

**From the European Herbal and Traditional Medicine Practitioners Association –**  
19/09/2009

**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.**

See [http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH\\_103567](http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_103567).

**Consultation questions and answers:**

**Question 1**

**What evidence is there of harm to the public currently as a result of the activities of acupuncturists, herbalists and traditional Chinese medical practitioners? What is its likelihood and severity?**

There is a certain irony in the fact that the first consultation question asks about ‘*harm*’ when acupuncture, herbal and traditional Chinese medicine (TCM) are becoming ever more popular. Clearly, the public perceive that there is benefit a plenty otherwise the growth of this sector would not be the phenomenon that it is. Survey data demonstrates high demand for complementary and alternative medicine (CAM). 10.6% of the adult population of England had visited at least one therapist providing any one of the six more established therapies (acupuncture, chiropractic, homoeopathy, hypnotherapy, medical herbalism, osteopathy) during 1998 with an estimated 22 million visits.<sup>1</sup> Nor is this just a UK phenomenon. National Health Interview Survey data (published by US National Health Statistics Reports) for 2007 indicate that the U.S. public makes more than 300 million visits to CAM providers each year and spends billions of dollars for these services, as well as for self-care forms of CAM. NHR summarises this survey noting, “These expenditures...constitute a substantial part of out-of-pocket health-care costs and are comparable to out-of-pocket costs for conventional physician services and prescription drug use”.<sup>2</sup>

**Whilst we understand that statutory regulation is based on perceived risk and the need to ensure public safety, it is important that potential benefit as well as public support and use of herbal/traditional medicine, acupuncture and traditional TCM is also weighed in the balance when determining if this sector should be statutorily regulated.**

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<sup>1</sup> Thomas K S, Nicoll J P, Coleman P C 2001. Use and expenditure on complementary medicine in England: a population based survey. *Complementary Therapies in Medicine* 9:2-11

<sup>2</sup> U.S. Department of Health and Human Services, *Centers for Disease Control and Prevention National Center for Health Statistics, National Health Statistics Reports*, Number 18, July 30, 2009.

The risks and evidence of harm from herbal medicine are clearly described on page 20 and 21 of the Consultation Document. This data is further elucidated in Annex B of the Consultation Document.

One other risk is that a number of potent herbs are allowed for use by herbal practitioners under The Medicines (Retail Sale or Supply of Herbal Medicines) Order 1977, SI 2130 but in this legislation herbal practitioners are not defined so that there is no assurance of the training of those prescribing these herbs.

As far as acupuncture is concerned, in its report on Complementary and Alternative Medicine (2000) the House of Lord's Select Committee was clear that the practise of acupuncture and herbal medicine posed a degree of risk that demanded statutory regulation of these modalities:

“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.” (Section 5.54).<sup>3</sup>

## **Question 2**

### **Would this harm be lessened by statutory regulation? If so, how?**

The case for statutory regulation reducing risk is well made by the Report of the Working Group on Extending Professional and Occupational Regulation (REPOR) which provides the “Ontario Model”<sup>4</sup> that defines “controlled acts” as a means of identifying such risk and taking legislative action to mitigate it. In particular, *inter alia*, the Ontario Model identifies the following as controlled acts.

- (a) Communicating to the individual or his or her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis.
- (b) Performing a procedure on tissue below the dermis, below the surface of a mucous membrane, in or below the surface of the cornea, or in or below the surfaces of the teeth, including the scaling of teeth.

(Item (a) is common to both herbal/traditional medicines and acupuncture. Item (b) is particularly applicable to acupuncture.)

- (c) Prescribing, dispensing, selling or compounding a drug as defined in the Drug and Pharmacies Regulation Act, or supervising the part of a pharmacy where such drugs are kept.

(Item (c) is particularly applicable in cases where herbal practitioners prescribe herbal medicines under section 12(1) of the Medicines Act of 1968.)

In addition, the REPOR identifies (page 20 Section 2.5) a range of other “dimensions of risk” including:

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<sup>3</sup> House of Lords' Select Committee on Science and Technology *Session 1999-2000 6<sup>th</sup> Report*: [www.parliament.the-stationery-office.co.uk/.../ldselect/.../12301.htm](http://www.parliament.the-stationery-office.co.uk/.../ldselect/.../12301.htm).

<sup>4</sup> *Definition of Controlled Act* – Government of Ontario, Canada, 1997 (quoted in REPOR pp.19-20).

- Whether the act is carried out by a professional on their own, or as part of a supervised team who can support, guide and scrutinise practice;
- Whether the act is carried out by a professional who is part of a well managed organisation that has in place managerial assurance systems to protect patients and the public;
- Whether the act is carried out by a professional who has a stable employment pattern, where any problems might be identified over time, or whether it is carried out by a more mobile short tenure practitioner working in a variety of locations, whose practice is less likely to receive consistent oversight;
- The quality of education and training of the practitioner carrying out the act;
- Whether there are systems in place to ensure that the practitioner is regularly and effectively appraised and developed to ensure that they are up to date with current practice.

In this context it should be taken in account that many practitioners using herbal medicine and acupuncture work on their own and are self-employed. They may also work in more than one location. Without statutory regulation there can be no reliable overall independent arbiter of the quality of education and training such as an autonomous accreditation process that statutory regulation might offer. In addition, without statutory regulation it is hard to see how secure systems can be put in place to ensure that practitioners (not already statutorily regulated) using herbal medicine and/or acupuncture are regularly and effectively appraised (see also our answer to Question 3 on this).

**Taking stock of these criteria set out in the REPOR, the logical conclusion has to be that the only sensible way forward in regulating herbal medicine and acupuncture in the UK is to ensure that all practitioners using these modalities are statutorily regulated.**

This is the conclusion reached by 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 published in May 2008 (henceforth termed “the Pittilo Report”).<sup>5</sup> For these reasons the Pittilo Report found:

“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).

In this context, it should be also be mentioned that a key finding of “*Towards a Safer Choice: The Practice of traditional Chinese medicine in Australia*”<sup>6</sup> (1996) was that:

“The practice of acupuncture and Chinese herbal medicine carries both inherent risks and risks associated with poor practitioner training... There is a link between the length of training in TCM and self-reported adverse incident rates.”

The need for statutory regulation of practitioners of herbal medicine and acupuncture was also highlighted by the House of Lords’ Select Committee on Science and Technology when it published its report on CAM in 2000.<sup>7</sup> Their Lordships said (Section 5.53):

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<sup>5</sup> *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*, DH May 2008, ISBN: 978 1 901085 93 8.

<sup>6</sup> Bensoussan A, Myers P. *Towards a Safer Choice: The Practice of traditional Chinese medicine in Australia*, 1996 Victorian Dept of Services NSW DoH & Queensland DoH, University of Western Sidney MacArthur.

**“It is our opinion that acupuncture and herbal medicine are the two therapies which are at a stage where it would be of benefit to them and their patients if the practitioners strive for statutory regulation under the Health Act 1999, and we recommend that they should do so.”**

As previously mentioned in our answer to Question 1, their Lordships went on to explain the reason for this recommendation as follows:

**“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.” (Section 5.54).**

In 2001 the Government accepted this House of Lords’ Select Committee proposal. The DH recommended that professions using either acupuncture or herbal medicine (thereby also including Chinese herbal medicine, TCM, Ayurveda and other traditional medicine systems) should, in the interests of public safety, be statutorily regulated and that “it would be desirable to bring both acupuncture and herbal medicine within a statutory framework as soon as practicable”.<sup>8</sup>

In 2002 the Department of Health and the Prince of Wales’s Foundation for Integrated Health jointly established two independent regulatory working groups to develop recommendations for the statutory regulation of herbal medicine and acupuncture. Both working groups published their reports in September 2003. The Department of Health considered and built on the working groups’ recommendations in developing the proposals for statutory regulation publishing a Public Consultation Document in 2004 regarding the question of regulation of this sector.<sup>9</sup>

Over 1000 copies of the consultation document were distributed to interested organisations and individuals by the Health Departments. The consultation document was also made available electronically on the Department of Health’s website. The consultation period closed in June 2004. This was followed in February 2005 by the publication of the *Statutory Regulation of Herbal Medicine and Acupuncture*<sup>10</sup> in which the DH presented a summary of the consultations received together with a detailed timetable for statutory regulation of herbal medicine and acupuncture practitioners (see below).

A total of 698 responses were received to the consultation. The respondents included nine organisations representing practitioners of acupuncture, 12 organisations representing practitioners of herbal medicine and nine organisations representing practitioners of Traditional Chinese Medicine (TCM). Other responses included:

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<sup>7</sup> House of Lords’ Select Committee on Science and Technology Session 1999-2000 6<sup>th</sup> Report: [www.parliament.the-stationery-office.co.uk/.../ldselect/.../12301.htm](http://www.parliament.the-stationery-office.co.uk/.../ldselect/.../12301.htm).

<sup>8</sup> Department of Health 2001. *Government response to the House of Lords’ Select Committee on Science and Technology’s report on complementary and alternative medicine*. Stationery Office, London p.7.

<sup>9</sup> Department of Health 2004. *Regulation of herbal medicine and acupuncture. Proposal for statutory regulation*. Stationery Office, London.

