JOINT ANH/BENEFYT POSITION PAPER

Working collaboratively to maintain the supply of products associated with traditional systems of medicine in Europe from 2011 onwards

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Executive Summary

This paper proposes a coordinated strategy to ensure the highest chance of uninterrupted sale and use of herbal products associated with various traditional systems of medicine, including those of non-European origin. The paper has been developed by two non-governmental organisations, the Alliance for Natural Health International (ANH-Intl) and the European Benefyt Foundation (EBF), that have each taken major initiatives aimed to ameliorate the regulatory challenges facing botanical products associated with traditional systems of medicine in the EU.

Based on the complementary nature of each organisation's strategies, the close coordination of activities will enable sharing of expertise and resources. It is hoped that ANH-Intl and EBF's collaboration will help demonstrate a united front and so encourage wide participation by relevant stakeholders in the sector, both within and outside of Europe.

Three main initiatives are proposed, addressing both short and longer term concerns. Two of these, namely the facilitation of an improved food supplement regime for botanicals across Europe, as well as a judicial review of the European laws affecting plant-based products associated with traditional systems of medicine, are intended to yield short-term benefits. Longer term benefits are proposed by a third action, which is the proposal to European authorities of an entirely new regulatory model for products (not only botanicals) associated with traditional systems of medicine.

The actions proposed are intended to prevent as far as possible interruption of the availability of products already on the market, to make maximum use of existing frameworks, to be both technically and economically feasible for stakeholders in the sector, and to be realistically achievable.

Background

Full implementation of the Traditional Herbal Medicinal Products Directive (THMPD) (EC Directive 2004/24/EC) as of 1st May 2011 is likely to force from the European market thousands of products associated with traditional systems of medicine that have up until now been sold mainly as food supplements. The end of the 7 year transition phase of the directive will be interpreted by many Member States as a fundamental regime change whereby many herbs products included in products that have been sold safely as food supplements, often for decades, will need to be registered under the THMPD if they are to continue to be available beyond 30th April 2011.

While, in theory, national food supplement regimes for botanicals are maintained following this date, a number of factors suggest that it will be increasingly difficult to use this route to continue to sell or dispense finished polyherbal botanical products that have long been associated with traditional systems of medicine, particularly non-European ones. Challenges within the food supplement regime in different Member States include: the application of positive lists, classification as 'novel' under the terms of the Novel Food Regulation (No. 258/97), classification as one or more constituents (or their dosage) within the product as medicinal (under the terms of amending Directive 2004/27/EC) and/or the imposition of onerous and disproportionate quality control requirements.

In order to facilitate the working of the single market and reduce variation in legislative approach to botanical food supplements in Member States, risk assessment guidelines for botanicals used in food supplements have been prepared by the European Food Safety Authority (EFSA). The Novel Food Regulation, although originally conceived to protect consumers from genetically modified foods (that now have their own regulatory regime) and foods modified by other technologies, poses a very great threat to many botanical constituents. Its basic premise is to require pre-market authorisation of such foods following evaluation by EFSA of extensive evidence of safety. The classification is applied to any food that has not been used significantly within the EU prior to the implementation of the Regulation, in May 1997. The Regulation has been used increasingly to instigate bans on botanicals which have not been used significantly within the EU, despite them often having a history of use outside of the EU that is known to span thousands of years. Such restrictions are not generally based on any health concerns and so may be contrary to the principles of European law.

Further exacerbating the problems for food supplements is the gradual implementation of the Nutrition and Health Claims Regulation (No. 1924/2006). The Regulation's health claims regime supersedes that under national regimes and requires, highly controversially, requires very specific data to verify causative relationships between a food or food constituent and a health benefit. To-date, nearly all of EFSA's evaluation of health claims for

botanicals have been unable to establish a causative relationship. Unless the requirements for health claims are changed, it can be assumed that almost all health claims will be disallowed. This will cause greater, rather than less, confusion among consumers, especially for over-the-counter (OTC) products.

The simplified medicinal product registration scheme offered by the THMPD provides an additional regulatory route, specifically intended for botanicals associated with traditional systems of medicine. However, a series of eligibility and technical challenges, as well as prohibitive costs, prevent a very large number of traditional medicines, especially from non-European traditions such as Ayurveda and traditional Chinese medicine (TCM), from being registered under the scheme. A failure to alter the regulatory regime for such products is therefore likely to lead to very substantial losses of products from the European market with consequential impact on businesses manufacturing and supplying them.

