



The College of Practitioners of Phytotherapy

13th November 2009

The College of Practitioners of Phytotherapy's Response to: A joint consultation on the Report to Ministers from the DH Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK.

The College of Practitioners of Phytotherapy (CPP) appreciates this opportunity to respond to the consultation.

The CPP is a leading professional association of "Western" herbal medicine practitioners.

This response was drafted by the CPP President Peter Conway (who sat on the Steering Group whose report this consultation considers) and then revised to include comments from CPP Council members, namely:

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General Comments

This consultation represents the culmination of many years of work since the formal process leading to this point began with the House of Lords Select Committee for Science & Technology Report on Complementary and Alternative Medicine in the year 2000. That report recommended that the professions of acupuncture and herbal medicine should become statutorily regulated and the Government concurred with the Select Committee's advice.

In the nearly ten years since the Select Committee Report was published a number of other reports have been published which have influenced the progress of the acupuncture and herbal professions towards achieving statutory regulation. These include the separate Acupuncture and Herbal Medicine Regulatory Working Group reports of 2003. Following these reports a series of delays in progress occurred as acupuncturists and herbal practitioners were asked by the Department of Health to await the outcomes of broader reports which would influence health care regulation policy more widely. Most notable amongst these latter documents are the White Paper *Trust, Assurance and Safety: the*

Regulation of Health Professionals in the 21st Century and the Report of the Working Group on Extending Professional Regulation.

The acupuncture and herbal medicine professions have waited patiently and participated constructively throughout the last decade and we now look forward to a positive conclusion to this lengthy process following the result of this consultation into the Steering Group report (commonly referred to as “the Pittilo report”) of 2008.

Over the course of the last decade a major issue has arisen which has influenced the need for statutory regulation for herbal practitioners. This has to do with the Traditional Herbal Medicinal Products Directive, which will be enforced from April 2011. From that date, if herbal practitioners are not statutorily regulated, we will lose the right to access many of the herbal products that we currently prescribe. This situation will prove disastrous not only for herbal practitioners but for the many patients who depend on herbal medicine to support their health, the businesses that supply herbal practitioners with products and the many students currently studying for herbal medicine BSc Honours degrees at UK Universities.

In the light of the above there is real urgency in the need for herbal practitioners to obtain statutory regulation in order to ensure the future of this most ancient profession so that patients and the public can continue to exercise their health care choices and access the medicines they rely upon.

It is important to be clear about the story so far:

2000 – House of Lords Report recommends statutory regulation for herbal medicine and acupuncture

2001 – The Government Response accepts this recommendation

2003 – Acupuncture and Herbal Medicine Working Group Reports published

2004 – Department of Health Consultation on the Working Group Reports shows widespread public and professional support for statutory regulation

2005 – Department of Health publishes its report on the Consultation and says that it expects to publish a draft Section 60 Order enabling statutory regulation for consultation later that year

2005 - 2008 Delays in progress justified by the Department of Health on the basis that we are to await the results of other reports that may impact on the regulation of acupuncture and herbal medicine

2008 – The Steering Group (Pittilo) Report is published recommending statutory regulation

2009 – The current Department of Health consultation on the Pittilo report is launched and introduces alternatives to statutory regulation

2010 – Department of Health is expected to deliver its verdict on the consultation

It can be easily seen from the above that the Government promised statutory regulation in 2000, then took five years to produce a report, consult on it and organise an action plan for providing statutory regulation. They then failed to deliver the Section 60 Order that was promised and have now spent another five years subjecting the acupuncture, herbal and traditional medicine professions to unnecessary delays. To add insult to injury the current (second) consultation introduces alternatives to statutory regulation at the last moment – an action that is highly inappropriate given the history of this process and the fact that the Government has **ALREADY FORMALLY APPROVED THE STATUTORY REGULATION**

OF ACUPUNCTURE AND HERBAL MEDICINE.

The Department of Health and the Government have been inconsistent and laggardly in their handling of this process and we have found this hugely frustrating. A number of questions stand to be answered: Why will it have taken ten years for the Department of Health and the Government to progress the regulation of these professions? Why has it been necessary to formally consult on this regulation **TWICE**? Why have other options than statutory regulation been introduced into the consultation at the last moment?