<sup>10</sup> DH. *Statutory Regulation of Herbal Medicine and Acupuncture, Report on the consultation* (266766 1p 300), February 2005.

NHS bodies (including NHS Trusts, Primary Care Trusts and Strategic Health Authorities) 15 responses;  
Health and Social Services Boards and Trusts in Northern Ireland – 7 responses;  
Patient and consumer organisations – 3 responses;  
Professional associations for regulated healthcare professionals – 6 responses;  
Royal Colleges – 9 responses;  
Statutory regulatory bodies – 5 responses.  
In addition, a large number of responses were received from patients and members of the public.

The majority of the responses indicated strong support for the introduction of statutory regulation, in order to ensure patient and public protection and enhance the status of the herbal medicine and acupuncture professions. **There was strong support for the application of a consistent system of statutory regulation across all four UK countries – England, Scotland, Wales and Northern Ireland with 98.5% respondents expressing support for a UK-wide system.**

As a result of this consultation the DH published a timetable for the statutory regulation of herbal medicine and acupuncture as reproduced here<sup>11</sup>.

Publication of analysis of consultation responses Spring 2005
Preparation of draft Order under section 60 of the Health Act 1999 Spring 2005
Clearance of draft s 60 Order by Parliamentary Counsel Spring 2005
Publication of draft section 60 Order for consultation Autumn/Winter 2005

The following is taken from the DH Website at the time of the launch of 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 (2006).

**“Statutory regulation of herbal medicine, acupuncture and traditional Chinese medicine practitioners. Summary:**

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.”<sup>12</sup>

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<sup>11</sup> *Ibid*

<sup>12</sup> DH Workforce Update

<file:///c:/Users/Mic/Documents/EHPA/Workforce%20update%20%20The%20Department%20of%20Health%20-%20P&G%20Human%20resources%20and%20training.htm>

It should also be noted that the Report of the Working Group on Extending Professional and Occupational Regulation (REPOR) similarly mentions that:

“Government has also agreed to extend regulation to practitioners of acupuncture, herbal medicine and traditional Chinese medicine practised in the UK.”<sup>13</sup>

**It is a matter of considerable regret that the DH has failed to meet its own targets on the statutory regulation of this sector. It would not be unjust to say the Government has singularly failed to live up to promises and public expectations.**

### **Question 3**

**What do you envisage would be the benefits to the public, to practitioners, and to businesses, associated with introducing statutory regulation?**

(a) Benefit to the public

There would undoubtedly be a benefit to the public from statutory regulation in that the public could be assured that those registered to practise acupuncture and herbal medicine had undertaken *bone fide* training and were subject to regular and effective appraisal to ensure that they are up to date with current practice. It would also make it possible for failing practitioners to be removed from the register thus effectively barring such individuals from practice.

Importantly, statutory regulation would enable referrals to this sector from health professionals who are themselves statutorily regulated. The GMC guidance on this (*Good Medical Practice* 2006), “Working with colleagues” (Delegation and Referral) says:

“55. Referral involves transferring some or all of the responsibility for the patient's care, usually temporarily and for a particular purpose, such as additional investigation, care or treatment that is outside your competence. You must be satisfied that any healthcare professional to whom you refer a patient is accountable to a statutory regulatory body or employed within a managed environment. If they are not, the transfer of care will be regarded as delegation, not referral. This means you remain responsible for the overall management of the patient, and accountable for your decision to delegate.”<sup>14</sup>

Lack of statutory regulation of the herbal/acupuncture sector is likely to perpetuate the existing unsatisfactory situation where patients often fail to tell their doctors that they are undergoing concomitant herbal or acupuncture treatment.<sup>15</sup>

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<sup>13</sup> *The Report of the Working Group on Extending Professional and Occupational Regulation, Extending Professional and Occupational Regulation*, DH August 2009, section 1.15.

<sup>14</sup> GMC. *Regulating Doctors – Ensuring Good Medical Practice*, [http://www.gmc-uk.org/guidance/good\\_medical\\_practice/working\\_with\\_colleagues/delegation\\_and\\_referral.asp](http://www.gmc-uk.org/guidance/good_medical_practice/working_with_colleagues/delegation_and_referral.asp).

<sup>15</sup> Kerr C. Patients use complementary and alternative medicines. *The Lancet Oncology*, Volume 6, Issue 11, Page 832, November 2005.

The Pittilo report emphasised that statutory regulation of this sector is in the public interest. It said:

“The Steering Group is strongly of the view that the decision to statutorily regulate professions practising herbal medicine and acupuncture is in the public interest. Survey data demonstrates high demand for complementary and alternative medicine. 10.6% of the adult population of England had visited at least one therapist providing any one of the six more established therapies (acupuncture, chiropractic, homoeopathy, hypnotherapy, medical herbalism, osteopathy) during 1998 with an estimated 22 million visits. It is important that those with whom they consult are properly trained, understand the limits of their competence and know when and to whom to refer. There has also been widespread concern about the safety, in particular, of traditional Chinese medicines when inappropriately administered...Statutory regulation can more effectively assure the standards of those regulated, protecting the public from poor or bad practice, because legal sanctions exist to remove individuals from a register.”

Response (b) - see below – is also pertinent. This explains how statutory regulation will maintain consumer choice but how if statutory regulation does not happen, there will be significant loss of consumer choice as many herbal products currently prescribed by practitioners to their patients will be removed from the market.

(b) Benefit to practitioners

Statutory regulation would deliver significant benefits to the herbal/traditional medicine and acupuncture professions as it would ensure a common and high standard of training and best practice as well as creating a climate which is likely to foster research and the development of evidence base for practice. It will improve the opportunity to access research funds and grants in pursuit of the knowledge base on which practice is based.

The Medicines and Healthcare products Regulatory Agency (MHRA) has proposed in its consultation on the reform of Section 12(1) of the Medicines Act 1968 that *statutorily regulated* herbal practitioners could be regarded as authorised healthcare professionals for the purposes of Article 5.1 of Directive 2001/83/EC (the main European medicines legislation). This is the provision under which a Member State may permit the supply of manufactured unlicensed medicines, if ordered by, and made to the specification of, an authorised healthcare professional, to meet the special needs of an individual patient. After April 2011, transitional protection afforded under the Traditional Herbal Medicinal Products Directive (THMPD) for certain existing unlicensed manufactured herbal products runs out. Subsequently such products would require either a marketing authorisation or a traditional herbal registration - which would not be a feasible process in most cases given the likely small scale of supply where practitioners require a specific formulation for individual patients. **The key point is that a scheme to allow the availability of such manufactured herbal products under the Article 5.1 derogation is not regarded by the MHRA as legally viable for herbal practitioners unless statutory regulation of the profession is in place. The consequence if such arrangements are not established is that after 2011 there is likely to be a drastic reduction in the scope and range of herbal medicines that herbal practitioners could use and a resultant loss of consumer choice.**

(c) Benefit to businesses

Statutory regulation is likely to increase the number of patients seeking herbal/ traditional medicine treatment and TCM because they will have security that both the practitioners they visit and the herbal medicines they use are subject to independent scrutiny and assurance. As explained above in (b) statutory regulation will ensure that small businesses run by individual practitioners are not financially disadvantaged by the loss of herbal medicinal products currently made by third parties which will otherwise no longer be available.

**On this subject, we have been advised by the Secretary of the Register of Chinese Medicine (RCHM) that if statutory regulation does not go ahead many “Approved Suppliers” (nominated as such by the RCHM) will go out of business because of the loss of such third party supply.<sup>16</sup> Many practitioners in the herbal sector will also no longer be able to practise as they rely on third-party supply of herbal medicines for their patients since the possibility of running their own dispensary is practically and financially unfeasible. The many universities and institutions that deliver training in herbal/traditional medicine, acupuncture and TCM will undoubtedly see the viability of their courses in herbal/traditional medicine and acupuncture seriously undermined. In short, the failure of the Government to deliver on its undertaking to bring in statutory regulation for this sector will have disastrous consequences for practitioners, suppliers and educational institutions across the sector. Thousands of patients across the UK who make regular use of these therapies are going to find that they can no longer access their practitioners or the herbal medicines they have been taking.**

**On the other hand, the advent of statutory regulation is likely to improve confidence in the long-term viability of the sector and encourage investment in herbal supply companies, particularly with regard to their quality assurance systems thereby bringing about an improvement in the quality assurance of herbal supply to practitioners in the UK. It will support the training programmes in these modalities throughout the UK and maintain current herbal availability via practitioners to their patients.**

**Question 4**

**What do you envisage would be the regulatory burden and financial costs, to the public, to practitioners, and to businesses, associated with introducing statutory regulation? Are these costs justified by the benefits and are they proportionate to the risks? If so, in what way?**

This question surely should be inverted to ask what the cost will be if statutory regulation does not go ahead. The answer is that there might be some severe consequences since poor unregulated practice may lead to the need for expensive medical intervention and even loss of life. What price can be put on this?

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<sup>16</sup> Correspondence to Chair of EHTPA (September 2009) from Secretary RCHM.

