PRINCE'S FOUNDATION FOR INTEGRATED HEALTH
Response to the DH Consultation on the Statutory Regulation of Practitioners of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK

Question 1

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

There are significant risks to the public from treatment by unregulated herbalists and acupuncturists:

- Anyone, including those without knowledge or training, can describe themselves as a herbalist or acupuncturist and then offer diagnosis and treatment to the public. Whilst there is some control over acupuncture through current local authority licensing, this is primarily concerned with premises and the safe storage and disposal of needles. It takes no account of the practitioner's qualifications or expertise.

- Many members of the public are unaware that there is no regulatory system to protect them from incompetent or disreputable practitioners. It is taken for granted that those offering acupuncture or herbal medicine must necessarily be trained and qualified, and their practice regulated, in the same way as conventional practitioners such as physiotherapists or art therapists. The public is understandably vulnerable to exaggerated or false claims of the expertise of the individual practitioner and of the efficacy of specific treatments.

- Reputable, trained and qualified practitioners have no effective means of differentiating themselves from the poorly trained or the disreputable.

- Untrained or inadequately trained practitioners may be unaware of the limitations of their competence, leading to patients delaying necessary – sometimes urgent – medical treatment.

- There is evidence that many patients who use CAM therapies such as herbal medicine and acupuncture alongside conventional treatment do not tell their doctors they are doing so because they anticipate a negative reaction. There is a significant risk of interactions with adverse consequences.

- The MHRA has logged instances of Chinese and Ayurvedic herbal products on the UK market of poor quality, containing substituted ingredients or contaminated with heavy metals or conventional medicines.

The issue of risk has been considered by in depth previously. We refer you to:

- *Complementary and Alternative Medicine*, the report of the House of Lords Select Committee for Science and Technology, 2000;

- *Safety of Herbal Medicinal Products*, report of the Medicines Control Agency (MCA): now the Medicines and Healthcare Products Regulatory Agency (MHRA), 2002;

- *Public Health Risk with Herbal Medicines: an Overview*, report of the Medicines and Healthcare Products Regulatory Agency (MHRA): 2008;

- The Reports of the Acupuncture and Herbal Medicine Working Groups, Department of Health, 2003;

- *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* (the Pittilo Report), Department of Health, 2008;

- Pages 20 – 21 and Appendix B of the current joint consultation document.

These expert analyses have concluded that there is a real and significant risk to the public from the current unregulated activities of acupuncturists, herbalists and traditional Chinese Medicine (TCM) practitioners. While many practise responsibly and safety, some do not. These reports all reached the same conclusion: practitioners providing herbal medicine and acupuncture to the public should be brought into statutory regulation as soon as possible.

Following its consultation on the statutory regulation of herbal medicine and acupuncture carried out in 2004, the Department of Health itself came to the same conclusion. It accepted the case for statutory regulation of these professions in its *Statutory Regulation of Herbal Medicine and Acupuncture: Report on the Consultation*, February 2005. The consultation had resulted in strong support for the application of a consistent system of statutory regulation across all four UK countries – England, Scotland, Wales and Northern Ireland – with 98.5% respondents expressing support for a UK-wide system.

Commenting on the January 2009 Ipsos Mori research on public attitudes to herbal medicines, the MHRA said:

> ". . . *the public still remains vulnerable to some of the less responsible operators who peddle low grade, and sometimes, dangerous herbal products - portraying them as natural and safe whilst failing to meet any meaningful standards of safety, quality and consumer information."*

In its 2008 report on the public health risk of herbal medicines, the MHRA notes that there has been no reliable estimate of ill health caused by herbal medicine in the UK or, indeed, internationally. We believe it is unlikely that respondents to this consultation will have better information than the MHRA on which to base any answer to the question: *What is its likelihood and severity*? It should be noted that the MHRA document of 2008 says in respect to herbal medicine: "There is no reason to suppose that a major incident could not occur in the UK.

While it is imperative that the risks described above are addressed, there are also benefits to patients and to the NHS from improving public access to herbal medicine and acupuncture. There is evidence of their effectiveness for certain conditions, while patient satisfaction

levels are reported to be high. The Foundation suggests that they may be particularly useful in treating long term conditions – and may contribute to a reduction in costs to the public purse. Several observational trials provide evidence of reduced prescriptions, reduced number of GP consultations and earlier return to work. These results need to be confirmed by further controlled trials on the model proposed by the recent King's Fund report: *Assessing Complementary Practice*. Long term conditions now account for some 78% of NHS spend on patient treatment. In the present economic climate, increased NHS use of herbal medicine and acupuncture may offer real financial benefits.

