

23 October 2009

HPC'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 Health Professions Council welcomes the opportunity to respond to this consultation.

The Health Professions Council (the HPC) is a statutory UK wide regulator of professionals governed by the Health Professions Order 2001. We regulate the members of 14 professions, called 'registrants'. We maintain a register, set standards for entry to our register, approve education and training programmes for registration and deal with concerns where a registrant may not be fit to practise. Our main role is to protect the health and wellbeing of those who use or need to use our registrants' services.

We have provided general comments in response to the consultation as well as responses to the questions within the document.

General Comments

The consultation we are responding to takes forward the Steering Group report on the regulation of Acupuncture, Herbal Medicine and Traditional Chinese Medicine.¹

We have a 'new professions process' by which we can receive applications from professions seeking regulation. Applications are normally made by professional organisations representing the interests of members of the profession. We look at each application against published criteria and can recommend to the Secretary of State that the profession is regulated.

In most cases, we would normally expect an application for regulation to be made. However, in some circumstances, the Council may wish to make a recommendation in the absence of an application, where it considers that this would be in the public interest.

In September 2008, the Council considered the report as an application under the new professions process. The application was assessed against the new professions process criteria, which includes whether there is a potential for harm,

¹ Report to Ministers from the Department of Health Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK

whether the professions had a discrete body of knowledge and whether there is evidence of efficacy. The Council recognised that each of these professions had a potential for harm and that the professions fully met most of the new professions criteria. As a result, the Council recommended that acupuncturists, medical herbalists and traditional Chinese medicine practitioners should be regulated. Our answers to the questions within the consultation document are based upon this recommendation.

We note that the consultation document takes account of work undertaken by the Extending Professional and Occupational Regulation Working Group and the group's report published in July 2009.² This report lays out a number of principles which the working group believed should guide considerations on extending regulation to professional and occupational groups within healthcare. These include that regulation should:

- be proportionate to the risk to patients and the public;
- command the confidence of the public and registrants; and
- lead to improvements in the quality of care for health care users.

We have used these principles to support our response to this consultation and our recommendation that practitioners of acupuncture, herbal medicine and traditional Chinese medicine should be statutorily regulated.

Specific Comments

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?

We are aware that the Medicines and Healthcare Products Regulatory Agency (MHRA) has reported on the risks involved in the use of unlicensed herbal medicines. The risks include interaction with other medicines, use of toxic ingredients and contamination. THE MHRA has also highlighted poor communication by practitioners with patients. The MHRA currently receives approximately 70 suspected adverse drug reaction reports about herbal medicines each year; there have also been a handful of identified UK deaths and a small number of cases of serious illness resulting from herbal medicine use.³

We are also aware that there is evidence of harm relating to acupuncture, some of which is anecdotal. This includes the risks posed by using improperly sterilised needles or by carrying out acupuncture techniques incorrectly. Again, we have not collated evidence ourselves but are aware that there was evidence cited in the House of Lords' Select Committee on Science and Technology's report in 2000 on complementary and alternative medicine. The report of the Acupuncture Regulatory Working Group 2003 also referenced examples of the risk of harm of

² Department of Health, Extending Professional and Occupational Regulation – the Report of the Working Group on Extending Professional Regulation

³ Medicines and Healthcare products Regulatory Agency, Public health risk with herbal medicines: An overview (2008)

acupuncture.⁴ The evidence suggests that the likelihood of the risk of harm is not high but that the outcome can be severe.

The evidence we have highlighted suggests that there is evidence of harm which ranges in likelihood and severity across the professions. The evidence of harm is such that we believe that it is necessary to bring acupuncture, herbal medicine and traditional Chinese medicine into statutory regulation.

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

No system of regulation can protect the public entirely. However, statutory regulation offers improved public protection over alternative systems of regulation. Statutory regulation will protect members of the public by setting standards, protecting commonly recognised professional titles and providing a way in which complaints can be dealt with fairly and appropriately. Statutory regulation means that the very small minority of practitioners who harm their clients can be removed from practising and prevented from continuing to practise and continuing to cause harm.