The Pittilo Report was strongly of the view that the decision to statutorily regulate professions practising herbal medicine and acupuncture is in the public interest. It said:

“Survey data demonstrates high demand for complementary and alternative medicine. 10.6% of the adult population of England had visited at least one therapist providing any one of the six more established therapies (acupuncture, chiropractic, homoeopathy, hypnotherapy, medical herbalism, osteopathy) during 1998 with an estimated 22 million visits<sup>17</sup>. It is important that those with whom they consult are properly trained, understand the limits of their competence and know when and to whom to refer.”

The fact that so many people are consulting acupuncturists and practitioners of herbal/traditional medicine and TCM is a strong argument for statutory regulation which will encourage good practice, protect the public and allow free interchange and referral between practitioners of these modalities and other healthcare professionals. These are significant benefits that certainly justify the costs involved.

Several itemised costs of statutory regulation listed in the Consultation Document are one-off costs such as drafting legislation and under Section 60 of the Health Act 1999 the Secretary of State for Health is empowered to make an order to bring an aspirant profession into statutory regulation. This is a much simplified and less expensive process than that employed to bring about the statutory regulation of osteopaths and chiropractors. The Health Professions Council (HPC) has made a clear and unequivocal recommendation to the Secretary of State for Health that Medical Herbalists, Acupuncturists and Traditional Chinese Medicine Practitioners should be regulated under Article 17 (a) of the Health Professions Order 2001.<sup>18</sup>

Few costing studies have been carried out but one relevant survey is that carried out by Mr Christopher Smallwood<sup>19</sup>. In its conclusions the report says:

“Evidence ... indicates that many of the most effective CAM therapies correspond to recognised “effectiveness gaps” in NHS treatment. The main areas comprise chronic and complex conditions, anxiety, stress and depression and palliative care... Despite the fragmentary nature of the evidence, there is good reason to believe that a number of CAM treatments offer the possibility of significant savings in direct health costs.... the benefits to the economy ... of a wider application of successful complementary therapies in the key areas could run to hundreds of millions of pounds...”

Smallwood also identifies statutory regulation for herbal medicine and acupuncture as: “important to remove a series of barriers that may stand in the way of GP referrals.”

Regarding herbal medicine, Smallwood said:

“In many cases where the herbal remedy is sufficiently effective, cost savings would be generated by its wider use. For example, in 2004 the NHS spent £400 million on anti-depressant drugs at an average net ingredient cost of £13.82 per prescription. Compared with this a weekly course of St John’s wort costs just 82p”.

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<sup>17</sup> Thomas K S, Nicoll J P, Coleman P C 2001. Use and expenditure on complementary medicine in England: a population based survey. *Complementary Therapies in Medicine* 9:2-11

<sup>18</sup> Minutes of the forty-seventh meeting of the Health Professions Council held on Thursday 11 September 2008. [http://www.hpc-uk.org/assets/documents/1000247Bcouncil\\_20081001\\_enclosure01.pdf](http://www.hpc-uk.org/assets/documents/1000247Bcouncil_20081001_enclosure01.pdf).

<sup>19</sup> Smallwood C. *The Role of Complementary and Alternative Medicine in the NHS*, FreshMinds Ltd, Oct 2005.

Since the Smallwood report the National Institute for Clinical Excellence (NICE) has published its guidelines on treating persistent, nonspecific low back pain recommending (May 2009) a course of acupuncture, up to a maximum of 10 sessions over a period of up to 12 weeks.<sup>20</sup>

An evaluation of a pilot project conducted in Northern Ireland, which provided patients with access to a range of CAM treatments through their GP practice, documented the positive impact of CAM on patients who are economically active, particularly in the context of helping people back into work following illness.<sup>21</sup>

The World Health Organisation estimates that 66% of all premature deaths are due to chronic diseases and that nearly 400 million people will die of a chronic illness in the next ten years.<sup>22</sup> Smallwood highlights that CAM therapies such as herbal/traditional medicine, TCM and acupuncture operate within “effectiveness gaps” where conventional medicine is generally perceived to have relatively poor outcomes. In 2004 the Wanlass Report warned that without a major overhaul, on its current trajectory the NHS by 2023 would consume more than 12% of GDP. Wanlass proposed a new conception of public health as:

“the science and art of preventing disease, prolonging life and promoting health through the organised efforts and informed choices of society, organisations – public and private, communities and individuals.”<sup>23</sup>

As Peters observes regarding effectiveness gaps:

“Such problems are complementary practitioners’ daily bread and surveys suggest high levels of satisfaction and useful outcomes. Their growing popularity with the public and acceptance by mainstream practitioners coincides with an increased interest in lifestyle change, health promotion and low technology treatments, approaches which if they could be integrated into primary care might provide inexpensive ways of augmenting conventional medicine... Integrated medicine marries the art and science of medicine.”<sup>24</sup>

## Question 5

**If herbal and TCM practitioners are subject to statutory regulation, should the right to prepare and commission unlicensed herbal medicines be restricted to statutorily regulated practitioners?**

**The Pittilo Report was clear on this matter answering unequivocally “yes” to this question and we completely concur with its views as reproduced here below.**

“Public health protection is best served if there is a consistent approach taken to the competencies, training and experience required to practise herbal medicine safely. Agreed standards of training and practice should be applied across the board to all those wishing to practise under Section (12)1.

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<sup>20</sup> <http://www.nice.org.uk/nicemedia/pdf/CG88NICEGuideline.pdf>. May 2009

<sup>21</sup> DHSSPS. *Evaluation of a CAM Pilot Project in Northern Ireland* (2008), [http://www.dhsspsni.gov.uk/final\\_report\\_from\\_smr\\_on\\_the\\_cam\\_pilot\\_project\\_-\\_may\\_2008.pdf](http://www.dhsspsni.gov.uk/final_report_from_smr_on_the_cam_pilot_project_-_may_2008.pdf).

<sup>22</sup> WHO report 2005, *Preventing Chronic disease – a vital investment* [www.int/chp/chronic\\_disease\\_report/en/](http://www.int/chp/chronic_disease_report/en/).

<sup>23</sup> Wanlass D. *Securing Good Health for the whole population*. London:HM Treasury 2004

<sup>24</sup> Peters D. Integration, long-term disease and creating a sustainable NHS. *J. Holistic Healthcare*, Vol 6, issue1, May 2009, 29-31.

The most clear-cut, reliable protection for the public is achieved if those who prepare unlicensed medicines to meet individual needs are subject to statutory regulation. If, to the contrary, practitioners who are not statutorily regulated are allowed to continue to make up unlicensed medicines under Section 12(1) this could create an incentive for some herbal/traditional medicine practitioners to opt out of statutory regulation while continuing to practise herbal medicine. Such a scenario would undermine the purpose of statutory regulation and compromise public health protection.”

For this reason the Pittilo report said:

“We recommend that use of Section 12(1) of the Medicines Act of 1968 should be restricted to practitioners who are subject to appropriate statutory regulation.”

### **Question 6**

**If herbal and TCM practitioners are *not* statutorily regulated, how (if at all) should unlicensed herbal medicines prepared or commissioned by these practitioners be regulated?**

**The evident response to this question is that there is no good way to regulate the use of unlicensed herbal medicines other than through statutory regulation.**

Alternatives to statutory regulation mentioned in the Consultation Document are:

- “*Caveat emptor*” ... retaining Section 12(1) and rely on informing the public that they buy at their own risk.
- Abolition of Section 12(1) of the Medicines Act of 1968.
- A voluntary regulation with an accredited register.
- A statutory or voluntary licensing scheme.

#### The “*Caveat emptor*” option

There are significant drawbacks in operating this option. This option offers no public protection and the MHRA has clearly identified that there are significant risks in continuing the current unregulated scheme (see Medicines and Healthcare products Regulatory Agency’s WebPages for example at [www.mhra.gov.uk](http://www.mhra.gov.uk)). As the Consultation Document itself points out, if practitioners are not subject to some form of systematic regulation one other significant issue for consideration would be the wider implications for the herbal medicines market. Potentially there could be a scenario where part of the market, the over-the-counter (OTC) sector, is operating within systematic regulation whereas practitioners and unlicensed medicines they use are not subject to any form of equivalent regulation. This would pose difficulties and possibly offer a means by which the OTC sector could sidestep regulation laid down by the Traditional Herbal Medicinal Products Directive (THMPD).

