Health Professions Council 7 October 2009

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

Executive summary and recommendations

Introduction

In May 2008, 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 United Kingdom' published its report. The report recommends the regulation of acupuncturists, medical herbalists and traditional Chinese medicine practitioners.

The Department of Health is now consulting on the published report.

Decision

The Council is invited to:

- discuss the attached draft consultation response and suggest any amendments necessary; and
- approve the response for submission (subject to any amendments suggested at the meeting).

Background information

The Council previously considered the Steering Group report at a meeting on 11 September 2008:
http://www.hpc-uk.org/assets/documents/100023FEcouncil_20080911_enclosure07.pdf

Resource implications

None

Financial implications

None

Appendices

- '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' – consultation document

Date of paper

23 September 2009

DRAFT RESPONSE NOT APPROVED BY COUNCIL

23 September 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.

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 Council recognised that each of these professions had a potential for harm and some involved invasive procedures. 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 also reflects the report which was published in July 2009.[1] We have also considered the questions in this consultation in light of the report. 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 recommendation that practitioners of acupuncture, herbal medicine and traditional Chinese medicine should be 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. These include interaction with other medicines, use of toxic ingredients, contamination and poor communication with patients. The MHRA currently receives about 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.[2]

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 acupuncture.[3] The evidence suggests that the likelihood of the risk of harm is not high but that the outcome can be severe.

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[1] Department of Health, Extending Professional and Occupational Regulation – the Report of the Working Group on Extending Professional Regulation

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

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

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 of the care for those using the services and ensures consistency in the quality of care 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.

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 work on the basis of professional self-regulation. This means that registrants are responsible for ensuring that they are fit to practise and that they should tell us if there are any changes to their fitness to practise. When registrants renew their registration we ask them to declare that they continue to meet the standards that we set and that there are no changes to their health or character. We believe that the declarations are a proportionate way of ensuring that registrants meet our standards, recognising that we receive very few complaints against those on our Register.[4]

[4] Health Professions Council, Fitness to Practise Annual Report, 2007-2008. Analysis of the number of complaints we receive about the professions we currently regulate suggests that complaints are very rare. Between 1 April 2007 and 31 March 2008 we received complaints against 0.24% of those on our Register, with a register size of more than 178,000.

We have developed a process for auditing registrants to ensure that they meet our standards for CPD. Again, 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.

The regulatory burden is reduced for both members of the public and employers. Employers can offer employees time off to undertake CPD activities or meet other requirements set by a regulator. Employers may also pay registration fees on behalf of their employees. 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?

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 product which are prepared or supplied by herbal medicine practitioners. As such, it has been recommended that herbal medicine practitioners should be regulated.

We have argued above that herbal medicine practitioners should be statutorily regulated on the grounds of public protection. We believe that statutory

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

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. The consultation document states that legal advice indicates that it is unlikely that non-statutorily regulated or accredited practitioners would be regarded as authorised healthcare professionals.[6]

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 could function in a similar way to the medicines exemptions.

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?

Our Council has considered different models of regulation as part of a discussion on extending professional regulation.[7] This included models based on voluntary

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[6] Department of Health, 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, pg 24.

[7] http://www.hpc-uk.org/assets/documents/100025D45Extendingprofessionalregulation.pdf

regulation, employer led regulation and licensing. Discussion included the role of regulation in reducing the risk of harm to the public and whether all the models discussed were effective in offering public protection.

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. This 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. This requires them to meet hygiene standards and means that they are subject to hygiene standards.

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. The legislation around health and safety and trading standards does not necessarily ensure that standards are followed or that the public is protected from poor practitioners. There is an inherent tension in the role of a professional body holding a voluntary register. 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. This means 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. Voluntary regulators could be assessed against certain criteria, for example lay involvement

in decision making. 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 considered the regulatory burden and financial costs associated with alternatives to statutory regulation as part of the discussion on extending professional regulation. 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 service users.

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.

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 have considered whether all three practitioner groups should be statutorily regulated as part of our consideration of the Steering Group report. 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.[8]

The risk of harm associated with traditional Chinese medicine and herbal medicine has been evidenced by the MHRA and other sources. The risks identified can include serious health problems and even fatalities. 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, 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 across the local authorities. In addition, local authority licensing may not be able to identify bad 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 recognised that the risks posed by the practitioners varied depending upon the nature of the intervention. However, we strongly believe that all three professions should be regulated to improve public protection. We believe that all three practitioner groups justify statutory regulation 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 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 ‘continues to enable the public to distinguish between legitimate and unproven treatments when making their choice’. The group felt it was important for public choice that awareness was raised not just of regulation but also of the evidence base of services being offered. However, it was acknowledged that even where the benefits of treatments in certain fields are

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

'unproven' or 'controversial' there may still be a need for formal regulation where the risk posed to patients and the public is significant.[9]

We considered the concerns around efficacy when we scrutinised the report against our criteria. The Council considered the available evidence of efficacy and the variations in the level of evidence across the professions.

In its discussions, the Council noted that the lack of accepted evidence of efficacy for these professions should not be a barrier to the regulation of these professions. We also noted the importance of educating the public about the different models of acupuncture and the differences between medical and traditional practitioners.

As part of its discussion, the Council considered the many arguments, (reflected both in the report and in commentary in the broadsheet press following its publication) around the evidence of efficacy of the practice of these groups. 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. The Steering Group concluded that a lack of evidence should not prevent regulation but that the professions should be encouraged and funded to strengthen the evidence base. [10]

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. A King's Fund report recently concluded with reference to complementary practice: 'The public health care system should not sanction an intervention without a demonstrative mechanism for direct health benefit in which there is a degree of common and expert confidence…'.[11] However, this may arguably 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.

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

[10] 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

[11] King's Fund, 'Assessing complementary practice – Building consensus on appropriate research methods' (August 2009)
www.kingsfund.org.uk/research/publications/complementary_meds.html

We do not believe that a perceived lack of an evidence base for clinical effectiveness should prevent statutory regulation of these 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 professions.

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 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 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 the Health Professions Council (HPC) is 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'.[12]

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 also designed to be light touch and to reduce the regulatory burden where that is appropriate. For example, registrants declare that

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

they meet the standards that we set, including our standards for continuing professional development. We then audit a sample of registrants to ensure that they meet our standards. The audit process balances our responsibilities to protect the public with developing systems which reduce the regulatory burden.

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.

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?

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 across the local authorities. In addition, local authority licensing may not be able to identify bad 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.

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.[13]

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?

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.

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[13] 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

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 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 the 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 pubic 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.

The level of English language proficiency for most of the professions we regulate is similar to those set by other regulators. For example, The General Dental Council requires a level of at least 7.0 with no section below 6.5 for dentists.

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. Practitioners would have continued rights to practise their profession if they could demonstrate that they were practising safely and effectively. We would need to consider these rights when looking at the issue of the level of English language proficiency.

If the professions become statutorily regulated then we would need to consider how to respond to these concerns. We might also 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. The solution could include having a transitional period during which the level of English language proficiency might not apply. This transitional period would be time limited, to give existing practitioners a ‘one off’ opportunity to register with us without meeting the English language standards.

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.

As indicated in our answer to question 21, we set a level of English language proficiency as part of the standards of proficiency. We believe that the ability to communicate effectively is important for public protection. There may be some practitioners who have been practising safely and effectively for a number of years who do not meet the level of English language proficiency. As such, we would need to consider their right to continue to practise their profession if they could demonstrate that they were doing so safely and effectively.

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.

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.

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

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For Recipient's Use	

Executive summary

This joint consultation, on behalf of the four UK Health Ministers, seeks respondents' views on whether, and if so how, to regulate acupuncturists, herbal medicine practitioners and traditional Chinese medicine (TCM) practitioners. It focuses on the purpose of regulation – public protection – explains the difference between professional regulation (whether statutory or voluntary) and system regulation, and explores the links between the work of the DH Steering Group on the statutory regulation of acupuncture, herbal medicine and TCM and the recommendations from the UK White Paper[1] Working Group on Extending Professional Regulation.

The consultation focuses on identifying the nature and degree of risks to the public associated with the practice of acupuncture, herbal medicine and TCM, and on whether these risks can best be managed by introducing statutory professional regulation for these groups or some other means of regulation. It asks what the costs and benefits of statutory professional regulation would be, and what its impact would be on practitioners, businesses and the public.

It offers potential alternatives to statutory professional regulation, such as product regulation, system regulation, voluntary professional self-regulation underpinned by better public information and/or accreditation of regulators, health and safety and consumer legislation, local authority licensing regimes, and statutory or voluntary licensing schemes. Not all of these are necessarily mutually exclusive. It asks similar questions as for statutory professional regulation: would one or more of these options represent a more effective and proportionate way of managing the risks for each of the three groups under consideration, and what would the impact of an alternative approach be?

The paper poses the question of whether it is appropriate for these groups of practitioners to be regulated in the same way and to the same extent as other healthcare professions with a physical / behavioural / social scientific evidence base, or whether a different approach is needed.

The paper considers related European and domestic legislation on regulating medicinal products and asks what the effect would be of statutorily regulating, or not regulating, herbal medicine/TCM practitioners. It also asks whether acupuncture should be subject to the same, or different, regulatory regime as the other groups under consideration, and whether it should be treated as a separate profession or as an extension to the practice of existing and future healthcare practitioners.

[1] DH. *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century* (February 2007). London. The Stationery Office.

The paper also considers the wider issue of reducing overall regulatory burdens in the healthcare sector and asks whether, if these groups are recommended for statutory regulation, there are other groups who could be de-regulated or regulated differently.

Finally, the paper considers how various issues should be dealt with, if a decision is made to statutorily regulate these groups. Issues covered are: acknowledging that there will be no new statutory regulatory bodies, who should the regulatory body be, and should it be the same for all three groups? How should we deal with registration and fitness to practise issues for practitioners eligible for acknowledgement / regulation by more than one regulatory body? Should we regulate by protection of title, protection of function, or (in the case of certain procedures) both? What should the “grandparenting” arrangements be for current practitioners who wish to join the register but who do not possess the threshold entry qualifications? What level of English language competence should be required of applicants seeking registration?