Statutory regulation is underpinned by the standards that a regulator sets. These standards describe the training necessary to join a profession, the proficiencies required to practice, the expected behaviour, the ethical principles that must be followed and often also outline how the individual will develop their skills and knowledge once they are registered.

These standards do reduce the risk of harm to the public as they ensure that practitioners are able to practise safely and effectively. Setting standards also improves the quality and consistency of the services provided. In statutory regulation, the standards that are set are supported by legislation which ensures that individuals must demonstrate that they meet the standards. Alongside setting standards, statutory regulation also protects commonly recognised professional titles. Only individuals who meet the standards set can use the protected titles.

Where standards are not met, action can be taken. At the moment, a member of any of these three professions who is removed from the membership of their professional body, for example, can simply continue in practice without any legal means for preventing continuing harm to members of the public. Protected titles means that someone who is 'struck off' the Register is unable to continue using the title related to their profession and could be prosecuted if they continued to do so. The HPC strongly believes that protecting professional titles is an important way in which statutory regulation protects members of the public, improving upon a voluntary system in which such titles can continue to be used without any means of redress.

In summary, registration sends a clear message to members of the public that their practitioner is accountable and committed to standards for their conduct and competence.

⁴ The Acupuncture Regulatory Working Group, The Statutory Regulation of the Acupuncture Profession: The Report of the Acupuncture Regulatory Working Group (2003)

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

The purpose of statutory regulation is to protect the public. Statutory regulation does this by setting standards, protecting commonly recognised professional titles and providing a way in which complaints can be dealt with fairly and appropriately. As such, there are clear benefits for the public as they can be confident that their practitioner is accountable and committed to standards for their conduct and competence. Members of the public can also feel confident that if something goes wrong, they can take their complaints to an appropriate body.

Although the purpose of statutory regulation is to protect the public, it does also bring benefits for practitioners. Practitioners can feel confident that if they refer to a regulated individual, that individual meets the register's standards and that action can be taken if the individual does not. It can also bring benefits in terms of enhancing the prestige and recognition of a profession. This in turn can bring benefits in terms of recruitment to a profession and also in terms of increased employment opportunities.

There are also advantages to businesses in statutory regulation. Employers can be confident that those they employ meet the necessary standards and that if there are serious concerns these can be raised with a regulator. We have developed systems to support employers. Our Register is available on-line so that employers can search it to check that individuals are registered. In addition, we have produced publications and hold 'employer events' to raise awareness of the importance of statutory regulation.

4) What do you envisage would be the regulatory burden and financial costs, to practitioners, to the public, 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?

We recognise that regulation can potentially create administrative burdens and direct costs which have to be borne by practitioners or businesses and are often passed on as a result to the public.

For practitioners, the regulatory burden is that around ensuring and demonstrating that they continue to meet the standards set by the regulator. The burden could include undertaking courses to meet continuing professional development (CPD) standards or demonstrating competence through an audit process.

We have developed a process for auditing registrants to ensure that they meet our standards for CPD. This system is designed to be proportionate as we audit a sample of registrants rather than all registrants. This reduces the burden and costs associated with meeting these standards. The standards for CPD and the audit process are an important way in which the HPC can ensure that registrants are keeping up to date with changes and developments in professional practice, to the benefit of their own practice and members of the public. The audit process

balances our responsibilities to protect the public with developing systems which reduce the regulatory burden.

Professional regulation can be expensive, in terms of paying application and registration fees. However, we believe that statutory regulation through HPC reduces the burdens and costs of regulation. As a multi-professional regulator, we can achieve economies of scale and as a result our registration fee, currently £76 per annum, is amongst the lowest of the healthcare regulators. In addition, for some registrants, the registration fee is tax deductible.

Statutory regulation can also create burdens and financial costs for both employers and members of the public. Employers may offer employees time off work to undertake CPD activities or to meet other regulatory requirements. This would create a burden for employers in having to cover staff absence and also create costs for the employer. Employers may pay registration fees on behalf of their employees, creating financial costs for the employer. Members of the public may also contribute to registration fees, either through the costs of services provided or as a result of the tax relief offered on registration fees.

One of the five principles of better regulation is proportionality.⁵ This means that regulators should only intervene when necessary and that the actions taken should be appropriate to the risks posed. We believe that the risks posed by the professions are sufficient to justify statutory regulation.

