number of registrations (474). This illustrates the fact that rather than enabling the development of herbal medicine, Directive 2001/24/EC is stifling innovation suggesting that the THMPD is failing as a suitable vehicle to make available the hundreds of herbal medicines used in traditional practice. In short, EU citizens are being deprived of the unique range and diversity of traditional herbal medicine.

As another EMA graph below shows, The Member States with the most THMP registrations (shown in descending order with those with the majority showed first) are the UK, Germany, Poland, and Austria. 18 Member States have registered 20 or fewer herbal products and three Member States, Denmark, Luxembourg and Malta as well as Liechtenstein and Iceland from the European Free Trade Association have not registered any THMPs at all.

¹⁰ EMA 2nd May 2016 EMA/HMPC/322570/2011 Rev 6. Uptake of the traditional use registration scheme and implementation of the provisions of the Directive 2004/24/EC in Member States (31 December 2015).

3.10. Hypothetical risks inhibit progress

Other problems arise from the overly restrictive focus of some Member States on hypothetical risks. For example, this overcautious approach currently prevents any herb containing furocoumarins (e.g. those from the genus *Angelica*) from being registered, regardless of the fact that the genus *Angelica* constitutes one of the most important medicinal plant families with over 60 species of medicinal plants used on a worldwide basis. Similar problems are caused by the requirement for genotoxicity. Directive 2004/24/EC does not imply extensive genotoxicity data for the TUR scheme as safety is provided by evidence of longstanding use. Nevertheless, some Member States require expensive and extensive genotoxicity studies despite the guidance of the HMPC which simplifies the process.

3.11. Restrictive time frame

In addition, the stipulation requiring 15 years use within the EU restricts the registration of herbal medicines from non-European medical traditions. In reforming TUR, means must be found to recognise traditional medicines from outside the EU, in accordance with the spirit of the THMPD (2004/24/EC) that states:

‘The long tradition of the medicinal product makes it possible to reduce the need for clinical trials, in so far as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience. Pre-clinical tests do not seem necessary, where the medicinal product on the basis of the information on its traditional use proves not to be harmful in specified conditions of use. However, even a long tradition does not exclude the possibility that there may be concerns with regard to the product’s safety, and therefore the competent authorities should be entitled to ask for all data necessary for assessing the safety.’

In view of this, it is fair to say that Directive 2004/24/EC has not met expectations. The EMA table below shows that the number of registrations peaked in 2011 falling sharply in 2014 and 2015. Full implementation of the Directive is yet to occur.

4. The borderline between food and medicine

4.1. Food supplements and the FSA

Numerous traditional herbal products remain in a grey area marketed as food supplements in many Member States. The definition of food supplements remains blurred. European law is increasingly confusing as evidenced by a ruling by the European Food Safety Authority (EFSA) which declared that Transitech[®], a herbal product containing 6 herbs including rhubarb root (*Rheum officinale*) which contains anthraquinones with a proven laxative (i.e. medicinal) effect, can be considered a food supplement and marketed as such with health claims.¹¹ In addition, Belgium, France and Italy have created the BELFRIT list of botanical food supplements with

¹¹ <http://www.efsa.europa.eu/en/efsajournal/pub/3412>

accepted health claims.¹² This can only add to the confusion and lack of harmonisation with respect to the marketing of herbal medicinal products in the EU.

Clearly, if BELFRIT were widely adopted, botanicals which should be registered as traditional herbal medicinal products may instead be marketed as food supplements in order to avoid scrutiny regarding considerations of safety and quality circumventing the registration procedures for traditional herbal medicinal products introduced by Directive 2004/24/EC.

The situation has become further complicated as the European Food Safety Authority (EFSA) has sought to verify the evidence for health claims which are permissible for food supplements. EFSA rules are currently laid down in:

- [Regulation 1924/2006 on nutrition and health claims made on foods](#)
- [Commission Regulation No 353/2008 establishing implementing rules for applications for authorisation of health claims](#)
- [Commission Regulation No 1169/2009 amending Regulation \(EC\) No 353/2008 establishing implementing rules for applications for authorisation of health claims](#)

In theory these regulations require that health claims should adequately demonstrate that they are substantiated by generally accepted scientific evidence, by taking into account the totality of the available scientific data. However, in practice, permitted claims are somewhat anecdotal and weak, and present no real information for the consumers and/or health practitioners.¹³ More significantly, the quality of the herbal products marketed as food supplements is not addressed properly, as market surveillance is mostly focused on correct labelling but crucially not on actual quality of the products themselves.

