SAVE OUR HERBS

The Campaign for the Protection of Herbal Medicine

Draft Response to the 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 Systems Practised in the UK.

Please note our responses concentrate on the concerns regarding herbal medicine and the regulation of herbalists. As a campaign group, 'Save Our Herbs, The Campaign to Protect Our Traditional Herbal Medicines', it is not appropriate for us to cover all issues regarding all professions. However, members of the campaign group may wish to comment separately on these issues.

We would also like it noted and amended that Western Herbal Medicine is also a traditional medicine system and is also one of the oldest medical systems. Unfortunately a number of our Western Herbal Medicine 'representatives' deny the Traditional Western Herbal system and have therefore not represented us satisfactorily.

We welcome the Governments foresight to provide yet another consultation document regarding the regulation of herbal medicines and herbalists. Whilst the process, for the last ten years towards the state regulation of herbalists, has been a total waste of the tax payer's money, a financial burden to herbalists and has caused unnecessary anxiety within the herbal world, at last, it seems that the Government is questioning the reasoning behind the Statutory Regulation of herbalists and changes of the 1968 Medicines Act. We do, however, feel concern that this may be for the wrong reasons with certain media and sectors of the scientific world influencing the Governments seeming change of heart. It is of some considerable concern to us that the current trend regarding 'scientific' research, is often of poor quality and unsuitable for herbal medicines, and yet has been repeatedly reported in the mainstream media as proven fact. It strikes us that 'science' is currently being used as a political tool. This, coupled with the heavy involvement from representatives of the pharmaceutical industry within all health advisory bodies, causes a problem regarding conflicts of interest and policies that stand to benefit the pharmaceutical companies. At the same time it is having an adverse affect on the public's freedoms, smaller industries and health professionals. It is with this in mind that we question why the statement 'benefits are unproven or controversial……' has been used and presumably includes herbal medicines?

It is disappointing to note once again that the vast amount of stakeholders who are intended to participate in this consultation are from a totally different medical system, who train and practise under a totally different philosophy and use completely different treatments to those under discussion. The heavy bias this brings to discussions within committees, reports, consultations and future regulation are concerning.

One of the oft quoted remarks as a reason for regulation is that there is not a definition of a herbalist defined in law. We would argue that there is a sufficient definition enshrined in law; Henry VIII's, 'Herbalists Oath' *'……having knowledge and experience of the nature of Herbs, Roots, and Waters…to practise, use and minister…without suit,,vexation, trouble, penalty, or loss of goods…'* and this is further supported by many prohibitions defining what a herbalist is not and cannot claim to be.

We are pleased to note that the Government will now look at risk –v- regulation, will not make assumptions and will not regulate a profession for any other reason than they feel it is vital for the public's safety.

However, we would challenge that the Government is still making assumptions presumably based on ill-founded or biased advice. As far as we are aware there has not been any research to ascertain whether state

regulation or any other suggested regulation increases public safety and would argue that the reverse may be true. The heart of safety lies in; a) ethical and moral codes of individuals b) the public having access to unbiased facts c) the public having confidence in themselves and being allowed to make choices. 'Risk' has not been defined or evaluated and assumed risk can also vary greatly from actual risk. It would seem that as tools to define and assess risk have not been finalized, this consultation is premature. In the UK, many people are very concerned with the amount of over regulation and the 'nanny state' situation. As reasonably intelligent beings and as part of the animal kingdom, we need and have to take risks. Eliminating all risk is not possible, warranted or wanted. The UK public wants to be able to have freedom of choice and do not want the Government restricting their freedoms with the false hope of eradicating all risk. We could all write a long list of the possible risks of playing conkers, crossing the road, climbing a tree or cooking a meal but it doesn't mean we need legislation to prevent us from doing these things. Under the heading 'Issues for Discussion and Questions' pg 20, 'risks' to consider are products, people, premises and providers. All of these things are already covered under current statutory laws to ensure the publics safety. Furthermore, 'Risks' of products refers to misidentification, adulteration, labeling. Not only are these already covered under current laws but these problems we would argue are also possible 'risks' within any situation where food or drink is supplied to someone else, from homemade jams sold at the WI stalls to restaurants and supermarkets. We do not statutorily regulate chiefs because they use mushrooms or chilli in their cooking, yet both could potentially be adulterated or misidentified. It is also worthy of note that knowledge of the potential interactions between pharmaceutical drugs and herbal medicines equally applies to those prescribing pharmaceutical drugs. When someone is taking herbal medicines, anyone prescribing pharmaceutical drugs should not do so unless they have sufficient knowledge of herbal medicines.