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?

We believe it is important that the right to prepare and commission unlicensed herbal medicines is restricted to statutorily regulated practitioners. Statutory regulation would ensure that the practitioners met the established standards and that action could be taken to protect the public.

Under European medicines legislation (Directive 2001/83/EC), a medicinal product placed on the market is required to have a marketing authorisation granted following demonstration of safety, quality and efficacy. However, under Article 5 (1) of Directive 2001/83, Member States are permitted to put in place national arrangements to apply allowing an authorised healthcare professional to commission the manufacture of an unlicensed medicinal product to meet the special needs of an individual patient under their direct personal responsibility.

It has been argued that it is not always appropriate to obtain a marketing authorisation for products which are prepared or supplied by herbal medicine practitioners. It has also been suggested that the circumstances in which herbal practitioners could become authorised healthcare professionals are not always clear. We note that legal advice obtained by the Department of Health indicates that it is likely that non-statutorily regulated practitioners or accredited practitioners would not be considered to be authorised healthcare professionals under the terms of the legislation.

⁵ Better Regulation Task Force, Principles of Good Regulation
<http://archive.cabinetoffice.gov.uk/brc/publications/principlesentry.html>

We have argued above that herbal medicine practitioners should be statutorily regulated on the grounds of public protection. We believe that statutory regulation would confer 'authorised healthcare professional' status. This status is necessary to allow practitioners to commission manufactured unlicensed herbal medicines to meet the needs of individual patients, under the requirements of the European legislation.

In addition, statutory regulation would ensure that those preparing and commissioning unlicensed herbal medicines met the necessary standards and that action could be taken if serious concerns were raised. We therefore believe that it is important that the preparation and commission of unlicensed herbal medicines should be restricted to statutorily regulated practitioners.

Currently, some of the professions we regulate, including paramedics, have exemptions from medicines legislation as a result of their registration with us. If the decision was made to restrict the right to prepare and commission unlicensed herbal medicines to statutorily regulated practitioners, this would function in a similar way to the medicines exemptions. Thus, only those on our Register would be able to prepare and commission unlicensed herbal medicines.

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?

We believe that herbal and traditional Chinese medicine practitioners should be regulated and so we do not have an opinion on this 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?

We believe that there would be the potential for a reduction in services offered to the public if practitioners were unable to supply manufactured unlicensed herbal medicines. This would reduce public choice and might also force the public to seek their herbal medicines from practitioners supplying medicines illegally. In turn, this might further reduce public protection as the medicines might not meet the necessary standards.

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?

The risk of harm can be reduced through other systems, for example self-regulation. However, we believe that the other systems do not offer sufficient public protection, unlike statutory regulation.

The present regulatory system for the three professions centres on self regulation and consumer protection legislation. There are a number of professional bodies which set standards and keep a voluntary register. This offers members of the public some protection by indicating that practitioners on a voluntary register meet the standards of that register. In addition, there is some legislation which protects consumers. This includes legislation which licenses herbal medicines so that they meet standards for efficacy, quality and safety. The licensing role is carried out by the MHRA. This also includes general legislation on health and safety and on trading standards, which businesses would have to meet. Finally, there is also local authority registration and licensing for individuals undertaking acupuncture.

The current system does reduce the risk of harm to the public. Practitioners who are members of voluntary registers meet the standards set by those regulators and complaints can be raised with the regulator. The legislation around licensing and health and safety does also protect the public by providing general safeguards and an alternative mechanism for considering complaints.

However, there are also weaknesses within the current system in terms of its ability to protect the public. Health and safety legislation and trading standards do not necessarily ensure that standards are followed or that the public is protected from poor practitioners.

Regulation through a voluntary organisation contains an inherent tension. The professional body is involved both in representing the profession and also taking action against members of the profession when concerns are raised. The standards set by a voluntary regulator vary depending upon the regulator and there is not always independent oversight. A lack of independent oversight can lead to inconsistency in decision making. In addition, where serious concerns are raised about an individual on the voluntary register, the regulator can remove the individual from the voluntary register but can not stop them from practising. Voluntary regulators may also not have the necessary resources to take action against practitioners, or they may not perceive it to be in the profession's interest to do so. There can also be a lack of clarity for members of the public, particularly when more than one voluntary register is established within a profession.

