

## **Statutory Regulation of Practitioners of Herbal and Traditional Medicine, Traditional Chinese Medicine and Acupuncture: Frequently Asked Questions and Answers:**

### **Q. Is statutory regulation (SR) of this sector going ahead?**

**A.** Following publication of the Steering Group Report in May 2008, on 12<sup>th</sup> June a meeting took place between Minister Ben Bradshaw, his advisors and Chair of the Steering Group Professor Mike Pittilo and Michael McIntyre, Chair EHTPA. Ben Bradshaw said that the SG Report should now go out for public consultation to determine public and professional support for statutory regulation. The Department of Health (DH) is currently preparing a consultation document and now estimates that this will go out for consultation in December. The consultation period is likely to be three months followed by time for the DH to assess the responses – probably another three months. After this the Minister will make a decision about whether statutory regulation will go ahead.

### **Q. Does SR have support from outside the herbal/traditional medicine sector?**

**A.** Yes. So far both the Royal College of Physicians and Royal College of General Practitioners have written in support of SR of the herbal/traditional medicine sector. In addition SR has strong support from the designated statutory regulator, the Health Professions Council and the Medicines and Healthcare products Regulatory Agency (MHRA).

In February 2005, the Department of Health reported on a previous consultation in a document

entitled “The Statutory Regulation of Herbal Medicine and Acupuncture”. The DH website records that over 1000 copies of the consultation were distributed to interested individuals and organisations and a total 698 responses were received to the consultation, the majority of the responses indicating strong support for the introduction of statutory regulation in order to ensure patient and public safety. The Report noted that 98.5% of respondents expressed support for a UK-wide system of regulation of this sector.

We expect that the result of this present consultation will be very much the same as the previous one and that SR will thus get the green light from Government.

### **Q. Statutory regulation – why the urgency?**

**A.** The move towards SR has been going on for over 10 years. The current proposals, set out in the Steering Group Report, are the result of almost two years of detailed examination of a way forward. The findings have been carefully considered by a wide spectrum of practitioners across the sector as well as by independent lay representatives appointed by the Department of Health. The fundamental drive towards SR is for the protection of the public. There are other legislative reasons too as explained below.

In 2011 the Traditional Herbal Medicinal Products Directive (THMPD) becomes law. One effect of this is that third parties would not be able to provide prescriptions for patients on behalf of herbal practitioners working under s12(1) unless these practitioners were statutorily regulated and thus able to be recognised as “authorised health professionals” under Directive 2001/83/EC (the main EU Medicines Directive). Authorised health professionals are able to have medicines made up by a third party. This facility could be important for practitioners who have not got the room for a herbal dispensary in their practice as they could

have prescriptions made up for their patients by such a third party. In addition, any tradition using finished herbal products (e.g. Chinese, Ayurvedic and Tibetan pre-prepared medicines) will be unable to access these unless the products have a market authorisation (i.e. medicines licence) or the person ordering their manufacture has authorised health professional status by virtue of being statutorily regulated. For this reason there is some urgency in getting statutory regulation before 2011.

**Q. Is Statutory Regulation our best option?**

**A.** It should be stressed that under current law, there is no legal definition of herbalist and so anyone may practise as a herbalist as long as they see a patient in person. This might have been considered viable in 1968 but today it is seen as unsustainable in the long term for public health reasons. In the present circumstances, it is unlikely for example that the potent herbs available to us through SI 2130 will continue to be so in the long term given the fact that, in reality, any unqualified member of the public may prescribe them having once seen a “patient” in person. Given an increasing amount of legislation at European level that affects both medicines law and the right to practise medicine, it seems essential to get a legal basis for herbal practice in the UK. UK herbalists have sought statutory recognition of herbalists several times in the last century because in the final analysis it was recognised that this was the only way to ensure security of herbal practice.

