WHY PRACTITIONERS SHOULD SUPPORT THE JUDICIAL REVIEW OF THE THMPD

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What's actually going on?

The Traditional Herbal Medicinal Products Directive (THMPD) comes fully into force after 30 April 2011. The scheme provides a simplified medicinal registration system for herbal products that can be demonstrated to have been used safely for at least 30 years, of which 15 or more must be in the EU. It is intended for manufactured products indicated for relief of symptoms associated with minor ailments only. Such products are intended mainly for self-care by the consumer and specifically without supervision of a medical practitioner.

Most Western herbalists have until now been using products exempted from the requirements of full-blown drug licensing under Sections 12(1) and 12(2) of the Medicines Act (1968). The former, commonly referred to as the 'herbalist's exemption', relates to medicinal products prescribed following one-to-one consultation, while the latter relates to Medicines and Healthcare Regulatory Agency (MHRA)-approved unlicensed herbal remedies. In the case of Asian traditions, such as Ayurveda and traditional Chinese medicine (TCM), the majority of products used by practitioners have been categorised, especially in the UK, as botanical food supplements. A small number are individualised by herbalists and provided under the terms of the Section 12(1) exemption, while an additional few have received exemption under Section 12(2).

The end of the transition phase of the THMPD will mark a considerable change in the overall regulation of herbal products in the UK and the rest of the EU. Many products that had been exempted under Section 12(2) will be 'upgraded' and be registered under the traditional herbal registration scheme (THRS) offered by the THMPD. The future status of the Section 12(1) exemption, although it has been a subject of considerable discussion between the MHRA, politicians and stakeholders, has still not been clarified and remains uncertain. As far as the Asian traditions are concerned, one of the problems of greatest concern is how national competent authorities may treat food supplements from May 2011 onwards.

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How to maintain access to herbal products prescribed by practitioners?

It is imperative that every effort is made to keep as many food supplement products on the market until such time that medicinal registration of the majority of its products is accessible. The substantial eligibility, technical and financial obstacles posed by the THRS have so far meant that not a single Ayurvedic or TCM product has yet to be registered under the scheme.

It is highly likely that food supplement products containing ingredients that have not had a history of food use will become increasingly difficult to maintain on the market after May 2011. This is primarily because regulators uphold the view that such products should be sold as medicines under the THRS after this time. Under the terms of the EU's Novel Food Regulation, regulators are also increasingly declaring food ingredients (especially herbs) that have not been used significantly, either in food supplements or as foods prior to May 1997, as novel foods.

The Alliance for Natural Health (ANH) and the European Benefyt Foundation have launched a joint initiative to help protect the availability of a wide range of herbal products. The initiative involves two main short-term actions, one being to keep the food supplements regime as wide open as possible, the other a judicial review of the THMPD. Regarding the latter, the campaign organisations argue that the text of the THMPD needs changing to make it more accessible to certain traditions, especially the Asian ones. Their third action is a longer-term one that involves the development of an entirely new framework for holistic medicinal systems such as Ayurveda and TCM. The European Commission has belatedly recognised the deficiencies of the THMPD and it seems very timely now to both show up its deficiencies via the judicial review as well as to present a new framework.

Since a new framework might take 5 or more years to instigate fully, it is essential to give immediate priority to the short-term actions. Most critical of these is for ANH/Benefyt to initiate the judicial review in the coming months, so that it is heard in the High Court in London well in advance of the expiry of the THMPD's transition phase.

Donations are urgently needed to fund the judicial review, and we sincerely hope that you will decide to contribute, in whatever way you are able. Please visit anh-europe.org for more information.