Statutory regulation involves the separation of the regulation function from that of representing the profession. We believe that there is greater consistency in decision making and that there can be independent oversight of the decisions made. In addition, where serious concerns are raised a statutory regulator can stop an individual from practising. Statutory regulation therefore offers better public protection than the current system, which is based upon voluntary regulation and some consumer protection legislation.

The Extending Professional Regulation working group recognised the concerns outlined above about the differences between voluntary regulators and proposed that there should be a process of 'accrediting' voluntary regulators. This would help to ensure that there was improved consistency amongst the voluntary regulators. However, this system would only offer improved protection for the public when they used the services of individuals on an accredited voluntary register. Where the public used the services of those not on the accredited register, it would not reduce the risks posed.

The working group also considered whether it would be appropriate to develop a licensing system for healthcare workers. A statutory licensing system would be more robust and offer improved public protection over a system of voluntary regulation. A statutory system would ensure that practitioners met the necessary standards and were not unsuitable to work with the public. However, it is not clear how the licensing system would support professionals to develop their competency after registration, nor continue to demonstrate that they remained competent. A voluntary licensing system would improve public protection but as a voluntary system, would not be able to prevent practitioners from practising even when serious concerns had been raised.

We recognise that the models proposed in the consultation document all do reduce the risk of harm. However, we believe that the risks to the public are sufficient to require statutory regulation of these professions.

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?

We recognise that there are different regulatory burdens and financial costs depending upon the model of regulation. Multi-professional regulation can reduce costs owing to economies of scale. By contrast, the costs associated with being a regulator of a single profession can be higher owing to the smaller size of the profession.

The regulatory burden and financial costs vary depending on a number of factors, including the regulatory model and the size of the profession. Voluntary regulation depends upon collaboration within the profession to establish standards and processes. The regulatory burdens vary depending upon the processes that the profession establishes. There is no direct burden to the taxpayer, but the costs are borne by practitioners and their patients. The financial costs would vary depending upon the numbers of practitioners on the voluntary registers and the processes established. A campaign for greater public awareness and production of consumer protection legislation would both involve financial costs. Voluntary regulation places only small burdens on businesses. However, where there is more than one voluntary register, businesses must make decisions about which register is most appropriate for the profession and also for the employee.

The Extending Professional Regulation working group recommended that further work should be undertaken to consider the accreditation of voluntary registers. This would include consideration of the cost of the accreditation process and the regulatory burdens associated. It is unclear whether the cost would be borne by the public or not. If voluntary registers have to develop new processes in order to become accredited, then the regulatory burden on practitioners and businesses could increase. This might also lead to increased membership fees for practitioners which could in turn be passed on to their patients.

Statutory or voluntary licensing also carries a financial cost and regulatory burden for practitioners. Depending upon the model, practitioners would have to pay for the license, for any training undertaken and for any tests of competence to obtain

the license. However, the costs might be lower than those of statutory regulation as there might not need to be accreditation of education or a fitness to practise process. Again, the costs of the license would be paid for by the practitioner and by those who used their services. A licensing model may place regulatory burdens on businesses. They would need to identify members of staff who required a license and ensure that those members of staff obtained their license.

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?

We recognise that there are some benefits associated with the alternatives to statutory regulation outlined above. Some of the alternatives, such as statutory licensing or accrediting voluntary registers may offer improved public protection over the current system. We have outlined some of these benefits in our response to question 8.

Voluntary regulation offers benefits to practitioners as the process is managed by the profession. As a voluntary scheme, it can also be more supportive of members and provide profession specific advice in a way that a multi-professional regulator can not. It also allows practitioners to demonstrate to employers that they are committed to meeting standards and are suitable for employment. Voluntary regulation also carries benefits for members of the public as they can look for membership of a voluntary register as an indication that the practitioner meets standards and that there is a body to complain to. All of these benefits would also follow from an accreditation system for voluntary registers.