**Q. If and when SR takes place, what will be the status and role of the statutory register?**

**A.** The purpose of the statutory register is to maintain a list of properly qualified, insured herbal and traditional medicine practitioners and acupuncturists. This register will be maintained by the regulator which is likely to be the Health Professions Council. In order to be on the register, practitioners have to demonstrate their fitness to practise and to fulfil the requirements of their continuous professional development schemes. There will also be a relatively small fee charged for regulation (as yet undetermined). The register will enable the public and other health professionals to identify properly trained and insured practitioners. Practitioners’ rights to remain on the register are dependent on adherence

to codes of ethics and practice and professional conduct and fitness to practice, etc.

Practitioners who are already in practice can qualify to join the statutory register by demonstrating that they have practised safely and professionally for a designated period of time (yet to be decided). Whenever HPC regulate a new profession, and protect a title, there will be a ‘grandparenting’ period. The length of the grandparenting period is defined by law, and has previously been two years. This two year ‘Grandparenting window’ allows people who have previously been practising to apply for registration, provided that they can demonstrate either three out of the last five years lawful, safe and effective practice, or that they meet the Standards of Proficiency for the profession. ( see the HPC website [www.hpc-uk.org](http://www.hpc-uk.org) When a profession becomes regulated)

This is a 'one-off' window of time during which individuals can apply to be registered. After this period of time has elapsed, the only way for a UK-trained individual to become registered is to complete a UK regulator-approved course. With regard to grandparenting, there are several aspects to be considered. In addition to individuals making their applications for registration, and being assessed individually, there is also the possibility for *bona-fide* members of voluntary registers to be transferred directly onto the HPC Register without having to go through such individual registration. There is therefore an option for the grandparenting of complete memberships of voluntary registers as well as of individuals.

**Q. Will we be able to ensure an effective voice for herbal/traditional medicine practitioners and herbal medicine within the HPC?**

**A.** Certain core competences are generic across the healthcare professions, but in matters specifically pertaining to herbal/traditional medicine practitioners, professional bodies would be consulted. For example if a herbal practitioner were involved in a fitness to practise procedure there would be representation of the profession at those proceedings in order to provide profession-specific information and expertise and to support the practitioner concerned.

**Q. There is some suggestion that the HPC restricts practice to “evidence based” practice. Will we be forced to accept the rather narrow remit of evidence-based practice by becoming part of the HPC?**

**A.** This has been discussed informally with the HPC. The HPC recognises that the evidence base for our sector is not yet complete and has accepted this as a basis to go ahead with SR. The SG Report specifically refers to this when it says, *“It is important to recognise that the fundamental approach and philosophy of complementary and alternative medicine, including acupuncture, herbal medicine, traditional Chinese medicine and other traditional-medicine systems (such as Ayurveda and Tibetan medicine) differ in many ways from the stance taken by orthodox healthcare professions. This has implications for developing a robust research base, underpinning evidence-based practice, and interfacing with other healthcare professionals. The HPC will need to take account of these differences, although they do not impact on its key role of effective protection of the public. The HPC will also need to devise suitable structures and processes to take account of the different and many traditional-medicine systems that use acupuncture and herbal medicine. There are clearly too many of these to enable representation at all levels within the Council. However, the Steering Group is of the view that the HPC will be able to accommodate the diversity of traditions that exist and ensure that decisions relating to, for example traditional acupuncture, Ayurveda, Western herbal medicine, Tibetan medicine or traditional Chinese medicine are informed by practitioners and experts in the relevant tradition.”* SG Report Section 12.

**Q. What about those not choosing to be on Register?**

**A.** Once the profession is statutorily regulated, the title of herbalist, acupuncturist or TCM practitioner (or whatever titles will be protected by law) will only be open to use by those on the statutory register. Anyone not on the statutory register making use of the restricted titles would be breaking the law. In addition, the Steering Group Report recommends that one-to-one prescription under section 12(1) should be limited to those on the statutory register so that anyone not on the register prescribing herbal medicines professionally to patients on a one-to-one basis

would also break the law. This restriction would not of course include the supply of herbal teas or herbs used as foods or herbal products licensed for over the counter sale under the Traditional Herbal Medicinal Products Directive (THMPD).