Your responses to these questions will be carefully analysed and will be used to help Ministers make a decision about the best way of ensuring an appropriate level of protection for the public when accessing treatment from these practitioners.

Contents

Foreword by UK Health Ministers – Ann Keen, Nicola Sturgeon, Michael McGimpsey and Edwina Hart

The report 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 (view Report) is the culmination of nearly two years' work and of a process which began several years ago with the publication of the House of Lords Select Committee on Science and Technology's report in 2000 on complementary and alternative medicine.

We would therefore first like to thank Professor Mike Pittilo in particular, for the very hard work he has put into pulling together the work of the Steering Group following the 18 month period over which it met. The Group has produced a very helpful report which informs the issue of regulation of acupuncturists, herbalists and traditional Chinese medicine practitioners.

We understand and acknowledge that the work involved in getting to the stage of producing the report was sometimes a frustrating process. We appreciate that there were complex issues which had to be addressed: Professor Pittilo, the Chairs of the three stakeholder groups (Mercy Jeyasingham, Michael McIntyre and Mike O'Farrell) and the members of the Group are to be commended for seeing the work through to its conclusion.

As far as England is concerned there have been two significant recent developments relating to system regulation and regulation of the health professions**.** The Department of Health (England) is therefore seeking to ensure consistency and coherence between system regulation and professional regulation.

In relation to **system** regulation, the Department consulted on the future regulation of health and adult social care during Spring last year. We published the Government's response to that consultation on 30 March this year and it is available on the Department's website at: www.dh.gov.uk/en/Consultations/Liveconsultations/DH_096991. The response sets out the decisions we have made about which activities will require providers to register with the Care Quality Commission. Alternative and complementary medicine will not be within the scope of registration with the new Commission. The response also launched a consultation on the wording of draft regulations which will set the

scope of registration in the legal framework. We are intending to set these regulations before Parliament in the Autumn.

The Government is also actively seeking ways to minimise the burden of system regulation and has established a new Ministerial committee in England to scrutinise planned regulation and proposals for new regulation that will have an impact on business. The new Committee will take account of the views of business in coming to its conclusions.

Alongside these developments there is also work in progress on professional regulation, flowing from the UK White Paper "Trust Assurance and Safety – The Regulation of Health Professionals in the 21st Century", looking at whether, and if so how, professional regulation should be extended to currently unregulated groups of practitioners. Work is ongoing on a UK-wide basis to develop criteria to help determine which roles should be statutorily regulated. On a Scotland only basis an alternative model to statutory professional self-regulation has been explored that relies on local governance arrangements to support delivery of nationally agreed standards for healthcare support workers.

In view of these developments, and due to the difficult and controversial issues involved in regulating acupuncture, herbal medicine and traditional Chinese medicine practitioners, this consultation is intended to further inform Ministers across the UK as to the way forward for these professions. All four UK countries are committed to a UK-wide system of regulation, sensitive to their own specific needs: we will look at the responses to the consultation and will respond in due course.

We very much want to hear your views on regulation: we need to balance all the arguments, look at the alternatives and ensure that the right decision is made. This is your opportunity to influence that decision and we hope you will make full use of it.

Ann Keen Nicola Sturgeon Michael McGimpsey Edwina Hart

Introduction

Why Regulate?

The purpose of regulation of healthcare professionals, whether statutory or voluntary, is to protect patients and the public from poor practice by practitioners. It aims to reduce the risk of harm by:
• setting standards to be achieved by practitioners, and
• ensuring that systems are in place to reduce and, as necessary, manage the risks posed by invasive, potentially dangerous or damaging activities.
The aim is to ensure, as far as possible, that the public is protected, and to promote public confidence in the competence and good standing of regulated professionals.

A regulatory system for healthcare professionals usually involves the establishment of a **register** of individuals who meet agreed standards of education, conduct and practice. Individuals who wish to practise may choose to join such a register, if it is voluntary, or will be obliged to do so by law if it is statutory.

Statutory regulation should be able to clearly demonstrate that it is proportionate and targeted to address the level of risk posed; transparent and consistent in its application; and that the benefits regulation brings in terms of increased public protection outweigh the costs to the taxpayer, businesses and Government.

There are cases where a call for statutory regulation is not considered appropriate. For example, in England it has been decided, working with the industry, to establish a voluntary scheme of self-regulation for low risk botox and dermal filler treatments. Consideration is also being given to the oversight of other cosmetic beauty treatments where the evidence is of very low risk of harm.

What do we mean by statutory professional self-regulation?

Where practitioners are regulated by statute, use of a specific title (eg. “osteopath”) is restricted to practitioners who have met the required standards for education, practice and conduct, and who are included on the statutory professional register. It is therefore illegal to practise, using this title, if unregistered. In addition sanctions, such as suspension or removal from the register, can be applied to any registered practitioner whose fitness to practise is impaired.

Devolved administrations

Despite being fully devolved to Northern Ireland, current statutory regulation of the healthcare professions is UK-wide (except for pharmacy in Northern Ireland), and it is anticipated that this will continue, sensitive to the needs of all four UK countries.

However, as a consequence of devolution, the extension of regulation to new groups of practitioners is now a matter for the Scottish Parliament and Northern Ireland Assembly, while in Wales it remains a matter for the Westminster Parliament.

What do we mean by system regulation?

The purpose of system regulation – that is, the regulation of service providers as opposed to practitioners – in health and social care is to lessen the risk of harm to the public by ensuring that treatment is carried out by those with the correct training, skills and experience in settings which have the appropriate equipment, systems and processes in place and are fit for purpose. Organisations or services that fail to meet the requirements of the regulatory system may be subject to a range of enforcement action or penalties. It is an offence to offer regulated services without being registered with the relevant regulatory body.

Each of the four UK countries has its own arrangements for system regulation/ monitoring: the names and functions of relevant bodies are described in detail in the table at Annex C. Apart from the Pharmaceutical Inspectorate in Northern Ireland, none of these bodies currently covers the kind of services provided by acupuncturists, herbalists and TCM practitioners. This avenue of protection for the public would therefore require changes in primary legislation in order to cover the services which form the subject of this consultation.

Extending Professional Regulation (EPR)

Many currently unregulated professions wish to be statutorily regulated and the UK White Paper Working Group on Extending Professional Regulation (EPR), which took forward one of the workstreams flowing from the UK White Paper[2], commissioned research to identify the risks associated with new professional/occupational groups and to develop an associated risk assessment/ decision making tool, and to explore alternative models to statutory professional self-regulation. All four UK countries were represented in this working group.

The group's remit is attached at Annex A. This working group reported to Ministers on 27 April 2009 with recommendations as to next steps. The report was published on 16 July 2009 and is available on the DH website or at this link Extending professional and occupational regulation: the report of the Working Group on Extending Professional Regulation : Department of Health., together with the response from all four UK Health Departments.

Key Principles

[2] Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century

The group reached consensus on some core / key principles, which are in line with the Better Regulation Commission's principles of Better Regulation, namely:

- The primary legitimate aim of regulation is to deliver enhanced patient safety and public protection;
- Statutory regulation may be unnecessary for all currently unregulated health professions or occupational groups;
- Where risk associated with the activities of a profession or occupational group suggests some form of regulation is desirable, full statutory regulation should not be the default solution – there are alternative lighter touch forms of regulation which may effectively mitigate against risks caused by professional or occupational groups; and
- An evidence-based risk/proportionality approach of measuring risk, and using this to identify the most appropriate regulatory vehicle in response, is the desirable approach.

The EPR Working Group therefore recommended that the above core / key principles should inform future work on extending professional and occupational regulation. The Working Group also recommended that the implementation of possible alternatives to statutory regulation set out in the Report should operate in tandem with other public protection mechanisms (e.g. the Independent Safeguarding Authority in England), and that the Health Professions Council should continue in its advisory role, assisting the Secretary of State in England, in decisions surrounding statutorily regulation for healthcare professions.

Of particular relevance to this consultation is Recommendation 6 of the EPR report: "*For fields of practice where benefits are unproven or controversial, there may nonetheless be a need for more formal regulation or registration because the treatments used pose a significant risk to patients and the public. In any regulatory system, patients and the public should be able to have confidence in the health professionals who are registered within that system. It is therefore important that the expectations of the patients and public in terms of both the treatment being offered and the evidence-base for that treatment, are well recognised and transparent*."

<u>Gatekeeper Role</u>

The EPR report also recommends (Recommendation 17) the establishment of a single Gatekeeper to lead the process around decision making on the future regulation of professional/occupational groups, building on the principles outlined by the Working Group to review and prioritise consideration for regulation of currently unregulated professions/occupational groups, acknowledging the suite of regulatory options available. It further recommends (Recommendations 18-21) that the Gatekeeper utilises both risk based analysis and the views and expertise of key stakeholders in its deliberations, before advising Ministers in the four countries. Such advice *could* be usefully informed by the development by the Gatekeeper of a mechanism to match the appropriate level of regulation with the risk posed by the

activities of the relevant groups, in other words the development of a risk-based decision making tool.

Ministers have asked for further work to be done before deciding whether this series of recommendations *could* or *should* be progressed. Officials in the four countries will collaborate with each other and key stakeholders to assess in detail the advantages and disadvantages of establishment of such a role, its feasibility, the impacts of its creation and any legislative implications.

Scottish Government pilot

In parallel with the work of the UK EPR Working Group, the Scottish Government, in order to further strengthen the evidence base, undertook a pilot to test out an alternative model to statutory regulation. This consisted of a set of induction standards and a Code of Conduct for **healthcare support workers** and a Code of Practice for their **employers**, as well as a list of names of those who achieved the standards and who complied with the code of conduct.

