

Severe threat to safe herbal choices!

Public consultation proposals

- The Department of Health is currently consulting on the proposed statutory regulation (closing date Nov 2nd!) of herbal/traditional medicine, TCM and acupuncture practitioners. After almost 10 years of commitment to this important step forward which is in the public interest there is now a very real possibility that the Government will **not** proceed with statutory regulation.
- Instead, the Government is considering imposing a lesser licensing system on practitioners which will crucially confer no special legal rights when it comes to medicines law (see below) and will relegate herbal/traditional medicine and traditional acupuncture practitioners to a second-rate category, using a similar licensing scheme to that currently employed to regulate bouncers, bodyguards and wheel clampers. Another suggested possibility is that voluntary regulation continues in one form or another.

Voluntary regulation – no security for patients or practitioners

- Voluntary regulation would mean that herbal practitioners will continue to be legally indistinguishable from ordinary members of the public. Failing practitioners cannot be prevented from practising, as would happen with statutory regulation, and there will be no long-term security of access to potent herbal remedies such as *Atropa belladonna* (deadly nightshade) or *Ephedra sinica* (ephedra herb) granted for herbal use under legislation passed in the early 1970s.
- In the long-term, this lack of legal professional identity will undoubtedly undermine the herbalist's right to prescribe herbal medicines under Section 12(1) of the Medicines Act of 1968. Indeed, for the first time the current Government Consultation Document actually contemplates the repeal of this vital piece of legislation that enables herbal/traditional medicine practitioners to prescribe individual herbal medicines for their patients. *It is clear that access to a full range of herbal medicines can only be preserved if herbal/traditional medicine practitioners are statutorily regulated.*

Voluntary regulation/licensing - no UK wide professional standards & no referrals

- Maintaining the *status quo* or imposing a lesser licensing scheme will mean that statutorily regulated health professionals (e.g. doctors) will not be allowed to make referrals to herbal/traditional medicine practitioners and acupuncturists. It will also fail to deliver the essential benefits of professional statutory regulation such as independent accreditation of training programmes, mandatory continuous profession development (CPD) and the development of best practice towards which for the last decade the profession has been working in anticipation of statutory regulation.

Threat to full range of herbal medicines

- If statutory regulation fails to go ahead there will be a loss of a wide range of herbal medicines currently supplied by manufacturers and suppliers to practitioners. Full implementation of the new European Traditional Herbal Medicine Directive in 2011 will see the end of Section 12(2) of the Medicines Act of 1968 and with it the right of practitioners to access finished medicines from manufacturers and herbal suppliers for prescription to individual patients. This includes all finished products such as medicinal herbal pills, tablets, capsules, dried herb mixtures and medicinal herbal

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ointments made up for individual patients by third-party suppliers. Also under threat are third-party herbal prescription services that supply individualised herbal prescriptions (including those comprising tinctures and dried herbs) to named patients at the practitioner's request. Over the past 40 years this mode of supply has become an essential part of herbal practice in the UK and many practitioners are totally reliant on such services. All that will remain will be herbal medicines prepared by practitioners from their own premises.

Statutory regulation –assures range and quality of herbal supply

- To solve this problem, the UK medicines regulator, The Medicines and Healthcare products Regulatory Agency (MHRA) has proposed that third-party medicines supplied on request of statutorily regulated practitioners for individual patients can continue under MHRA licence via Section 5.1 of the main European Medicines Act 2001/83/EC¹. The key point here is that this facility is only available to statutory regulated health professionals.
- In short, if herbal practitioners were to secure 'authorized health care professional' status through statutory regulation, they could legally commission herbal medicines from manufacturers for supply to their patients. These would have to be made to assured medicinal quality. The statutorily registered herbal practitioner would ensure high standards in the supply of the many useful traditional medicines for the benefit of patients.

Failure to statutory regulate will disrupt herbal supply

- Because this ability to order medicinal products from suppliers for individual patients is only available to statutory regulated health professionals, if statutory regulation of herbal/traditional medicine and acupuncture does not take place many patients will be unable to obtain their medicines. Moreover, the loss of this facility will put many practitioners and several of their suppliers out of business. This will further damage the UK economy and swell unemployment during the current economic downturn.
- Particularly affected will be the Chinese medicine and Ayurvedic sectors that rely on traditional formulations made by third-party supply.
- The loss of planned arrangements to enable continuing supply, under the supervision of the MHRA, will undoubtedly mean an unacceptable increase in the purchase of unregulated medicines via the internet: these remedies often lack any reliable quality assurance and some have been found to be illegally mixed with conventional drugs.

Statutorily regulated practitioners - an outstanding resource

- The public will have a professional group able to deliver expert herbal treatment tailored to the individual. Herbalists will be a source of information and education about the use of herbal and traditional remedies.
- The public will have access to a wider range of high-quality herbal medicines from around the world that can be individually tailored to their needs.
- Doctors and other health professionals will gain important new partners in helping integrate the healthcare of the huge number of patients who use herbal remedies.²

¹ This proposal can be read in detail on the MHRA website at <http://www.mhra.gov.uk/home/groups/es-herbal/documents/websiteresources/con2024908.pdf>

² Herbal medicines dominate the UK natural health market accounting for almost 60 per cent of the sector value (Mintel, *Complementary Medicines*, 2003).

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Call to action

- The Government appears to be reluctant at the last minute to move ahead with regulation, in spite of the fact that a great deal of the groundwork has already been done and there will little cost to the public purse. The public consultation process has become overly bureaucratic and issues are presented in a complicated way that makes it difficult for members of the public to respond. Despite the fact that statutory regulation of this sector was recommended by the House of Lords' Select Committee on Science and Technology and three subsequent Department of Health Working Groups, there is a serious risk that now, at the eleventh hour, it will be aborted.
- Ministers must be called to account for this threatened U-turn and asked how they can justify the reduced public choice and increased public risk if statutory regulation does not go ahead. Respond to the Dept of Health Consultation by closing date Nov 2nd (see [Consultation Document](#)). Read our "**Herbal Supporters**" letter about how to do this at <http://www.ehpa.eu/>.
- **With ever increasing numbers seeking treatment from the herbal/traditional medicine and acupuncture sector, failure of Government to honour its long-term commitment to statutory regulation of these professionals is a betrayal of the public interest.**

For a fuller explanation of these issues, please read the EHTPA *Response to DOH Joint Consultation on the Report to Ministers from the DH Steering Group on the Statutory Regulation to EHTPA* available on the EHTPA website <http://www.ehpa.eu/>.

The European Herbal and Traditional Medicine Practitioners Association (EHTPA) was founded in 1993 when it became clear that, with the development of the European Union, the legislative framework under which herbal medicine was practised in the UK and Europe was likely to undergo radical change. It is an umbrella body which represents professional associations of herbal/traditional medicine practitioners offering variously western herbal medicine, Chinese herbal medicine, Ayurveda and traditional Tibetan medicine. The EHTPA is dedicated to the development of herbal/traditional medicine, preserving and enhancing the legal basis of practice across EU Members States and promoting best practice throughout the traditions.

For any further information please contact EHTPA at ehpa@globalnet.co.uk

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