JOINT ANH/BENEFYT ABBREVIATED 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 has been developed by two non-governmental organisations, the Alliance for Natural Health International (ANH-Intl) and the European Benefyt Foundation (EBF). It 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.

Background

Full implementation of the Traditional Herbal Medicinal Products Directive (THMPD) (EC Directive 2004/24/EC) as of 1st April 2011 is likely to force from the European market thousands of products associated with traditional systems of medicine. 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 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 31st March 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. These challenges 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)
- imposition of onerous and disproportionate quality control requirements
- gradual implementation of the Nutrition and Health Claims Regulation (No. 1924/2006).

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.

Weaknesses of the existing regulatory framework include:

- disproportionate regulation, especially on products from non-European traditional medicinal systems
- lack of transparency over legal requirements
- threat to the free movement of food supplements between Member States
- Infringement of human rights

Ways forward

We propose three actions, all to be conducted simultaneously.

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

ACTION 1: Improvement of the food supplements regime

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 traditional herbal registration (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.

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.

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.

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 and is now near-complete.

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. It is intended that the Benefyt model will provide the basis for a future legislative proposal.

A major 'selling point' of the Benefyt model to legislators and politicians alike will be that it 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.

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.

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