#### The possibility of abolishing Section 12(1) of the Medicines Act of 1968

In well over a decade of cooperative negotiation and ongoing discussion about reform of Section 12(1) between the herbal/traditional medicine sector and the MHRA, the possibility of abolishing Section 12(1) of the Medicines Act of 1968 has never once been mooted let alone discussed. This is clearly evident in that this possibility is not even mentioned in the

eight papers published on its website by the MHRA in its published draft proposals for reform of Section 12(1) in 2007.<sup>25</sup> Nor was it on the agenda at any time during production of the Pittilo report. **It is manifestly unacceptable to suggest the abolition of a statute under the auspices of which many practitioners practise and the public obtain herbal treatment. We emphatically reject this suggestion.**

#### Voluntary regulation with an accredited register.

Voluntary regulation with an accredited register would confer no significant advantages to the majority of the profession that is already regulated by well-established and well-run voluntary professional associations. Moreover, such voluntary regulation would not provide the legal status to allow practitioners to be regarded as “authorised healthcare professionals” for the purposes of complying with European legislation after April 2011, so they would be unable legally to commission manufactured unlicensed herbal medicines from a third party under Article 5.1 of the main European Medicines Directive 2001/83/EC. Voluntary regulation will not prevent anyone who chooses to practise outside of the voluntary regulatory regime from doing so or prevent anyone from continuing to practise even though removed from the voluntary register and will therefore offer limited, if any, real public protection. **For these reasons, this option is not be acceptable to the EHTPA.**

#### A statutory or voluntary licensing scheme

Neither voluntary nor statutory licensing has been discussed during the many years of discussion about statutory regulation by the profession with the DH and MHRA and their implementation is only outlined in this Consultation Document. Nevertheless, it is possible to see that these schemes are clearly unsuitable for regulating practitioners practising internal herbal medicine or acupuncture.

**Voluntary licensing suffers from all the weaknesses of the voluntary regulatory scheme discussed in 3 above and so for reasons given there, appears impractical. We do not support this option.**

It is asserted that statutory licensing would provide a more robust form of public protection than voluntary regulation, and would be less onerous for practitioners, businesses, taxpayers and Government than orthodox statutory regulation. It is explained that a “light touch” licensing regime, based on the model employed by the Security Industry Authority, would involve licensing anyone who has an accredited qualification and has also undergone a satisfactory criminal record check and has been confirmed as not appearing on any list of persons regarded as unsuitable to work with vulnerable adults or children.

The Security Industry Authority (SIA) licenses bodyguards, bouncers and wheel clampers and hardly seems the model on which to base proper regulation of health professionals

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<sup>25</sup> See

<http://www.mhra.gov.uk/Howweregulate/Medicines/Herbalandhomoeopathicmedicines/Herbalmedicines/PlacingherbalmedicineontheUKmarket/Unlicensedherbalremediesindividualpatients/index.htm>

treating the sick and infirm. Moreover, in consideration of the provision of “robust public protection”, it would appear that the SIA has been anything but robust in carrying out this task. Its Chief Executive stepped down in November 2008 after a report showed that almost 40 agency staff working at the SIA had not received proper security training. In the previous year, according to a BBC report it emerged that the SIA had wrongly given licences to more than 6,600 illegal immigrants.<sup>26</sup>

There are other serious shortcomings with regard to such statutory licensing. Whilst it would carry out a criminal record check, it would not operate formal fitness to practise procedures consisting of an investigation committee, panel hearings and an appeal to an independent body as is usual when examining such fitness to practise matters. Nor would such a licensing system supervise continuous professional development (CPD) schemes, maintain quality and standards in the profession (e.g. regulate accreditation of training programmes) or encourage advancement of the profession in terms of practice and research. In addition, it would fail to provide a means by which herbal practitioners could access herbal products made by third parties under Article 5.1 of the main EU medicines Directive, 2001/83/EC (see our answer to Question 7 for further detail on this).

In short, a statutory licensing system would fail to deliver a thoroughly professional body of practitioners who could work side by side with other similarly regulated health practitioners for the public good. It might be argued to be a cheaper option but there is no question that in the long term it would have poor outcomes and therefore fail to deliver value for money. It will relegate acupuncture; herbal/traditional medicine and TCM to a partial and ineffective regulatory scheme that clearly distances these therapies from healthcare professions that are statutorily regulated making it impossible for statutorily regulated health professionals to make referrals to practitioners within this sector. This would make communication between professionals difficult which will not be in patients’ best interests. *The Report of the Working Group on Extending Professional Regulation*<sup>27</sup> recommends psychological therapists, psychotherapists and counsellors for statutory regulation on the basis that “they can be relatively easily located within the groups of professionals suited to statutory regulation by the HPC.” Yet, as mentioned in our answer to Question 4, the HPC has made a recommendation to the Secretary of State for Health that Medical Herbalists, Acupuncturists and Traditional Chinese Medicine Practitioners should be regulated. Surely this is the time to bring these therapies into statutory regulation to provide an integrated approach to healthcare enabling patients to have the best of both.

**For these reasons we do not support this option.**

**In summary: None of the options mentioned other than statutory regulation appears to deliver a properly regulated profession. It is clear that statutory regulation of this sector is in the public interest.**

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<sup>26</sup> BBC News Channel “Security licence body chief quits”, Nov 6 2008, <http://news.bbc.co.uk/1/hi/uk/7713493.stm>.

<sup>27</sup> *Op cit.* (Section 1.14).

### **Question 7**

**What would be the effect on the public, practitioners and businesses if, in order to comply with the requirements of European medicines legislation, practitioners were unable to supply manufactured unlicensed herbal medicines commissioned from a third party, after 2011?**

There is an urgent and compelling need to ensure statutory regulation for practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK (currently undergoing consultation after a series of deplorable delays). Until now, a large number of herbal medicines manufactured by third parties have been available for prescription for individual patients by practitioners in this sector under Section 12(2) of the Medicines Act of 1968. However, Section 12(2) is to be effectively repealed once the THMPD becomes fully implemented in April 2011 after which these herbal products manufactured will no longer be available as the majority are not suitable for the THR scheme. This will significantly and adversely restrict the scope of herbal remedies currently available to the public who wish to consult herbal/traditional medicine practitioners. The ramifications of this are explored in our answer to Question 3 above.

In addition, the loss of these herbal medicines is likely to have serious financial consequences for small and medium-sized enterprises (SMEs) both at practitioner and herbal supplier levels. In particular, herbal suppliers are already coping with significant increases in costs as they gear up for the implementation of the THMPD. The loss of a significant proportion of their turnover due to the fact that practitioners are unable to use the derogation under Article 5.1, is likely to have serious negative regulatory impact on these SMEs.<sup>28</sup> Both of these issues would undoubtedly contribute to rising unemployment figures (see also again our answer to Question 3). **We urge the Government to fulfil its earlier promises to move to statutory regulation of this sector as soon as possible.**

### **Question 8**

**How might the risk of harm to the public be reduced other than by statutory professional self-regulation? For example, by voluntary self-regulation underpinned by consumer protection legislation and by greater public awareness, by accreditation of voluntary registration bodies, or by a statutory or voluntary licensing regime?**

As we have explained at some length in answer to question 6 above, there is no sensible or effective way to regulate this sector other than by statutory regulation.

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<sup>28</sup> Micro, small and medium-sized enterprises are socially and economically important, since they represent 99 % of all enterprises in the EU and provide around 65 million jobs and contribute to entrepreneurship and innovation. However, they face particular difficulties which the EU and national legislation try to redress by granting various advantages to SMEs. See EU Enterprise and Industry website: [http://ec.europa.eu/enterprise/enterprise\\_policy/sme\\_definition/index\\_en.htm](http://ec.europa.eu/enterprise/enterprise_policy/sme_definition/index_en.htm).

### **Question 9**

**What would you estimate would be the regulatory burden and financial costs, to the public, to practitioners, and to businesses, for the alternatives to statutory regulation suggested at Question 8?**

It is clear that the true cost to the public (which in the final analysis is what counts) would be high if, to save money, a regulatory regime were put in place that did not deliver on quality. The public would be the losers. Statutory regulation is tried and tested and for the reasons explained in the answer to question 6 is clearly the only rational option.

### **Question 10**

**What would you envisage would be the benefits to the public, to practitioners, and to businesses, for the alternatives to statutory regulation outlined at Question 8?**

See our answers to questions 6, 8 and 9. There will be no real benefit to the public by adopting the alternatives to statutory regulation outlined at Question 8. As we have shown, all the schemes mentioned in Question 8 will be detrimental to public interest.

### **Question 11**

**If you feel that not all three practitioner groups justify statutory regulation, which group(s) does/do not and please give your reasons why/why not?**

All these three practitioner groups, herbal/traditional medicine, traditional Chinese medicine and acupuncture may use herbal medicines under Section 12(1) of the Medicines Act of 1968.

Many traditional acupuncturists and practitioners of TCM base their practice on TCM theory and treatment may be given via acupuncture and/or herbal medicine. For this reason, many acupuncturists and TCM practitioners use herbal medicines. It should be noted that when the DH published its *Statutory Regulation of Herbal Medicine and Acupuncture* in February 2005, it both understood and accepted this fact noting: "Practitioners of Traditional Chinese Medicine usually practise both Chinese herbal medicine and acupuncture".<sup>29</sup>

In addition, practitioners in the western tradition, as well as those practising Ayurveda and Tibetan medicine also prescribe herbal medicines. If these three groups are not regulated together, a thoroughly chaotic situation could develop where some of the practice is statutorily regulated and some not. This would not be in the public interest.

As highlighted in the Pittilo Report, all those using herbs under Section 12(1) of the Medicines Act of 1968 should be statutorily regulated. This will allow these practitioners to access herbal medicines made up by third parties via Article 5.1 of the main EU Medicines

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<sup>29</sup> DH. *Statutory Regulation of Herbal Medicine and Acupuncture, Report on the Consultation* (266766 1p 300), February 2005, footnote page 2.