Despite the above, the acupuncture, herbal and traditional medicine professions have been very patient and highly co-operative and constructive in working with the Department of Health over the last decade. We now trust that those responsible for assessing the responses to this consultation and for making the decisions that arise from it will make the choice that we believe is evidently the one which will be most in the public interest – namely to statutorily regulate the professions of acupuncture, herbal medicine and traditional medicine as rapidly as the legislative process will allow but certainly before April 2011.

Specific Responses to the Consultation Questions

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?

Annex B of the consultation document provides ample evidence of the risk of harm to the public from unregulated practitioners. In the most severe cases of herbal toxicity fatalities have occurred. It is clearly a dangerous anomaly that currently any person can set themselves up in business as a herbalist or acupuncturist without any training or qualifications at all.

The Medicines and Healthcare products Regulatory Agency's 2008 document *Public Health Risk with Herbal Medicines: an Overview* states that:

“There may be an erroneous perception in some quarters that the practice of herbal medicine poses few safety issues. In fact, given that in some cases practitioners, who may be inexpert, are supplying potentially powerful unlicensed herbal medicinal products, the range of opportunities for things to go wrong is significantly greater than is the case with many other complementary and alternative medicine therapies.”

The clear risk of harm from unregulated herbal and acupuncture practitioners prompted the House of Lords Select Committee on Science and Technology to recommend the **statutory** regulation of these professions in 2000 (in their report on *Complementary and Alternative Medicine*¹). In their response to that report the Government stated that:

“The Government accepts that, at this point in their development, and bearing in mind certain public health risks, it would be desirable to bring both acupuncture and herbal medicine within a statutory framework as soon as practicable”².

It should be a matter of some embarrassment for the Department of Health and the

Government that, nearly 10 years later, they have still not delivered on this promise.

1. House of Lords Select Committee on Science and Technology, 2000. *Complementary and Alternative Medicine*. The Stationery Office.
2. Department of Health, 2001. Government Response To The House Of Lords Select Committee On Science And Technology's Report On Complementary And Alternative Medicine. The Stationery Office.

Question 2

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

Answers to Question 1 from members of the public who have used herbal medicine following consultations with voluntarily regulated herbal practitioners (i.e. practitioners who are members of well established professional bodies for herbal medicine) are likely to attest to its safety. The evidence of harm from herbal medicine is almost exclusively associated with use related to practitioners who are not included within voluntary professional registers. Raising regulation to statutory status and thereby requiring all herbal practitioners to operate within that standard will extend and strengthen public protection. By setting a minimum standard of education for herbal practitioners at BSc degree level (as the Pittilo report recommends) and making practitioners fully accountable to the Health Professions Council (as the report also advises) a huge step can be taken towards enhancing public safety.

The Medicines Control Agency's 2002 report *Safety of Herbal Medicinal Products* identified a number of areas of risk associated with herbal medicines, including: self-medication; intrinsically toxic constituents of herbal ingredients; quality related safety issues; herb-drug interactions; risks associated with specific patient groups; and failure to report adverse reactions to herbal medicines. Statutory regulation of herbal practitioners will substantially help to address these issues by: making it easier for the public to identify well trained practitioners utilising high quality herbal products; improving and standardising herbal practitioner education; and making it easier to operate a universal "yellow card" adverse event reporting scheme for herbal medicines.

The safe practice of herbal medicine rests on two key components: safe practitioners and safe herbal preparations. As the Medicines and Healthcare products Regulatory Agency's 2007 *Discussion Paper: no 1 on Reforms of s12(1) of the Medicines Act 1968* puts it:

"the competence and professionalism of the practitioner is critical as well as the quality and safety standards of the individual product."

We believe that statutory regulation is the best means of ensuring the competence and professionalism of herbal practitioners. As the Pittilo report states:

"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."

Any lesser form of regulation than that of statutory regulation will lack the standards and teeth to ensure a high level of public protection. Indeed, any less rigorous form of regulation is likely to provide space to include inadequately trained or bogus practitioners

and, by conferring a degree of spurious legitimacy on them it will INCREASE risk to the public. There is no room for half measures in ensuring the public's safety.