The pilot has now completed and the independent evaluation report was published on 5 June 2009. It can be viewed along with the six page research summary at http://www.scotland.gov.uk/Publications/2009/06/01144730/0 and http://www.scotland.gov.uk/Publications/2009/06/01144651/.

Following conclusion of the pilot, Nicola Sturgeon, the Scottish Government's Deputy First Minister and Cabinet Secretary for Health and Wellbeing, has announced her intention to make the standards and Codes mandatory across NHS Scotland in 2010. An implementation action plan is currently being developed.

The purpose of this consultation

It is the intention of this consultation to offer the opportunity to comment on the risks associated with the practice of acupuncture, herbal medicine and traditional Chinese medicine, and to consult as widely as possible on options for regulation of these practitioners. Consultees are invited to consider, in the light of the recommendations of the recent report of the Steering Group set up by DH Ministers to look at statutory regulation for these practitioners (view Report), the move to proportionate, risk-based regulation, and wider Government policy on extending professional regulation, and whether, and if so how, these practitioners should be regulated. This consultation seeks views on alternatives to statutory regulation and asks whether the risks identified could be adequately managed by non-statutory means, or whether statutory professional self-regulation should be the model used in order to safeguard the public.

This consultation has interacted with the work of the EPR Working Group, and in addition to focusing on a particular sector of the healthcare professional workforce is

part of a wider programme of work to establish coherent regulatory policies and systems across Government.

Finally, this paper poses a series of associated questions about how and by whom the professions of acupuncture, herbal medicine and TCM should be statutorily regulated, if that is the direction chosen.

Background

Background to each of the three therapies proposing statutory regulation

Acupuncture

Acupuncture is described in the Pittilo report as a primary healthcare profession which emphasises, but is not limited to, the use of holistic traditional East-Asian medical theory, art and science to assess, diagnose and treat illness, injury, pain and other conditions. It aims to promote, maintain or restore physical, psychological and social health and wellbeing.

Acupuncturists work in a range of healthcare settings and operate both as independent practitioners and as members of integrated healthcare teams. Acupuncturists often operate as independent healthcare professionals from whom patients may seek direct care without referral from another healthcare professional. They may refer patients on where appropriate, or liaise with other healthcare professionals where there is shared responsibility for patients.

A distinctive feature of the practice of acupuncture is the ability of individual practitioners to use solid sterilised needles which are inserted into specific tissues of the human body for disease prevention, therapy or maintenance of health.

Those practising acupuncture comprise a complex mixture of professionals, including full-time professional acupuncturists; those who practise acupuncture as part of clearly defined but limited techniques for specific therapeutic purposes; statutorily regulated healthcare professionals, such as doctors, nurses and physiotherapists, who have undergone extra training to use acupuncture as part of their day-to-day practice; and those who practise it as part of a more comprehensive package of Traditional Chinese Medicine. Therefore, in the UK there is as yet no single body representing all acupuncturists, although all of the main associations with histories of thirty or more years representing those who practise acupuncture are now grouped under the aegis of the Acupuncture Stakeholders Group (ASG).

Currently, regulation of acupuncture practitioners is purely voluntary, unless the practitioner is already statutorily professionally regulated by one of the UK regulatory bodies, for example a doctor or physiotherapist. Practitioners may register with a professional body representing the acupuncture profession in order to promote agreed professional standards.

Herbal Medicine

Herbal medicine can be defined as the use of plant materials for the treatment of disease and the maintenance of good health. There are traditional medicine systems which also make use of non-plant ingredients alongside plant materials.

The practice of herbal and traditional medicine in the UK at the beginning of the 21st century presents a varied landscape and includes the following categories (in alphabetical order):

Ayurveda
Chinese Medicine
Kampo
Traditional Tibetan Medicine
Unani Tibb
Western Herbal Medicine

It is also important to note that :

- Practitioners typically use other forms of treatment alongside herbal medicines. This is apparent in the Eastern traditions in which the use of medicinal substances appears as one modality amongst others. In the field of Western herbal medicine other forms of intervention are used such as dietary therapy and the use of essential oils.
- Practitioners of herbal and traditional medicine work in a variety of settings: on their own or in larger group practices; in clinics attached to shops and occasionally in orthodox settings such as specialist rehabilitation and HIV/AIDS centres. The great majority practise in the private sector, outside the NHS.

Currently, regulation of herbal medicine practitioners is purely voluntary. Any practitioner who wishes to practise may register with a professional body in order to promote their own professional standards.

Traditional Chinese Medicine

Traditional Chinese Medicine (TCM) is one of the world's oldest medical systems still widely practised today. A TCM practitioner uses Chinese herbal medicine, TCM acupuncture, moxibustion, cupping, Qi Gong, and Tui Na (therapeutic massage) or a combination of these therapies. In the great majority of cases practitioners of TCM are also qualified in acupuncture and herbal medicine. Some are also qualified in Western medicine and registered as such in their country of origin.

Practitioners of TCM can register with one of the voluntary bodies representing this practice in the UK.

Background to the establishment of the Steering Group

The House of Lords' Select Committee on Science and Technology's report in 2000 on complementary and alternative medicine represented a significant milestone in shaping government policy with regard to complementary and alternative medicine. Inter alia it specifically recommended that practitioners of acupuncture and herbal medicine should be statutorily regulated under the Health Act of 1999. The House of Lords' report recommended statutory regulation for herbal medicine and acupuncture because they met key criteria that included risk to the public through poor practice, the existence of a voluntary regulation system and a credible, if incomplete, evidence base. It did not consider that Ayurvedic medicine, Chinese herbal medicine or traditional Chinese medicine should be covered by statutory regulation. However, the Government response proposed that professions using either acupuncture or herbal medicine (thereby also including Chinese herbal medicine, TCM and Ayurveda) should, in the interests of public safety, be statutorily regulated and that "it would be desirable to bring both acupuncture and herbal medicine within a statutory framework as soon as practicable".

In 2001 the Department of Health, in partnership with the Prince of Wales's Foundation for Integrated Health, established two Working Groups for the regulation of acupuncture and herbal medicine. The Acupuncture and Herbal Medicine Regulatory Working Groups both reported in 2003

The 2004 consultation exercise

On 2 March 2004, the UK Health Departments published a consultation paper, *Regulation of herbal medicine and acupuncture*, setting out their proposals for the statutory regulation of herbal medicine and acupuncture practitioners. The formal consultation period closed on 7 June 2004. In February 2005, the Department of Health responded to the consultation indicating that it expected to publish a draft Order under section 60 of the Health Act 1999 (commonly known as a "Section 60 Order") for consultation later that year.

Responses to the 2004 consultation

A total of 698 responses were received to the consultation. The majority of the responses indicated strong support for the introduction of statutory regulation, in order to ensure patient and public protection and enhance the status of the herbal medicine and acupuncture professions. The detailed comments focused mainly on the way in which statutory regulation should be introduced, with a strong emphasis on the importance of the professions having a level of ownership of the regulatory process. Areas of particular discussion and debate included the type and name of

the proposed regulatory body, protected titles, the composition of the proposed regulatory body, collaborative regulation and registration procedures.

Establishment of the Steering Group under the Chairmanship of Professor Michael Pittilo

In June 2006, the Department of Health Steering Group for the Statutory Regulation of acupuncture, herbal medicine and traditional Chinese medicine practitioners was established by Jane Kennedy, then Minister of State in the Department of Health. Although the Steering Group was formed by the Department of Health in England, from the outset it considered the needs of all four home countries and its membership was UK-wide. The Devolved Administrations have indicated that they wish to participate on a UK-wide basis in considering the Steering Group's report.

The Steering Group was made up of practitioners and lay members appointed by the Department of Health. It was also advised by representatives from the Department of Health, the Medicines and Healthcare products Regulatory Agency (MHRA) and the Health Professions Council (HPC). In addition the Steering Group consulted representatives of the devolved Parliament and Assemblies.

The overall purpose or aim of the Group was to prepare the ground for the regulation of acupuncture, herbal medicine and TCM practitioners, including a range of smaller groups mainly of herbal practitioners following specific cultural traditions (e.g. Ayurvedic, Tibetan etc). This encompassed three tasks.

(i) Consider the implications of the broader reviews of regulation for regulation of acupuncture, herbal medicine and TCM practitioners;

(ii) Co-ordinate stakeholder comments on specific proposals for legislation; and

(iii) Prepare the way for formal regulation by identifying issues and proposing options in relation to education and training, registration, fitness to practice and other aspects of regulation.

A subsidiary but important area was to provide a forum to identify and resolve any conflicts emerging between the various groups involved, whose practice has strikingly different cultural and conceptual frameworks, to ensure that the process of introducing regulation (if introduced) proceeds smoothly on the basis of a broad consensus.

The Steering Group delivered its report to Ministers in May 2008 and Ben Bradshaw, Minister for Health Services (England), decided in June 2008 that, because of the difficult and controversial issues involved, the report should be subject to a consultation exercise with the wider healthcare community. The three Health

Ministers for Wales, Scotland and Northern Ireland have agreed that this consultation should be UK-wide.

You can view the report HERE

Issues for Discussion and Questions

What are the risks to be managed?

The Steering Group's report strongly supports the view that the three professions of acupuncture, herbal medicine and traditional Chinese medicine should be statutorily regulated in the interests of public safety. The Government response must therefore tackle the perceived risks in ways that are both proportionate and effectively targeted.

There are three broad areas of risk to consider:

- The **products** themselves: many herbal medicines may have a powerful effect on the body. Risks are increased with poor practice: some less responsible and less competent practitioners may source low grade products or ingredients. This can give rise to problems such as inclusion of the wrong (toxic) herb due to misidentification of plants with similar names or appearance; adulteration, eg with powerful pharmaceutical substances; high levels of heavy metals; labelling which contains inaccurate information on ingredients, or lacks important safety information, or may not include information in English. In parts of the TCM sector in particular, there is considerable and persistent evidence of public health risks, and a real potential for avoidable illness and deaths.