4.2. Quality issues of herbal food supplements

This lack of quality is most certainly not in the interests of those citizens accessing herbal medicinal products. A recent BBC TV programme “Trust Me I’m a Doctor” analysed over 70 herbal products from various high street stores and internet retailers. Some of the products were Traditional Herbal Registered (THR) products sold as herbal medicines under the THMPD (Directive 2004/24/EC) while others were food supplements.¹⁴

The team at UCL then analysed their chemistry to see whether each one really contained what the label says. The three popular herbal remedies that were at a lab tested by high-performance thin layer chromatography at University College London were Milk thistle (*Silybum marianum*), ginkgo (*Ginkgo biloba*) and evening primrose (*Oenothera biennis*).

The UCL team carried out tests on both food supplements and THRs (registered via the THMPD). In every THR product tested, the product contained what was claimed on the label. However, the food supplements showed a wide range of quality. Of the food supplement

¹² <http://www.nutraingredients.com/Regulation-Policy/BELFRIT-leads-Europe-in-botanicals-harmonisation-as-Italy-affirms-1000-strong-list>.

¹³ <http://naturalsolutionsradio.com/blog/natural-solutions-radio-administrator/fears-persist-consumers-will-struggle-understand-efsas-cl>.

¹⁴ <http://www.bbc.co.uk/programmes/articles/4hX30rMYkMv9YjMTH38MY6/do-herbal-supplements-contain-what-they-say-on-the-label>

products labelled as ginkgo that were tested, 8 out of 30 (27%) contained little or no ginkgo extract. 36% of the food supplement milk thistle products contained no detectable milk thistle. Furthermore, in one milk thistle product, unidentified adulterants suspected to be synthetic compounds were present. Although, all of the evening primrose food products tested did contain what the packet claimed, the UCL team's methodology had been developed through their work on assaying OTC herbal products containing turmeric (*Curcuma longa*) and roseroot (*Rhodiola rosea*). Here too they found similarly alarming results. The UCL team concluded that that a regulatory system for herbal products, like the THR scheme, ensures that the public have access to safe herbal medicine products and advised the those considering buying herbal products to look out for those carrying the THR mark.

5. Suggested solutions to enable the THMPD to provide access to a full range of herbal treatment

5.1. Opening the traditional registration scheme to non-herbal ingredients

As currently drafted and implemented the THMPD does not allow a full range of non-herbal constituents commonly used in traditional medicine systems.

Article 2 of Directive 2004/24/EC states:

“Notwithstanding Article 1(30), the presence in the herbal medicinal product of vitamins or minerals for the safety of which there is well-documented evidence shall not prevent the product from being eligible for registration in accordance with paragraph 1, provided that the action of the vitamins or minerals is ancillary to that of the herbal active ingredients regarding the specified claimed indication(s).”

Ingredients of THMPs can be herbal substances, herbal preparations and minerals. This is currently interpreted and applied differently by Member States. The EMA Action Plan for herbal Medicines 2010 -2011 notes that:

“A possible extension of the scope of Directive 2004/24/EC has been proposed by the European Commission and is supported by the Herbal Medicinal Products Committee (HMPC), i.e. the simplified registration procedure could be opened to other traditional products of a long-standing tradition in the EU, including certain products of animal origin.”¹⁵

It is suggested that the national competent authorities as well as the Herbal Medicinal Products Committee (HMPC) are provided with clear guidance as to how this can be achieved. Examples of materials whose use needs elucidation are:

- Minerals and other ingredients, which have an ancillary use according to a traditional system of medicine
- Common foods such as honey, ghee, propolis etc.