In the absence of statutory regulation the public will be unable to identify and easily access safe and credible experts in herbal therapy. Additionally, as a consequence of the enforcement of the Traditional Herbal Medicinal Products Directive (THMPD) in April 2011, if there is no statutory regulation the public will be unable to obtain high quality herbal medicinal products from herbal practitioners and will increasingly turn to backstreet sources and unscrupulous suppliers on the internet to obtain the medicines they desire. The sequelae of such an eventuality, given that in the worst case scenario herbal medicine products have been known to cause fatalities, could be catastrophic.

The Department of Health must ask itself:

Q. What provision is being made to ensure public access to high quality herbal medicines under the care of expert practitioners after the enforcement of the THMPD in 2011?

The answer *should* be clear:

A. Through the statutory regulation of herbal practitioners.

Question 3

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

Benefits to the Public:

The overarching aim in the regulation of health care professionals is to promote public safety. Statutory regulation is the most effective form of regulation to achieve this end and the statutory regulation of herbal practitioners will provide the following public benefits –

- a reduced risk of experiencing poor treatment or care
- setting of high standards for entrants to the profession and ensuring that practitioners undergo a high quality education to meet those standards
- the ability to easily identify well trained, safe and fully accountable herbal medicine practitioners
- easy access to an effective and transparent complaints procedure (via the Health Professions Council) should a practitioner fail to meet the required standards
- maintenance of freedom to make autonomous health care choices, including continuing access (via professional prescription) to the herbal medicinal products they require following the introduction of the Traditional Herbal Medicinal Products Directive in 2011
- potential to achieve easier access to herbal treatment given that statutory regulation may enhance health insurance cover of herbal practice and will make it easier for GPs to refer patients to herbal practitioners

Benefits to Practitioners:

These will include –

- having a continuing, and perhaps increased, capacity to meet the health care needs of

patients

- the basis to identify themselves to the public, other health care practitioners and insurance companies as having met high standards
- attainment of statutory regulation should confer the status of being considered an “authorised healthcare professional” which will enable practitioners to continue to access and commission third party products
- without statutory regulation many herbal practitioners may be forced out of business
- attainment of statutory regulation will provide a boost to the herbal profession and is likely to stimulate an increase in research that will aid development of the effectiveness of practice

Benefits to Businesses:

Statutory regulation will, quite simply, make the difference between survival and extinction for many herbal businesses. Herbal businesses are generally small to medium sized enterprises that could ill afford the reduction in revenue that would inevitably occur if herbal practitioners failed to achieve statutory regulation and hence ceased to have access to third party products.

Since statutory regulation is likely to set the ground for the expansion of the herbal profession the herbal supply businesses will benefit from the accompanying growth in demand for their products.

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?

The Pittilo report recommends that herbal practitioners should be regulated by the Health Professions Council (HPC). The costs involved with regulating herbal practitioners should be no greater than those associated with regulating other professions already included within the HPC. Appointing the HPC as regulator is not only the best option available in general terms, it is also the best in economic terms – obviating the attendant costs associated with establishing a new regulator. The cost to practitioners of registering with the HPC is currently £76 per annum. The costs to practitioners of any alternative regulatory arrangement are likely to be substantially greater.

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?

Yes it should. This is essential to ensure that statutory regulation actually improves public safety.

The Medicines and Healthcare products Regulatory Agency’s 2007 *Discussion Paper: no 4 on Reforms of s12(1) of the Medicines Act 1968: quality standards where a practitioner prepares unlicensed herbal medicines* proposes a “practitioner’s professional code as the principle means of giving the public assurance as to quality” but cautions that:

“this approach could only be applied effectively if it is possible to identify in law which practitioners are allowed to operate under s12(1); and if these practitioners are required to be held accountable for meeting the required standards by a body that has the capability of operating this oversight. Effective arrangements for enforcement of the code would be an important consideration.”

The *Paper* goes on to state the importance of statutory regulation in this regard.

Another MHRA paper - The Medicines and Healthcare products Regulatory Agency's 2007 *Discussion Paper: no 2 on Reforms of s12(1) of the Medicines Act 1968: who should be allowed to operate under s12(1)* – posed the question:

“What are the consequences if the s12(1) exemption remains open to all, including practitioners who are not subject to statutory regulation?”