Directive 2001/83/EC. Other reasons why all three groups should qualify for statutory regulation are discussed in our answer to Question 1.

**In summary, all three practitioner groups justify statutory regulation.**

## **Question 12**

**Would it be helpful to the public for these practitioners to be regulated in a way which differentiates them from the regulatory regime for mainstream professions publicly perceived as having an evidence base of clinical effectiveness? If so, why? If not, why not?**

### False Assumptions

There is an *a-priori*-assumption in this question which posits that mainstream medical practice is rooted in an established evidence base of clinical effectiveness and it is exactly this notion that has promoted a misleading perception that conventional medicine is mostly based on evidence-based medicine (EBM). However, whatever public perception may be, this is certainly not the case as the following recent editorial from the *BMJ Journal Evidence Based Medicine*<sup>30</sup> makes clear. It draws attention to a clear double standard which sees CAM therapies under fire for lack of evidence and contrasts this to the way conventional medicine is incorrectly portrayed as being largely supported by a secure evidence base.

“Is the concept of evidence-based medicine flexible enough? In particular, can it embrace interventions for which there is a long history of use, but a lack of hard research data? It should do, according to a famous definition published 12 years ago in which evidence-based medicine (EBM) was portrayed as ‘the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients’. This definition made allowances for missing or inappropriate evidence, and, crucially, required the application of clinical judgment and recognition of patient values. Today, however, there is a common, rigid mindset that equates EBM solely with the conclusions of randomised controlled trials and systematic reviews of these studies, to the exclusion of other 'best evidence' and the needs of individual patients. This simplistic thinking is being increasingly challenged by new moves to enhance the status of older, under-researched treatments: for example, the registration of herbal medicinal products by the UK Medicines and Healthcare products Regulatory Agency (MHRA).

When it comes to older treatments, there is often a gap between empirical evidence, clinical practice, and patient experience. Moreover, 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.

There are also obvious problems associated with focusing entirely on published trial literature as the supposed basis for evidence-based practice. The efficacy studies that form the backbone of EBM represent only a small part of the total research literature, and may be of limited value in assessing safety. And, of course, most efficacy research is sponsored by the pharmaceutical industry and is drug orientated. Potentially valuable traditional medicines, non-drug interventions, or other aspects of health care receive much less attention. It is dangerous to assume that concentrating exclusively on published trials and systematic reviews

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<sup>30</sup> Barnett H, Iheanacho I. Editorial in *BMJ Evidence Based Medicine* –August 28th, 2008.

at least identifies those interventions that have proven their worth to clinical practice. In reality, a good look through the Cochrane Library or other research databases reveals that the interventions and questions assessed by RCTs are often far removed from the real needs of patients and their healthcare professionals. This distortion reflects not just the selectivity of the research conducted, but also positive and negative publication biases. Examples include publication biases in trials of treatment for acute stroke, and also in trials of antidepressant drugs.

Less obviously, and more controversially, there are questions about whether the pharmacological randomised controlled trial model for research is sufficient to assess long-established interventions. One concern is that, because many of these interventions comprise several components, the individual effects of which may be hard to isolate and measure separately (e.g. palliative care, public health, or many complementary and alternative therapies), artificially standardising them to fit a drug-trial model may involve over-simplification. This will then raise questions about the real-world applicability of the study results. Accordingly, there is an argument for a different type of research strategy for long-established interventions, with a different order of priority...”

This editorial is supported by recent data also published in the BMJ’s on-line Journal *Clinical Evidence*.<sup>31</sup> It shows that far from having a complete evidence base, only about 13% of 2,500 medical treatments surveyed are rated as beneficial with 46% “of unknown effectiveness”

“So what can *Clinical Evidence* tell us about the state of our current knowledge? What proportion of commonly used treatments are supported by good evidence, what proportion should not be used or used only with caution, and how big are the gaps in our knowledge? Of around 2500 treatments covered 13% are rated as beneficial, 23% likely to be beneficial, 8% as trade off between benefits and harms, 6% unlikely to be beneficial, 4% likely to be ineffective or harmful, and 46%, the largest proportion, as unknown effectiveness (see figure 1). Dividing treatments into categories is never easy hence our reliance on our large team of experienced information specialists, editors, peer reviewers and expert authors... However, the figures above suggest that the research community has a large task ahead and that most decisions about treatments still rest on the individual judgements of clinicians and patients.”<sup>32</sup>

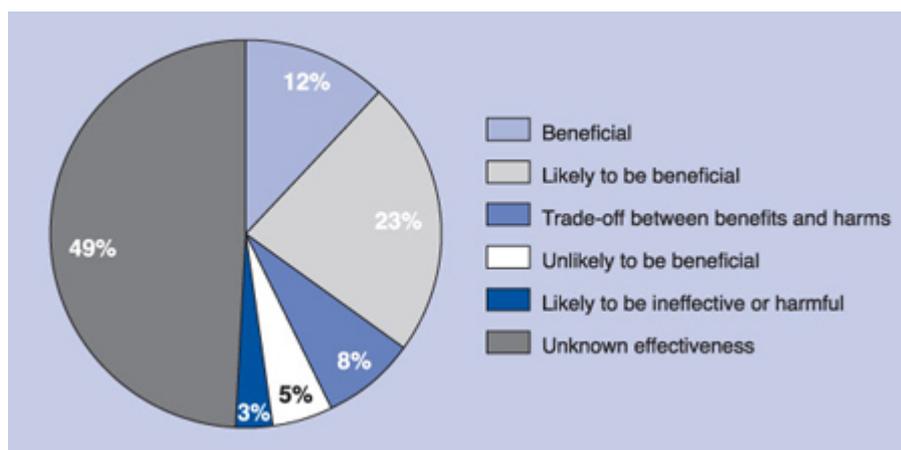


Figure 1. (From BMJ Clinical Evidence)

<sup>31</sup> BMJ Clinical Evidence, <http://clinicalevidence.bmj.com/ceweb/about/knowledge.jsp>. Accessed 3 September 09.

<sup>32</sup> *Ibid*

### Existing research on acupuncture, herbal/traditional medicine and TCM

The EHTPA would also like to draw the DH's attention to the many research papers that are mentioned in Annex 1 of the Pittilo Report, "*Developing Research and Providing an Evidence Base*". It is now some time since this section was written and a few papers mentioned may now be superseded, but this section of the Report underlines the growing evidence base for acupuncture, herbal and traditional medicine as well as TCM. Research has challenged the notion that the quality of the evidence on the effectiveness of herbal medicine is generally inferior to the evidence available for conventional medicine<sup>33</sup> and as mentioned above, in May 2009 NICE published its guidelines on treating persistent, nonspecific low back pain recommending a course of acupuncture, up to a maximum of 10 sessions over a period of up to 12 weeks.<sup>34</sup>

This Annex also calls for appropriate methods of research to be applied to the practice of herbal medicine and acupuncture.

"Herbal/traditional medicine and acupuncture have for the most part been practised for hundreds, even thousands of years – a feature which needs to be considered when it comes to building an evidence base. This is recognised in the *European Directive on Traditional Herbal Medicinal Products* which notes that "The long tradition of the medicinal product makes it possible to reduce the need for clinical trials insofar as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience." (Directive 2004/24/EC). Nonetheless, whilst taking into account generations of clinical experience, ongoing experimental research is an essential process to establish further the safety and effectiveness of these forms of intervention. Acupuncture and herbal/traditional medicine typically involve individualised treatments based on a complex clinical encounter. This suggests that to measure effectiveness in a meaningful way requires a specific programme of research to be developed for these therapies which combines pragmatism with scientific rigour...The recorded history of traditional use over many years should be evaluated and incorporated into the evidence base supporting the effectiveness and safety of herbal/traditional medicines and acupuncture. In addition, stakeholder needs, including those of the patient, service providers, and the practitioners, require that this corpus of knowledge is subjected to a particular scientific scrutiny that needs to combine methodological rigour with an appreciation of the complex and individualised nature of these forms of medical intervention."

### Suitable evidence

Question 12 also fails to take into account that there is growing concern, already referred to above, about the appropriateness of research to provide EBM. This concern was explored by Professor Sir Michael Rawlins, Chairman of the National Institute for Health and Clinical Excellence (NICE) in his Harveian Oration to the Royal College of Physicians in October 2008.<sup>35</sup>

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<sup>33</sup> Nartey L, Huwiler-Muntener K, Shang A, Liewald K, Juni P, Egger M.

Matched-pair study showed higher quality of placebo-controlled trials in Western phytotherapy than conventional medicine. *J Clin Epidemiol.*;60(8):787-94 Aug. Epub 2007 Mar 26. 2007.

<sup>34</sup> <http://www.nice.org.uk/nicemedia/pdf/CG88NICEGuideline.pdf>, May 2009

<sup>35</sup> Rawlins M, *De Testimonio* – 'On the evidence for decisions about the use of therapeutic interventions', *The Harveian Oration*, Royal College of Physicians, Oct 2008, ISBN 978-1-86016-347-0.

