

ANH and Benefyt clarify confusion about EU herbal campaign



Prepared by Alliance for Natural Health Europe and the European Benefyt Foundation

We at ANH in Europe and our collaborators in the European Benefyt Foundation have joined forces to deal with the grave problems facing the availability of particular herbal products in Europe.

Our detailed and comprehensive joint initiative has been understood by those closest to the problems. But it is less well understood by those who are not directly affected. To further confuse things, many well meaning citizens and even other campaign organisations have got some of the issues confused and all of this does little to help the cause. The confusion also causes some to think there isn't really going to be a problem next May, which couldn't be further from the truth.

We've decided the best way to deal with the confusion is to provide detailed answers to some of the most commonly asked questions.

Please forward this [link](#) as widely as you can to help people understand why concerted efforts are required to stop unjustified restriction of our ability to heal and maintain our bodies using plant products.

QUESTION 1. Given that the THMPD registration scheme is open to and applied equally to all producers of traditional herbal medicines, why should the cost of entry to the scheme be a challenge to some and not to others?

ANSWER: The simplified medicinal registration scheme for herbal medicines is ideally suited for single herbs or limited combinations of herbs which have a long history of use in Europe and are also the subject of Community monographs developed by the European Medicines Agency (EMA). In contrast, the Directive imposes major obstacles for herbal producers making multi-herb products that are associated with non-European traditions, such as Ayurveda, traditional Chinese medicine (TCM), Amazonian, Kampo (Japan), etc. To-date, only around 200 registrations have been issued for herbal products across the 27 EU Member States, all of which are associated with western herbal traditions.

In the case of products where no monographs exist for constituent herbs, and which contain multiple herbs that have not necessarily been long-used or well-studied in Europe, there are major challenges, or even barriers, to registration. The challenges can generally be divided into two main areas. The first of these relates to difficulties in meeting the preset eligibility requirements for access to the medicinal registration scheme. Of these, decisions by national authorities or the Committee on Herbal Medicinal Products (HMPC) of the European Medicines Agency (EMA) to prevent use of traditional indications (medicinal claim) are among the most serious. Equally significant is the difficulty of meeting the traditional use criteria, where bibliographic or expert evidence is needed to verify 30 years' safe use, of which at least 15 are within the EU (i.e., the so-called '30-year rule'). The second major obstacle to registration under the simplified medicinal registration scheme of the THMPD is caused by the often prohibitive costs of meeting the quality control guidelines set by the

HMPC. These are inappropriate for complex, poly-herbal products typical of non-European traditions and do not necessarily guarantee the safety of products, which is their main purpose. Where the required data – which include stability and genotoxicity testing – can be accumulated for registration dossiers, the costs may rise above €250,000 per product.

Even in cases where eligibility requirements can be met, and where there is a clear ability to validate the safety of products, a high cost for registration of, say, €250,000 per product represents an insurmountable burden for companies whose business model is based on selling a wide variety of products, each with a relatively small sales volume. This kind of model is actually typical of manufacturers and suppliers of Ayurvedic and TCM products. By contrast, manufacturers and suppliers of European herbal products tend to sell a much narrower range of products, with each line generally selling at a much greater volume. Consequently, high product registration costs are much easier to justify economically for typical European herbal suppliers, as compared with those selling products associated with the major Asian and other non-European traditions.

QUESTION 2. How can the THMP registration scheme act as a barrier to the free movement of food supplements within the EU, since the Directive is designed for herbal medicinal products only and is not food supplement legislation?

ANSWER: For the last two or more decades, many products associated with the Asian traditions of Ayurveda and TCM have been sold as food supplements in countries such as the Netherlands, Belgium and the UK. Food law, as opposed to medicinal law, governs food supplements. In itself, medicines regulation should not interfere with products under the jurisdiction of food law. However, certain competent authorities, including those in the three above-mentioned EU Member States, appear to wish to reduce or eliminate dual categorisation – as both food and medicines – of particular herbs or herbal products. Full implementation of the THMPD after April 2011 appears to be seen by these Member States as a suitable occasion to force manufacturers and suppliers to abide by one system or the other. In all three of these Member States, we are aware of instances where products that have long been sold as food supplements are now considered illegal by national authorities, unless they can be successfully registered under the THMPD. In some Member States, it is becoming increasingly difficult to get products notified as food supplements, given that authorities now consider the THMPD to be the appropriate regulatory regime for herbs associated with traditional systems. Such a view is ironic, given the recognition, even by the [European Commission](#), that the THMPD is unsuitable for products associated with Ayurveda, TCM and other ‘holistic’ systems of medicine. Such impacts of the THMPD on free movement of food supplements that have a safe history of use may contravene elements of European law, such as mutual recognition and rules governing the functioning of the single market. The Commission indicated, in this same report, that it may consider development of an entirely new framework for the practice of such traditions. However, our concern is that a framework of this type is likely to take many years to be agreed and implemented.

