29/09/2009

To all herbal/traditional medicine practitioners from the European Herbal and Traditional Medicine Practitioners Association

Dear colleagues,

The next few weeks could make or break our future!

Public consultation proposals

- As you no doubt know, the Department of Health is currently consulting on the proposed statutory regulation of herbal/traditional medicine, TCM and acupuncture practitioners (closing date Nov 2nd!). After almost 10 years of commitment to this step in the public interest there is now a 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 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 herbalists' 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 practitioners to prescribe herbal medicines for their patients. *It is clear that access to a full range of herbal medicines can only be preserved if herbal 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. 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 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. Although we would still be able to use simple tinctures, extracts and dried herbs as 'starting materials' for our individualized prescriptions, over the past 40 years this third-party 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 the herbal medicines we make up and dispense from our own premises.

Maintenance of 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] The key point, however, 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 does not take place many patients will find that they will not be able to obtain their medicines.
- If you use Chinese or Indian herbal medicines as finished products these will also disappear.
- The loss of this facility will unfortunately 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.

Three things you can do before November 2nd (when the consultation closes)

1. Please respond to the Consultation Document yourself. Our critics are doing this against us – we must make sure we counterbalance their efforts. 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 EHTPA website see http://www.ehpa.eu/. Also available at the same site is an EHTPA briefing paper, *Severe Threat to Herbal Choices,* which summarises the main points of the EHTPA Consultation Response. The Consultation Document is very complex but do

[1] [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

not be daunted. An incomplete response will also send your message just as well – maybe even better!

Points to make

- The Consultation Document asks you to choose between several regulatory options. Please make the point that **only statutory regulation will allow the herbal practitioner to commission herbal medicines under the terms of Section 5.1 of Directive 2001/83/EC**. Only this 'authorized health care professional' status that comes with statutory regulation will give the practitioner the legal right to do so.
- Statutory Regulation gives herbal/traditional medicine practitioners a legal position that will enable them to defend threatened herbal medicines which is difficult to do if we are legally indistinguishable from ordinary members of the public.
- It also will prevent failing practitioners from practising and enable high standards of training and CPD to be rolled out across the whole of our sector.
- It will also enable other statutorily regulated healthcare professionals to refer patients to us.

The fight for legal recognition

- Although some are philosophically opposed to any form of regulation, it is unrealistic to imagine that we can continue to have rights to prescribe herbal medicines without satisfactory legal status. Throughout the latter part of the nineteenth century and the twentieth century, UK herbalists fought an ongoing battle to gain a secure legal basis for their right to practise and access their medicines. We must not lose the opportunity to achieve this now!

2. Write 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.

- Emphasise the risk of loss of consumer choice, increased risk to the public of poor quality products and the negative regulatory impact on your business and any threat to jobs you can see in your constituency.
- 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.

3. Most importantly ask your patients to respond to the Consultation Document (http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_103567) **by closing date Nov 2nd** and to write to their MPs. We must flood the system!

- Please give your patients a copy of the ***Briefing Paper*** from the EHTPA (see http://www.ehpa.eu/) together with the accompanying sheet ***"Dear Herbal Supporter"*** that outlines a number of points your patients can make.
- Please explain that many questions in the Consultation Document are difficult to answer but it is more than sufficient that they make the main points in their response. This can be done via the DH 'automated response system' at: http://www.info.doh.gov.uk/questionnaire/ahmtcm_consultion.nsf/questionnaire?openform . They may also 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. Their response may be made public but if they prefer it to remain private they can make this clear in their reply.

Please get to work on this without delay. We can achieve our goal by working together!