

Dear Herbal Supporter,

Severe threat to patients' herbal choices: a call to action!

Summary of the situation

- The Department of Health is currently consulting on the proposed statutory regulation of herbal/traditional medicine, TCM and acupuncture practitioners – *closing date November 2nd* ! 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, now 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 will 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, lack of legal professional identity will undoubtedly undermine the herbalist's right to prescribe herbal medicines on a one-to-one basis. 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 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 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 a wide range of herbal medicines currently supplied by manufacturers and suppliers to practitioners. This includes all finished products such as medicinal herbal pills, tablets, capsules, dried herb mixtures and medicinal herbal 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 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.

Maintaining herbal supply via statutory regulation

- 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 practitioners for individual patients can continue under MHRA licence via Section 5.1 of the main European Medicines Act 2001/83/EC.¹
- In short, if herbal practitioners were to secure 'authorized health care professional' status, 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.
- The key point, however, is that this facility is only available to statutory regulated health professionals and so if statutory regulation of herbal/traditional medicine and acupuncture does not take place many patients will find that they cannot access the medicines on which they have come to rely. 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.
- 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. 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.
- **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**

How to respond

Please respond to the [Consultation Document](#) by **closing date Nov 2nd**. If you have time please read the *Response to DOH Joint Consultation on the Report to Ministers from the DH Steering Group on the Statutory Regulation of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK* written on behalf of the EHPTA to guide you. You can access this on the EHPTA website see <http://www.ehpa.eu/>. Alternatively, you can read the Briefing Paper on the same website.

The Consultation Document is presented in a complicated way that makes it difficult for members of the public to respond. Do not be daunted. An incomplete response will also send your message just as well – maybe even better! Below are some points you can make.

Key points

1. Statutory regulation is in the public interest as it means that the public wishing to consult herbalists can be assured that they are well trained and competent at their

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

job. Should any practitioner be found seriously wanting, he or she can be struck off the practitioners' register. Voluntary regulation cannot deliver this and any other licensing system will do nothing to ensure that high quality training and professional development is maintained across the UK.

2. If herbal/traditional medicine practitioners are not statutorily regulated, it will not be legal for doctors and other healthcare professional who are statutorily regulated to make referrals to them. This is certainly not in the interests of patients who wish that the health professionals they consult all work together in a complementary fashion on their behalf.
3. Only statutory regulation can allow herbal/traditional medicine practitioners to access finished herbal products supplied by a herb company. Because statutory regulation will enable practitioners to be recognised as 'authorised health professionals' under the main European Medicines Directive, this will enable practitioners to order up herbal remedies from herbal suppliers for individual patients. Since this is done under Government licence, the quality of these products will be assured.
4. Without statutory regulation, when legislation changes in 2011, the supply of medicinal herbal pills, tablets, capsules, dried herb mixtures and medicinal herbal ointments made up for individual patients by third-party suppliers will come to a halt. Also under threat are third-party herbal prescription services that supply individualised herbal prescriptions (including 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. 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.
5. To make matters worse many patients will be forced to turn to internet supply. Unfortunately, these remedies often lack any reliable quality assurance and some have been found to be illegally mixed with conventional drugs. For these reasons statutory regulation is the only sensible way forward.
6. 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.
7. In addition, please do write as soon as you can to your MP to ask him/her to take up your concern with the responsible Minister - Ann Keen MP, Parliamentary Under Secretary of State for Health.
You could ask your MP if he/she is aware that the Department of Health has issued a Consultation Document and ask him/her to write the Health Minister to seek reassurance that the statutory route is not being abandoned.

The Consultation Document (closing date Nov 2nd!) is available at:

http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_103567) You can respond via the 'automated response system' template provided by the DH at:

http://www.info.doh.gov.uk/questionnaire/ahmtcm_consultation.nsf/questionnaire?openform

but if you don't wish to use the template you can respond directly by email at

hrdlistening@dh.gsi.gov.uk or alternatively by post to the AHMTCM Consultation Team, Department of Health, Room 2N09, Quarry House, Quarry Hill, Leeds LS2 7UE. You should indicate whether you are replying as an individual or on behalf of a group of people. Your response may be made public but if you prefer it to remain private you can make this clear in your reply. If you have difficulty in understanding the questions in the consultation document, please let us know by emailing us at gail.breeze@ehpa.eu. We are reporting such difficulties!

Thank you so much for taking the time to do this! We are most grateful...