¹⁵<http://www.ema.europa.eu/ema/index.jsp?curl=search.jsp&q=Directive+2004%2F24%2FEC&btnG=Search&mid=>

5.2. Strengthening the coordinating role of the HMPC

The Herbal Medicinal Products Committee (HMPC within the European Medicines Agency (EMA) was established via Directive 2004/24/EC. It works to unify the different standpoints of Member States. In addition, the HMPC prepares monographs and guidelines for registration. Despite the best efforts of the HMPC to date, Member States have failed to apply these guidelines in a coherent manner. As a result THMPs registered in one Member State face difficulties when an application is filed in another Member State using the same data. Despite the fact that the same HMPC guidelines apply, the national competent authorities too often interpret them in completely different ways.

Such heterogeneous approaches undermine the intention of Directive 2004/14/EC, Which states that Member States should take ‘due account ‘of positive decisions taken by another Member State. Currently positive decisions on registering a herbal product taken by one Member State are more often than not ignored by other Member States for no apparent reason. In order to achieve a harmonised market, the recognition by all of Member States of positive decisions taken with regard to a THMP by a single Member State should be the rule rather than the exception and “due account” should be taken.

Support is needed from DG SANTE and the European Parliament to enable the HMPC to strengthen its status and coordinating power with respect to the Member States. As the HMPC has to work on the basis of majority voting, Member States with a poor record of THMPL registrations often inhibit the implementation of Directive 2004/24/EC across the EU. Those Member States that are slow in implementing the Directive need encouragement and monitoring.

5.3. Extending the scope of the traditional herbal registration scheme make it much more flexible

So far, only few THMPs from other medical traditions (especially Asian medical traditions) have been registered which leaves a huge number of essential THMPs unregistered and thus unavailable for the treatment of patients by qualified practitioners. As mentioned, the Commission itself has acknowledged this particular deficit of the THMPD in a Communication to the EP in 2008.¹⁶

The current limited range of possible indications by the HMPC is open to broader interpretation. Directive 2001/83/EC determines in Art 16a.1(a) that THMPs “*have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment.*” Nevertheless, the range of indications appropriate to THMPs can be extended,

¹⁶ COM (2008) 584 final; Communication from the commission to the Council and the European Parliament concerning the Report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to traditional herbal medicinal products 29/9/2008. Available from <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0584:FIN:en:PDF>.

without violating the intentions of Directive 2001/83, Art 16a. This could be achieved by designating particular formulations as being for use by an ‘authorized health professional’ which proviso is already in use in Article 5.1 of Directive 2001/83/EC. Side by side with this innovation, should be the recognition by Member States of trained of practitioners of traditional medicine and the designation of ‘authorised health professional’ for those qualified to practise these traditional medicine systems. The scope of indications for THMP could be extended to “after being diagnosed by a physician or health practitioner.” Such wording is already in use in some Member States, e.g. the UK and Austria.

6. Clarifying borderline between food and medicine

At present, in many Member States, food supplements fall well short of the appropriate strength and quality for medicinal use. Indeed, they are neither intended nor fit for the purpose of treating consumers. It is to be hoped that the Commission and European Parliament will work with the Member States to make clear the legal difference between food supplements and medicines. As mentioned above, France, Belgium and Italy currently favour the classification of herbal products as food supplements and Member States following this approach do not register any THMPs. The European Commission has so far not clarified this situation.

As a consequence, the European Food Standards Agency (EFSA) and the HPMC lack a coherent strategy how to give clear and definite guidance to Member States. The potential of the THMP registration scheme can only be achieved if DG SANTE clarifies the therapeutic scope and differences as well as the borderline between herbal products marketed as food supplements and herbal medicines.

