



Regulation of Practitioners of Herbal Medicine, Traditional Chinese Medicine and Acupuncture

Position statement

Introduction.....	1
Consensus	2
Impact of European law on herbal medicine.....	4
Risks to patients and the public.....	5
Benefits of statutory regulation	7
Conclusions	8

Introduction

The Prince's Foundation for Integrated Health believes that public and patient safety is best protected by statutory regulation of complementary therapies that provide diagnosis to individual patients and/or prescribe medicines or undertake invasive procedures. It has vigorously campaigned to bring that about over many years and was a member of both the Department of Health Acupuncture Working Group and the DH Herbal Medicine Regulatory Working Group.

The Department of Health is currently carrying out its second public consultation on whether practitioners of acupuncture and herbal medicine (including Traditional Chinese Medicine and other traditional medicine systems) should be statutorily registered. The consultation questions are unnecessarily complex but essentially offer three options:

- full statutory regulation of practitioners
- no regulation, with the possible option of repeal of Section 12(1) of the Medicines Act 1968 which permits herbalists to practise;
- a range of alternatives including voluntary regulation, local authority licensing or a statutory or voluntary licensing system based on the model employed by the Security Industry Authority, set up to control the activities of wheel clampers, bouncers and security guards.



Consensus

This follows almost ten years of work by the Government and stakeholders which has seen virtually universal agreement that statutory regulation of this sector is the best way forward to protect the interests of both patients and practitioners.

- The House of Lords Select Committee for Science & Technology Report on Complementary and Alternative Medicine (2000) found there was an evidence base to herbal medicine and acupuncture, and strongly recommended that the safety of the public would be best protected by statutory regulation of these modalities. It said:

"Our main criterion for determining the need for statutory regulation is whether the therapy poses significant risk to the public from its practice. We believe that both acupuncture and herbal medicine do carry inherent risk, beyond the extrinsic risk that all CAMs pose, which is the risk of omission of conventional medical treatment." (par 5.54)

- Three separate Department of Health Steering Groups have come to the same conclusion, most recently the *Report to Ministers from The Department of Health Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK* (2008), chaired by Professor Michael Pittilo, Vice-Chancellor of Robert Gordon University. It concluded that:

". . . there is an urgent need to proceed without delay to statutory regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems." (Page 20, Section 26)

- There was overwhelming agreement to statutory regulation in response to the first Department of Health public consultation on this issue (2004/05). The Government announced its support and published a timetable for implementation. This proposed the publication in Autumn/Winter 2005 of a Draft Order under Section 60 of the Health Act 1999. In the event, this did not take place.
- However in 2006, the Department again announced its commitment to regulation:

"The Government is committed to the statutory regulation of herbal medicine, acupuncture and traditional Chinese medicine practitioners. We are in the process of setting up a Joint Working Group. We hope to have the Working Group set up and the first meeting arranged around June 2006 and to move gradually towards statutory regulation, probably in 2008/9."

- Following the publication of the Pittilo Report (2008) the Health Professions Council made a recommendation to the Secretary of State for Health advocating the regulation of acupuncturists, medical herbalists and Traditional Chinese Medicine practitioners. The HPC stated it would welcome the opportunity to regulate these practitioners. In a position statement published August 2009, it said:

"As a multi-professional regulator, the HPC is confident that it is well placed to regulate these professions and has the necessary experience of successfully taking on new professions and integrating them into the Register. The HPC was set up in order to protect the public and we strongly believe that statutory regulation can more effectively assure that practitioners are meeting standards and are fit to practise."

- In addition, the World Health Organisation (WHO) published a statement on Traditional Medicine December 2008. This said:

WHO and its Member States cooperate to promote the use of traditional medicine for health care. The collaboration aims to:

- *support and integrate traditional medicine into national health systems in combination with national policy and regulation for products, practices and providers to ensure safety and quality;*
- *ensure the use of safe, effective and quality products and practices, based on available evidence;*
- *acknowledge traditional medicine as part of primary health care, to increase access to care and preserve knowledge and resources; and*
- *ensure patient safety by upgrading the skills and knowledge of traditional medicine providers.*

Impact of European law on herbal medicine

The EU Traditional Herbal Medicinal Products Directive (THMPD) will be fully implemented from 1st April 2011, when it will replace Section 12(2) of the Medicines Act 1968. From this date, the sale or supply of "industrially produced" herbal products for prescription to individual patients will be restricted to "authorised healthcare professionals", that is, practitioners who are statutorily registered.

This will have a considerable impact in two respects on both Western and traditional herbal medicine in the UK. It will limit over-the-counter sales of herbal products to those with a "traditional herbal registration", available only for medicines intended to treat "mild and self-limiting illness". Many remedies currently available direct to the public will be withdrawn. At the same time, only statutorily regulated practitioners will be able to order finished medicinal products for their individual patients. They will be permitted to do so under Article 5.1 of the main EU medicines Directive (2001/83/EC).

Because of this, if herbal medicine practitioners are *not* statutorily regulated, they will lose access to medicines from all third-party manufacturers 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. 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.

Over-the-counter herbal remedies registered under the THMPD will not be suitable for the needs of most patients consulting herbal/traditional medicine practitioners. All that will remain is the right of herbal practitioners, via Section 12(1) of the Medicines Act of 1968, to compound and supply herbal medicines for their patients from their own premises. It is unclear that this will be sustainable in the long term.

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 Article 5.1 of the European Medicines Directive 2001/83/EC. The key point is that this facility would be available only to statutorily regulated health professionals, but *not* to those who are statutorily licensed or voluntarily regulated.

If statutory regulation is not approved, there will be a particularly devastating effect on Ayurveda and Traditional Chinese Medicine, used by many in the South Asian and Chinese communities respectively, as well as by the wider population. Both these systems rely to a considerable extent on third party provision of herbal medicinal products and supplies.