Certain companies operating in Europe have been successfully obtaining relatively small numbers of registrations under the scheme. However, such companies are atypical of those associated with the Indian or Chinese traditions, as well as minor European traditions and other lesser non-European traditions. Typical stakeholders involved with Ayurveda and TCM generally supply a large number of polyherbal products, each with low annual sales volumes. It is the unnecessary complexity of the quality control requirements associated with THMPD that provide the primary obstacle as well as the prohibitive costs associated with the scheme. Many products are also simply not eligible to the scheme, given in particular the lack of use of equivalent products within the EU for 15 years (a requirement of the '30-year rule'; Article 16c). In addition, many traditional uses have been deemed unacceptable by Member State competent authorities or the Committee on Herbal Medicinal Products (HMPC), often because they relate to 'major' ailments or their use is seen to require the supervision of a medical practitioner (Article 16a1(a)). Finally, many companies have had great difficulty meeting the technical requirements stipulated by the European Medicines Agency, or they simply have been unable to afford the costs of required quality control (especially stability) tests. This has meant that many applications for the scheme have either not been able to be started or ones which have started have had to be aborted.

A proportionate scheme would allow the costs of registration for a given product to be readily borne from profits yielded by one or two year's sales of that product. Presently, the scheme typically costs €60,000 – €350,000 per product and so is inaccessible to the majority of stakeholders engaged with non-European traditional medicinal systems. Some of the stakeholders (all of which are small-to-medium-sized enterprises [SMEs], often employing less than 10 persons) support product lines comprised of more than 1000 herbal products, the majority being polyherbal.