“The dispute about the evidential basis of modern therapeutics has become particularly apparent with the emergence, over the past 30 years, of what are known variously as ‘rules’, ‘levels’ or ‘hierarchies’ of evidence... Such hierarchies place randomised controlled trials (RCTs) at their summit with various forms of observational studies nestling in the foothills. They are used – as a form of shorthand – to provide some intimation of the ‘strength’ of the underlying evidence; and, particularly by guideline developers, to then ‘grade’ therapeutic recommendations on the basis of this perceived strength...

The notion that evidence can be reliably placed in hierarchies is illusory. Hierarchies place RCTs on an undeserved pedestal for, as I discuss later, although the technique has advantages it also has significant disadvantages. Observational studies too have defects but they also have merit. Decision makers need to assess and appraise all the available evidence irrespective as to whether it has been derived from RCTs or observational studies, and the strengths and weaknesses of each need to be understood if reasonable and reliable conclusions are to be drawn. Nor, in reaching these conclusions, is there any shame in accepting that judgements are required about the ‘fitness for purpose’ of the components of the evidence base. On the contrary, judgements are an essential ingredient of most aspects of the decision-making process....

Hierarchies attempt to replace judgement with an oversimplistic, pseudoquantitative, assessment of the quality of the available evidence. Decision makers have to incorporate judgements, as part of their appraisal of the evidence, in reaching their conclusions. Such judgements relate to the extent to which each of the components of the evidence base is ‘fit for purpose’. Is it reliable? Does it appear to be generalisable? Do the intervention’s benefits outweigh its harms? And so on. Decision makers have to be teleoanalysts. Although techniques such as Bayesian statistics will undoubtedly assist they will not be a substitute for judgement. As William Blake (1757–1827) observed: ‘God forbid that truth should be confined to mathematical demonstration’.”

A recent editorial on Integrative Medicine in the BMJ reflects on the conundrum facing those who wish to integrate herbal/traditional medicine, TCM and acupuncture into healthcare alongside mainstream medicine:<sup>36</sup>

“We do not currently have enough evidence to close the door on research into integrative medicine and pronounce it ineffective. However, we will not be serving the best interests of evidence informed choice simply by undertaking more, and expensive, placebo controlled trials with non-typical patients and artificially standardised interventions, and ever more systematic reviews of existing heterogeneous, underpowered, and low quality studies. Rather, we should work towards closing the evidence gap by broadening the range of evidence we use to evaluate the complex interventions that are characteristic of, although not exclusive to, integrative medicine. “

#### Other professions included in statutory regulation

The Extending Professional Regulation Working Group recommends (Section 1.14 of its Report) that psychotherapists and counsellors should be brought into statutory regulation. If these groups qualify for statutory regulation alongside arts therapists (already regulated), it is hard to see any reason on grounds of evidence base that acupuncture, herbal/traditional medicine and TCM should not be similarly regulated like other CAM therapies such as osteopathy and chiropractic.

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<sup>36</sup> MacPherson H, Peters D, Zollman C. ‘Closing the evidence gap in integrative medicine’, *British Medical Journal* 2009;339:b3335, doi: 10.1136/bmj.b3335 , 1 September 2009.

### Public demand for properly regulated CAM

Since question 12 refers to public perceptions, it seems appropriate to include in our answer to this question two recent letters published together in *The Times* that emphasise public support for complementary medicine, integrated with conventional practice. They highlight the need to encourage complementary therapies to develop alongside conventional medicine because this is clearly what patients want.

*The Times* February 3, 2009

No doubt to the dismay of your correspondents (letter, Jan 30) complementary therapies are being used by about 60 per cent of my cancer patients. They are used by millions who suffer from long-term conditions for which, despite the efforts of scientists, there is no effective conventional treatment. Many knowledgeable and trained doctors use complementary therapies in their everyday treatment of patients where it is appropriate.

Those of us who are faced daily by real human suffering use the best evidence available to help our patients. At the same time, patients do their best to help themselves. The ill-thought-through arguments of those who are not doctors — and so have no experience of the practice of medicine — are ridiculous.

According to the Department of Health, about one in five adults use complementary therapies. That means we need more education for practitioners, not less. And we certainly need better research, not the Stalinist repression that Professor Colquhoun and his colleagues demand.

Armchair physicians are welcome to their views, but clearly patients know better.

***Professor Karol Sikora, Professor of Cancer Medicine, Imperial College School of Medicine, Hammersmith Hospital.***

**Sir,**

Whatever your beliefs about complementary medicine (CM), many patients choose to see CM practitioners and an increasing number of frontline clinicians are providing access to them. It is, therefore, important that those CM practitioners are as well educated, trained, safe and regulated as possible.

Nor are these academics being fair by lumping all CM therapies together. Some, such as acupuncture and manipulation, have been validated by august institutions such as NICE and the Cochrane Collaboration. Others are less evidence-based but often used in areas (such as chronic tiredness, musculoskeletal pain or frequent minor infections) where the evidence base and effectiveness of conventional therapies is poor and where making a choice between the conventional or complementary or doing both may be appropriate and safe.

By supporting CM regulation, the Government is trying to ensure that it is as safe as possible whenever and wherever practised. It is in no position to dictate which therapies are proven or disproven because conclusive evidence often does not exist.

That is partly owing to the lack of research funding for complementary medicine — the UK Clinical Research Collaboration funding for CM research (according to its own 2008 report) came to a grand total of 0 per cent! It is also partly because we have failed to do the right kind of research, which needs to compare the cost effectiveness of CM therapies to that of other treatments currently given for various conditions.

Meanwhile, most academics and universities thankfully are and should continue to be open minded on this issue and the Government should continue to put patient safety first.

***Dr Michael Dixon, Medical Director, Prince's Foundation for Integrated Health***

### Question 13

**Given the Government’s commitment to reducing the overall burden of unnecessary statutory regulation, can you suggest which areas of healthcare practice present sufficiently low risk so that they could be regulated in a different, less burdensome way or de-regulated, if a decision is made to statutorily regulate acupuncturists, herbalists and traditional Chinese medicine practitioners ?**

This is surely a matter for the DH rather than us to determine but it is fair to question the notion that because one sector clearly qualifies for statutory regulation another type of healthcare practice should be removed from statutory regulation. What are the reasons for this assumption? Is it driven mainly by financial expediency? If so the proposition would seem misguided. It does not suggest public protection is at the heart of regulation: the requirement to provide the public with adequately trained, providers of healthcare surely cannot be relegated to some system of a pre-determined number of ‘available seats’.

### Question 14

**If there were to be statutory regulation, should the Health Professions Council (HPC) regulate all three professions? If not, which one(s) should the HPC not regulate?**

We have answered this question already (see response to question 11). **The HPC should regulate all three.**

### Question 15

**If there were to be statutory regulation, should the Health Professions Council or the General Pharmaceutical Council/ Pharmaceutical Society of Northern Ireland regulate herbal medicine and traditional Chinese medicine practitioners?**

Question 14 assumes that if statutory regulation goes ahead, the HPC would be the regulator. We agree with this proposal. The HPC already regulates a diverse range of professions e.g. paramedics and art therapists, The HPC has the knowledge and experience in regulating diverse professions and is therefore the best suited body to regulate herbalists, acupuncturists and TCM practitioners. The Pittilo Report reviewed the question of which regulator would be most appropriate. Regarding the HPC, it said:

“the Steering Group recognises that the creation of several statutory regulatory bodies to accommodate the wide range of professionals that exist is neither practical nor consistent with the recommendations within the White Paper, *Trust, Assurance and Safety – the Regulation of Health Professionals in the 21st Century*<sup>37</sup> and Government policy to reduce the numbers of regulatory bodies. We are mindful that costs are reduced as a statutory regulatory body increases in size...

The Steering Group takes the view that effective, safe and cost-effective statutory regulation has been demonstrated by the multi-professional Health Professions Council (HPC) and is convinced that this could

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<sup>37</sup> Department of Health 2007. *Trust, assurance and safety – the regulation of health professionals in the 21st century*. Stationery Office, London.

be extended to cover practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional-medicine systems practised within the UK...

The Steering Group has every confidence in the ability of the HPC to statutorily regulate practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems effectively and efficiently and thus to protect the public from poor practice.”

Regarding regulation by the General Pharmaceutical Council/ Pharmaceutical Society of Northern Ireland, the Pittilo Report had this to say:

“It should be noted that there was some discussion as to whether practitioners preparing and supplying unlicensed herbal medicines to meet the needs of individual patients might be statutorily regulated alongside pharmacists. Little enthusiasm for this option could be identified amongst both pharmacists and herbalists suggesting that such an arrangement could only be achieved by a level of coercion. As the White Paper determined that the HPC should be the preferred regulator and in view of other doubts which some members of the Steering Group had about the appropriateness of this option, we did not pursue the idea further.”

In addition, it should be pointed out that the General Pharmaceutical Council/ Pharmaceutical Society of Northern Ireland is not the most suitable regulating body to oversee acupuncture which has no connection with pharmacy.