The numbers affected if statutory regulation is not approved should not be under-estimated. Research by Ipsos Mori for the MHRA, published January 2009, found that some 12.5 million adults in Great Britain had used herbal medicines 2006 – 2008, and more than 6 million had used herbal products obtained from a practitioner.

Risks to patients and the public

There is a significant risk to the public from treatment by unregulated herbalists and acupuncturists:

- Anyone, including those without knowledge or training, can describe themselves as a herbalist or acupuncturist and then offer diagnosis and treatment to the public. Whilst there is some control over acupuncture through current local authority licensing, this is primarily concerned with premises and the safe storage and disposal of needles. It takes no account of the practitioner's qualifications or expertise.
- Many members of the public are unaware that no regulatory system protects them from incompetent and dishonest practitioners; they take it for granted that those offering acupuncture or herbal medicine must necessarily be trained and qualified, and their practice regulated in the same way as conventional practitioners such as physiotherapists or art therapists. The public is understandably vulnerable to exaggerated or false claims of the expertise of the individual practitioner and of the efficacy of specific treatments.
- Reputable, trained and qualified practitioners have no effective means of differentiating themselves from the poorly trained or the disreputable.
- Untrained or inadequately trained practitioners may be unaware of the limitations of their competence, leading to patients delaying necessary – sometimes urgent – medical treatment.
- There is evidence that many patients who use CAM therapies such as herbal medicine and acupuncture alongside conventional treatment do not tell their doctors they are doing so because they anticipate a negative reaction. There is a significant risk of interactions with adverse consequences.

- The MHRA has logged a significant number of instances of Chinese or Ayurvedic herbal products on the UK market of poor quality, containing substituted ingredients or contaminated with heavy metals or conventional medicines.

Because of the restrictions in access to herbal medicines that will come about with the implementation of the Traditional and Herbal Medicinal Products Directive, there is an additional danger of increasing public use of unregulated internet sites that sell poor quality or contaminated herbal products. Many patients who use herbal medicines have long term conditions and are convinced of the benefits of the remedies they use in relieving symptoms. If these are no longer available, it would not be surprising if these patients risk purchasing from unreliable suppliers. There have already been reported instances of inferior or adulterated products sold from internet sites, some presenting a considerable health risk to users. Without statutory regulation, this risk to public safety can only increase.

While it is imperative that these risks are addressed, there are also benefits to patients and to the NHS from improving public access to herbal medicine and acupuncture. There is evidence of their effectiveness for certain conditions, while patient satisfaction levels are reported to be high. The Foundation suggests that they may be particularly useful in treating long term conditions – and may contribute to a reduction in costs to the public purse. Several observational trials provide evidence of reduced prescriptions, reduced number of GP consultations and earlier return to work. These results need to be confirmed by further controlled trials on the model proposed by the recent King's Fund report: *Assessing Complementary Practice*. Long term conditions now account for some 78% of NHS spend on patient treatment. In the present economic climate, increased NHS use of herbal medicine and acupuncture may offer real financial benefits.

Benefits of statutory regulation

The alternatives to statutory regulation put forward by the Department of Health consultation report are not capable of providing the same benefits to the public and patients as statutory regulation of practitioners of acupuncture, herbal medicine and Traditional Chinese Medicine. In particular, statutory regulation is the only system that can:

- Provide and enforce UK wide standards of practice.
- Provide the public with full reassurance that any practitioner who is described as a herbalist, traditional medicine practitioner or acupuncturist is properly trained, accredited and regulated, and can be relied on to provide acceptable standards of diagnosis and treatment.
- Ensure the quality of professional training and education, including continuous professional development.
- Assess and, if necessary, remove unfit or failing practitioners from a national register.
- Maintain consumer choice in the range of herbal treatments available.
- Permit practitioners of herbal medicine to access manufactured herbal supplies from a competent, approved third party and to have individual prescriptions made up by specialist suppliers.
- Ensure herbal practitioners use quality-assured materials.
- Address the problem of poor quality herbal products, including those marketed as Ayurvedic or traditional Chinese remedies, by limiting the use of Section 12(1) of the Medicines Act to statutorily registered herbal practitioners *and* requiring such practitioners to obtain their herbal supplies from manufacturers and suppliers operating under Good Manufacturing Practice (GMP).
- Allow referrals from GPs and other medical practitioners to support conventional NHS treatment, for example, as envisaged by the recently published NICE guidelines on the treatment of low back pain which recommend that patients be offered acupuncture as well as orthodox care.
- Give patients the confidence to discuss their decision to use acupuncture or herbal medicine with their medical advisers.

Neither voluntary regulation nor a licensing system is able to provide these benefits to public safety. If one of these alternative proposals is adopted, then public access to herbal medicine, Ayurveda, Traditional Chinese Medicine and acupuncture will be significantly curtailed.



Conclusions

For these reasons, the Foundation remains of the view that, in the interests of public safety, patient choice and ethnic diversity, there is an urgent need for practitioners of acupuncture, herbal medicine and Traditional Chinese Medicine to be brought into statutory regulation.

The Foundation endorses the recommendations of the House of Lords Select Committee for Science and Technology and the several Department of Health Steering Groups that all allied health professionals, including practitioners of acupuncture, herbal medicine and Traditional Chinese Medicine, should be regulated by a single regulator: the Health Professions Council.

More information

For more information and for the Foundation's full response to the *Joint Consultation on the Report to Ministers from the Department of Health Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems* from the Prince's Foundation for Integrated Health, please contact:

The Prince's Foundation for Integrated Health
18 Charlotte Road
London
EC2A 3PB

telephone: 020 7033 4955

email: contactus@fih.org.uk

website: www.fih.org.uk