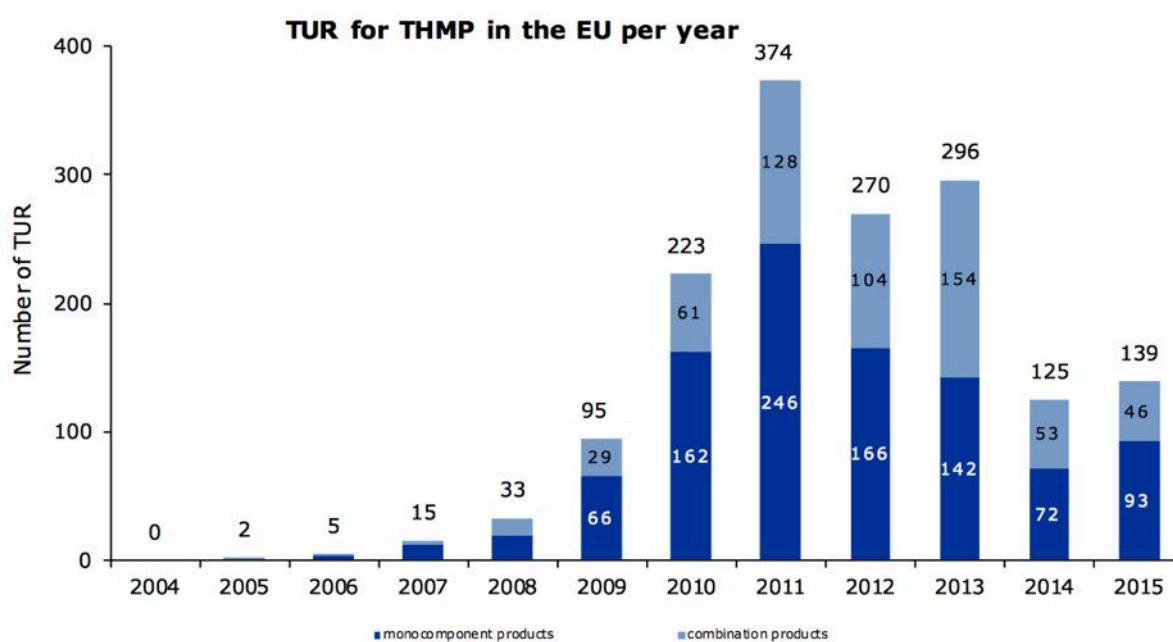
The EFSA and the national authorities should concentrate on ensuring the good quality of herbal food supplements rather than focusing on labelling issues and the exact of wording of rather vague and confusing health claims.

Appendix

Tables taken from EMA published data ¹⁷

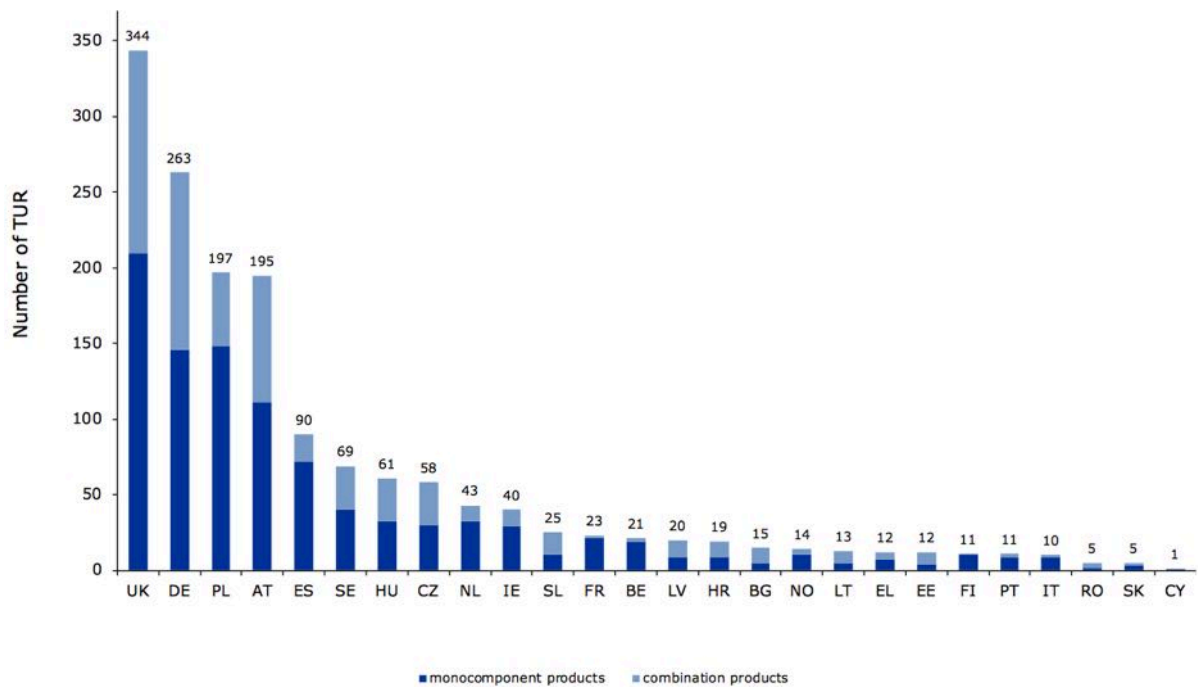
Uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States

