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ANH SET TO CHALLENGE EU HERB LAW
Alliance for Natural Health International announces its intention to initiate a legal challenge to the European directive on traditional herbal medicines

An expert's workshop in Budapest, sponsored by the Indian government and convened by the European Ayurvedic Association, provided the venue for the Alliance for Natural Health International to announce its intention to initiate legal proceedings against the European Directive on Traditional Herbal Medicinal Products (THMPD) (EC Directive 2004/24/EC).

The directive poses a major obstacle for the continued use and practice of long-standing traditions of healthcare involving herbal products in Europe, including those of Ayurveda and Unani from the Indian sub-continent and that of traditional Chinese medicine (TCM).

Many such products, including those from Western herbal traditions, have up until now been sold in the EU as botanicals under the food supplement regime. But most Member States are anticipating narrowing the regime when the directive's 7-year transition phase expires on 31 March 2011. Legally, the directive requires that the same pharmaceutical standards applied to conventional, synthetic drugs are applied to herbal products. This requirement is the main reason for the technical difficulties and very high costs of compliance.

Dr Robert Verkerk, executive director of Alliance for Natural Health International (ANH-Intl), said, "Getting a classical herbal medicine from a non-European traditional medicinal culture through the EU registration scheme is akin to putting a square peg into a round hole. The regulatory regime ignores and thus has not been adapted to the specific traditions. Such adaptation is required urgently if the directive is not to discriminate against non-European cultures and consequently violate human rights."

The ANH-Intl has been working alongside its lawyers, Cheyney Goulding of Guildford, UK, and has sought advice from a leading London-based barristers' chambers, 11KBW, which specializes in European competition and human rights law.

ANH-Intl has been working for several years towards creating the necessary changes to the directive to prevent discrimination against smaller herb producers and non-European healthcare cultures.

Referring to ANH-Intl's legal advice, Verkerk stated: "We are now confident that our legal counsel has found a solid way forward that will be in the long-term interests of European and non-European citizens alike. Given the challenges facing the health of the people of Europe, especially as a result of the burden of chronic diseases, the EU should be welcoming—not locking out—these very long-standing, multi-faceted and effective healthcare traditions. We are now assured that a diverse range of interests are willing to work with us to initiate the judicial review process."

ENDS.

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NOTES TO THE EDITOR

About the EU Directive on Traditional Herbal Medicinal Products
For further information about the EU directive on traditional herbal medicines (THMPD) and concerns over its implementation, please download the following ANH briefing paper: http://www.anhcampaign.org/files/080630_ANH-Briefing_Paper_THMPD.pdf

The European directive provides a simplified registration scheme for herbal medicines, whereby evidence of traditional use is accepted in place of the clinical trials used for conventional drugs that aim to prove their effectiveness for given indications. The directive, which is restricted to products indicated for mild ailments (without the intervention of a practitioner), still requires that conventional pharmaceutical standards are met to verify quality, purity and stability of herbal medicines. These standards are either technically not feasible for many multi-herb products common to non-European healthcare traditions, or they are prohibitively and disproportionately expensive.

Less common traditional healthcare cultures dependent on herbal products, such as those from other regions of Asia (such as Tibet, Mongolia and South-East Asian countries), Africa and South America will be impacted to an even greater extent given the technical hurdles and costs of the European licensing regime provided by the directive.

Both Ayurveda and TCM have over many years developed very specific approaches to maintaining the quality and consistency of herbal medicines and these are detailed in their respective pharmacopoeia. While there have been a small number of well-publicised instances where exports from both India and China have been found to be sub-standard in quality or contaminated, this has been through failure to adopt standards set by the tradition-specific pharmacopoeia. Enforcement in both India and China has improved in recent years and the directive's requirement for licensing of overseas manufacturers by EU authorities provides a control against sub-standard operators.

The ANH argues that the EU authorities should respect the equivalence of non-European standards as set by their respective pharmacopoeia, rather than force non-European herbs through western scientific standards that are neither appropriate nor relevant.

To-date, not a single product from either the Ayurvedic or Chinese tradition has been registered. Restrictions on eligibility, including the general requirement to demonstrate 15 years of use of the product in a European Member State, out of a total of 30 years, provide further obstacles to successful registration of products from non-European traditions under the EU scheme.

The traditions of Ayurveda and TCM have evolved over more than 4,000 years. These traditions alone are common to over one-third of the world's population. They represent multi-faceted approaches to whole body healthcare that include detailed attention to diet and lifestyle, as well as the use of natural products and specific mental or spiritual practices.
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