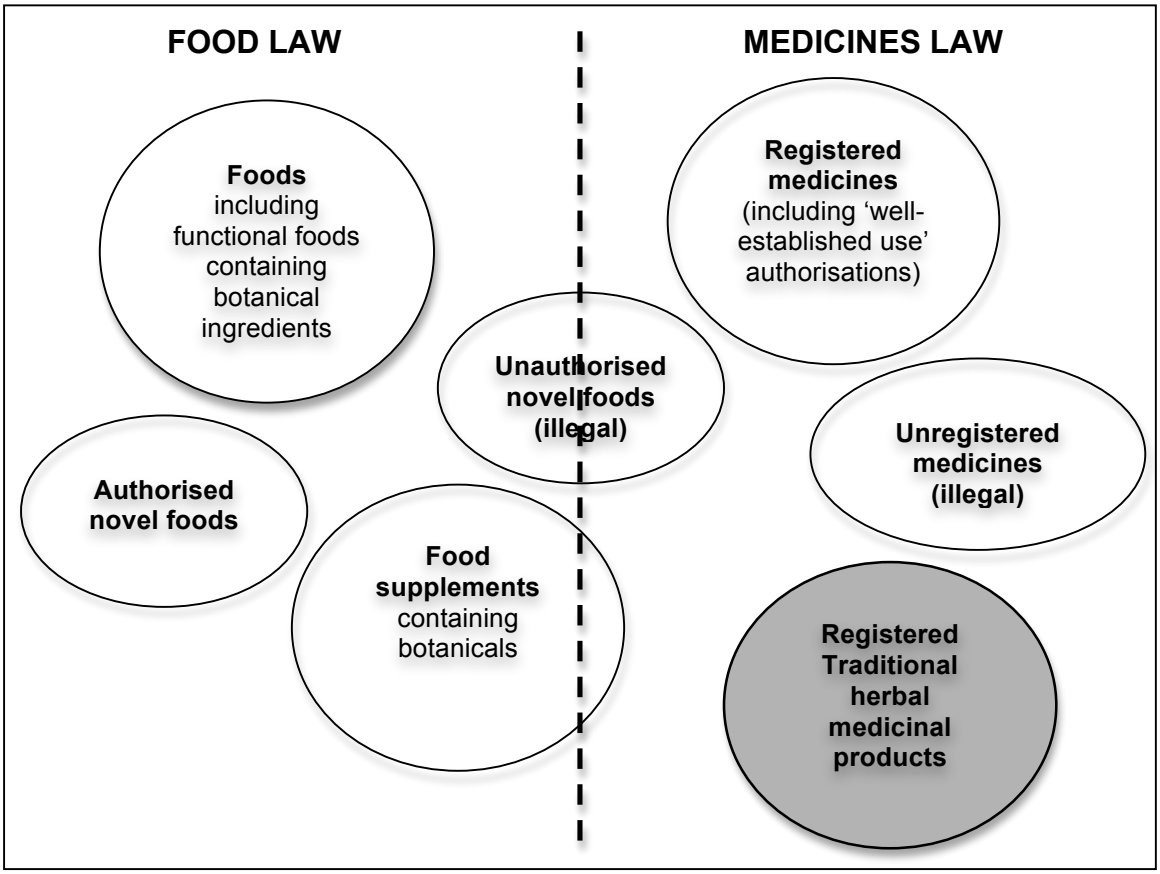

Figure 1. European legal context of traditional herbal medicinal products (THMPs) in relation to other categories of products containing botanical ingredients. Foods are regulated under EU General Food Law (Regulation (EC) No 178/2002); novel foods under the Novel Foods Regulation (No 258/97, as amended); food supplements under the Food Supplements Directive (2002/46/EC, as amended), medicinal product market authorisations under the Human Medicinal Products Directive (HMPD) (2001/83/EC, as amended) and THMPs under the amending directive (2004/24/EC) of the HMPD.

Weaknesses of the existing regulatory framework

The majority of products associated with traditional systems of medicine have to-date been sold as food supplements, rather than as medicines (Fig. 1). These products have a remarkably good safety record, with only limited examples of adverse events, these often having been associated with poor quality control, misidentification of herbs used in formulations, or even deliberate 'spiking' with pharmaceuticals. It is well recognised that measures to reduce such risks would further safeguard public health, however, excessive and disproportionate regulation could dramatically reduce consumer choice and so impede the ability of the general public to access safe natural products used to support their wellbeing.

The European Commission has made clear[1] that it will not harmonise EU-wide food supplements containing botanical ingredients, at least in the near future. Accordingly, botanical food supplements will be regulated at a national level, although the European Food Safety Authority (EFSA) has issued guidance[2] to facilitate this process. Considerable differences in national regulatory systems mean that free movement of food supplements between Member States is far from assured, especially following the end of the transition phase of the THMPD. The European Commission has also stressed how the Novel Food Regulation will provide an important regulatory tool to harmonise the market for botanicals used in food supplements, stressing how it might regard a plant extract as 'novel', even when the plant from which the extract is derived is not regarded as 'novel'.[1] Such an approach will prove highly restrictive for many botanicals associated with traditional systems of medicine.

Consequentially, after 30th April 2011, polyherbal products associated with traditional medicinal systems that are unable to negotiate the THR scheme, whether for eligibility, technical or economic reasons, are at grave risk of being classified by Member State competent authorities as unauthorised novel foods or unlicensed medicinal products (Fig. 1). Such products would effectively 'fall between the two stools' of European food and medicinal law (Fig. 1). The loss of such products would be catastrophic both to the many SMEs involved in the sector, and they would infringe human rights, so breaching the principles set out in the Charter of Fundamental Rights which is now recognized in European law following the passage of the Lisbon Treaty.

[1] European Commission (2008). Report from the Commission to the Council and the European Parliament on the use of substances other than vitamins and minerals in food supplements. COM(2008) 824 final. European Commission, Brussels.

[2] EFSA Scientific Committee (September 2009 update). Guidance on Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements. European Food Safety Authority, Parma.

Ways forward

In order to address the problems for the sector that are otherwise due to manifest in the second half of 2011, it is imperative to take a range of concerted actions. These actions must address both the immediate problems associated with the existing regulatory frameworks, as well as helping to facilitate the development of a more appropriate framework that allows not only the viability of traditional systems of medicine in Europe, but also allows such systems to expand and flourish. Concerted actions of this type must at the same time be realistic, taking into account existing European and national legislative models, principles of European law and scientific understanding and perceptions of traditional systems of medicine.

