# European Union Prepares for Full Enforcement of Traditional Herbal Medicine Regulations

## *Controversy and confusion grow in United Kingdom*

**In less than one year, consumers across the European Union will have access only to herbal medicines that have obtained a product license or registration.[1] Beginning in April of 2011, if an herbal product is considered a medicine and has not received traditional-use registration or full marketing authorization, it will be taken off the shelves of pharmacies, stores, and practitioners' businesses.**

This enforcement is based on the Traditional Herbal Medicinal Products Directive (THMPD), which the European Union adopted in 2004 as an amendment to earlier medicines legislation (EU Directive 2001/83/EC) requiring all human medicines—ranging from pharmaceuticals to herbal medicines—to obtain full marketing authorization.[2,3] The THMPD is meant to provide a simplified registration process for traditionally-used herbal medicines that do not meet the stringent efficacy standards for obtaining marketing authorization as medicines.

In order to obtain traditional herbal registration (THR), the herbal medicine must meet the safety and quality standards required for all fully-licensed medicines, including good manufacturing practices (GMPs) and pharmacovigilance (adverse event reporting). Instead of requiring evidence of efficacy, manufacturers of these products must provide evidence of a minimum of 30 years of traditional use, with at least 15 of these years having taken place within the European Union. The product must also be traditionally prepared and used (although in some cases, preparations other than traditional macerations and infusions, e.g., complex extracts, are allowed if the herbal product has been on the EU market for more than 15 years).

Traditional-registered herbal medicines must feature statements on their labels and in advertisements noting that any health claims are based on traditional usage.[1,2] Herbal medicines supported by strong scientific evidence that wish to use strong claims, on the other hand, may do so by obtaining full marketing authorization after meeting the requirements outlined in EU Directive 2001/83/EC. Herbal products not classified as medicines* can be marketed as foods, food supplements, or ingredients of functional foods or cosmetics; such products are not allowed to use any medicinal claims.

**Acronyms Used in this Article**

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| ANH: | Alliance for Natural Health |
| CNHC: | Complementary and Natural Healthcare Council |
| CPHM: | Campaign for the Protection of Herbal Medicine |
| DH: | UK Department of Health |
| EC: | European Commission |
| EHTPA: | European Herbal and Traditional Practitioners Association |
| MHRA: | Medicines and Healthcare products Regulatory Agency |
| PFIH: | Prince's Foundation for Integrated Health |
| RCP: | Royal College of Physicians |
| THMPD: | Traditional Herbal Medicinal Products Directive |
| THR: | traditional herbal registration |

### Effects on Consumers and Practitioners

In the introduction of *A Practical Guide to Licensing Herbal Medicinal Products*, Elizabeth M. Williamson, PhD, director of pharmacy practice at the University of Reading, writes that the THMPD will benefit patients *and* practitioners.[1] Although traditionally-registered products are restricted to making general claims, the registration process serves as a good option for products that do not meet the requirements for full marketing authorization as medicines, as it allows them to use more expansive claims than those permitted for food supplements. She writes that "for a reputable manufacturer, there seems to be little point in trying to avoid registration, and much to be gained from complying with these standards and being rewarded with the certificate of registration and the authority it provides."

But according to the Alliance for Natural Health (ANH), a legal and scientific policy organization, the THMPD is resoundingly negative as it discriminates against non-European cultures and could "effectively steam-roller ancient and effective medicine cultures," such as Traditional Chinese Medicine (TCM) and Ayurveda, "out of existence."[4]

"It's not just a question of cost, which obviously impacts smaller companies much more than larger ones—it's also that some of the requirements are simply very difficult to meet from a technical perspective, especially for complex herbal products typical of these traditions," said Robert Verkerk, PhD, founder of ANH. Dr. Verkerk noted that no Ayurvedic or TCM products have obtained a THR thus far.

A September 2008 report from the European Commission (EC) echoed this sentiment.[5] The EC said that some of these products are not appropriate candidates to apply for a THR because they can sometimes consist of several non-herbal components, be administered by injection, require practitioner supervision, be used to treat serious diseases, and lack evidence of 15 years of traditional use within the European Union.

Dr. Verkerk also claims the THMPD has negatively impacted other herbal manufacturers.

"For many [manufacturers] who have thus far been successful in getting registrations, these registrations represent only a small or very small proportion of their full product range," he said. "For most companies, the [Directive] represents too big an obstacle and they have to make do with continuing to sell botanical food supplements." In March of 2010, ANH announced its intentions to take legal action challenging the THMPD.