Licensing, whether voluntary or statutory, offers similar benefits to the public, to practitioners and to businesses. When the licensing is voluntary, employers and members of the public can look for membership of the system as an indication that the practitioner meets the standards set. Statutory licensing offers greater benefits to the public as all practitioners would need to be members. When serious concerns are raised the statutory licensing body could take action which would stop a practitioner from practising if appropriate. Whilst this would bring clear benefits for the public, it would also benefit practitioners by upholding the reputation of the profession.

However, it is important to stress that the benefits offered by alternatives to statutory regulation are not as significant as those offered by statutory regulation, particularly around public protection.

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?

We believe that all three practitioner groups justify statutory regulation because of the risk of harm posed by these professions.

We have considered whether all three practitioner groups should be statutorily regulated as part of our consideration of the Steering Group report. In particular, whether the risk of harm meant that statutory regulation was necessary. We note that risk was also an area considered within the Extending Professional

Regulation Working Group report. The report identified a number of possible factors which might indicate the risk of discrete acts undertaken by health professionals. This includes whether an act is undertaken within a managed environment, the experience of the practitioner and the quality of education and training.⁶

The risk of harm associated with traditional Chinese medicine and herbal medicine has been evidenced by the MHRA and other sources. We have outlined the risks in response to question one. We believe that the risks are sufficiently serious to justify statutory regulation as the public are not sufficiently protected under the current system.

The risks posed by acupuncture are different to those of traditional Chinese medicine and herbal medicine. At present, some practitioners are already statutorily regulated and some practise within managed environments such as the NHS. This includes physiotherapists and doctors who practise acupuncture as part of their scope of practice. Combined with the licensing role undertaken by local authorities and existing voluntary registers, this can reduce the risk of harm posed by practitioners of acupuncture.

However, not all practitioners are already regulated or work in managed environments. In addition, licensing varies across the local authorities as there is a licensing and inspection scheme in some areas but the level of intervention is not consistent. In addition, local authority licensing may not be able to identify poor practice by practitioners. Although these factors mitigate the risks, we do not believe that they offer sufficient public protection.

We recognised that the risks posed by practitioners vary depending upon the nature of the intervention. However, we strongly believe that all three professions should be regulated to improve public protection because of the risk of harm to the public.

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?

We do not believe it would be helpful to the public for these practitioners to be regulated in a way which differentiates them from the regulatory regime for mainstream practitioners. We recognise that there are concerns around the efficacy of these professions. However, we do not believe that concerns around efficacy should prevent the profession from being regulated.

We note that the Extending Professional Working Group report recommended that evidence of efficacy of practice should be considered when making decisions about extending regulation. The report concluded that it was important that the regulatory system allowed the public to distinguish between 'legitimate and unproven treatments'. However, the group noted that there may still be a

⁶ Department of Health, Extending Professional and Occupational Regulation – the Report of the Working Group on Extending Professional Regulation, paragraph 2.5.

need for formal regulation where the risk posed to patients and the public is significant, even where the benefits of treatments are ‘unproven’.⁷

We considered the concerns around efficacy when we scrutinised the Steering Group report against our criteria, including the available evidence of efficacy and the variations in the level of evidence across the professions. The efficacy criterion was scored part met overall, in recognition that although the report acknowledges the limitations of the available evidence base overall, the Steering Group had shown that there is variation in the available evidence base between the groups and that in some areas good quality evidence does exist. The Steering Group had also argued that the practise of these areas does not always readily lend itself to traditional research designs such as randomised control trials (RCTs) and that other forms of research had a role to play in developing the evidence base.⁸

We believe that the lack of accepted evidence of efficacy for these professions should not be a barrier to the regulation of these professions, nor should it mean that they are regulated in a way which differentiates them from the regulatory regime for ‘mainstream’ professions. It is important to realise that debates about efficacy are not limited to acupuncture, herbal medicine and traditional Chinese medicine but can also be found in other professions. In addition, the evidence base for efficacy is changing as a result of research and developments within the regulated professions.