**Q. Will there be any allowance made for additional traditions e.g. traditional African medicine and others which may arise in future to be included/or be incorporated into the herbal/traditional medicine materia medica?**

**A.** The MHRA suggests that once statutory regulation takes place, a committee within the regulator, working with the already established Herbal Medicines Advisory Committee, reviews the introduction of herbs that have not been traditionally used in the UK. To facilitate this process, the MHRA also suggests the publication, overseen by herbalists, of a herbal formulary which would list all the herbs in common practice.

**Q. What is the scope and nature of the THMPD and its relationship to statutory regulation of practitioners?**

**A.** The THMPD has been agreed by the European Commission and Parliament after several years of discussion. Essentially it provides a legislative home for traditionally used herbal medicines throughout the EU that otherwise would require a full marketing authorisation under the main EU medicines Directive 2001/83/EC. It would cost millions of pounds to obtain full marketing authorisation for each herbal medicine placed on the market. The THMPD grants a much cheaper traditional medicines licence based on a history of safe traditional use.

The THMPD was passed into law throughout the EU in April 2004 and all Member States are legally obliged to implement it by April 2011. In the UK, the THMPD will replace section 12(2) of the Medicines Act of 1968 which currently allows over the counter (OTC) herbal medicines to be sold without a licence as long as they make no medicinal claims. From April 2011 all OTC herbal medicines will have to have traditional medicines licence which can be granted once they have proved their safety and traditional use for at least 30 years, 15 of which must have occurred within the EU. Any member of the public can purchase and use products with a traditional medicines licence. These remedies are only

available for mild and self limiting disorders. It should be stressed that the THMPD does not affect the legal position of section 12(1) and our right to prescribe on this basis. As we understand it, there would be no effect on the provision of tinctures in that we can combine and/or compound these for our patients because these are deemed to be start up materials and not finished products. At present under section 12(1) of the 1968 Medicines Act, herbal/traditional medicine practitioners are allowed to prescribe and compound herbal ingredients for their patients on their own premises. Statutory regulation will continue to enable this facility to be available to herbal/traditional medicine practitioners seeing patients in person as laid down in Section 12(1)..

**Q. What is the role of the professional associations (PAs) post statutory regulation?**

**A.** Professional bodies will play a vital role post SR. They will continue to be the centres of excellence through and in which best practice is developed. For example, continuing professional development is likely to be run by PAs. In addition, the PAs will act as trade unions to represent the rights and needs of individual practitioners.

The HPC depends upon the professional knowledge and expertise from the professions it regulates to provide detailed input, particularly into its standard-setting process. This would normally be done by a Professional Liaison Group which is a working group formed from HPC Council members plus external stakeholders with particular knowledge and expertise to consider a defined project in detail. This provides a way for the HPC to draw on expertise from outside its Council, including membership from professional bodies, and it is anticipated that this mechanism would be used for establishing standards for practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems.

**Q. Are the standards of training, conduct and ethics currently subscribed to by the HPC acceptable to practitioners within our sector?**

**A.** Yes. Throughout the two-year process of the SG, subcommittees from the herbal/traditional medicine sector reviewed in detail the standards of training, conduct and ethics currently subscribed to by the HPC and deemed them all

acceptable. In addition the SG agreed that the threshold entry route to the Register for new practitioners would normally be through a Batchelor degree with Honours which is comparable to the majority of other professions regulated by the HPC (Section 17 SG Report).