Status: 31 December 2015



Number of traditional use registrations (TUR) for THMP in the EU grouped by year of registration for mono-component and combination products (2004 until December 2015; total 1577).

¹⁷ EMA Uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States Status: 31 December 2015.
<http://www.ema.europa.eu/ema/index.jsp?curl=search.jsp&q=Directive+2004%2F24%2FEC&btnG=Search&mi>



Number of granted TUR for mono-component and combination THMP in EU Member States (since implementation of Dir. 2004/24/EC until 31 December 2015). Total 1577: 983 for mono-component products, 594 for combination products (No TUR granted for DK, IS, LI, LU and MT).

Number of TUR for herbal substances used in monocomponent THMP in the EU by 31 December 2015 and status/outcome of the corresponding HMPC assessment.

Herbal substances ¹	TUR ²	Status HMPC assessment ³	Final monograph publication date	Draft monograph publication date	Outcome ⁴ (TU/WEU) ⁵	Outcome ⁴ (MO/LE/PS) ⁶
Total (158)	975					
Harpagophyti radix	60	F	06/11/2008	10/01/2008	TU	MO
Pelargonii radix	59	F	04/02/2013	26/04/2011	TU	MO
Valerianae radix	52	F	26/10/2006	24/10/2005	TU+WEU	MO
Hyperici herba	44	F	20/12/2009	06/11/2008	TU+WEU	MO
Thymi herba	39	F	30/10/2007 (02/06/2014)	08/05/2007	TU	MO
Passiflorae herba	37	F	07/09/2007 (18/06/2014)	07/03/2007	TU	MO
Echinaceae purpureae radix	25	F	28/01/2011	16/07/2009	TU	MO
Ginseng radix	25	F	22/05/2014	16/04/2013	TU	MO
Salviae officinalis folium	25	F	03/02/2010	14/01/2009	TU	MO
Crataegi folium cum flore	23	PF		14/10/2014	TU	MO+LE
Silybi mariani fructus	23	PF		23/07/2015		MO
Hippocastani semen	20	F	16/07/2009	04/09/2008	TU+WEU	MO
Agni casti fructus	19	F	05/08/2011	17/09/2009	TU+WEU	MO
Melissae folium	19	F	31/10/2007 (05/08/2013)	08/05/2007	TU	MO
Rhodiolae roseae rhizoma et radix	17	F	29/05/2012	20/09/2011	TU	MO
Cucurbitae semen	16	F	25/03/2013	17/10/2011	TU	MO
Cynarae folium	16	F	21/12/2011	18/01/2011	TU	MO
Ginkgo folium	16	F	08/04/2015	14/02/2014	TU+WEU	MO
Matricariae flos	16	PF		24/07/2014		MO
Plantaginis lanceolatae folium	14	F	24/02/2012	15/11/2008	TU	MO
Echinaceae purpureae herba	13	F	08/05/2008 (13/04/2015)	08/05/2007	TU+WEU	MO+LE
Equiseti herba	13	F	03/07/2008	30/10/2007	TU	MO
Visci albi herba	12	F*				PS
Vitis viniferae folium	12	F	03/01/2011	20/12/2009	TU+WEU	MO+LE
Arnicae flos	11	F	22/07/2014	22/08/2013	TU	MO
Hederae heliis folium	11	F	19/04/2011	08/03/2010	TU+WEU	MO
Menthae piperitae folium	11	F	20/01/2011	17/09/2009	WEU	MO
Tanacetii parthenii herba	11	F	11/02/2015	19/05/2014	TU	MO
Cimicifugae rhizoma	10	F	05/07/2007	05/07/2007	TU	MO