*Article I of EU Directive 2001/83/EC defines a medicinal product as "any substance or combination of substances presented for treating or preventing disease in human beings," or "any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting, or modifying physiological functions in human beings."





The UK-based Herb Society, an herbal education organization, has likewise said that the expensive cost might cause many popular herbal medicines to become unavailable.[6] The Herb Society also claims that promising new herbs with less than 30 years of traditional use might be taken off the market, and that the availability of herbs imported from the United States and other countries could decrease because they are not manufactured under the same regulations/licensing requirements. But, like Dr. Williamson, the Herb Society also recognizes that THMPD could establish a legal basis for herbal medicine and improve the quality of over-the-counter (OTC) herbal medicines.

### Controversy in the United Kingdom

In the United Kingdom, 105 THR applications have been submitted and 48 have been granted for products containing such herbs as the root and rhizome of rhodiola (*Rhodiola rosea*, Crassulaceae), the rhizome of black cohosh (*Actaea racemosa*, Ranunculaceae; syn. *Cimicifuga racemosa*,) and the root of echinacea (*Echinacea angustifolia*, Asteraceae), among others.[7] The current majority of UK herbal medicines, however, remain unlicensed.[1]

A particularly heated disagreement has arisen, centering on whether statutory regulation of herbal practitioners will enable them to continue supplying *unlicensed* herbal medicines.

While most UK groups agree that many herbal remedies will have difficulty in obtaining a THR, a particularly heated disagreement has arisen, centering on whether statutory regulation of herbal practitioners will enable them to continue supplying *unlicensed* herbal medicines.

According to Michael McIntyre, chair of the European Herbal and Traditional Practitioners Association (EHTPA), EU Directive 2001/83/EC will make it impossible for herbalists to commission unlicensed, finished herbal prescriptions made by third-party suppliers unless they gain "authorized health professional" status via statutory regulation (e-mail, February 22, 2010).

Often called "specials," these medicines are used to meet the special needs of individual patients and are often made of complex mixtures and sent directly from the third party to the patient. Many Western herbalists do not have the room for an herbal pharmacy on their own premises to make their own remedies, and they have therefore depended on third-party commission services over the past 30 years, said McIntyre. Additionally, commissioning special prescriptions from third parties is essential as it is the only way Ayurvedic and TCM practitioners can legally supply their patients with manufactured complex remedies, he continued.

"The fundamental problem for practitioners who see patients face-to-face is that THR remedies are not sufficiently flexible or precise enough to enable the practitioner to treat a range of conditions on an individual basis," he said. "THR products would not answer the specific needs of these individual patients."

Representatives of the UK's Medicines and Healthcare products Regulatory Agency (MHRA) confirmed that herbal practitioners would not be able to use third-party services beginning in April 2011 unless a national arrangement is made to consider them authorized health professionals through systematic professional regulation and accountability (J. Kyne, F. Palmer, e-mail, February 17-19, 2010). The representatives noted that this does not apply to remedies made by the practitioner on his or her own premises, as these are considered non-industrial medicines and can be dispensed unlicensed.

The majority of the UK's herbal profession, including various alternative medicine organizations such as the EHTPA, supports statutory regulation of herbalists. The Prince's Foundation for Integrated Health (PFIH) has said that if herbalists and TCM practitioners are prevented from prescribing many herbal medicines due to unauthorized status, then customers will seek such medicines on a dangerous black market of bogus practitioners or Internet retailers.[8]

According to McIntyre, without statutory regulations, anyone who calls themselves an herbalist can prepare remedies on their own premises and practice on patients. He noted the recent criminal trial of a TCM practitioner who, allegedly unknowingly, prescribed medicines containing aristolochic acid, a nephrotoxic and carcinogenic substance from the genus *Aristolochia* (Aristolochiaceae), to a woman who later developed kidney failure and cancer. (The use of products containing the ingredient *Aristolochia* is banned in the United Kingdom.)

"In these circumstances it is difficult for the public to distinguish between the good, the bad, and the ugly," said McIntyre.

Other organizations, however, disagree on the value of statutory regulation of herbalists. The Campaign for the Protection of Herbal Medicine (CPHM), an alliance of herbal medicine practitioners, patients, and retailers, has stated that herbalism is already a legitimate profession and does not need statutory regulation. According to Jennifer Wharam, ND, co-founder of CPHM, herbalism is safe and statutory regulation would not increase safety. And while THMPD might cause some difficulties for Ayurvedic and TCM practitioners, statutory regulation is not the answer (e-mail, February-April 2010).

"It is not impossible for these practitioners to prepare the medicines themselves, in which case it will mean more work in their practice but will provide access to the medicines without the need for regulation," she said.