

Dear

The statutory regulation of practitioners of herbal medicine and acupuncture

I am a user of herbal medicine and am writing to you to urge the Government to move to statutory regulation of herbal practitioners without delay.

As you may be aware, The Department of Health (DH) recently consulted on the proposed statutory regulation (closing date 16/11/09) of herbal/traditional medicine, TCM and acupuncture practitioners.

Statutory regulation of herbal practitioners is a matter of considerable public interest. Recent research by Ipsos MORI for the Medicines and Healthcare products Regulatory Agency (MHRA) has found that millions of people in the UK use herbal medicines. In particular:

- more than a quarter of the population had bought herbal medicines over-the-counter in the previous two years;
- one in twenty had consulted a practitioner of traditional Chinese Medicine;
- around one in twelve had consulted a practitioner of Western herbal medicine.
- 77% of adults agree it is important that herbal medicines are regulated, with this figure rising to 87% among regular users of herbal medicines (defined as those who have used a herbal medicine within the last 2 years).

Statutory regulation has been under consideration for a decade since the call in 2000 from the House of Lords' Select Committee on Science and Technology for the statutory regulation of practitioners of herbal medicine and acupuncture. The Government itself backed statutory regulation of this sector in 2001 and more recently key regulatory bodies, the Health Professions Council (HPC) and the Medicines and Healthcare products Regulatory Agency (MHRA) have both concluded that, like the osteopaths and chiropractors, acupuncture and herbal medicine practitioners should be subject to statutory regulation. As recently as 2006 the DH website recorded that "*The Government is committed to the statutory regulation of herbal medicine, acupuncture and traditional Chinese medicine practitioners.*"

Over the past eight years the Department of Health (DH) has initiated three working groups to look at implementing this policy. All three working parties strongly supported the aim of statutory regulation of this sector. In 2005, the DH ran a public consultation on the statutory regulation of herbal medicine and acupuncture. This registered a 98% response in favour of statutory regulation. As a consequence the DH published a timetable for the statutory regulation of this sector with a section 60 order (the legal process to bring this about) to be published later that year. This timetable has not been adhered to. The Government says it will make a decision on this matter but continues to dilly-dally. As explained below, if statutory regulation does not go ahead with immediate effect, there will be a significant loss of consumer choice and huge damage to many small and medium sized businesses across the herbal supply and manufacturing sector as well as to many herbal practices throughout the UK. **It is clear that in not making a decision to go ahead with statutory regulation, the Government is effectively undermining herbal medicine practice in this country.**

Why is statutory regulation vital?

Firstly it is important to ensure that those practising herbal medicine are properly qualified. Today, most practitioners are educated to degree level with a curriculum which includes a significant amount of orthodox training such as pharmacology and differential diagnosis. However, there is currently no regulation whatsoever: anyone, whether trained or not, can

call themselves a herbalist or traditional practitioner and gain access to powerful herbal medicines. This is clearly not in the public interest.

A second important reason for statutory regulation is that if it fails to go ahead there will be a loss of a wide range of herbal medicines currently supplied by practitioners to their patients. Full implementation of the new European Traditional Herbal Medicine Directive in April 2011 will see the end 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 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. Thus without statutory regulation, from **April 2011**, many patients will be unable to obtain their usual medicines. 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.

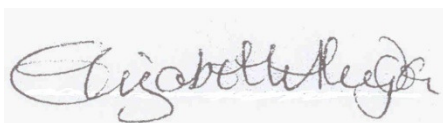
The loss of planned arrangements to enable continuing supply, under the supervision of the MHRA, will undoubtedly mean an unacceptable increase in the purchase of unregulated medicines via the internet and from bogus back-street traders: these remedies lack any reliable quality assurance and some have been found to be illegally mixed with conventional medicines. *Lack of statutory regulation puts the public at significant risk!*

How will statutory regulation assure the range and quality of herbal supply?

The 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. 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.

I hope you will agree that these are all compelling reasons why the Government should, honour its previous commitment and adopt statutory regulation for herbal medicine and acupuncture without further delay. I would be most grateful if you were to press this case home with the Minister of Health. Yours sincerely,



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>