The MHRA answers that this would result in:

- “continuing risk to public health...”
- “a reduction in incentives for practitioners to join any statutory register...”
- “responsible practitioners could be undercut by practitioners offering lower prices or extravagant claims...”
- “significant difficulties in successfully establishing statutory regulation of the herbal medicine profession...”
- “leav(ing) the main safeguard for the public as the message ‘buyer beware’...”

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?

These practitioners should be statutorily regulated. No other form of regulation is capable of being effective in addressing this situation.

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?

The public's access to medicines upon which they currently rely would be substantially curtailed. This would reduce patient choice and pass the burden of health care that is currently shouldered by herbal medicine elsewhere. In order to obtain the medicines that they have previously relied upon or wish to utilise, the public will be forced to turn to potentially dangerous unscrupulous suppliers. Herbal practitioners will see a substantial reduction in their scope to assist patients and consequently a drop in business – for some practitioners this drop is likely to force them out of business. We have consulted our members in the College of Practitioners of Phytotherapy (160 members) and discovered that loss of ability to commission from a third party would have a hugely negative impact on their ability to operate a viable business and to meet the health care needs and

expectations of their patients. Many members consider that they would lose revenue totalling thousands of pounds (for some above £15,000 p.a.). For many of our members this represents a large percentage loss of income and could threaten the viability of their practices. Some members consider that their loss of revenue could exceed 40% of total annual income. For those members who operate dispensaries as part of shops the loss of third party products is likely to force them out of business. There would be a further impact on the manufacturers of herbal products of course, whose businesses are also likely to prove unsustainable should the number of practitioners who can commission products from them decline.

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?

All of the alternatives to statutory regulation have substantial weaknesses and none represents a reliable and effective means of ensuring public safety. Only statutory regulation can provide a high level of public protection that is commensurate with the risks posed by acupuncture, herbal medicine and traditional medicine and engender a high level of public confidence. Additionally only statutory regulation will enable practitioners to continue to provide a full service to patients (i.e. by continuing access to third party commissioning). None of the alternatives to statutory regulation will meet with the approval of practitioners and would therefore have to be forced upon them – this situation would be highly undesirable leading to practitioner dissent, non-compliance and resistance. In practice the alternatives suggested here would prove totally unworkable.

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?

The alternatives suggested in Q8 are likely to prove more costly than statutory regulation since they would require new initiatives to be created and a new system of overseeing to be established. Statutory regulation with the Health Professions Council requires no new layers of infrastructure or policing since the HPC are already established to provide statutory regulation. The costs to the public and to practitioners of the alternatives suggested in Q8 could be substantial and, in the case of practitioners, the cost could be unfeasible – certainly it would be hugely more than the cost of annual membership of the HPC. None of the alternatives proposed in Q8 are practically workable and would meet huge practitioner resistance – it would be very difficult to sell these alternatives to practitioners and any scheme other than statutory regulation would likely require continuing costly reworking in order to attempt to overcome practitioner demands and resistance.

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?

There would be no benefits; rather the public, practitioners and business would all suffer losses. The public would be deprived of the opportunity to gain enhanced protection from unscrupulous practitioners and suppliers and they would lose access to third party medicines in 2011. Practitioners would lose access to third party medicines and many would go out of business. Herbal medicine related businesses would lose huge amounts of income forcing many to go bust. The only winners in this scenario would be the ideological opponents of complementary and alternative medicine, and dodgy herbal medicine suppliers who would be quick to exploit the unmet consumer demand for herbal products – with potentially disastrous consequences. Should anything other than statutory regulation be established this will serve as a green light to such companies.

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 three practitioner groups justify statutory regulation and should be statutorily regulated together.

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?

It is inaccurate to maintain that “mainstream professions” possess an “evidence base of clinical effectiveness” whereas practitioners of herbal medicine, traditional medicine and acupuncture do not. The evidence base in all cases (mainstream and herbal/traditional/acupuncture) is both incomplete and open to debate but there is no essential disparity between the two groups – evidence exists in both sectors and more can be generated in each sector. It should not be assumed that the evidence base in conventional medicine is necessarily superior to that in other health care sectors.