It is of great concern that our Traditional Medicine systems, which have all survived for thousands of years, are now being demonized, judged as pharmaceuticals and streamlined into mainstream standards and philosophies. People should be enabled not disabled by fear; equally fear should not be used to warrant restrictions on freedom.

We note with some disbelief, that whilst SR, including protection of both title and function and, further restriction of herbal medicines, are being considered, the Government conversely has ruled out the need to SR botox, dermal filler and cosmetic treatments.

The Traditional Registration Scheme (enacted into UK law 2005/EU THMPD) plus further Regulation and restriction of our herbal medicines is ludicrous. Plants grow in our garden, our countryside and our towns. A few of them need to be used with care, many are also used as foods. Are we to restrict the sale and use of all plants that contain, amongst hundreds of chemical constituents one or two 'dangerous' ones? How do we define a food, a medicine and a poison and at what point do they change from a food to a medicine to a poison?

How can we have consistent and coherent policies regarding healthcare when considering the issues raised in the previous two paragraphs?

There is some contention amongst the herbal world as to whether non-plant based medicines should be included under herbal medicines. This is not to say that these medicines should not be used but that a separate classification is needed to enable the public access to clear choices.

Many Herbalists from all traditions have felt unrepresented in this whole process (please see answer to Q24. below).

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?

As far as we are aware, there is not any evidence of harm to the public. Replies received from the MHRA and DH, our combined clinical experiences and research that we have undertaken cannot point to any evidence of harm. There has possibly been the odd one or two who have broken current laws. History, common sense and current problems like knife crime, gun crime, cocaine, alcohol, drink driving and cannabis, shows us that we cannot prevent those who wish to break the law from doing so by adding new laws. Many laws, it would seem do not prevent crime but merely provide a reason for punishing those who break them.

It would seem that few problems associated with herbal medicines are also related to the breaking of current legislation or non-traditional preparations.

All statutory laws should be based on commonly accepted ethics and morals, guided by common law, with minimal impact on personal freedoms.

Government should not be swayed by popular press articles or any conflicts of interest.

Question 2
Would this harm be lessened by statutory regulation? If so, how?
What are the disadvantages associated with introducing statutory regulation?

This question is biased, starting with the assumption that the answer to Q1 found there was evidence of harm!

As far as we are aware there has not been any research to ascertain whether statutory regulation lessens harm. Based on recent and current knowledge, we cannot see that statutory regulation would lessen any harm; in fact the reverse would seem to be true. Traditional herbalists have an exemplary safety record. Contrary to popular myth there are many laws which aim to ensure the public are protected from unscrupulous people. These laws ensure, as much as possible, that herbalists behave honestly, ethically and morally.

The disadvantages associated with introducing statutory regulation are vast and include:

- Loss of traditional philosophies and diversity of practice due to orthodox standards in education, science and CPD.
- Loss of experienced and highly qualified herbalists due to refusal on moral grounds to become Statutory Regulated and orthodox standards being set for entry onto a state register that do not allow for the true judgment of quality and experience. Existing patients of these practitioners would lose their chosen health practitioner which could lead to unnecessary adverse effects on their health, possibly putting their lives at risk.
- Protection of function will criminalise the above practitioners; an underground body of practitioners would likely emerge.
- Likely loss of our Traditional medicines in favour of 'phytomedicines' due to ever increasing tendencies to allow mainstream 'science' to demand unsuitable research, distortion of 'scientific' research, biased and uneducated media reports, governmental agencies and advisors being very

heavily influenced by the pharmaceutical companies, lack of common sense, ridiculous EU and Codex regulations.