Scientists (including pharmacognosists and pharmacists), stakeholders, practitioners and European lawyers have been brought together by ANH-Intl and EBF to develop both short and longer-term actions to facilitate the survival, viability and expansion of the sector. A key part of this process is to ensure products are subjected to appropriate quality controls to ensure both their effectiveness and safety.

Three coordinated actions are proposed by ANH-Intl and EBF as follows:

Short-term actions

a. Improvement of the food supplements regime EU-wide
b. Judicial review of the THMPD

Longer-term action

c. Facilitation of a new regulatory framework for traditional medicinal products

Further detail on each action is given below.

Note: while a changes to the health claims regime under the Nutrition and Health Claims are much needed, the Regulation is so poorly conceived that a very broad cross-section of stakeholders across the food and natural health product sectors are working to positively shape it. Accordingly, for the time being, both ANH-Intl and EBF will not directly contest the Regulation given their existing commitments.

ACTION 1: Improvement of the food supplements regime

There is a great need for clarification of the food supplements regime, in different Member States, especially to facilitate the functioning of the single market of the EU. While the EFSA guidance for botanicals will facilitate a more harmonised approach, there are many ways in which the guidance, and

associated compendium, can be interpreted. Some interpretations by Member State competent authorities are not scientifically rational (e.g. France; green tea, only aqueous extracts allowed). A more equitable approach between Member States is also required given the requirements of the Mutual Recognition Regulation (No. 768/2008), which ensures that goods sold safely in one Member State should be available in others.

ANH-Intl and EBF are developing a workplan to:

a. Facilitate the expansion of the EFSA compendium of botanicals used in food supplements as well as its appropriate, scientifically-based interpretation
b. Lobby EFSA, relevant Member State authorities and the European Parliament to modify the existing compendium where necessary
c. Consult with Member State competent authorities to ensure a more 'level playing field' in the approaches taken to the approval of botanicals in food supplements
d. Reduce the inappropriate categorisation by European authorities of botanicals of non-European origin as novel foods, or unlicensed medicinal products.

ACTION 2: Judicial review of the THMPD

The legal text of the THMPD is problematic. It is this text, and its specific reference to quality control guidelines in the over-arching Directive 2001/83/EC that is responsible for the excessively restrictive eligibility requirements of the THR scheme, as well as the onerous quality controls that result in the prohibitive costs for registration of polyherbal products associated with non-European traditions, such as Ayurveda and TCM.

These regulatory requirements were not developed following adequate appraisal of the types of business operating in the sector, information that should have been available to the European Commission (the responsibility of the Directorate-General for Enterprise and Industry until late 2009), Member States and the European Parliament at the time the directive was proposed and passing through the legislative process in the European Parliament (2001-2004). Regulatory impact assessments carried out during this time were woefully inadequate and did not represent sufficiently the sectors most directly responsible for the manufacture or supply of classical medicines, especially those relating to non-European or minor traditions. Accordingly, SMEs involved with non-European and minor traditions are most adversely affected by the existing regulatory framework, which is currently set to force closure of those businesses whose operation is engaged solely with the manufacture or supply of traditional medicinal products in Europe.

Furthermore, given that regulatory systems for traditional medicinal products are in the process of development in many other parts of the world, and given the known influence of EU regulatory models outside of Europe, the existence of an inappropriate EU framework could yield negative impacts well beyond the European region.

It is therefore of paramount importance that the EU regulatory framework for traditional medicines is re-shaped, prior to it being fully 'cemented' following the expiry of its transition phase. Such amendment can be achieved in one of two ways; either through a willingness for amendment by the European Commission, Member States and the European Parliament (potentially achievable by effective lobbying and advocacy), or through judicial review.

It is the considered opinion of the ANH-Intl and EBF experts that there is inadequate willingness for amendment of the THMPD by at least the European Commission and Member States at the present time, and especially prior to 30th April 2011. A moderate level of lobbying over the problems caused by the Directive, as well as consultations by the Chinese and Indian governments which have raised many concerns to the European Commission and Member States, have so far yielded little. Accordingly, judicial review is proposed. ANH-Intl has received an opinion from a leading, London-based firm of European lawyers (11KBW), which is guiding its legal strategy.