The originators of the concept of evidence based medicine defined it as “the integration of best research evidence with clinical expertise and patient values.”¹ This is a means of operating that is as available to the herbalist/acupuncturist/traditional medical practitioner as to the mainstream medical practitioner. Phytotherapy, for example, presents an approach to the practice of herbal medicine that is founded on engagement with the “evidence base of clinical effectiveness” and which actively promotes extending this base.

Attempting to regulate on the basis of differentiating between “mainstream professions” and herbal medicine/traditional medicine/acupuncture in terms of their evidence base is scientifically unjustifiable. Such regulation would create and then enshrine an artificial divide that would have significant negative outcomes since it would manufacture an inaccurate representation of herbal medicine/traditional medicine/acupuncture that would serve to inhibit rather than to advance the development of the evidence base in these fields. Such regulation would, in effect, ghettoise these approaches as “non-evidence based” – an assertion that is untrue. Regulation should be based on a sober assessment of the facts and not by recourse to stereotyping or prejudice.

It should be noted that the Pittilo report recommended that herbal/traditional medicine/acupuncture practitioners should be statutorily regulated by the Health Professions Council. **The fields of herbal medicine/traditional medicine/acupuncture arguably have a more substantial evidence base than some of the professions already statutorily regulated by the HPC!** This provides a further reason why creating a new regulator based on the lack of an evidence base would be unjustifiable and untenable.

Additionally the premise of this question fails to account for the complexities and controversies surrounding the notion of evidence based medicine (EBM). Questions and concerns about the credibility and applicability of EBM exist within the “mainstream professions” as well as outside of them. For example Tracy² found that doctors’ concerns about EBM included:

- EBM “as a devaluation of the ‘art of medicine’ and a threat to their professional/clinical autonomy”
- “issues of credibility, bias, and the trustworthiness of evidence (especially) regarding the role of the pharmaceutical industry in the funding and conduct of clinical research”
- the case that “patients’ preferences are often at odds with the evidence”
- the frequent lack of a “clear consensus within the literature” and the occurrence of “directly conflicting evidence”
- the lack of fit between research aims and the realities of practice; one interviewee commented: “I can see lots of conflict between the goals of a study and the goals in real life”

Such concerns belie the wisdom of any attempt to regulate or segregate professions on the basis of “evidence” alone.

1. Sackett, D.L.; Strauss, S.E.; Richardson, W.S.; Rosenborg, W.; Haynes, R.B. 2000. *Evidence-Based Medicine: how to practice and teach EBM*. Churchill Livingstone.
2. Tracy, C.S.; Dantas, G.C.; Upshur, R.E.G. Evidence-based medicine in primary care: qualitative study of family physicians. *BMC Family Practice* 2003;4(6).

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 ?

The supreme principle of statutory regulation is that it serves to protect the public. As such the statutory regulation of professions cannot operate in terms of a balance sheet (one profession in, one out). The premise underlying this question is therefore highly questionable.

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?

As recommended by the Pittilo report, The Health Professions Council should regulate all three. In the White Paper *Trust, Assurance and Safety: the Regulation of Health Professionals in the 21st Century*¹ it was stated that: “the Government will not establish any new statutory regulators.” Of the existing statutory regulators the Health Professions Council is clearly the one best suited to regulate all three professions. The HPC was represented at the Steering Group meetings and has been very supportive of all three professions being regulated by them. You will have received a response to this consultation document from the HPC in which they clearly state that they should be the regulator for these three professions. The HPC have also written to the Secretary of State for Health to recommend that the three professions are regulated by them.

1. Secretary of State for Health. 2007. *Trust, Assurance and Safety: the Regulation of Health Professionals in the 21st Century*. The Stationery Office.

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?

The Health Professions Council should regulate herbal medicine and traditional Chinese medicine practitioners – along with acupuncture. The General Pharmaceutical Council/ Pharmaceutical Society of Northern Ireland are not suited to act as a statutory regulator for herbal practitioners. Statutory regulation by the Pharmaceutical bodies has no support either from the herbal or pharmacy professions and any suggestion that this might occur would likely meet considerable objections from both sides. The Pittilo report considered whether herbal practitioners might be regulated alongside pharmacists and concluded that:

“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.”