- Large numbers of the public have lost confidence in the Government, statutory regulated health systems and professions. It is an assumption that SR increases safety and the reverse would actually appear to be the case.
- The state regulatory body will be based on a system whereby the majority of board members will be from professions who do not share the same philosophies or training and will be biased towards orthodox standards and philosophies that may be inappropriate, restrictive and damaging.
- State regulation will be extremely and unnecessarily expensive to the tax payer, as are all these repetitive committees, reports and consultations.
- Statutorily regulation can encourage elitism and arrogance; two traits that we believe do not go hand in hand with safe practitioners or caring for the wellbeing of others.

Question 3
What do you envisage would be the benefits to the public, to practitioners, and To businesses, associated with introducing statutory regulation?
The only advantage would seem to be an increase in jobs, the workforce needed for the extra bureaucracy and court cases,

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?
After ten years of the tax payer's monies being used for umpteen committees, consultations and reports should this not have been ascertained already?
The regulatory burden and financial costs of SR would be immense; many small businesses would fold causing a great loss to the public, future generations and adding to the unemployment burden. Add to this the disastrous effects that the THMPD legislation had and will have, it would seem not excessive to assume traditional herbalists and traditional medicine suppliers will be all but extinct.
Regulatory burden and financial costs of statutory regulation could not be justified unless a definition of 'risk' and what is an accepted 'risk' were ascertained. Also, the "actual" and not the "assumed" benefits of SR need to be stated. Neither of these things have been achieved, therefore the burden is not justified.

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?
No, the right to prepare and commission unlicensed herbal medicines should not be restricted to SR Practitioners. Traditional herbal medicines have been used for thousands of years all over the world, in a variety of situations from home use prescribing for the family, to prescriptions from herbalists, naturopaths, nutritionists, aromatherapists, homeopaths and until relatively recently the medical

establishment also prescribed them. It is the people's medicine. Herbalists do not own herbal medicine and there is no evidence that traditional herbal medicines are a cause for concern. How can you ban something that people can make in their own kitchen, which are often used as foods and grow in our gardens?
The vast majority, if not all pharmaceutical drugs available OTC cause side-effects, some of which can be life threatening. If people are trusted to be perfectly capable of taking responsibility when using these OTC drugs, mothers prescribing 'Calpol' to their children, advising 'Paracetamol' to their ill husbands, 'aspirin' to their elderly parents, how then can one legislate against the preparation, prescribing and use of unlicensed herbal medicines like chamomile?

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?
Prior to the introduction of the Traditional Herbal Medicines Registration Scheme in 2005 (EU THMPD) the 1968 Medicines Act, coupled with various other laws was sufficient to keep the public protected. The 1542 Herbalists Oath defines what a herbalist is and despite the 'quacks', herbal medicines has an exemplary safety record. Unlike, pharmaceutical drugs, the vast majority of herbal medicines are very safe with no side-effects. The vast majority of herbal medicines have also been used as food at some point in history, which is what makes the current trend towards unfounded regulation ridiculous. When is a herb a food and when does it become a medicine? Popular 'scientific' research and certain groups of herbalists would have us all believe that herbs are very dangerous. We must ask ourselves what they stand to gain by issuing such a message. Common sense is needed - are we going to ban potatoes and tomatoes because they contain harmful alkaloids?
If these previous laws have at times broken, this does not infer we need more laws but that we need to uphold current laws.
The danger of genetically modifying herbs and foods is of much greater concern to our safety, our plants and our environment. Yet the Government continues to pursue these avenues.

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?
Many small businesses and practitioners, especially those practising or manufacturing medicines from non-indigenous traditional medicine systems would collapse. These systems tend to commission medicines from a third party to a greater extent than the Western Tradition.
The public using these practitioners and medicines would inevitably suffer greatly from loss of their healthcare and in some cases this could be life threatening. Due to the EU legislation the public will see herbal medicines wiped from our shelves, taken from practitioners, with the likelihood that the only so called 'herbal medicines' available will be owned by multinational companies, who will be the only manufacturers and suppliers able to afford the extreme legislation and licensing system.
The public, our patients, the environment, traditional medicines, choice, access and freedom will all suffer from this ridiculous legislation that uses a sledge hammer to crack a nut.

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?

This question carries the above mentioned assumptions. It assumes there is a risk of harm to the public without any evidence. It is strange that you refer to statutory professional self-regulation (SSR), now that the proposals are not for SSR but have changed to SR.