**Public Response to the Steering Group Report**

As many of you will know, public response to the publication in May of 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* has been mixed. Whilst the Report has engendered positive letters of support from the Royal College of Physicians and the Royal College of General Practitioners as well as a declaration of support from the Health Professions Council (see detail below), political commentators like Dominic Lawson (brother in law of the late and well-known CAM critic, John Diamond) and Alice Miles have rubbished the notion of regulation of this sector in the *Independent* and *Times* newspapers respectively. Another prominent opponent of CAM is David Colquhoun, Emeritus Professor of Pharmacology at University College London. Colquhoun argues that CAM lacks evidence base and that thus CAM disciplines should not be taught at British Universities because they are not proper academic subjects. He further argues that CAM professions should not be regulated because they lack a credible scientific basis.

Colquhoun wrote an opinion column in the *Times* (August 29, 2008), entitled '**Regulating quack medicine makes me feel sick**'. In this article Colquhoun declared: '*It is fashionable to think things are true for no better reason than you wish it were so. Anything goes, from fairies, crystals and Ayurvedic medicine (as advocated by Cherie Blair) to fooling yourself about WMD (as advocated by her husband).*

*The latest sign of this trend is a report to the Department of Health from Professor Michael Pittilo, Vice-Chancellor of the Robert Gordon University, Aberdeen. His May report - on acupuncture, herbal medicine, traditional Chinese medicine and the like - recommends that these therapies should have statutory regulation run by the Health Professions*

*Council, and that entry for practitioners should “normally be through a bachelor degree with honours”. Consultation is supposed to begin around now.*

*Both of the ideas in the report are disastrous. The first thing you want to know about any sort of medical treatment is: ‘Does it work?’ [The evidence] does not exist for herbal and Chinese medicine, which remain largely untested. For acupuncture the evidence does exist and it shows very clearly that acupuncture is no more than a theatrical placebo. ...*

*The problems that Professor Pittilo's recommendations pose for universities are even worse. You cannot have universities teaching, as science, early 19th-century vitalism, and how sticking needles into (imaginary) meridians rebalances the Qi so the body systems work harmoniously. To advocate that degrades the whole of science.’*

To this Professor Michael Pittilo (Chair of the Working Group) and Michael McIntyre responded in the letter pages of the *Times* September 2, 2008 as follows:

*The Times*

*Public health needs protection*

### **Regulation of acupuncture and herbal medicine has been subject to much scrutiny**

Sir, Professor Colquhoun's campaign to discredit our report (“[Regulate quack medicine? I feel sick](#),” Aug 29) is in danger of placing public health at risk. He is entitled to challenge existing evidence for the effectiveness of complementary and alternative medicine (CAM) but fails to acknowledge the key recommendation from the steering group on the essential need to demonstrate efficacy, safety and quality assurance as a prerequisite for NHS funding.

Professor Colquhoun dismisses CAM because of the absence of a rigorous scientific foundation and he asserts that to teach and practise it is unethical. Survey data consistently demonstrates very high demand for CAM with one report estimating that 22 million visits involving 10.6 per cent of the population in England alone occurred in 2008. This demand is one reason why his alternative model of trade law enforcement will not work. He may argue that these people are uncritical

recipients of nonsense, but data from the Medicines and Healthcare products Regulatory Agency confirm that they are at significant risk from poor practice. It is essential that we protect the public by implementing statutory regulation alongside demanding evidence of efficacy. Professor Colquhoun's resistance to the teaching of science to CAM practitioners will do little to help them to critically evaluate effectiveness.

**Professor Michael Pittilo**  
**Chair of the Department of Health Steering Group**

Sir, David Colquhoun is mistaken that the matter of regulation of acupuncture and herbal medicine has not been subject to scrutiny. The House of Lords' Select Committee on Science and Technology called for the statutory regulation of practitioners of these therapies in a report published in 2000. The Government accepted the need for this and the recent working group was set up to advise how best to implement this process. As to proof of efficacy, those who live in glass houses should not throw stones. The current editorial of the online journal *BMJ Clinical Evidence* records “there are conspicuous double standards in attitudes to older treatments. For example, about half of all so-called conventional healthcare interventions continue to be used even though research on their efficacy is non-existent or equivocal. By contrast, traditional complementary and alternative therapies that have been widely used for many years and continue to be popular with patients are regularly dismissed out of hand on the grounds that there is little ‘scientific’ evidence to confirm whether they work.”