The Pharmaceutical bodies have a specialist regulatory interest whereas the HPC represents a broad range of professions and has the capacity to extend that range. The White Paper referenced in the answer to Q14 indicated that most new professions should be regulated by the HPC because the HPC was “designed for this purpose and (has) the most expertise in bringing new professions into statutory regulation and also in regulating a wide range of professions within a common system.” The Pharmaceutical bodies have no such capacities.

Question 16

If neither, who should and why?

The Health Professions Council should regulate all three professions.

Question 17

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

No it should not. There is no reason why these professions should be regulated differently. The HPC is the most appropriate regulator for all three.

Further than this it is essential that all three professions are regulated together since a significant number of acupuncturists also practise herbal medicine. Should the herbal and acupuncture profession be regulated separately considerable and unnecessary problems are likely to arise connected with dual registration. In addition separate regulation would complicate and problematise the effective regulation of herbal medicine. Separate regulation is not in the best interest of public safety.

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

No it cannot. Only statutory regulation offers the appropriate level of public protection appropriate to this profession.

Question 18

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

b) If your answer is "No", which ones do you consider should not be legally protected?

These titles should be protected since, as the Steering Group Report observed: "these are widely used, commonly recognised and simple titles that lend themselves easily to being protected."

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?

No, there is no evidence to suggest that protection of functions offers greater benefits in terms of assuring public safety than does protection of titles. Protection of function is generally dissatisfying to the public (since it is highly confusing given that regulated practitioners cannot be clearly identified by their title) and to practitioners (since non-regulated practitioners would be allowed to use the same title as the regulated practitioner and it would be very difficult for regulated practitioners to assert their identity and authority). Since protection of function is highly confusing for the public it mitigates against the key goal of regulation – which is public protection. There is no credible rationale to recommend using the three professions as guinea pigs for a new form of regulation and testing a new model is likely to be much more costly than using existing established mechanisms of statutory regulation as provided by the Health Professions Council. Protection of function has no support from the professions concerned in this consultation and coercion would be required to force them to submit to such regulation.

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. The Pittilo Report observes that:

“In addition to individuals making their applications for registration, and being assessed individually, there is also the possibility for *bona-fide* members of voluntary registers to be transferred directly onto the HPC Register without having to go through such individual registration.”

We agree that the HPC should take steps to assure themselves of the credentials of voluntary registers and then to admit members of worthy registers en masse. This will reduce costs and administration for both the HPC and practitioners.

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?

Yes we do. We agree with the Pittilo report recommendations in this regard.

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?

We believe that practitioners can only comply with regulatory requirements and professional levels of communication if they are competent in using the English language.

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?

This is hard to estimate since it is unclear how many such practitioners exist in the UK. This highlights a problem enabled by the current lack of statutory regulation – since there is no legal requirement for practitioners of the three professions to be registered it is impossible to be clear who is practising (outside of the current voluntary registers). It is essential that statutory regulation be achieved in order to address this situation.

In order to help practitioners make the transition from an inadequate IELTS score to an appropriate one we agree with the suggestion made by the authors of the Joint Consultation document:

“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?

A. The complexity of this consultation document.

This consultation document is highly complex and represents a technical consultation that is difficult for members of the public to respond to. We have had many reports from members of the public who have attempted to respond to this consultation stating that they found it very difficult to understand and to reply to. Although many of the matters under discussion here are necessarily technical in nature we regret that the document did not provide more specific and tailored opportunities for the public to express their opinion.

B. The purpose of regulation.

The *Report of the Working Group on Extending Professional Regulation*¹ stated that:

“The primary purpose of regulation is to secure safe, effective, high quality, and respectful care for the individuals who depend on health care staff for their health and well-being.”