**For this reason, we concur with the Pittilo report that the most suitable regulator to regulate practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems is the HPC.**

As mentioned (our answer to Question 4), **the HPC has already made a clear and unequivocal recommendation to the Secretary of State for Health that Medical Herbalists, Acupuncturists and Traditional Chinese Medicine Practitioners should be regulated under Article 17 (a) of the Health Professions Order 2001.**<sup>38</sup>

#### **Question 16**

**If neither, who should and why?**

This question is not applicable as we support regulation by the HPC. See answer to previous question.

#### **Question 17**

**a) Should acupuncture be subject to a different form of regulation from that for herbalism and traditional Chinese medicine? If so, what?**

**b) Can acupuncture be adequately regulated through local means, for example through Health and Safety legislation, Trading Standards legislation and Local Authority licensing?**

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<sup>38</sup> Minutes of the forty-seventh meeting of the Health Professions Council held on Thursday 11 September 2008. [http://www.hpc-uk.org/assets/documents/1000247Bcouncil\\_20081001\\_enclosure01.pdf](http://www.hpc-uk.org/assets/documents/1000247Bcouncil_20081001_enclosure01.pdf).

- a) As already made clear in our answer to question 11, we do not agree with separate regulation for herbalism and traditional Chinese medicine so this question is not applicable.
- b) Acupuncture (as mentioned on page 30 of the consultation document) is currently regulated via local authority licensing that lumps acupuncture in with tattoo artists, cosmetic piercing and electrolysis (hair removal), a regime that is rudimentary in the extreme and is only concerned with acupuncture needle sterilisation and safe disposal. It plays no role in overseeing training standards, fitness to practise schemes etc and in conjunction with voluntary regulation has no jurisdiction in removing failing practitioners from practice. **The assertion (see table on page 51 of the Consultation Document) that this scheme “Could work well for acupuncture in combination with voluntary professional self-regulation” seems totally mistaken. In addition, such a scheme would not provide protection for the public in relation to herbal medicine.**

### **Question 18**

- a) Should the titles "acupuncturist", "herbalist" and "[traditional] Chinese medicine practitioner" be protected?**

We largely agree with the recommendation of the Pittilo Report that said:

The Steering Group ...recommends that the titles of 'acupuncturist' and 'herbalist' should be protected, since these are widely used, commonly recognised and simple titles that lend themselves easily to being protected.

Registered individuals who wished to add to these titles to show a particular area of practice (for example, 'Medical Herbalist') could do so, whereas those who were not registered could not use these titles, nor any title which contained the words 'acupuncturist' or 'herbalist'. In addition, the Steering Group recommends that the title 'traditional Chinese medicine practitioner' should be protected. Similarly, those who are not registered will not be allowed to use this title, nor any title which contains the words 'Chinese Medicine Practitioner'. The group recognises that there is a variety of other titles used by traditional Chinese medicine practitioners, along with Ayurveda, Kampo, and Tibetan Medicine, but believes that protecting a large number of further titles would be counter-productive in terms of public protection. It is also unlikely that legislation could protect every individual title that existing practitioners use in this field. Hence the group believes it is more practical to protect a small number of titles, recognising at the same time that this must necessarily represent a compromise, and may not be the preference of all practitioners or all professional associations.

We recognise, however, that this needs further discussion.

- b) If your answer is “No”, which ones do you consider should not be legally protected?**

N/A.

### **Question 19**

**Should a new model of regulation be tested where it is the *functions* of acupuncture, herbal medicine and TCM that are protected, rather than the *titles* of acupuncturist, herbalist or Chinese medicine practitioner?**

We do not believe a new model of regulation is necessary and agree with the Pittilo Report on this matter which says:

“Although the HPC will be protecting title and not function, the changes to Section 12(1) of the Medicines Act **1968 currently envisaged by the MHRA will regulate function so far as the practice of herbal medicine is concerned.** We do not envisage any difficulties for other statutorily regulated healthcare professionals wishing to use acupuncture, herbal medicine or traditional Chinese medicine as part of their practice provided that they ensure they are appropriately qualified.(See Sections 14 and 27). It will be important for the HPC to provide guidance to other statutory regulatory bodies with regard to minimum levels of education and training required for other professionals to practise acupuncture, herbal medicine, traditional Chinese medicine and other traditional-medicine systems.”

It should be noted that as far as herbal medicine is concerned, the Pittilo report recommended “that use of Section 12(1) of the Medicines Act of 1968 should be restricted to practitioners who are subject to appropriate statutory regulation.”

**Were this proposal to be implemented, it would, in effect, also regulate by function those using herbal medicine under Section 12(1) of the Medicines Act of 1968. We agree with this scheme.**

#### **Question 20**

**If statutory professional self-regulation is progressed, with a model of protection of title, do you agree with the proposals for "grandparenting" set out in the Pittilo report?**

**Yes, we do.**

#### **Question 21**

**In the event of a decision that statutory or voluntary regulation is needed, do you agree that all practitioners should be able to achieve an English language IELTS score of 6.5 or above in order to register in the UK?**

**We agree with the Pittilo report on this subject:** It says:

“The Steering Group is of the view that English-language proficiency is essential for all healthcare professions. We do not believe that public safety is assured through the use of interpreters whether this be in communicating with patients or with other healthcare professionals. We are, however, aware that this could cause a significant difficulty particularly with regard to the traditional Chinese medicine sector and that some practitioners who are very experienced and proficient might no longer be able to practise.

Furthermore, there are Chinese-speaking members of the community who might consequentially be denied access to traditional Chinese medicine because their Chinese-speaking practitioner was disbarred from practice due to poor English-language skills. Taking all this into account and after careful consideration, we believe that all those practising acupuncture, herbal medicine, traditional Chinese medicine or other traditional medicine modalities should be able to achieve an International English Language Testing System (IELTS) score of at least 6.5, or utilise other methods of testing to achieve an equivalent standard, by the time these professions are regulated. In the meantime, we urge organisations representing and working with Chinese-speaking practitioners and other practitioners for whom English is not their first language to work with the HPC to ensure that there is no discrimination against such practitioners whilst at the same time recognising that protection of the public health must be the paramount concern. This is facilitated through

excellent communication with patients and other healthcare practitioners to whom referral might be made or who are also responsible for treating shared patients.”

### **Question 22**

**Could practitioners demonstrate compliance with regulatory requirements and communicate effectively with regulators, the public and other healthcare professionals if they do not achieve the standard of English language competence normally required for UK registration? What additional costs would occur for both practitioners and regulatory authorities in this case?**

There should be a reasonable transition period to allow the standards of English competence to be achieved.

It is unlikely that effective communication could be achieved with regulators, the public and other healthcare professionals if practitioners do not achieve the standard of English language competence normally required for UK registration.

The costs of achieving these standards can be met by individual practitioners with some help from their Professional Body e.g. a reduced membership fee whilst undertaking English language training. See also our answer to Question 23 – a possible compromise.

### **Question 23**

**What would the impact be on the public, practitioners and businesses (financial and regulatory burden) if practitioners unable to achieve an English language IELTS score of 6.5 or above are unable to register in the UK?**

Organisations representing and working with Chinese-speaking practitioners and other practitioners for whom English is not their first language to work with the HPC need to ensure that there is no discrimination against such practitioners whilst at the same time recognising that protection of the public health must be the paramount concern.

We agree with the Consultation Document that:

“A possible compromise could be for existing practitioners who apply for “grandparenting” to be allowed to register and practise with conditions attached to their registration – that if they did not achieve the appropriate IELTS score, they could only practise using an interpreter. All new registrants applying after the initial “grandparenting” period would have to achieve the agreed IELTS score.”

### **Question 24**

**Are there any other matters you wish to draw to our attention?**

Yes, two (see below):

- 1. The question of practitioner regulation in the rest of the European Union.**

On page 24 of the Consultation Document the DH says:

“We are not aware that any other MS propose to legislate to regulate practitioners of acupuncture, herbalism and TCM. This contrast is likely to be a reflection of the position that in the UK, unlike most other MS, there is specific legal recognition of the practice of herbal medicine – there has long been legislative provision in the UK permitting herbal practitioners (undefined) to prepare and supply unlicensed herbal remedies following consultation”

We would like to comment on this as follows:

The reason why CAM has thrived in the UK (making it a world leader in this development) is due to the fact that unlike most of continental Europe, Britain was not part of the Napoleonic Empire and thus not subject to Napoleonic Code established by Napoleon in 1804 to determine civil law throughout the French Empire.

Napoleonic Code remains the basis of the legal system used by several EU Member States; Italy, the Netherlands, Spain, Portugal, Luxembourg and Belgium all cite the Napoleonic Code as the basis for their laws. Napoleonic Code has also had significant influence on the legal systems of Austria, Germany, Greece and Romania. A ramification of Napoleonic Code is that, in the countries where it applies, it would require specific legislation to enable CAM practitioners who are not doctors to practise medicine. An example of such legislation is that passed in 2003 in Portugal to regulate the practice of acupuncture, homeopathy, osteopathy, naturopathy, phytotherapy and chiropractic, which had previously been illegal by nonmedical professionals<sup>39</sup> However, for this reason, in the majority of European Member States, including France, Spain, Italy, Luxembourg, Greece and Belgium, the practice of medicine except by statutorily recognised health professionals is illegal. A corollary of this is that nearly all practitioners practising herbal/traditional medicine, TCM and acupuncture in most Member States are thus regulated health professionals (mainly doctors) and already have access to herbal remedies via Article 5.1 of the main EU Medicines Directive (2001/83/EC).