  Where practitioners make up or commission an unlicensed herbal medicine from a third party to meet individual patient needs, UK medicines legislation on unlicensed herbal medicine is weak and is hampered by the absence of assurance that the practitioner (currently undefined in legislation) has any expertise or accountability. Product regulation on its own in relation to unlicensed medicines cannot therefore offer the public effective protection if the practitioner's methods of practice are unsafe: a drug which is safe for use on one person may not be safe for another – the practitioner's knowledge is critical. Statutory professional regulation as currently applied to other professions may not, however, be the only way of assuring the expertise of a practitioner.

- The **people**: risks resulting from the activities of practitioners who are incompetent, unscrupulous or inadequately trained, or who may be unable to communicate effectively in English. Examples from acupuncture include issues of cross-infection, needles being left in patients, burns from moxibustion and electro-acupuncture problems (too much current). Examples

from herbal medicine include prescribing the wrong herb or herbal medicine; the wrong dosage; failing to take into account a patient's medical condition (eg diabetes, epilepsy, heart disease) and associated medications, or the possibility of interactions with other conventional routine medications such as warfarin, anaesthetics or oral contraceptives.

In all cases there are risks from encouraging a patient to discontinue important, even life saving, conventional treatment or to delay in seeking advice from a doctor about potentially serious conditions. Patients might also be encouraged to have costly treatments and consultations that are unnecessary. Again, a drug which is safe for use on one person may not be safe for another – the practitioner's knowledge is critical.

- The **premises/providers**: general hygiene, health and safety (eg for the use and disposal of needles). In the case of acupuncture, there are avoidable risks such as dirty needles leading to infection. Although the probability is likely to be low, the potential effects are very serious, for example, transmission of hepatitis and HIV or other infections. For herbal medicines there can be issues over storage of ingredients in hygienic, controlled conditions, reflecting the risk of infestation or microbial contamination; also appropriate segregation and labelling of ingredients and monitoring shelf life.

The MHRA has prepared an overview of the public health risk from herbal medicines and this is attached at Annex B.

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?

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

What are the disadvantages associated with introducing statutory regulation?

Statutory regulation is not the only, and may not necessarily be the most appropriate, way of dealing with the risks posed to patients by products, practitioners or the environment in which services are delivered. Whilst it may offer a high level of public protection, it comes at a cost. There are the direct costs to the practitioner of registration itself, and the associated costs to the practitioner of meeting the standards required for initial registration and maintaining them subsequently. For example, they may need to invest in gaining additional post-registration qualifications, make improvements to their premises, or pay for training courses.

Some of the cost of registration is borne by the general taxpaying public in the form of tax relief on professional fees.

It is one of the principles of good regulation that it should be proportionate, i.e. not unduly burdensome to the registrant given the degree of risk to the public. Most acupuncturists, herbalists and TCM practitioners are self-employed in small independent businesses, and some practise part –time. They do not have the flexibility of larger organisations to absorb additional costs or to spend time on form-filling, and could cease or curtail their services as a result. This could result in less choice and access for the public to these kinds of alternative healthcare services.

Statutory regulation inevitably costs the taxpayer: it requires expenditure of time and effort by officials and lawyers in developing and drafting legislation and taking it through the necessary Parliamentary procedures. This is Government and Parliamentary time which could be spent on other much-needed legislation. There will also be the costs involved in running the relevant regulatory body (though in most cases these bodies are self-funding through registrants' fees), and in exercising scrutiny and accountability mechanisms such as performance reviews of the UK health professions' regulatory bodies by the Council for Healthcare Regulatory Excellence (CHRE).

In order to justify a decision to statutorily regulate, Government needs to be convinced that the benefits to the public of statutorily regulating these practitioners on the grounds of public protection outweighs the disadvantages of additional costs and unnecessary bureaucracy. This is especially so in the case of services which are a matter of personal consumer choice and largely funded outside the NHS.

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

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?

Alternatives to statutory regulation of practitioners

A table summarising the advantages and disadvantages of these alternatives is at Annex C.

Product regulation

Industrially produced medicines are subject to systematic regulation under European legislation. A 2004 European Directive confirmed that herbal medicines are included within these arrangements and established a specific scheme of regulation for manufactured over the counter (OTC) traditional herbal medicines. The UK was a leading advocate of this legislation in the interests of informed patient choice. The traditional herbal registration (THR) scheme is now up and running and will achieve full effect on the expiry of a transitional period in 2011. Alongside the growing number of regulated OTC herbal products with a THR there are herbal medicines with a marketing authorisation (product licence) which are also made to assured standards.

However, many practitioners either themselves prepare, or commission from a third party, *unlicensed* herbal medicines to meet individual patient needs identified in consultation. There is an exemption from various medicines licensing requirements in Section 12(1) of the Medicines Act 1968 which permits practitioners to do this. Previous consultation by the MHRA has shown there is wide acceptance that this provision is weak, a key issue being that there are currently no safeguards as to the competence or professional accountability of these practitioners. There have also been concerns about the variable safety and quality standards of the products themselves.

An issue raised by the Steering Group is that some herbal and traditional medicine practitioners make significant use of manufactured unlicensed herbal medicines commissioned from a third party to meet individual needs. The safety and quality standards of such products, notably products used in TCM, has not always been reliable. After the end of the transitional period in European medicines legislation (2011) the default position is that such manufactured herbal medicines require either a marketing authorisation (MA) or a THR.

The Steering Group considered it unlikely that in practice most such products would achieve either an MA or THR and proposed an alternative a way of permitting and regulating these unlicensed products in the interests of public health. There is a derogation in European medicines legislation (under Article 5.1 of European Directive 2001/83/EC) which permits a Member State to put in place national arrangements whereby an “authorised healthcare professional” can commission from a third party a manufactured unlicensed medicine to meet the special needs of a patient. The Steering Group proposed that if herbal practitioners were subject to statutory regulation it should be possible for UK to make use of this derogation and introduce regulatory provisions in medicines legislation.

This approach could only be considered as a legally viable option where it was realistic to regard a herbal practitioner as an authorised healthcare professional. If this was not the case there does not appear to be a feasible option for permitting these unlicensed products in a regulated environment.

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

The 2004 European medicines legislation served to clarify that after April 2011 only those practitioners designated by an EU Member State as "authorised healthcare professionals" under a national scheme (set up under Art 5.1 of 2001/83/EC) can commission manufactured unlicensed herbal medicines to meet the special needs of individual patients. This presents the opportunity to strengthen UK legislation so that only certain defined practitioners recognised as competent can use the S12(1) regime as well as being able to commission manufactured unlicensed herbal medicines. The issue arises as to the circumstances in which herbal practitioners could be regarded as authorised healthcare professionals. Legal advice has suggested that it is unlikely that non-statutorily regulated or accredited practitioners would be so regarded. There is, however, room for debate around what kind of statutory registration or licensing regime this might entail, for example regulating these practitioners in a way which is different from the regulation of mainstream evidence-based healthcare workers.

If practitioners are not subject to some form of systematic regulation one other significant issue for consideration would be the wider implications for the herbal medicines market. Potentially there could be a scenario where part of the market (the OTC sector) is operating within systematic regulation whereas practitioners and unlicensed medicines they use are not subject to any form of equivalent regulation. This may pose some difficulties, particularly for operators at the borderline between the regulated and less regulated parts of the market.

Alternatives to statutory regulation of practitioners include

- A statutory or voluntary licensing scheme – see pages 30 and 32.

- Voluntary regulation with an accredited register

- Abolition of Section 12(1) of the Medicines Act, in effect banning the supply of herbal medicines by practitioners unless the medicines have been through the licence/ registration process. Subject to the extent of transitional protection needed – and the extent of compliance with the restriction – this option could certainly reduce the risk to the public from poor practice, and would comply with European legislation. However, there would also be a reduction in consumer choice. The absence of practitioner regulation means that these practitioners realistically could not be regarded as "authorised healthcare

professionals" for the purposes of complying with European legislation after April 2011, so would be unable legally to commission manufactured unlicensed herbal medicines from a third party.

- Retain Section 12(1) of the Medicines Act and rely on informing the public that they buy at their own risk, coupled with ad hoc bans/restrictions as and when specific safety issues are identified with particular products/ingredients. There would be no statutory provision identifying who is competent to act as a practitioner and consequently there would be no scheme put in place to permit practitioners to commission manufactured unlicensed herbal medicines from a 3rd party. There could be increased efforts to inform the public of the risks associated with buying unlicensed herbal medicines supplied by unregulated practitioners. This is essentially an extension of the current situation, but there would be an adverse impact on practitioners who currently make significant use of herbal medicines commissioned from a 3rd party. The absence of practitioner regulation means that these practitioners would probably not be "authorised healthcare professionals" for the purposes of complying with European legislation after April 2011.

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?

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?

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?

System regulation

On 30 March we published the Government's response to the consultation we held in England during spring 2008[3] on the new registration framework to be introduced from 2010. The consultation response set out the decisions we have made about which health and adult social care activities will be within the scope of registration. One of

[3] "A consultation on the framework for registration of health and adult social care providers", published 25 March 2008.

the key features of the new framework will be that the requirement to register with the new Care Quality Commission will be based on the kind of activity being provided (eg personal care, surgery, mental health care), rather than the organisation or setting that it is provided in as it is now (eg care home or hospital). That will mean that patients and users of services will have the same level of assurance of the quality and safety of their care and treatment, no matter who is providing it. In reaching our decisions about which activities should be within the scope of registration we have considered the level of risk inherent in the activity, the cost of regulation and the effectiveness of system regulation in mitigating that risk.

The consultation was clear that the functions of the Care Quality Commission would not duplicate the functions of other regulators or bodies who already have a role in protecting consumers e.g. local authority trading standards.

In the consultation document, we proposed that alternative and complementary medicine, including, for example, acupuncture, chinese medicine and homeopathy should not be within the scope of registration with the new Commission. The consultation response confirms that position.