QUESTION 3. As many herbal products are currently sold as food supplements in many Member States, are there any impediments to continued sale of such products?

ANSWER: In at least 5 Member States, regulatory authorities have circulated letters or other communications that unilaterally and arbitrarily classify herbal ingredients as either foods or medicines. On such occasions, relevant and affected sectors representing the Asian herbal industry have not been consulted. In one Member State, the competent authority has even suggested that all positive (food) listed traditional ingredients should be transferred to a negative (medicines) list, in order both to be eligible for medicinal registration under the THMPD, and to protect such ingredients from the Novel Food Regulation (No 258/1997). The Regulation requires burdensome pre-market authorisation of any food or food ingredient that has not been used significantly in the EU prior to the Regulation coming into force on 15 May 1997. Furthermore, at least one Member State has

confirmed in writing to a major Ayurvedic supplier that dual status of an equivalent product, as both a food supplement and a medicine, will not be accepted. In principle, forcing such products into a medicinal regime would not present a problem if the THMPD had been created to facilitate registration of the majority of products associated with traditional systems of medicine. However, many products from non-European traditions are effectively 'locked out' by their inability to comply with the eligibility requirements of the THMPD. This means that blocking their sale as food supplements effectively bans these products from the market altogether, despite them being manufactured according to traditional specifications and being established as being completely safe to consumers.

QUESTION 4. Does the definition of a medicine under European law not make it easy for both manufacturers and regulators to determine which products should be designated as medicines and which can be sold as food supplements?

ANSWER: The extremely broad scope of the definition of a medicine in European law (amending Directive 2004/27/EC, Article 1.2) technically makes all foods and food ingredients medicines by function. However, Recital 7 of the same Directive exempts from medicinal law those substances that are regarded "clearly" as foods, food supplements or cosmetics. Should there be any doubt over the categorisation, Article 2.2 of the Directive gives regulators arbitrary power to apply medicinal law over any other Community law. While some case law originating from the European Court of Justice has aimed to clarify the application of medicinal law to herbal products and ingredients, there are still considerable differences in how different Member States apply food and medicinal law. Complicating matters further from the perspective of manufacturers and suppliers, individual national authorities continue to 'move the goalposts' as the date of full implementation of the THMPD (1 May 2011) approaches.

This lack of coherence between medicinal and food law, as interpreted by various EU Member States, is creating considerable legal uncertainty for many operators. A bizarre situation may arise where an herbal ingredient that may have been sold for decades as a food supplement, given a) its history of use as a food, b) its "physiological effect" (food supplement definition, Directive 2002/46/EC, Article 2) and c) the absence of any therapeutic claim, will now be accepted as a medicine (under the THMPD) yet be banned as a food ingredient for the same alleged physiological function.

QUESTION 5. Why is there confusion among the sector over the classification of herbal products as foods or medicines, given that both terms are clearly defined by the EU and that European monographs exist for many herbs?

ANSWER: Given the great overlap in the respective definitions of food supplements and medicines in European law, as well as the supremacy of medicines law over any other legislation, it is far from certain whether the sale of products long available as food supplements will continue under that regime (see answers to Questions 2–4 above). So far, less than 60 Community monographs for herbal products have been adopted, these all being for herbs common to European, rather than Asian, traditions. There are several hundred individual herb species associated with each of the Ayurvedic and TCM traditions, and their absence from the EC monograph listing makes it much harder to establish quality control standards for use in THMPD registration applications. In addition, meeting the quality control requirements, which are better suited to single or very limited combinations of herbs with well-established analytical markers, is a much greater challenge for Asian herbal medicines than it is for common ones from western traditions.