Some ideological opponents of the regulation of the three professions maintain that statutory regulation amounts to a form of state approval or official legitimisation of practices, which these opponents consider to be in some manner inherently illegitimate. This is an erroneous assertion and should not be allowed to obstruct statutory regulation to be enacted in line with its true purpose of providing public protection. The *Report of the Working Group on Extending Professional Regulation* advised that:

“When considering all the factors at play that drive professional and occupational groups to seek regulation the Working Group recommends that safety of patients and the public, as well as enhancing effective, high quality, and respectful care, are the legitimate benefits to be considered in assessing whether to extend professional and occupational regulation. The Working Group felt that respect, respectability, status and legitimacy was earned from the public rather than conferred by statutory regulation...”

We agree with this assessment.

C. Responses against regulation.

Over the course of the decade since the House of Lords Report on Complementary and Alternative Medicine and the Government Response to it, it has become fashionable in some quarters to attack complementary and alternative medicine (CAM) as part of an ideological assault on forces that are seen to be “anti-science” or “anti-rational.” This is, paradoxically, a non-scientific and non-rational position. “CAM” is not a unified movement but a label applied to a complex social phenomenon, which encompasses a heterogeneous group of practices. Some notionally “CAM” practices, such as acupuncture, herbal and traditional medicine have an ancient history (in fact it is interesting and notable that the three professions under discussion in this consultation represent the oldest forms of medicine not just in “CAM” but *on earth*). These three professions also have (contrary to what their ideological opponents would have you believe) a surprisingly large scientific

evidence base when one accounts for the fact that these professions have until recently existed outside of formal educational and research-linked institutions (in the West), and without recourse to the huge financial resources that are available to mainstream medicine.

Nonetheless a very small number of strident voices persist in taking an ideological stance against all forms of “CAM.” We are aware that such opponents of CAM will have responded negatively to this consultation. Mass negative responses of this type are now engendered particularly by a very small number of ant-CAM internet bloggers – a phenomenon that has developed over the latter part of the last decade. These bloggers have significant power to throw a spanner in the works of consultation processes such as the one at hand. The motivation of respondents of this type must be appreciated as one that is fundamentally ideologically opposed to “CAM” – no action that could be construed as promoting the interests of CAM professions will ever be acceptable to this group. We urge the Department of Health and the Government to have the courage to resist such ideological and prejudiced representations.

D. The necessity of linking regulation with other developments in legislation.

Regulation of professions does not take place in a vacuum and the case of herbal practitioners illustrates that point especially well. The change in legislation made by the Traditional Herbal Medicinal Products Directive has direct implications for the way in which herbal practitioners are regulated. Anything short of statutory regulation for herbal practitioners will fail to ensure our continuing right to access and prescribe a full range of herbal medicinal products to meet the needs of our patients. This would have a major adverse impact on patients, practitioners and businesses (as explained above). We believe that recent major works looking at regulation (such as the *White Paper Trust, Assurance and Safety: the Regulation of Health Professionals in the 21st Century*² and the *Report of the Working Group on Extending Professional Regulation*¹) have failed to adequately recognise, anticipate or account for situations such as the one that we as herbal practitioners find ourselves in. We trust that the assessors of this consultation will take the special features of the herbal practitioners’ case into account.

E. Should statutory regulation not be awarded.

The Department of Health and Government Ministers should be left in no doubt that herbal practitioners have a high level of expectation that we will be awarded statutorily regulated status. This is not from any arrogant sense of entitlement, far from it – rather this expectation stems from a cold reading of the history of this process since 2000 and of the criteria by which worthiness for statutory regulation is assessed. Should the Government fail to award statutory regulation we will not take the decision positively and we will not accept it meekly. Rather we would be entitled to assert that, after ten years, the Government had reneged on its promise and had capitulated to pressure from prejudiced sources. We very much hope that such a scenario will not occur.

1. Department of Health. 2009. Extending Professional and Occupational regulation: Report of the Working Group on Extending Professional Regulation. DH Website.
2. Secretary of State for Health. 2007. Trust, Assurance and Safety: the Regulation of Health Professionals in the 21st Century. The Stationery Office.

We trust that you will find these comments helpful in forming your decision. Should you wish to discuss any aspect of this response with us then please do not hesitate to contact us.

Yours sincerely

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Iman Amanpour, Council Member

Dr. Saul Berkowitz, Council Member

Kristin Jeffs, Director

Alex Laird, Council Member

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