¹ Herbal substance or preparation thereof used as single active substance in products with TUR

² May include several TUR in different EU Member States for the same product

³ Status by December 2015 (R: Rapporteur assigned, D: Draft under discussion, P: Draft published, PF: Assessment close to finalisation [pre-final], F: Final opinion adopted, C: Call for scientific data, n.p.: not on the HMPC priority list (EMA/HMPC/278067/2006)

⁴ Outcome for not finalised assessments is anticipated according to the published draft

⁵ Existing monograph for traditional use (TU), well-established use (WEU) or both (TU + WEU)

⁶ HMPC assessment outcome (MO: monograph, LE: list entry, PS: public statement)

Table continued

Herbal substances ¹	TUR ²	Status HMPC assessm ent ³	Final monograph publication date	Draft monograph publication date	Outcome ⁴ (TU/WEU) ⁵	Outcome ⁴ (MO/LE/PS) ⁶
Lichen islandicus	10	F	20/01/2011	28/05/2010	TU	MO
Urticae folium	10	F	17/01/2011	08/05/2008	TU	MO
Zingiberis rhizoma	9	F	04/06/2012	20/09/2011	TU+WEU	MO
Sabalis serrulatae fructus	8	PF		10/09/2014	TU+WEU	MO
Calendulae herba	7	C				
Menthae piperitae aetheroleum	7	F	08/05/2007	31/10/2007	TU+WEU	MO+LE
Rusci aculeati rhizoma	7	F	04/09/2008	07/09/2007	TU	MO
Tiliae flos	7	F	10/07/2012	20/10/2011	TU	MO
Urticae radix	6	F	05/11/2012	19/10/2011	TU	MO
Allii sativi bulbosus	5	D				call for scientific data
Eleutherococci radix	5	F	08/05/2008 (06/10/2014)	05/07/2007	TU	MO+LE
Liquiritiae radix	5	F	24/08/2012	19/08/2011		TU
Myrtilli fructus recens	5	F	09/12/2015	09/02/2015	TU	MO
Orthosiphonis folium	5	F	03/01/2011	16/07/2009	TU	MO
Taraxaci radix	5					
Uvae ursi folium	5	F	19/04/2011	16/06/2008	TU	MO
Althaeae radix	5	F	14/05/2009	03/07/2008	TU	MO
Arctii radix	4	F	03/01/2011	08/03/2010	TU	MO
Betulae folium	4	F	08/05/2007 (13/03/2015)	08/05/2007	TU	MO
Glycine max (Lecithin)	4	C				call for scientific data
Lupuli flos	4	F	11/07/2008 (07/08/2014)	05/07/2007	TU	MO
Millefolii herba	4	F	30/09/2011	09/11/2010	TU	MO
Piceae summitates	4	n.p.				
Solidaginis virgaureae herba	4	F	04/09/2008	31/10/2007	TU	MO
Calendulae flos	4	F	08/05/2008	05/07/2007	TU	MO+LE
Other 14 substances with 3 registrations	14 x 3	(F: 10, PF: 0, P: 0, D: 0, R: 0, C: 1, n.p.: 3)				
Other 31 substances with 2 registrations	31 x 2	(F: 21, PF: 0, P: 0, D: 2, R: 0, C: 0, n.p.: 8)				
Other 59 substances with 1 registration	59 x 1	(F: 28, PF: 0, P: 2, D: 1, R: 0, C: 1, n.p.: 27)				

¹ Herbal substance or preparation thereof used as single active substance in products with TUR

² May include several TUR in different EU Member States for the same product

³ Status by December 2015 (R: Rapporteur assigned, D: Draft under discussion, P: Draft published, PF: Assessment close to finalisation [pre-final], F: Final opinion adopted, C: Call for scientific data, n.p.: not on the HMPC priority list (EMA/HMPC/278067/2006))

⁴ Outcome for not finalised assessments was anticipated according to the published draft

⁵ Existing monograph for traditional use (TU), well-established use (WEU) or both (TU + WEU)

⁶ HMPC assessment outcome (MO: monograph, LE: list entry, PS: public statement)