QUESTION 6. Why is the sector not pressuring the European Medicines Agency to develop more monographs, with the aim of ensuring that more herbal products are approved as traditional herbal medicines on the basis of their mechanisms of action and safety profile?

ANSWER: On 16th November 2010, representatives of various Asian traditions – under the auspices of the [Alliance for Natural Health International](#), the [European Herbal & Traditional Medicine Practitioners Association](#) and the [European Initiative for Traditional Asian Medicine](#) – initiated a [proposal](#) to encourage the HMPC of the EMA to develop more, and more appropriate, monographs, especially those relating to herbs associated with the Asian traditions.

QUESTION 7. Why is there concern amongst sectors of the herbal medicine community over a ban on polyherbal products after April 2011, as licenses for individual herbal products are increasingly being granted under the THMPD regime?

ANSWER: While nearly 200 registrations have so far been approved under the THMPD, and considerably more are likely prior to the end of the transition phase of the THMPD on 30 April 2011, this does not yet include any products associated with the great Asian traditions of Ayurveda and TCM. Not only is it very difficult, or even impossible, to register products associated with these non-European traditions under the THMPD (see answers to Questions 1, 5 and 6 above), it is also increasingly difficult to ensure the sale of herbal products from these traditions under the food supplements regime, owing to their arbitrary classification as either medicines or novel foods (see answers to Questions 2 through to 5 above). As a result, a significant number of products are at risk of falling between the two ‘stools’ of food and medicines legislation. Products that are amenable to neither regulatory regime will effectively be banned. Such bans will disproportionately affect products from non-European traditions. A medicinal regime is, in principle, entirely appropriate for products being used directly by consumers for self-care, or that are prescribed by healthcare professionals. However, the eligibility criteria for the THMPD’s simplified medicinal registration scheme conspire to exclude a very large number of products from the scheme. Since the key aspect of simplification offered by the THMPD involves bypassing the requirement to prove efficacy as required for conventional medicines, once traditional use is established, the only additional criterion for registration should be the need to establish safety. Unfortunately, in its present form, the THMPD focuses on functionality by considering only minor, self-limiting ailments, and prevents the use of a large number of products from traditional systems for the indication stipulated in their indigenous pharmacopoeia. Furthermore, it would be straightforward to make the technical guidelines set by the HMPC more effective in ensuring the quality and safety of products, while also being less technically challenging and costly. It is important to recognise that an enriched extract of an herb of European origin is likely to meet the quality standards set by the THMPD considerably more easily than a product made according to the traditional method given in the relevant Chinese or Indian pharmacopoeia. This gives rise to the paradox that a product containing a high concentration of a particular, pharmacologically active constituent, such as a particular alkaloid or glycoside, will more easily obtain registration under the THMPD than a product made using a watery decoction of multiple herbs. Ironically, in such cases, there is a high likelihood that the European product would present a considerably greater potential public health risk than the Asian product.

QUESTION 8. Given the frequency of major adverse events among members of the public following the use of herbal products, surely product registration under the THMPD is vital to safeguard public health?

ANSWER: There has been an extremely low rate of significant adverse reactions caused by products associated with traditional systems of Asian medicine that are sold to the consumer as food supplements. This adverse event rate is far lower than that associated with conventional foods, implying that such herbal products are, on average, substantially safer to consumers than

conventional foods. There have been a very small number of well-publicised cases in which practitioners, including medical doctors, have prescribed herbal products alongside pharmaceutical drugs, and adverse events have been reported. However, in such cases, there is uncertainty over the actual role played by the herbal products as against the pharmaceutical drugs and their respective interactions. While specific and rather isolated quality problems have been identified with respect to the manufacture of particular herbal products, the worst of these tend to have been associated with products legally sold as unlicensed medicines under specific exemptions in the UK. Such malpractice in the area of unlicensed medicines manufacture should not be allowed to further constrain registration requirements for herbal medicinal products or products sold as food supplements. The former requires pre-market establishment of safety, the latter places the burden of safety on the manufacturer or supplier with no need to have safety validated by a national authority prior to a product being put on the market.

QUESTION 9: Why are companies reluctant to pay for the quality control requirements of the THMPD, when they are essential to ensure product quality and consumer safety?