We reiterate the laws pre 2005 EU legislation were sufficient to safeguard the public. Voluntary regulated systems work extremely well and do not need changing. There is always room for evolutionary improvements and these should be able to evolve naturally.

Regulation can never eradicate those intent on breaking the law as we so often see in our regulated professions.

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 Q8?

Product Regulation; Herbal medicine is totally different from pharmaceutical drugs and therefore cannot and should not undergo the same procedures and licensing criteria. THMPD (Traditional Herbal Registrations) should not have been enshrined in UK law. It will wipe traditional herbal medicines from the shelves, put small cottage industries out of business and hand the market over to pharmaceutical and multinational companies. As previously stated misidentification, adulteration and labeling problems can occur whenever food, drink or drugs are being given/sold to another, and at times this can be serious. We cannot legislate to prevent this as we so often see within the regulated industries. Schedule three herbs provide restriction of those herbs that should only be prescribed by someone '*having knowledge and experience of the nature of Herbs, Roots, and Waters* and this should remain so. THMPD needs to be scrapped, the 1968 Medicines Act needs to be returned to its pre 2005 state regarding herbal medicine and herbalists and left alone. The MHRA should not regulate herbal medicines but a separate body set up. The MHRA is funded by pharmaceutical companies and cannot regulate herbal medicine impartially.

We should withdraw from the EU if needs be to ensure that we keep our unlicensed herbal medicines for use by non-SR herbalists. It is vital for our freedom, our health, choice, access, environment, traditional knowledge, OUR FUTURE that we keep the people's medicine.

System Regulation – Current proposals have come about due partly to the lack of policing current laws and partly due to horrendous problems within the statutorily regulated sectors. How can this work? This resembles the popular Government trends applied to teachers/schools, hospitals etc, forcing everything to concentrate on inspections, reaching goals etc. This does place a huge pressure on professionals, takes the focus away from providing care to continually having to attain and be granted approval. This is totally inappropriate considering that the vast majority of herbalists work in the private sector and market forces (word of mouth/patient approval/success) determine who is able to continue to practise.

Voluntary regulation – Works very well and should be allowed to continue as it is. As stated previously, market forces (word of mouth/patient approval/success) work very effectively within the private sector. There are plenty of existing laws (Common and Statutory) to protect the public, even when practising

outside of a voluntary register. Standards, education and CPD can be set which are appropriate to traditional practise as opposed to mainstream philosophies and standards. Professional self interest trumpets public protection in state regulated professions and it is doubtful whether this can ever be truly and completely wiped out. In the private sector the public should and are able and capable of choosing for themselves. Better Public Information can only be applauded but with the proviso that this information should be factual and come from the professions in question. Biased information would be extremely damaging to patient choice and practitioners and should therefore be avoided.
Voluntary regulation by independently accredited registration body – Similar problems will arise as for SR due to trying to apply the standards of education, fitness to practice and CPD from one philosophy to another as seen with the new CMA voluntary body. As stated previously existing laws are sufficient to protect the public. Ironically, the whole processed towards SR has led to an exodus of practitioners away from their voluntary associations due to lack of representation and disagreements with the current drive towards SR.
Legislation on Health and Safety/Trading Standards/Advertising Legislation – As stated these laws help protect the public and coupled with other existing laws are sufficient. If acupuncture, herbal medicine or TCM will not be seen as a priority for health and safety and trading standards officers, then presumably this is because they are not posing a problem.
Local authority licensing – Works well for acupuncture. Other current laws are sufficient to protect public in relation to herbal medicine and TCM.
Statutory Licensing Scheme – Totally alarming proposal. Reminds one of the Governments new ability to hold a suspected terrorist without charge and the mandatory introduction of ID cards. Too ridiculous to merit answer!
Voluntary Licensing Scheme – As above

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 answers to question 9.

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 do not justify statutory regulation due to absence of any definition of actual risk and absence of any proven risk from these practitioners.
Statutory regulation would lead to dire consequences for our traditions and medicines, as stated above.
The 1968 Medicines Act (pre 2005 legislation), Henry VIII charter, current Common laws and Statute laws are adequate to protect the public.

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?