In Scotland, the Care Commission in Scotland is unable under current legislation to regulate complementary/alternative services in Scotland under the Regulation of Care (Scotland) Act 2001, as these services are not provided by a registered doctor or dentist and do not fall within the scope of that Act. NHS Quality Improvement Scotland (NHS QIS) is also currently unable to provide a monitoring service for complementary/alternative services if provided outside the NHS. If provided as part of NHS care in Scotland, they would, of course, be caught by wider clinical governance and risk management arrangements. It should be noted that a new health scrutiny body, Healthcare Improvement Scotland (HIS), is to be set up to bring together the existing functions of NHS QIS and also take on the scrutiny of independent healthcare currently carried out by the Care Commission. It will also have new responsibilities in relation to review and inspection of performance on healthcare acquired infections. The work will transfer to HIS from April 2011. On 28 May 2009 the Public Services Reform (Scotland) Bill was introduced to the Scottish Parliament. Part 5 of the Bill relates to the creation of HIS. There are no immediate plans for HIS to regulate complementary/alternative services in Scotland. However, the Bill will include a Ministerial power to add new services in the future, subject to consultation and the approval of the Scottish Parliament.

In Northern Ireland, the Regional Quality and Improvement Authority (the independent health and social care regulatory body for Northern Ireland) is also unable under current legislation to regulate the complementary/alternative services which are the subject of this consultation.

Similarly in Wales, Health Inspectorate Wales (”HIW”) does not currently have the power to regulate complementary/alternative health care services, as they do not fall

under the scope of the Care Standards Act 2000. Where regulation of complementary/alternative healthcare such as acupuncture is in place, it is often carried out by Local Authorities via the use of bye-laws.

A table showing System Regulation Arrangements is attached at Annex D.

Voluntary Professional Self-Regulation/Better Public information/"Buyer Beware"

Practitioners may choose to join a voluntary professional register, which will usually mean that (as in statutory regulation) they will need to meet required standards for education, practice and conduct. Voluntary regulation therefore indicates that registrants have met minimum standards and implies a quality "kitemark" for service users, but cannot provide assurance as to how high those standards are or how diligent the voluntary regulator or the practitioner is in applying them. There are no legal sanctions against practitioners who fail to meet these standards.

Practitioners who choose *not* to join such a register will still be able to practise legally and to use the relevant title, as will a practitioner who has been removed from the register by the registering body.

The fact that the industry or profession sets its own standards and ensures adherence to those standards means that self-regulatory schemes can be changed relatively easily to keep up with developments in a fast-paced industry or profession, and members may feel a greater sense of "ownership" of standards produced under a self-regulatory scheme. Costs of voluntary regulation are borne by practitioners and their customers, without burdening the taxpayer. Members of the public are however unlikely to know which self-regulatory schemes or industry or professional bodies are reputable, and which practitioners are safe to use.

The Department of Health has encouraged the development of an "umbrella" voluntary registration body, the Complementary and Natural Healthcare Council (CNHC) which could be encouraged to work with existing acupuncture, herbal medicine and TCM professional associations with a view to admitting these practitioners to its register. This would however depend on the voluntary co-operation of all bodies involved.

Acupuncture already has a robust system of voluntary self-regulation through professional bodies, so it is particularly important to identify the added value of statutory regulation for users and practitioners of acupuncture. There are also some reputable voluntary registers which herbalists and TCM practitioners can join. The Steering Group report concluded however (and we concur) that not all these voluntary registers have sufficiently high standards for the public to have confidence in them as a "kitemark" of practitioner quality. It is therefore important that the public should have access to information and be aware of risks when accessing complementary and alternative therapies on a "buyer beware" basis. DH currently

provides web-based information to help people across the UK make informed choices on non-surgical cosmetic treatments, and similar information could be commissioned for acupuncture, herbal medicine and TCM (on the DH website and/or sites such as NHS Choices or Consumer Direct). The information could ultimately be endorsed by the Devolved Administrations, who could decide how to ensure it reached the right audiences in their respective countries.

The EPR Working Group recommends (Recommendation 7) in its report Extending professional and occupational regulation: the report of the Working Group on Extending Professional Regulation : Department of Health that "the Department of Health in England and the Devolved Administrations should jointly commission CHRE to develop and publish, in conjunction with stakeholders, a simple guide for the public that describes key considerations in making a decision about approaching a health provider, which sets out the range of roles, professionals, carers and therapists working in health care, describes the extent to which they are regulated and provides advice on how best to ensure safe, effective, high quality and respectful care from them. This will help to ensure, whatever the balance of different regulatory mechanisms in place, that the public have access to clear advice about the nature of the risks involved and are able to make an informed judgement about their care." The EPR report further recommends (Recommendation 8) that "The Department of Health in England and the Devolved Administrations should consider how awareness of information about regulation could be promoted through GP surgeries and other sources of public information in the NHS in England (and its equivalents in Scotland, Northern Ireland and Wales) and CHRE and the professional regulatory bodies should consider what further action can be taken in this regard".

Accreditation of voluntary registration bodies

At the moment there is no way of "policing the policemen" where voluntary regulators are concerned – there is no organisation analogous to the Council for Healthcare Regulatory Excellence (CHRE), which oversees and reviews the UK statutory regulators of healthcare professions. Nor is there currently any external, independent consideration of cases referred to voluntary regulators for "fitness to practise" (FTP). It is possible however that in the future voluntary regulators could adopt a model similar to that being proposed for some of the statutory regulators, whereby adjudication in FTP cases is handed over to an independent adjudicatory body in order to encourage consistent standards across the professions. They would do this, however, with no underpinning legislative power.

The EPR Working Group were concerned that there was insufficient consistency of standards in voluntary regimes, so that it was difficult for members of the public to assess the degree of assurance that they could expect from different registers. The Working Group considered (Recommendation 9) that "with a stronger degree of assurance and accreditation, the approach of a voluntary registration regime could play a valuable part in the overall system of regulation." They further recommended

(Recommendation 10) that "the Department of Health in England and the Devolved Administrations work with CHRE and other key stakeholders to consider the costs, benefits and feasibility of developing a formal voluntary accreditation regime to supplement voluntary registers within the menu of regulatory choices. This might, for example:

- set out minimum standards of governance, to ensure, for example, that only regulators with lay majorities on their governing bodies received accreditation;
- set minimum standards for timely investigation of complaints by members of the public; and
- require adherence to codes of conduct on openness and transparency in the conduct of their affairs.

In doing so, this may enable fewer professions or groups to be drawn into a full statutory framework, by providing more robust and consistent approaches to voluntary registration, as the public will know that if they are receiving care from a person who is registered with a voluntarily accredited register, then they can expect a reasonable level of objective oversight and assurance. However, careful thought would also have to be given to ensure that maintenance of voluntary regimes considers what should be done to highlight those individuals subject to bars under the Independent Safeguarding Authority (and equivalent regimes)."

Legislation on Health and Safety/Trading Standards/Advertising Legislation

General legislation on health and safety, trading standards and advertising exists to protect the public, and applies to businesses across the board. This legislation provides a valuable general safeguard for the public, with procedures for complaint and redress. Local authorities and central government also provide advice to businesses, including specific advice for herbal medicine businesses, on trading standards. However this legislation will not necessarily protect the public from all cases of bad practice and will not necessarily ensure that appropriate standards are followed. There is also no guarantee that issues involving acupuncture, herbalism or TCM will be seen as a priority for health and safety and trading standards officers.

If acupuncture, herbal medicine and traditional Chinese medicine are not statutorily regulated or licensed, voluntary professional self-regulation will need to be underpinned by better public information across the UK on the risks, as described on page 27.

Local Authority Registration and Licensing

In England the Local Government (Miscellaneous Powers) Act 1982, as amended by the Local Government Act 2003, gives local authorities specific powers to regulate the practice of acupuncture and businesses providing tattooing, semi-permanent

skin-colouring, cosmetic piercing and electrolysis through registration and the enforcement of local byelaws on hygiene. The Department of Health has produced model byelaws for local authorities to use. In London, there is a licensing and inspection regime using private legislation. These powers, combined with the strong voluntary self-regulation systems in place, provide a degree of protection for the public when accessing acupuncture services.

In Scotland the Civic Government (Scotland) Act 1982 (Licensing of Skin Piercing and Tattooing) Order 2006 regulates tattooing and skin piercing, including acupuncture, by giving local authorities powers to license and inspect businesses carrying out these activities.

In Northern Ireland the Local Government (Miscellaneous Provisions)(Northern Ireland) Order 1985 regulates ear piercing, tattooing, acupuncture, electrolysis, semi-permanent skin colouring and cosmetic piercing by giving local councils powers to register businesses carrying out these activities. Equally in Northern Ireland the Department of Health, Social Services, and Public Safety, through its Pharmaceutical Inspectorate, provides licences or Group Authorities for a wide range of practitioners and organisations for specific substances controlled under the Misuse of Drugs regulations.

In Wales the Local Government (Miscellaneous Powers) Act 1982, as amended by the Local Government Act 2003, gives local authorities specific powers to regulate the practice of acupuncture and businesses providing tattooing, semi-permanent skin-colouring, cosmetic piercing (ear-piercing and piercing of other parts of the body for the insertion of jewellery) and electrolysis, and to enforce local byelaws on hygiene.

Consultation on new model byelaws for Wales covering acupuncture, tattooing, semi-permanent skin colouring, cosmetic piercing and electrolysis was completed in May 2008. New model byelaws are currently being devised by the Welsh Assembly Government to provide Local Authorities with a standard template to use as an alternative to drafting their own byelaws.

Statutory Licensing Schemes

Statutory licensing would provide a more robust form of public protection than voluntary regulation, and would be less onerous for practitioners, businesses, taxpayers and Government than orthodox statutory regulation. A “light touch” licensing regime, for example based on the model employed by the Security Industry Authority, would involve licensing anyone who has an accredited qualification and has also undergone a satisfactory criminal record check and has been confirmed as not appearing on any list of persons regarded as unsuitable to work with vulnerable adults or children. Such a scheme would not operate formal fitness to practise procedures consisting of an investigation committee, panel hearings and an appeal

to an independent body. The relevant licensing authority would have the power to revoke a person's licence, following a complaint and investigation, if he/she broke the conditions upon which the licence was issued, or if the licensing body received information suggesting that a case existed for withdrawal of a licence.