As many people currently seek acupuncture and herbal treatment, it is in the public interest to regulate this sector. Regulation is not a badge of efficacy but it will provide a responsible cohort of practitioners who in time can develop sound clinical evidence for what they do.

**Michael McIntyre**  
**Chair, European Herbal and Traditional Medicine Practitioners Association**

### **Statement in support of statutory regulation from the Health Professions Council**

(see <http://www.hpc-uk.org/mediaandevents/pressreleases/index.asp?id>)

## **HPC welcomes DH Steering Group report that proposes regulation of complementary and alternative medicine by the HPC**

16/06/2008 - 15:00

HPC welcomes the opportunity to regulate practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK

The Health Professions Council (HPC) welcomes today's publication of the '*Report to Ministers from the Department of Health (DH) Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and other Traditional Medicine Systems Practised in the UK*'

The report proposes that the HPC regulate acupuncturists, medical herbalists and traditional Chinese medicine practitioners and highlights that the HPC continues to demonstrate effective, safe and cost effective statutory regulation.

The HPC currently regulates 13 professions varying from dietitians to biomedical scientists and as a multi-professional regulator the HPC has the required experience of successfully taking on new professions.

### **HPC's president, Anna van der Gaag, said:**

"These practitioners provide an important service to the public and we welcome the proposals for statutory regulation

"The HPC depends upon the professional knowledge and expertise from the professions it regulates to provide detailed input, particularly into its standard-setting process. We look forward to working with these professions in the coming months and years as we move towards statutory regulation.

### **HPC's Chief Executive, Marc Seale, said:**

"The HPC welcome the opportunity to regulate acupuncturists, medical herbalists and traditional Chinese medicine practitioners. As a multi-professional regulator we are aware that without robust regulation the public is not protected from incompetent or unethical practitioners.

"Public protection is paramount and it's important that the public feel protected by knowing that practitioners will have to meet our high standards. The HPC firmly believe that statutory regulation can more effectively assure that practitioners of

complementary and alternative medicine are meeting appropriate standards and are fit to practise."

## **Excerpt taken from Health Professions Council meeting summary of minutes Thursday 11 September 2008**

See

[http://www.hpc-uk.org/assets/documents/1000243Ecouncil\\_decisions\\_September\\_2008.pdf](http://www.hpc-uk.org/assets/documents/1000243Ecouncil_decisions_September_2008.pdf)

### **Regulation of medical herbalists, acupuncturists and traditional Chinese medicine practitioners**

A steering group set up by the Department of Health has recommended that these professions should be regulated by the HPC. The Council discussed the steering group's report and recommended statutory regulation to the Secretary of State for Health.

## **Education Update**

The work of the Education Committee

**It has been a busy year for the Education committee. At the start of the year we were supporting the completion of the Department of Health Working Group report. As the year went on we have completed some major activities, the highlights of which include:**

- Updating of the Core Curriculum – we have reviewed all sections as well as slightly increasing the overall hours and in particular we have raised the requirement for Clinical Practice hours from 450 to 500 (to be phased in);
- Developing detailed guidelines for Clinical Practice placement;
- An agreement on the credit to be given to BAAB accredited Acupuncturists who wish to train in Chinese Herbal Medicine.

If you wish to find out more about our work please visit the EHTPA website:

<http://www.ehpa.eu/index.html> )

The Education Committee's agenda for the forthcoming year will include the following:

- A need to keep a watching brief on the Department of Health consultation on the Working Group Report.
- We will keep under review the need for additional 8<sup>th</sup> modules for other traditions.
- We will commence planning for transfer of our accreditation procedures to the new regulatory body.