Please explain and define this statement 'evidence base of clinical effectiveness?' This statement would seem to be either making assumptions based on biased and inadequate information or deliberately misleading the public.

For the above reasons, it would not be helpful but very damaging and consistent with the current trend to discredit herbal medicine, traditional medicines and our traditional practises.

We would urge the UK Government to consider science as a broad church; often used at present as a political tool, a good Government would not be swayed by such political tools but would seek the truth.

To ascertain whether something has an evidence base of effectiveness, the first question has to be what is classed as an evidence base?

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 question would seem ambiguous and we therefore cannot answer.

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?

The HPC *should not* regulate any of these three professions.

Question 15

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

Neither the HPC nor the General Pharmaceutical Council/Pharmaceutical Society of Northern Ireland should regulate the above practitioners. Statutory regulation of these professions should not take place.

Question 16

If neither, who should and why?

Statutory regulation should not take place for these practitioners. Voluntary regulation as it is now is sufficient.

Question 17

a) **Should acupuncture be subject to a different form of regulation from that for herbalism and traditional Chinese medicine? If so, what?**
Our understanding is that acupuncture is a part of traditional Chinese medicine and therefore cannot be separated without compromising and diluting the traditional philosophies and knowledge.
None of these practitioners should be statutorily regulated.

b) **Can acupuncture be adequately regulated through local means, for example through Health and Safety legislation, Trading Standards legislation and Local Authority licensing?**
Acupuncture is part of a traditional medicine system, as above. Current laws are sufficient.

Question 18

a) **Should the titles "acupuncturist", "herbalist" and "[traditional] Chinese medicine practitioner" be protected?**
No, as the Government has previously stated the term 'herbalist' is generic and cannot be protected. Presumably the same is true for the other two.

b) **If your answer is "No", which ones do you consider should not be legally protected?**
All should not be legally 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? 37

Definitely not, this is ludicrous. Common sense would surely not allow such a bizarre legal action. The 'function' of a herbalist is not and has never been throughout human history, confined to a particular profession. Throughout history, the prescribing of herbs has occurred on all levels, through all cultures, through all classes and through all races. Herbal Medicine is the People's medicine. This is as ludicrous as protecting the function of a green grocer.

As far as we are aware, there has never been a vote to protect the function of these practitioners within these professions. The Steering Group report did not therefore seek to represent our professions in this matter and the consequences of such an act would likely lead to a massive underground movement and the criminalization of many excellent practitioners.

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?

We do not believe in statutory professional self-regulation or statutory regulation and understood the Steering Group report to refer not to self-regulation but to state regulation, regulation by the HPC. Automatically transferring individuals from an accepted voluntary register to a statutory register would seem to be completely at odds with the purported reasons to introduce state regulation. If voluntary regulation is considered safe, let it continue. If it is not, then how can you transfer practitioners from an existing voluntary register to a statutory one and ensure safety?

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?

Regardless of regulation, it is our belief that in order to practise in the art of any healing profession, including mainstream medicine, traditional herbal medicine, acupuncture and traditional Chinese medicine should be able to communicate with those who they are treating. This is not to say that it is necessary to speak English but that it is necessary to speak the same tongue as those whom you are treating.

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?

Yes, it should be up to the practitioner to ensure an available interpreter to communicate where needs be.

Question 23

What would the impact be on 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 surely is a question that should have been answered by the Government a long time ago and prior to this further consultation.

We would imagine the impact to be vast on those practitioners, their suppliers, their patients and the population that currently seeks their services.

We would also imagine that these practitioners would either cease to practice, thereby endangering their patient's health or they would continue illegally. Both of these scenarios would have a tremendous impact on the financial and regulatory burden of the UK and raise serious safety concerns.

Question 24

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

We would welcome a meeting with the DH to discuss these issues in more depth.

Responding to the consultation: The consultation will conclude on 3rd November 2009.

Our preferred method for receiving your responses is via the automated response system, you may also respond in writing to the AHMTCM team at the address below.

Please indicate whether you are replying as an individual or on behalf of an organisation or group of people. Your response may be made public but if you would prefer it to remain private please make this clear in your reply.

- **Contact:**

  AHMTCM Consultation Team

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- Automated response system (opens new window)