The judicial review must be initiated through a domestic (European Member State) court and, in order to gain standing for judicial review, it would need to follow the rejection of an application to the THR scheme. The intention would be to seek from this national court a reference to the European Court of Justice.

The principle grounds for challenge have been identified as follows:

a. *Proportionality* combined with a restriction of freedom of movement of goods argument (under Article 28 EC of the Treaty of the European Community). This argument will expose the manner in which the Directive, and associated European laws and guidelines, disproportionately impacts stakeholders associated with non-European and minor traditional systems of medicine in Europe. Amongst other things, the monographs developed by the Committee on Herbal Medicinal Products will be challenged, the unnecessarily onerous nature of the technical requirements for the scheme will be exposed in terms of the intended purpose of the Directive, and, deficiencies in the technical requirements will be revealed, demonstrating that they do not adequately guarantee the safety of products

b. *Transparency*, an argument focusing mainly on the lack of transparency as to the nature of the technical (including quality

control) requirements at the time the THMPD was passing through the legislative process, prior to 31st March 2004

c. A human rights/cultural discrimination argument, which will delineate the social and cultural impacts of the planned restriction of access to products associated with traditional medicinal systems.

In parallel to the proposed EU legal process, it is expected that a formal complaint may be made to the World Trade Organization by the Chinese and Indian governments, supported possibly by other governments. This complaint will ramp up the concerns already expressed to European authorities about the impact of the THMPD on exports to the EU of herbal raw ingredients and finished products from China and India. It is proposed that experts in ANH-Intl and EBF will be able to facilitate this process. Such a complaint will apply much needed pressure on European authorities over the period that the judicial review of the THMPD is in process.

ACTION 3: Facilitation of a new regulatory framework for traditional medicinal products

The need to facilitate a new regulatory framework was the justification for the establishment of the EBF. Work on a draft regulatory model was commenced in early 2010, and has received considerable inputs from Peter Bogaert, a leading European lawyer specialising in EU medicinal law, pharmacognosists, analytical chemists, phytotherapists, practitioners of Chinese and Indian medicine systems and a diverse range of stakeholders in the sector. The model has become known as the Benefyt model.

The purpose of the model is to act as the basis for a new regulatory framework that not only replaces the THMPD, but also expands on its present scope. The model, therefore, aims not only to cater for OTC herbal medicines, but deals with practitioner prescribed and pharmacy-dispensed traditional herbal products, as well as those that are currently sold in some Member States as food supplements. The model effectively helps forge a 'third category' of products, that could be created between the regulatory regimes for foods and medicines. It is known that this type of framework, used in some other parts of the world (e.g. Canada, Australia) is of interest to regulators within the European Commission and it is intended that the Benefyt model will provide the basis for a future legislative proposal.

Critically important to the development of the model has been the inclusion of quality control requirements that are both feasible for the vast majority of stakeholders in the sector, while at the same time ensuring a very high level of quality and safety of products. A major 'selling point' of the Benefyt model to legislators and politicians alike will be that the Benefyt model offers a higher level of safety for products than the THMPD, while at the same time considerably cheaper. Additionally, the quality control elements of the

Benefyt model could also readily be applied to an amended version of the THMPD.

An extremely important element of the Benefyt model has been to utilise a category-based, or graded, approach. This allows different levels of regulatory stringency to be applied to different categories of product. The present model includes 3 grades of product. Class I includes those products which present no significant risks to human health. Class III includes those products containing constituents that may cause adverse effects in certain individuals and so need to be labelled with specific precautions to protect susceptible groups. The remaining class, Class II, includes those 'ambivalent' products, that are categorised neither in Class I nor in Class III.

Considerable advocacy and lobbying work will be required by EBF, ANH-Intl and other organisations to facilitate the acceptance of this model, and its acceptance is likely to be accelerated by the judicial review of the THMPD which will expose many of the weaknesses of the existing framework.

Concluding remarks

ANH-Intl and EBF has established a joint working group to coordinate these actions. Given that immediate work is required along with funding to continue the work, the working group is seeking expressions of interest from those stakeholders wishing to collaborate and help fund the work, which is highly time-sensitive.

The level of funding by individual stakeholders is negotiable, and contributing parties will continue to be invited to participate in regular meetings and communications as the work progresses.

Please reach us via the following contact details:

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