The licensing authority would have the power to suspend a licence where it was reasonably satisfied that a clear threat to public safety would exist if it did not suspend the licence and in other circumstances if it was in the public interest to do so, for example, breach of licence conditions.

Where a person's licence was revoked, that person would then have 21 days in which to exercise a right of appeal in the appropriate Court in England and the corresponding competent Court within the Devolved Administration jurisdictions as appropriate.

People receiving services from a licensed worker would know that the worker:

- had undergone criminal record checks and checks that confirmed that he/she was not on any list of people considered unsuitable to work with vulnerable adults or children;
- had undertaken a basic level of training/qualifications (possibly based on standards agreed by Skills for Health); was signed up to a code of conduct and that a means of redress existed if that person breached the relevant code.

Skills for Health and other stakeholders could agree with stakeholders the qualifications, training and educational standards that the health care worker needs in order to secure a license to do their jobs safely, effectively and respectfully. At a basic level, this could be a single uniform standard for the group as a whole, or in a more sophisticated model, could involve a suite of licenses reflecting different levels of risk and different occupational roles.

A central licensing authority (yet to be defined, but it could potentially be one of the existing statutory regulators or another existing body) would hold a list of licensed workers. This would ensure that persons who had had their licence revoked following a serious incident could not just change employer and continue in the same occupation. The HPC has set out detailed proposals about how such a scheme might work for healthcare workers – a summary of these proposals is at Annex E.

The EPR report recommends (Recommendation 12) that "the Department of Health in England and the Devolved Administrations carry out further work, in conjunction with stakeholders, on the feasibility, costs, legislative and legal implications and benefits of a licensing regime for health care workers. In addition, the Working Group recommends that this model also be considered for other professional or occupational groups that are judged to need further regulation."

<u>Voluntary Licensing Schemes</u>

Such a scheme would operate in a similar fashion to the statutory scheme described on page 30, with the difference that practitioner licensing would be voluntary rather than compulsory with no statutory underpinning or involvement of a statutory regulatory body. The advantages and disadvantages would be similar to those outlined for voluntary professional self-regulation.

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?

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?

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?

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?

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?

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 ?

How to statutorily regulate

The Steering Group report addresses not only whether but **how** the three professions under consideration should be statutorily regulated. In particular it raises the following issues:

Who should statutorily regulate?

Paragraphs 8 to 13 of the Steering Group report consider who the regulator should be, if Government decides to pursue statutory regulation. The White Paper "Trust, Assurance and Safety – the Regulation of Health Professionals in the 21st Century", published in 2007, recommended that there should be no new regulators. We have not therefore considered creating a new regulator specifically for acupuncture, herbal medicine and TCM.

The option of creating a complementary and alternative medicine council, formed by amalgamating the General Osteopathic Council (GOsC), General Chiropractic Council (GCC) and taking on the regulation of acupuncture. herbal medicine and TCM, is considered but dismissed in the report. The advantages of regulating acupuncture, herbal medicine and TCM alongside osteopathy and chiropractic would be that these professions could clearly be distinguished from those regulated professions operating in mainstream healthcare that have an accepted evidence base for efficacy. DH is committed to reviewing the structure and number of professional regulators at a later stage, as set out in the White Paper.

On the other hand, it would be more difficult for a combined "complementary/ alternative therapies" council to charge practitioners a low registration fee at a similar level to that which the HPC (because of its sheer size and existing infrastructure) is currently able to charge registrants, so this option would presumably be more expensive for acupuncture, herbal medicine and TCM practitioners. Neither the GOsC nor the GCC favoured amalgamation and/or expansion to include acupuncture, herbal medicine and TCM practitioners, partly owing to the nature of their practice and its dissimilarity to the professions they currently regulate (but the same argument could apply in relation to the current HPC-regulated professions).

The two remaining options canvassed in the report are for these groups to be regulated by

- The Health Professions Council (HPC) – this is the Steering Group's favoured option for all three groups
- The new General Pharmaceutical Council/Pharmaceutical Society of Northern Ireland (PSNI) for herbalists and traditional Chinese medicine practitioners only. Acupuncturists would either be placed with another regulator or could be subject to a different model of regulation, such as voluntary professional self-regulation, or statutory or voluntary licensing based on protection of function.

The EPR report recommends (Recommendation 24) that "the Health Professions Council would statutorily regulate new health groups, [the working group] recommended that, for those groups where there is a degree of uncertainty about the appropriate regulator, the Department of Health, working with the Devolved Administrations and Council for Healthcare Regulatory Excellence, should develop clear criteria for agreeing the most appropriate body to take forward regulation.

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?

Question 15
If there were to be statutory regulation, should the Health Professions Council or the General Pharmaceutical Council/ Pharmaceutical Society of Northern Ireland regulate herbal medicine and traditional Chinese medicine practitioners?

Question 16
If neither, who should and why?

Question 17
a) Should acupuncture be subject to a different form of regulation from that for herbalism and traditional Chinese medicine? If so, what?
b) Can acupuncture be adequately regulated through local means, for example through Health and Safety legislation, Trading Standards legislation and Local Authority licensing?

Dual/distributed regulation

Some healthcare professionals who are already statutorily regulated (eg doctors, nurses, physiotherapists) also practise as acupuncturists, herbalists or TCM practitioners. If the latter professions were also subject to statutory regulation with protection of title, there are various possibilities:

- Dual registration (the practitioner would have to register with their primary regulator, eg the GMC, but also with the body regulating their second profession). This would of course have cost implications for the registrant. Should a fitness to practice (FTP) issue arise, the practitioner would be dealt with by the most appropriate regulator, depending on whether the issue concerned solely their practice in their primary profession, their secondary profession, or both. It might be necessary for both regulators to take fitness to

practise proceedings. **Legal advice has been that this model is problematical and is not favoured**.

- Registration with only the primary regulator, but with their registration annotated to show that they also practise within a circumscribed area of practice (e.g. acupuncture) and meet an associated set of standards normally associated with a separate secondary profession. In order to merit such an annotation the registrant would have to meet the appropriate professional standards set by the secondary regulator who is the lead regulator for that profession (or in partnership with the primary regulator). Both regulators would have to agree that these standards were appropriate in order to establish a system of annotation. In this case the primary regulator would investigate FTP issues, but might need to give due regard to professional advice and assistance from the secondary regulator (i.e. the regulator which would normally regulate the second profession for "stand-alone"/direct entry practitioners).

- Regulation with only the primary regulator but without annotation (eg as an acupuncturist). All issues relating to the practitioner would be dealt with by the sole regulator. Protection of title would mean that technically the practitioner would be committing an offence if they described themselves as an acupuncturist without being sanctioned by the appropriate statutory regulator, but it might be possible for the regulatory bodies to agree that action would only be taken if the practitioner had deliberately used the title with intent to deceive. This option could also present difficulties.

All of the above options are speculative and require more detailed work, especially on what may and may not be legally and practically possible. For example, it may not be possible under existing legislation for the primary regulator to take FTP proceedings against practitioners accused of failing to meet standards over which they have no jurisdiction (because it is not one of the functions of, e.g. the GMC, to set standards in relation to acupuncture. This is the current situation but the challenge is not insurmountable).

Protection of title

The steering group report discusses the issue of which titles should be protected at paragraph 19 and concludes that the titles "acupuncturist", "herbalist" and "[traditional] Chinese medicine practitioner" should be protected. This means that whilst practitioners would still be able to use other non-protected appelations in addition to these titles, and would be able to amplify the titles (eg "medical herbalist" rather than just "herbalist"), it would be illegal for a non-registered practitioner to use any title which contained these words.

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?

Protection of function

An alternative to protection of title is protection of function (also referred to as "controlled acts" or "reserved procedures") whereby certain activities may only be legally performed by identified statutorily regulated or licensed professional groups, although the title itself need not be protected. So for example only those who had met the defined standards would be allowed to insert needles in certain ways for specific purposes (this function would have to be described in a way distinct from skin piercing eg for injections, for tattooing or body piercing). The practitioner would still have to be regulated or licensed in some statutory manner, so that protection of function would not replace or obviate the need for statutory regulation of the practitioner in some form.

In Ontario for example, where this system operates, regulated health professionals may delegate the performance of an act to an unauthorised professional or unregulated person providing they had met the necessary standards of competence: there are also exceptions for first aid, emergencies and supervised students.

Protecting the functions detailed under section 12(1) of the Medicines Act by reserving them to regulated practitioners without protecting the titles of "acupuncturist","herbalist" and "traditional Chinese medicine practitioner" would result in a situation whereby people could call themselves by these titles and practise as long as they did not undertake the reserved activities - so they could for example offer massage and herbal treatments which did not involve preparing, or commissioning from a third party, unlicensed herbal medicines to meet individual patient needs. It is difficult however to see what advantage this would have over protection of title, which offers a more straightforward and transparent (for the public) way of identifying who can practise legally.

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?

Grandparenting

The Steering Group report explains in some detail (at paragraph 20) how individuals who are already practising safely and effectively but who do not possess the threshold qualifications for registration can, for a limited period after the register opens, join the register through undergoing a process of individual assessment ("grandparenting").This has worked successfully for a range of newly regulated professions. It is also possible for entire memberships of voluntary registers to transfer en masse to a regulator (this happened in the case of Operating Department Practitioners). The report recommends similar arrangements in respect of the professions of acupuncture, herbal medicine and traditional Chinese medicine.

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?