It might be appropriate to draw a distinction between the decisions involved in service delivery and those in professional regulation. For a service provider (particularly those using public money) evidence of effectiveness is likely to be important in deciding whether to fund a particular intervention. However, this may be less relevant to the regulatory goal of mitigating risk of harm – i.e. if patients and clients are already seeking and undergoing treatment that poses a risk of harm, it may be appropriate to regulate even if that treatment might not conform to a traditional scientific assessment of efficacy. Further, whilst the development of an evidence base and ongoing debate of efficacy is important to the professions and to professional bodies in their role as ‘learned societies’, this may be of less direct concern to professional regulators.

We believe that the risk of harm means that acupuncture, herbal medicine and traditional Chinese medicine should be statutory regulated. Any move to bring these professions into regulation would be accompanied by a public campaign designed to highlight the importance of seeing a registered professional and the differences within the profession. We believe that statutory regulation allows the public choice in their professional whilst conferring the strongest protection.

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

⁷ Department of Health, Extending Professional and Occupational Regulation – the Report of the Working Group on Extending Professional Regulation, paragraphs 3.7 and 3.9.

⁸ Council paper, ‘Regulation of Medical Herbalists, Acupuncturists and Traditional Chinese Medicine Practitioners’, 11 September 2008

www.hpc-uk.org/assets/documents/100023FEcouncil_20080911_enclosure07.pdf

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 ?

We have no comments on this 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 believe that we are the most appropriate regulator to regulate all three professions.

We note that in February 2007, the government published a White Paper on the future of regulation, 'Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century'. This White Paper indicated that most new professions should be regulated by us because we were '...designed for this purpose and have the most expertise in bringing new professions into statutory regulation and also in regulating a wide range of professions within a common system'.⁹

We are a multi-professional regulator and have developed the processes and systems to regulate different professions which are based in very different environments and work to different models of practice. Our processes and systems are flexible to allow us to take on more professions. Since the HPC was established in 2002, we have brought operating department practitioners and practitioner psychologists into statutory regulation. The government has also indicated that we should regulate hearing aid dispensers from 2010, taking over the functions of the Hearing Aid Council.

Our regulatory systems are based on risk assessment and proportionate. They are designed to protect the public and to reduce the regulatory burden where that is appropriate. We have given an example of these processes in our answer to question four.

We believe that the risk of harm posed by these professions is sufficient for them all to be brought within statutory regulation through the HPC.

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?

We believe that HPC should regulate herbal medicine and traditional Chinese medicine practitioners as we believe that we are the most appropriate regulator. Please see our answer to question 14.

⁹ Department of Health, 'Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century', pg 85.

16) If neither, who should and why?

We believe that we should regulate all three professions. Please see our response to question 14.

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?

We have considered the risks and whether there is a sufficient risk of harm to require statutory regulation in our answer to question 11. The risks posed by acupuncture are different to those of traditional Chinese medicine and herbal medicine. At present, some practitioners (for example physiotherapists) are already statutorily regulated and some practise within managed environments such as the NHS. Combined with the licensing role undertaken by local authorities and existing voluntary registers, this can reduce the risk of harm posed by practitioners of acupuncture.

However, not all practitioners are already regulated or work in managed environments. In addition, the level of licensing varies across the local authorities as there is a licensing and inspection scheme in some areas but the level of intervention is not consistent. In addition, local authority licensing may not be able to identify poor practice by practitioners. Although these factors mitigate the risks, we do not feel that they are sufficient to prevent the statutory regulation of acupuncture.

We are aware that some acupuncturists are currently subject to inspection by Local Authorities as part of a local licensing system. However, this system relies upon the Local Authorities in each area undertaking such a system and is therefore open to potential variation.

Statutory regulation through the HPC is UK wide. As a result, the standards that are set apply to all registrants irrespective of the area in which they work. This ensures better public protection through consistency in standards.

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?

We agree that the protected titles should be 'acupuncturist', 'herbalist' and 'traditional Chinese medicine practitioner'. We believe that it is preferable to protect a small number of titles that can easily be recognised by members of the public. We have found that protecting a smaller number of titles makes it easier to communicate messages about the importance of seeing a registered professional to the public. In addition, it can help to support professionals who may be making referrals to their colleagues in other professions.

We currently regulate on the basis of protection of title. When a title is protected by statutory regulation, an individual commits an offence if with intent to deceive (either expressly or by implication) they use a title whilst not being registered. We apply the protection of titles powers on a pragmatic basis from the point of view of public protection.