ANSWER: The quality control requirements for the THMPD are far from the only obstacles to registration (see answer to Question 1). In many cases, there are other constraints to registration, such as the inability to meet the requirements for traditional use, which require bibliographical or expert evidence to verify 30 years' safe use, at least 15 of which are within the EU. Guidelines imposed on registrants for the THMPD include the provision of 6 months of stability data, based on specific marker compounds known to occur within specific herbal ingredients. In the case of polyherbal products, especially where there are seven, eight or more herbs represented within the formulation, finding suitable markers can be both extremely difficult and very expensive (see answer to Question 1 above). There are other quality control methods, such as those involving the use of high-performance thin-layer chromatography (HPTLC), that can be used to qualitatively evaluate the 'fingerprint' associated with complex polyherbal mixtures. Once standards have been established, such methods would not only be considerably more cost effective than existing methods, they would also guarantee a higher level of quality.

QUESTION 10. How do the presently disparate approaches to the regulation of herbal products in EU Member States fit with EU principles that aim to govern the free movement of goods within the single market of the EU, while adequately protecting consumers and upholding free choice and human rights?

ANSWER: It is clear that the situation is disproportionate with respect to the disparate approaches being taken by different EU Member States to the regulation of herbal products associated with non-European healthcare traditions. The current approach will lead to barriers to trade of herbal products that have, until now, been sold safely as food supplements (see answers to Questions 2 through to 5 above). The loss of particular products from the market will dramatically reduce consumer choice. This loss is caused simply because an unsuitable regulatory regime has been created in the form of the THMPD, which excludes both products prescribed by practitioners and a vast array of products from non-European traditions. It thereby infringes human rights, given that these products are central to the holistic healthcare systems with which they are associated. The data requirements for the Directive were subject to a lack of transparency, and this was particularly acute in terms of the quality control requirements, which were not forthcoming until several years after the passage of the Directive into European law. Accordingly, ANH-Intl and the European Benefyt Foundation have seen fit to prepare a [case](#) for judicial review of the Directive and its associated impact on herbal products in the EU. The primary aim of such a judicial review is to focus attention on those aspects of medicine and food laws that should be amended, or interpreted differently, to prevent unnecessary distortions of the European market. The legal challenge also aims to ensure that consumer choice and fundamental freedoms are not unjustifiably curtailed.

QUESTION 11. If the THMPD is intended for herbal products without supervision of a medical practitioner, is there another system of regulation for traditional medicines that are prescribed by practitioners?

ANSWER: The THMPD was always intended as a regulatory regime for industrially manufactured products that are intended for use by consumers for treatment of minor, self-limiting ailments without the intervention of a healthcare professional. Such products are sometimes referred to as self-care products. The reality is that a lot of traditional medicines are designed to be prescribed by a practitioner, this particularly being the case with Chinese and Indian traditional medicines. At present there is no adequate regulatory regime for such products, the only exemption being for “authorised health care professionals” who are able to make and prescribe unlicensed medicines under the main European medicines code (Directive 2001/83/EC, Article 5.1). But across the EU, these “authorised health care professionals” are regarded by national competent authorities as only doctors and pharmacists. In both cases, these people may have little or no training in the complexities of herbal medicine or their production. They may even be unaware of the traditional methods of production for which traditional indications are made and for which they claim. In the UK, efforts led by the [European Herbal & Traditional Medicine Practitioners Association](#), are being made to statutorily regulate herbal medicine practitioners. Statutory regulation in the UK aims to continue to allow registered herbalists, who are non-medical doctors, to prescribe unlicensed herbal medicines, as per a long-standing exemption that has uniquely existed under UK medicines law. Enthusiasm for a similar system in continental Europe is simply not there. But there is widespread recognition that the THMPD isn't suitable for Ayurvedic, TCM and other holistic systems of medicine, even on the part of the European Commission. The Commission went on to indicate in its experience [report of 2008](#) that it could evaluate the suitability of a new system. On this basis, the [European Benefyt Foundation](#) (EBF) initiated work around two years ago to help develop a new framework that would be specifically applicable to practitioner prescription of traditional medicines. You can find out more about this initiative in ANH-Intl and EBF's [joint position paper](#). The problem with any system of new regulation is that it takes time to develop and this could be years off. The first step is to ensure there is enough desire from the European Parliament to get the European Commission to initiate a proposal. That work is already well under way (see answer to Question 2).