English language competence

The Steering Group report considers carefully the arguments around language competence and recommends a threshold level for registration of English language competence of 6.5 under the IELTS system, or its equivalent. This recommendation is controversial as there may be a significant proportion of TCM practitioners who would have difficulty attaining this level and might find themselves debarred from practice. There would be a need for a future regulator to work with Chinese medicine organisations to consider how intensive support and language training could be offered to practitioners in this situation. An alternative suggestion, considered but rejected by the Steering Group, has been to allow practitioners to register with a lower standard of English but to insist that they use interpreters for interactions with English-speaking patients and other healthcare professionals.

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 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?

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?

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?

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

Summary of 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?

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

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

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?

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?

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?

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?

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?

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?

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?

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?

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?

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 ?

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?

Question 15
If there were to be statutory regulation, should the Health Professions Council or the General Pharmaceutical Council/ Pharmaceutical Society of Northern Ireland regulate herbal medicine and traditional Chinese medicine practitioners?

Question 16
If neither, who should and why?

Question 17
a) Should acupuncture be subject to a different form of regulation from that for herbalism and traditional Chinese medicine? If so, what?
b) Can acupuncture be adequately regulated through local means, for example through Health and Safety legislation, Trading Standards legislation and Local Authority licensing?

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?

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?

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?

Question 21
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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?

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

Consultation – Next Steps

Individuals and organisations are invited to submit comments on any issues dealt with in the Report to Ministers from the Department of Health Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK.

Response to the Consultation

Replies to this consultation should be received no later than 2nd November 2009. Please respond using the response template provided on the website. If you cannot access the template, please e-mail the address below or write to us and we will send the consultation document and/or template to you. Your response will be automatically sent to our team for analysis.

The template on which to respond is available on the Department of Health website at http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_103567

Our preferred method for receiving your responses is via the automated response system available on the Department of Health website at http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_103567

You may also respond in writing to:

AHMTCM Consultation Team
Department of Health
Room 2N09
Quarry House
Quarry Hill
Leeds
LS2 7UE

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

Comments or Complaints about the Consultation Process

This consultation is being run in accordance with the Cabinet Office Code of Practice on Consultations. This is a full public consultation which runs for three months from the date of publication. If you have any comments or complaints about the consultation process please write to :

Consultations Co-ordinator

Department of Health
Room 3E58
Quarry House
Quarry Hill
Leeds
LS2 7UE

e-mail: consultations.co-ordinator@dh.gsi.gov.uk

Freedom of Information

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes. The relevant legislation in this context is the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 1998 (DPA).

If you want the information that you provide to be treated as confidential, please be aware that under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

ANNEX A

Tasks & Terms of Reference from the Extending Professional Regulation Working Group

Summary of White Paper tasks for the Working Group

1. **develop criteria to determine which roles should be statutorily regulated;**

2. **discuss with the Devolved Administrations and key stakeholders whether a formal mechanism should be devised to consider the national need for new roles and the regulation of new roles;**

3. **assess that role's state of readiness for regulation against agreed criteria, such as those used by the Health Professions Council;**

4. **explore the practicality of a system of distributed regulation, including its relationship to revalidation;**

5. **evaluate the results of the Scottish pilot study [into regulation of healthcare support workers] and consider the way forward with stakeholders;**

6. **consider whether there is sufficient demand for the introduction of statutory regulation for any assistant practitioner roles at levels 3 and 4 on the Skills for Health Career Framework."**[4]

Terms of Reference

To consider the recommendations in *Trust, Assurance and Safety* relating to extending the scope of statutory professional regulation to appropriate professional healthcare groups, and create a Framework for Extending Professional Regulation, which:

1. Sets out what models of regulation for healthcare professional and occupational groups are available across the four nations.

2. Sets out criteria, against which, all healthcare professional and occupational groups and roles seeking or requiring statutory regulation in the UK will be judged to determine whether statutory regulation, or another model of regulation, is appropriate. The criteria should take account of :

[4] Trust, Assurance and Safety – The regulation of health professionals in the 21st century; Department of Health

2.1. the wide variety of existing and emerging professions that are either seeking statutory regulation or, on the basis of risk, may require regulation;

2.2. the work carried out by the UK New Ways of Working Group that seeks to provide strategic direction on the development of new roles;

2.3. existing evidence that supports the demand for regulation of emerging professional and occupational groups within healthcare services across the UK;

2.4. the existence and appropriateness of different types, levels or models of regulation.

3. Tests groups known to be seeking statutory regulation against the criteria and identifies where there may be a need for an alternative solution or different model of regulation.

4. Undertake research into internationally used alternatives to statutory regulation.

5. Sets out guidance on how to prioritise the professional and occupational healthcare groups seeking or requiring statutory regulation.

6. Work closely with the Non-Medical Revalidation and Health for Health Professionals Working Groups, developing and using shared products and outputs as necessary.

7. Take account of the implications for healthcare workers of developments in the regulation of the social care workforce.

8. To act on recommendations from UK health policy.

ANNEX B

Public Health Risk with Herbal Medicines: Summary

The main safety issues are as follows:

Products

Use of potent or toxic herbs *(e.g. Senecio species used in TCM which may cause liver toxicity or liver cancer)*

For example:

Women attending a slimming clinic in Belgium were given a herbal medicine containing the **wrong, toxic, herb** *Aristolochia* species, (which has been used in TCM). **Over 100 women developed kidney failure and many subsequently went on to develop cancer.** Despite a ban on this ingredient in many countries, including the UK, problems still recur with the accidental supply of products containing *Aristolochia* (it has a similar common name in Chinese and similar appearance to several other herbs). Given the pattern of mostly small, dispersed herbal clinics across the UK it is likely that a "cluster" of cases of kidney failure would be spread over a number of different renal units and not be picked up.

Reports from Japan indicate that in 2001 – 2002 **more than 800 cases of serious liver damage and at least 4 deaths** resulted from the use of Chinese slimming products containing fenfluramine or nitrosofenfluramine, a drug closely related to prescription only medicine, fenfluramine which is now banned

Unexpected rare but serious liver toxicity of plants *(e.g. Kava, Black cohosh) leading to liver transplants in some cases)*

Confusion over standards (*e.g. in TCM sector over whether traditional formulae have or have not had known toxic ingredients removed)*

Lack of patient information (unregulated products only)

Low manufacturing standards in some cases (unregulated products only). This can include:

Contamination during manufacturing process (*e.g. poor control on use of pesticides, mycotoxins, microbiological loads)*

Addition of heavy metals/toxic elements as ingredients *(e.g. TCM product in clinic found with 117,000 times level of mercury permitted in foods, leading to a number of hospital admissions. TCM and Ayurveda traditionally use heavy metals and other toxic elements as ingredients. These include realgar (arsenic sulphide), cinnabaris (mercuric sulphide), calomelas (mercurous chloride), hydrargyri oxydum rubrum (red mercuric oxide). The current Chinese Pharmacopoeia includes 48 products containing at least one of these ingredients)*

Adulteration with pharmaceutical substances is a frequent occurrence and has involved potent medicines such as anti-diabetics (glibenclamide), drugs for erectile dysfunction (sildenafil), appetite suppressants (sibutramine) etc)

Addition of analogues of pharmaceutical substances. *(This is a growing activity where a chemical derivative of a known pharmaceutical substance is included in a product e.g. nitrosofenfluramine, sildenafil (Viagra) analogues (homosidenafil, acetildenafil). The analogue is often more toxic than the parent molecule (e.g. nitrosofenfluramine) or is of unknown toxicity as in the case of many of the sildenafil derivatives)*

Every year the MHRA seizes and recovers dangerous products, but these probably represent only a small proportion of those on the market. A recent example was a seizure in May 2008 by the MHRA and Police in a joint operation of nearly 500 boxes containing bottles of an unlicensed “herbal” lotion containing steroids. The issue had been brought to MHRA’s attention by a paediatric dermatologist concerned about the use of the product by parents on babies.

Patients

Use by patients with **serious medical conditions** e.g. cancer, heart disease, diabetes

Use by or on behalf of **vulnerable patients** such as babies/toddlers, people with mental health issues such as depression/anxiety disorders, terminally ill (e.g*. parents wanting baby/child to have ”natural” cream for eczema, unaware that the products supplied actually contain undeclared steroids)*

Use over **long periods of time** by patients with long-term, chronic conditions (e.g. skin conditions, depression) which may not respond well to orthodox treatment

Many patients don’t tell their doctor that they are taking a herbal remedy (and most doctors don’t ask) and so the doctor would have no reason to suspect that **ill health** was **linked to consumption of a herbal remedy**, or to the **interaction of prescription drugs with herbs** *(e.g. St John’s Wort can interact with many prescribed medicines including contraceptive pill and immunosuppressant medicines. This has resulted in unwanted pregnancies and rejection of*

transplanted organs; gingko can interfere with the action of anaesthetics). The MHRA currently receives about **70** suspected adverse drug reaction reports relating to herbal medicines each year. This is believed to represent only a small proportion of cases (e.g. in a year when there was considerable publicity about St John's Wort interacting with other medicines, reporting doubled). There have been a **handful of identified UK deaths** associated with use of herbal medicines; there is a **small but reasonably steady flow of cases entailing very serious illness** such as kidney or liver failure requiring transplant; and other cases (e.g. coma) involving prolonged hospitalisation. A high proportion of such cases have only come to light because of the actions of very alert clinicians who have taken the time to investigate causation of ill health and/or perhaps refer the case to a poisons unit.

Practitioners

Practitioner **lack of expertise** - may supply inappropriate herbal medicines (e.g wrong, toxic plant) due to lack of qualifications/knowledge (or even intentionally due to practice in TCM of substituting one ingredient for another believed to have a similar action)

Potential drug-herb interactions, where practitioner lacks relevant knowledge

May **act beyond the limits of their competence** and/or fail to refer to other practitioners, resulting in **delay in effective treatment** for serious condition (*e.g. TCM practitioner advertising that herbal remedy will obviate need for coronary artery bypass graft*) or **interference with vital treatment** (*e.g. Ayurvedic clinic advising patient to discontinue antipsychotic medication and take alternative Ayurvedic remedies*)

Possible **practitioner irresponsibility** owing to commercial self-interest in the private sector (e.g. supplying large quantities of expensive, unnecessary products, or failing to refer elsewhere). This can lead to **overloading patient with multiple medications** (*e.g. 16 year boy with acne on over 100 TCM tablets a day for several months; patient hospitalised with serious unexplained abdominal pain*)

Communications - Inability of practitioner to communicate in English – e.g. to find out whether patient has a serious medical condition, such as diabetes, is on other medication, or is pregnant, breastfeeding).