We note that the Steering Group report identified that acupuncture and herbal medicines are used by some already statutorily regulated professionals, including some regulated by us (such as physiotherapists) as part of their extended scope of practice. The report suggests that these professionals would be able to continue to offer these services and perhaps use the protected title so long as there was no intention to mislead members of the public.

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 have carefully considered the suggestion that the functions of acupuncture, herbal medicine and traditional Chinese medicine should be protected, rather than the titles. On balance, we believe that regulation through protection of title offers greater flexibility than regulation on the basis of a protected function.

The HPC regulates by protection of title. This approach to regulation tends to be common amongst the UK regulators of healthcare professionals. However, some regulators also have protection of function. This means that a particular task or role is protected by law and can only be undertaken by someone who is registered.

An example of this is the fitting of contact lenses which has to be undertaken by someone who is appropriately qualified and registered with the General Optical Council. Internationally, some of the state boards in the United States regulate by protection of function – their legislation prescribing what licensees in each profession can and cannot do.

The relative advantages and disadvantages of protection of title versus protection of function are often the subject to debate. A common criticism of protection of title is that this does not prevent individuals who wish to avoid regulation 'rebranding' their services and continuing in practice.

Conversely, a common criticism of protection of function is that this would fetter the change and development of professions, and the emergence of new roles and new professions. Further, whilst it might be possible to define in law specific 'physical' functions that are specific to a small number of professions, this may be far more problematic for other professions where the nature of the intervention would be far harder to define in law. An example of this might be acupuncture. Acupuncture is a discrete physical act but might be difficult to define in law in a way which did not prevent the use of needles by other professionals or in other contexts, such as the administration of medicines.

We note that the Steering Group report identified that acupuncture and herbal medicines are used by some already statutorily regulated professionals, including

some regulated by us (such as physiotherapists and doctors) as part of their extended scope of practice. The report suggests that these professionals would be able to continue to offer these services and perhaps use the protected title so long as there was no intention to mislead members of the public. We believe that this recommendation is sensible and pragmatic and would avoid large scale dual registration, which the government has indicated it wishes to avoid.¹⁰

We are concerned that a model of protected function would not allow this flexibility for professionals who use acupuncture or herbal medicine as part of their extended scope of practice. Instead, we believe that the individuals would have to dual register.

We believe that regulation of protected titles is a more flexible system than protected functions as protecting titles does not prescribe the work that registrants can undertake. Protecting certain functions may also bring into regulation groups which were not intended to be regulated. The protection of titles allows professions to develop new and innovative ways of working which can be sensitive to local needs. We do not believe that a model of protected functions is appropriate for these professions.

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 agree with the proposals laid out in the Pittilo report around 'grandparenting'. We believe that the proposals are appropriate.

A 'grandparenting' period of registration is necessary when introducing statutory regulation and protecting a professional title. The grandparenting period allows people who have previously been practising the profession, but who do not hold an approved qualification, to become registered if they can demonstrate they meet certain criteria.

The report makes recommendations for the 'grandparenting of complete registers' to our Register. We normally call this a 'voluntary register transfer' and differentiate it from 'grandparenting' which we have defined in the above paragraph.

When a new profession comes on to our Register, the legislation specifies the voluntary register or registers which will transfer to our Register. In July 2009, we became responsible for regulating practitioner psychologists and all those whose names appeared on registers held by the British Psychological Society and Association of Educational Psychologists and met set criteria transferred to our Register.

Previously, decisions about which registers transfer have been made by the Department of Health, with input from the HPC Council. We note the report's

¹⁰ Extending Professional Regulation Working Group Report, pg 47 and 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

recommendations that we should undertake an in depth audit of the information that voluntary registers submitted before final decisions are made about the registers which transfer.

There may be other organisations holding voluntary registers who may wish to transfer to the HPC. These organisations could be invited to submit evidence to us to show how they meet the criteria set by the working group.

However, we agree with the proposals set out in the report in terms of the voluntary register transfer. Where individuals have joined a professional body with robust standards, the individuals have made a commitment to meeting standards. We recognise this and so understand the importance of being inclusive in the registers which transfer, so that as many practitioners as possible can be incorporated within statutory regulation from the beginning.