As Chair of the Education Committee it has been my great pleasure to work with a very wide range of colleagues to ensure that we move forward with our activities. I would like to thank all that have contributed and I look forward to what will be another challenging and interesting year.

Philip Lockett  
Independent Chair of the Education Committee  
October 2008

## **Accreditation Update**

The EHTPA receives a steady stream of enquiries about accreditation and educational matters: Typically asked questions and answers are provided here to illustrate the variety of queries dealt with.

### **Q. How long does it take to achieve course accreditation?**

A. How long is a piece of string?! The answer depends very much on the time it will take the college/university to plan the course and compile the documentation needed by the accreditation board. Once documentation has been received - and if it contains enough information to demonstrate how accreditation criteria will be met - then the accreditation process and panel visit can proceed. (See EHTPA website for accreditation criteria). Some institutions need considerably more time than others.

### **Q. I will qualify as a practitioner of herbal medicine at the end of 2008: the course is not accredited. Which Professional Association can I join when I qualify?**

A. All newly qualified practitioners are free to apply to any relevant Professional Association of their choice. Each association will specify criteria, used as part of the process of deciding whether to admit a practitioner to their register. At the present time

qualifying from a course that is not accredited will not necessarily prevent you from being accepted, although the process of application and admission procedure may differ to that for graduates from an accredited course.

### **Q. Please can you recommend a course in HM and which college I should apply to?**

A. The EHTPA recommends that students apply to a college/university offering an EHTPA/NIMH accredited programme. We do not recommend specific courses or colleges as the needs of potential students differ widely: it is important that an informed choice is made after individual applicants have explored and considered the alternatives available.

### **Q. I am a student at XYZ, hope to qualify in 2009 and have been told that course accreditation will be achieved before I qualify. Can you confirm this for me?**

A. Although I can confirm that XYZ is seeking accreditation and has begun the process, it is not possible to predict when/if this will be achieved. The outcome can never be guaranteed prior to the actual panel visit and consideration by all board members of the panel's written report and recommendation.

### **Q. How does the EHTPA approve clinics used for students' clinical teaching as part of their course?**

A. It doesn't!  
This is the responsibility of the institution BUT the accreditation board expects each institution to have a documented system in place for the selection, approval and monitoring of all clinics used for teaching purposes and can follow this up during accreditation or review visits.

### **Q. What is meant by conjoint accreditation and validation?**

A. This is the means by which the EHTPA and a specific university work together in order professionally to accredit and academically validate a course at one shared panel visit /event. Such courses may be delivered by a university or an independent college - or a combination of both. Some independent colleges do provide a university degree course that is accredited by the EHTPA. Students can usually spend the majority of their time on the course in the college and

college approved clinics and are taught and assessed by college staff.

**Q. I qualified in Australia in 2007 at OZZ and attach a summary of my training programme. Is my training recognised by the EHTPA?**

A. The EHTPA does not accredit overseas courses and does not have a process whereby overseas courses already completed can be recognised. Individual professional associations may have procedures to accept such overseas applicants on to their registers and post regulation the HPC will arrange procedures for acceptance of overseas qualified practitioners to be accepted on to the statutory register..

**Q. I am returning to the UK after working abroad for 3 years and wish to be placed on the EHTPA Register of HM practitioners so that I can practise when I return. Please can you tell me how to go about this?**

A. The EHTPA is an umbrella organisation not a

Professional Association (PA) and therefore does not maintain a register of practitioners. EHTPA membership consists of a number of Professional Associations each of which holds its own register of practitioners. You will need to apply to a PA of your choice for advice about the best way to achieve your intention to practise on your return to the UK.

Lynn Copcutt  
Chair of EHTPA Accreditation Board

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## **2009 Diary Date**

**Research Conference;**

**Title: 'Developing Research in CAM'**

**Date: Thursday 30<sup>th</sup> April 2009**

**Time: 9am – 5pm**

**Venue: Hendon Campus, Middlesex University, The Burroughs, Hendon. London. NW4 4BT**