ANNEX C

Alternatives to Statutory Regulation

Advantages and Disadvantages

Type of Regulation	Advantages	Disadvantages
Product Regulation	Medicines regulation provides effective regulation of OTC products without need for practitioner expertise. Public is assured that licensed medicines (including traditional herbal registrations) are made to assured standards and accompanied by systematic product information. Some medicines are designated as prescription only or pharmacy, reflecting the need for intervention by qualified healthcare professional. Product regulation for unlicensed medicines provides fewer safeguards but can be effective when linked to clinical judgement and accountability of the healthcare professional, eg the prescribing doctor.	Product regulation in relation to unlicensed medicines cannot offer the public effective protection if the unregulated practitioner's methods of practice (eg diagnosis, prescribing) are unsafe. A medicine which is safe for use on one person may not be safe for another – the practitioner's knowledge is critical. Only the products are regulated, not the practitioners.
System Regulation	Practitioners themselves need not be regulated, but there is a quality assurance regime (usually involving standards, audit and periodic inspections) to ensure that the organisations they work in are effectively policed and that safe procedures and satisfactory practice are followed. Much less bureaucratic and burdensome for practitioners.	The effectiveness of policing depends on the frequency and thoroughness of inspection, and the regulators' ability to prioritise and target potentially substandard services. This model can be resource-intensive and difficult to operate where there is a multiplicity of independent, self-employed providers (as with acupuncture, herbalism and TCM) and does not involve inspection of practitioners. Current legislation does not provide for system regulation of complementary and alternative medicine.

Voluntary Regulation/ Better Public Information	Practitioners who choose to join a voluntary professional register will need to meet required standards for education, practice and conduct which will give patients some degree of assurance that the practitioner they are using is bona fide. There will be a high level of professional ownership and expertise where the voluntary regulator is profession-led.	Lack of legal sanctions owing to absence of legal protection of title - this system is purely voluntary and practitioners are not obliged to register. Consequently those who choose not to do so will still be able to practise legally and to use the relevant title, as will a practitioner who has been removed from the register by the registering body. Members of the public are unlikely to know which self-regulatory schemes or industry or professional bodies are reputable and which practitioners are safe to use. The regulator may set standards unnecessarily high or too low – no external control over quality standards. Danger of professional self-interest trumping public protection.
Voluntary regulation by independently accredited registration body	Accreditation willl reassure patients that practitioner is registered with a bona fide, reputable body and has had to meet a minimum benchmark to do so. External control over quality standards. Practitioners who choose to join a voluntary professional register will need to meet required standards for education, practice and conduct . There will be a high level of professional ownership and expertise where the voluntary regulator is profession-led.	Lack of legal sanctions owing to absence of legal protection of title - this system is purely voluntary and practitioners are not obliged to register. Consequently those who choose not to do so will still be able to practise legally and to use the relevant title, as will a practitioner who has been removed from the register by the registering body.
Legislation on Health and Safety/Trading Standards/ Advertising Legislation	General legislation on health and safety, trading standards and advertising exists to protect the public and applies to businesses across the board. This legislation provides a	This legislation will not protect the public from all cases of bad practice and will not necessarily ensure that appropriate standards are followed. There is also no guarantee that issues involving

	general safeguard for the public with procedures for complaint and redress. Local authorities and central government also provide advice to businesses, including specific advice for herbal medicine businesses on trading standards. Useful ”safety net” to underpin voluntary professional self-regulation.	acupuncture, herbal medicine or TCM will be seen as a priority for health and safety and trading standards officers.
Local authority licensing	Provides safeguards for public in relation to acupuncture, but not herbalism/TCM. Does not require new legislation or additional burdens on practitioners/businesses. Could work well for acupuncture in combination with voluntary professional self-regulation.	No protection for public in relation to herbal medicine and TCM.
Statutory Licensing Scheme	This involves licensing anyone who has an accredited qualification and has also undergone a satisfactory criminal record check. Provides adequate safeguards where there is some risk but not enough risk to warrant statutory professional self-regulation. Less expensive and burdensome than full-blown statutory professional self-regulation. Faster and more responsive too – standards can be changed without requiring new legislation. The relevant licensing authority would have the power to revoke a practitioner’s licence if he/she broke the conditions upon which the licence was issued or if the licensing body received information suggesting that a case existed for withdrawal of a licence. The licensing authority would have the power to	Less protection for public - a practitioner will not have to be registered with a professional body in order to practise. Licensing schemes will not operate fitness to practise procedures but simply withhold or revoke a licence. Statutory licensing would still require legislation and a licensing body of some kind – arguably not that much less bureaucratic than “proper” regulation.

	suspend a license if there was a clear threat to public safety.	
Voluntary Licensing Scheme	As for statutory licensing scheme with the difference that practitioner registration would be voluntary rather than compulsory. Very "light touch" and not burdensome for practitioners.	Few real safeguards for the public as this system would be purely voluntary and practitioners would not be obliged to register. Those who chose not to do so would still be able to practise legally and to use the relevant title, as would a practitioner who had been removed from the register by the relevant licensing authority. Public would need to be aware of the dangers of using unlicensed providers.

ANNEX D

System Regulation Arrangements

COUNTRY	NAME OF REGULATOR	LEGISLATED BY	SYSTEM REGULATOR'S FUNCTION
England	Care Quality Commission (from April 2009)	Health and Social Care Act 2008	In April 2009, the Care Quality Commission, established under the Health and Social Care Act 2008, took over from the Healthcare Commission, The Commission for Social Care Inspection and the Mental Health Act Commission. During 2009/10 the new Commission will continue to regulate health and adult social care under the Care Standards Act 2003. From April 2010 the new regulatory framework for health and adult social care services will be introduced. The scope of registration will be based on the activities that providers carry out and determined by the risk of harm to people using those services. The scope of registration is set out in the consultation response published on 30 March.-
Scotland	Care Commission	Regulation of Care Scotland Act 2001	Regulates a wide range of health and social care services in Scotland, including independent healthcare (IHC) services. The definition of independent healthcare in the Act includes private and psychiatric hospitals, hospices, independent clinics (i.e. clinics in and from which services are provided by a registered doctor or dentist), and medical agencies. Private hospitals and hospices have been regulated by the Commission since it was established. Regulation of the remaining IHC services has yet to be

	NHS Quality Improvement Scotland (NHS QIS)		commenced. In addition, NHS Quality Improvement Scotland (NHS QIS), a special health board rather than a regulator, has the role of leading improvement in the quality and safety of healthcare in Scotland. However, its powers extend only to the NHS. The work of NHS QIS, plus the regulation of independent healthcare currently carried out by the Care Commission, will transfer to the new healthcare body, Healthcare Improvement Scotland (HIS), from April 2011.
Northern Ireland	Pharmaceutical Inspectorate	Medicines Act, Misuse of Drugs Act, Poisons Order and Pharmacy (Northern Ireland) Order	Regulates practitioners, premises and products (in this case medicines) - its remit extends well beyond the health and social care sector. The Pharmaceutical Inspectorate also works very closely with a wide range of other agencies and statutory bodies including the Medicines and Healthcare Products Regulatory Agency (MHRA), which is a UK wide body.
Northern Ireland	The Regional Quality and Improvement Authority	Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003	Registers and inspects a wide range of health and social care services but is unable to regulate the complementary/alternative services which are the subject of this paper.
Wales	Healthcare Inspectorate Wales (HIW)	Care Standards Act 2000	Regulator of independent health services which fall within the scope of the Care Standards Act 2000. (This includes the regulation of independent clinics where certain procedures are provided by medical practitioners, but does not include the regulation of such cosmetic procedures as the subcutaneous injection of a substance or substances

			into the skin for cosmetic purposes or alternative or complementary procedures such as acupuncture.) HIW has full delegated authority for its regulatory decisions. In addition, the Medicines and Healthcare Products Regulatory Agency (“MHRA”) is sponsored by the Department of Health in relation to non-devolved matters in Wales. MHRA also facilitates the enforcement in Wales of provisions of the Medicines Act 1968 as regards medicines for human use, by virtue of arrangements arising under section 83 of the Government of Wales Act 2006.

ANNEX E

Health Professions Council – Licensing Proposals for Healthcare Workers

Individuals would use a single protected title, *Licensed Healthcare Practitioner.* Licensing would not be compulsory, but would be voluntary and with the lead of large key employers, become part of the standard conditions of employment. In the medium term the regulator would commence a communications campaign encouraging the public only to be treated by those who are licensed practitioners.

Individuals would join the register after passing a practical test that would normally be achieved after the equivalent of four to six weeks of full time training. Part-time and on-the-job training would be strongly encouraged to minimise costs. The test would be held frequently each year in numerous facilities and the costs of taking the test would be minimal. There would be a single straightforward Standard of Conduct, Performance and Ethics for all licensees. The Standards of Training would focus on issues such as: communication, confidentiality, delegation of tasks, infection control, patient rights, record keeping and team working.

Registrants who fail to maintain standards would have their licence revoked by tribunal, with appeals heard at an appropriate Court. Once the register opened, the regulatory system would be self-funding and would be designed to be affordable to healthcare workers whose salaries can be significantly lower than those of healthcare professionals. The annual £30 registration would be payable in two instalments and would be tax deductible, thus amounting to £2 per month for basic rate taxpayers. Large employers would make the holding of a licence a condition of employment for specific jobs and this would also apply to agency workers.