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 believe that all practitioners should be able to achieve the English language score indicated within the document. We believe that this is necessary to ensure public protection and so that there can be effective communication between the practitioner and service user. We note that some of the MHRA evidence of harm indicated that poor communication can put service users at risk.

The Steering Group concluded that a minimum level of English language proficiency is essential for all healthcare professions, on the grounds of public safety. The Steering Group has acknowledged that this may cause difficulty for a potentially significant proportion of the traditional Chinese medicine community for whom English is not the first language. The Group stated that in their opinion public safety would not be assured by the use of interpreters to communicate with patients or other healthcare professionals.

Most of the professions we regulate have a level of English language proficiency set at International Language Testing System (IELTS) of at least 7.0, with no element below 6.5. This level is set higher for speech and language therapists. A number of other tests are also approved at levels equivalent to the IELTS.

We note that the level of English language proficiency is lower than that of the other professions we regulate. It is not clear from the working group report whether the recommended level is a result of pragmatism or a misunderstanding around our requirements.

We recognise the concerns raised about the impact of the level of English language proficiency on practitioners and upon the Chinese speaking community. We believe that it is important that we approach this issue pragmatically. Practitioners currently practising within any of the three professions have acquired rights to continue to do so. We would need to consider these rights when looking at the issue of the level of English language proficiency.

We propose that all those individuals who are on voluntary registers which transfer to the HPC should not have to meet the language requirements. In addition, we believe that the language requirements should be waived during the grandparenting period, to allow individuals who are in practise at the time of registration, the opportunity to apply for registration without having to meet the language requirements. Once the grandparenting period was finished, only those who completed an approved course within the UK or who applied via the international route (and demonstrated a level of English language proficiency) would be able to be registered.

We would want to work with professional bodies to produce guidance on the use of interpreters and making referrals or to promote English language training. It is important to stress that these are only draft proposals. Any proposals would require further work and discussion with stakeholders identifying whether the proposals were appropriate and proportionate.

We believe that the level of English language proficiency should be set at 7.0, with no element below 6.5. We believe that this level is necessary in order to protect the public.

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?

A number of the concerns raised by the MHRA relate to communication with practitioners and patients. We recognise that the Steering Group has acknowledged that the level of English language proficiency may cause difficulties for a proportion of the traditional Chinese medicine community. This is an area in which, if the decision was made to proceed with regulation, the HPC would need to liaise with representatives of the community in order to reach a solution which protects the public and recognised the concern of practitioners. We have proposed a solution above to this issue, based upon a transitional period in which the level of English language proficiency might not apply (please see our answer to question 21).

This transitional period would reduce the costs occurred by individuals as existing practitioners would not have to pay for additional training to meet the level of English language proficiency. If practitioners registered without meeting the English language proficiency, there might be additional costs for practitioners around their communications with members of the public and professionals, such as providing an interpreter where appropriate. We would want to explore the costs and burdens of any proposals before the proposal was agreed.

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?

The potential impact could be that sectors of the community would not be able to register and would therefore be unable to work. This would vary depending upon the numbers unable to achieve the English language level and also upon the outcome of any dialogue with representatives within the professions.

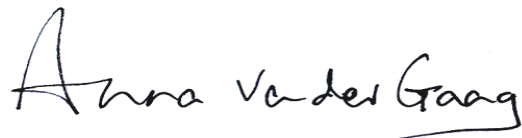
24) Are there any other matters you wish to draw to our attention?

We welcome the opportunity to respond to this consultation. We strongly believe that these professions should be regulated and that we are the most appropriate regulator for these professions.

Conclusion

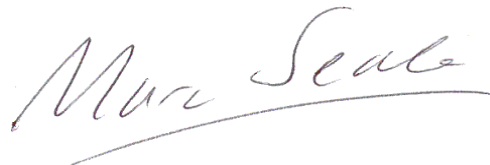
We hope that you find these comments useful. Should you wish to discuss any of our comments then please do not hesitate to contact us.

Yours sincerely,



Anna van der Gaag

Chair



Marc Seale

Chief Executive and Registrar