In the UK (and Ireland), on the other hand, common law precedent has allowed willing patients to be treated by non-doctor CAM practitioners subject in the UK to minor legal limitations. For example, non-doctor practitioners may not advertise that they treat cancer, Bright's disease, venereal disease and diabetes. It is because of such common-law practice, that Section 12(1) of the Medicines Act of 1968 granted rights to a herbal practitioner to supply “*a remedy for administration to a particular person after being requested by or on behalf of that person ... to use his own judgement as to the treatment required.*”

The difference between the UK and the rest of much of the European Union stems from these legal niceties. Britain has cause for considerable self-congratulation in providing a benign legal environment that has permitted CAM therapies to flourish over the past thirty years or so. For example, non-doctor osteopaths and chiropractors are statutorily regulated in the UK but not permitted to practise in some other EU countries. In addition, a number of British universities currently offer degrees in herbal and traditional medicine systems as well as acupuncture and many UK trained practitioners of these modalities are recognised as pre-

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<sup>39</sup> Dixon A. Regulating Complementary Medical Practitioners: an International Review, King's Fund, 2008.

eminent in their field. Moreover, in many EU Member States, as previously mentioned, practitioners of herbal medicine and acupuncture are registered medical doctors and so are already statutorily regulated. Because of this their regulation is not an issue. Here in the UK anyone can practise as a herbalist or acupuncturist and so statutory regulation certainly is an issue given that herbalists are able via Order 1977 (SI 1977 No. 2130) to prescribe some potent remedies such as *Atropa belladonna* (Deadly nightshade) and *Ephedra sinica* (Ephedra herb).

This historical legal difference between continental Europe and the UK is a major reason why Britain now leads the world in CAM development. As previously established, the British public want to avail themselves of treatment from well-trained herbal and acupuncture practitioners and the Government now has an opportunity further to develop this burgeoning sector by introducing statutory regulation. In this way the public can be assured that these practitioners practise according to agreed standards - prescribing quality-assured herbal medicines.

The House of Lords' Select Committee on Science and Technology and three subsequent DH-sponsored working groups have all strongly recommended that statutory regulation of this sector should go ahead as soon as possible. In these circumstances, it is to be hoped that this process will not be subject to further delay simply because Britain has a different legal system from much of the rest of the EU.

Note: Statutory regulation of sector outside the EU.

Statutory regulation of non-doctor practitioners of acupuncture and TCM is in place in jurisdictions outside the EU that are also outside the South-Eastern and East-Asian zones where TCM has wide official recognition. In Australia traditional Chinese medicine practitioners are statutorily regulated in the state of Victoria. A Chinese Medicine Registration Board was launched in 2002 under the Chinese Medicine Registration Act of 2000. The Board registers Chinese herbal medicine practitioners, acupuncturists and dispensers of Chinese herbs and conducts investigations into complaints about registrants' professional conduct. Only registered traditional Chinese medicine practitioners are allowed to use the respective title of their area of specialisation e.g. registered Chinese medical practitioner, Chinese herbalist, and acupuncturist.<sup>40 41</sup> In May 2009, it was announced that the Chinese medicine profession is to be nationally registered in Australia by 2012. The Australian Health Ministers met on 8 May 2009 and approved the inclusion of the Chinese medicine profession in the new National Registration and Accreditation Scheme for the Health Professions. The national scheme will come into effect on 1 July 2012 and will

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<sup>40</sup> *Ibid*

<sup>41</sup> <http://www.cmr.vic.gov.au/>. Accessed 19 Sept. 09

register practitioners of acupuncture and Chinese herbal medicine, as well as dispensers of Chinese herbal medicine products.<sup>42</sup>

In Canada, regulation of CAM practitioners is carried out on a territorial/provincial basis and TCM practitioners are regulated in some provinces.<sup>43</sup> For example, the College of Traditional Chinese Medicine Practitioners and Acupuncturists of British Columbia is the regulatory body established by the Government of British Columbia to regulate the practice of Traditional Chinese Medicine (TCM) and acupuncture in the Province.<sup>44</sup> Traditional Chinese medicine (TCM) and acupuncture are since 2007 also officially recognized as a health profession in Ontario.<sup>45</sup>

In the United States of America, acupuncture practice is a regulated medical service within many states. Acupuncture is licensed in 42 States and the District of Columbia.<sup>46</sup> Some states, such as California and Florida, have laws that accept acupuncturists as primary care providers. Most states allow acupuncturists to practice without a referral from another medical practitioner.<sup>47</sup>

## 2. Hierarchies within professional regulation

As a result of the Shipman tragedy, the Government decided to launch two reviews of professional regulation which were published in July 2006. The first of these reviews, *Good Doctors, Safer Patients*<sup>48</sup>, was undertaken by the Chief Medical Officer for England and the second, *The Regulation of the Non-Medical Healthcare Professions*<sup>49</sup>, was led by the then Director of Workforce for the Department of Health in England.

A noteworthy feature of these reviews is that it was perceived that we needed *two*, the former for doctors and the latter for all other health professionals. From the patient perspective, this would have made little sense as, when it comes to regulation, patients experience healthcare delivery as a whole and not as an “officers and other ranks” pecking order with doctors apparently therefore subject to qualitatively different regulatory criteria. Some of the latter group also diagnose and prescribe prescription-only-medicines (e.g. dentists and nurse prescribers): in these circumstances how could the second group be referred to as “the Non-Medical Healthcare Professions”? Statutory regulation is essentially about competence and fitness to practice and surely the same general principles should apply throughout healthcare provision.

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<sup>42</sup> Australian Acupuncture and Chinese Medicine Association. <http://www.acupuncture.org.au/news.cfm?item=47.0>. Accessed 19 Sept. 09.

<sup>43</sup> *Ibid*

<sup>44</sup> CTCMA. <http://www.ctcma.bc.ca/index.asp>. Accessed 19 Sept. 09.

<sup>45</sup> *Canadian Medical Association Journal*. <http://www.cmaj.ca/cgi/content/full/176/4/43>. Accessed 19 Sept. 09.

<sup>46</sup> Bodekar G, Ong C, Grundy C, Burford G, Shein K. *WHO Global Atlas of Traditional, Complementary and Alternative Medicine*, WHO Kobe, ISBN 978-9241562867, 2004.

<sup>47</sup> Wikipedia. *The Regulation of Acupuncture*. Accessed 17 Sept. 09.

<sup>48</sup> Department of Health 2006. *Good doctors, safer patients: Proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients*. Stationery Office, London.

<sup>49</sup> Department of Health 2006. *The regulation of the non-medical healthcare professions*. Stationery Office, London.

Such hierarchical thinking seems similarly to bedevil the question of statutory regulation of herbal/traditional medicine, acupuncture and TCM. As pointed out earlier, this attitude is implicit in the Consultation Document Question 12.

“Would it be helpful to the public for these practitioners to be regulated in a way which differentiates them from the regulatory regime for mainstream professions publicly perceived as having an evidence base of clinical effectiveness?”

Statutory regulation is not a badge of rank and clearly, as highlighted in our answer to Question 12, nor can it be considered an emblem of efficacy -whatever some may assert. Instead, it is clearly primarily a means to provide the public with the safe health services it desires, ensuring that as far as possible the practices in question do no harm.

As we have set out in our answer to Question 2, the process of evaluating herbal/traditional medicine, acupuncture and TCM for fitness for statutory regulation has been ongoing for a decade encompassing four working parties (including a House of Lords’ Select Committee report), two consultations, a number of specific MHRA proposals concerning relevant medicines law reform, as well as a call by the HPC to move to statutory regulation of this sector as soon as practicable. All of these initiatives (with the exception of course of the current consultation) have agreed that statutory regulation is the best way forward. As has been shown, the Government itself has for several years been fully committed to the statutory regulation of this sector.

**If the Government fails to deliver statutory regulation to this sector, the public, which makes great use of these modalities, will undoubtedly register this failure (no doubt noting the resultant loss of herbal remedies hitherto available for decades) and conclude that there is unwarranted prejudice being displayed against these therapies which have roots going back hundreds, even thousands of years. We urge the Government not to renege on its commitments and to bring this sector into statutory regulation. This is evidently in the public interest and, given time, may well offer real-world solutions to the growing funding crisis that faces our National Health Service.**

The EHTPA was founded in 1993. EHTPA membership is limited to professional associations which have agreed standards of conduct and are working towards the implementation of educational standards as laid down in the EHTPA common core curriculum. In the UK, EHTPA membership comprises:

**Association of Master Herbalists  
Ayurvedic Practitioners Association  
British Association of Traditional Tibetan Medicine  
College of Practitioners of Phytotherapy  
National Institute of Medical Herbalists  
Register of Chinese Herbal Medicine  
Unified Register of Herbal Practitioners**

In the case of any questions about this EHTPA submission, please contact the Chair, Michael McIntyre, via email [ehpa@globalnet.co.uk](mailto:ehpa@globalnet.co.uk). ENDS