We also draw your attention to the recent Report of the *Working Group on Extending Professional and Occupational Regulation* that points to the *Ontario Model* as a means of identifying risk by determining "controlled acts" i.e. those regulated by law.

These include:

- Communicating to the individual or his or her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis.

- Performing a procedure on tissue below the dermis, below the surface of a mucous membrane, in or below the surface of the cornea, or in or below the surfaces of the teeth, including the scaling of teeth.

- Prescribing, selling or compounding a drug [as defined in law] or supervising the part of a pharmacy where such drugs are kept.

Other factors to be taken into account according to the Ontario Model are whether practitioners are self employed and working on their own, as is the case for many in this sector, and whether there are systems in place to ensure that practitioners are regularly and effectively appraised and developed to ensure that they are up to date with current practice. The Ontario Model lists these criteria as weighing in favour of making the practice a "controlled act." The concerns that these issues raise (being self–employed, working solo and the absence of appraisal systems) can clearly only be met by the statutory regulation of this sector.

Question 2

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

Harm would be "lessened" by:

- Providing and enforcing UK wide standards of practice;

- Overseeing the training, accreditation, continuous professional development and revalidation of practitioners;

- Assessing and, if necessary, removing unfit or failing practitioners from a national register;

- Providing the public with the reassurance that any practitioner who is described as a herbalist, traditional medicine practitioner or acupuncturist is properly trained, accredited and regulated, and so can be relied on to provide acceptable standards of diagnosis and treatment;

- Maintaining consumer choice in the range of herbal treatments available;

- Permitting practitioners of herbal medicine to access manufactured herbal supplies from competent, approved third parties and to have individual prescriptions made up by specialist suppliers;

- Ensuring that herbal practitioners use quality-assured materials;

- Addressing the problem of poor quality herbal products, including those marketed as Ayurvedic or traditional Chinese remedies, by limiting the use of Section 12(1) of the Medicines Act to statutorily registered herbal practitioners *and* requiring such practitioners to obtain their herbal supplies from manufacturers and suppliers operating under Good Manufacturing Practice (GMP);

- Allowing referrals from GPs and other medical practitioners to support conventional NHS treatment, for example, as envisaged by the recently published NICE guidelines on the treatment of low back pain which recommend that patients be offered acupuncture as well as orthodox care.

- Giving patients the confidence to discuss their decision to use acupuncture or herbal medicine with their medical advisers.

With the possible exception of the last, these benefits would either not be achieved at all from the alternatives to statutory regulation proposed by the current consultation, or would be achieved to only a limited extent.

Almost ten years of work by Government and stakeholders has led to virtually universal agreement that statutory regulation of this sector is the best way forward to protect the interests of patients and the public. Again, we refer you to the documents listed in our response to Question 1 above. We endorse the conclusions reached by these expert groups. For example:

- The House of Lords Select Committee for Science & Technology Report on Complementary and Alternative Medicine (2000) said:

  "Our main criterion for determining the need for statutory regulation is whether the therapy poses significant risk to the public from its practice. We believe that both acupuncture and herbal medicine do carry inherent risk, beyond the extrinsic risk that all CAMs pose, which is the risk of omission of conventional medical treatment." (par 5.54)

- Three separate Department of Health Steering Groups have come to the same conclusion, most recently 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 (2008), chaired by Professor Michael Pittilo, Vice-Chancellor of Robert Gordon University. It concluded that:

". . . there is an urgent need to proceed without delay to statutory regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems." (Page 20, Section 26)

- The Health Professions Council has made a recommendation to the Secretary of State for Health advocating the regulation of acupuncturists, medical herbalists and traditional Chinese medicine practitioners. Its position statement of August 2009 states:

  The HPC was set up in order to protect the public and we strongly believe that statutory regulation can more effectively assure that practitioners are meeting standards and are fit to practise."

- In addition, the World Health Organisation (WHO) published a statement on Traditional Medicine December 2008. This said:

  WHO and its Member States cooperate to promote the use of traditional medicine for health care. The collaboration aims to:

  - *support and integrate traditional medicine into national health systems in combination with national policy and regulation for products, practices and providers to ensure safety and quality;*
  - *ensure the use of safe, effective and quality products and practices, based on available evidence;*
  - *acknowledge traditional medicine as part of primary health care, to increase access to care and preserve knowledge and resources; and*
  - *ensure patient safety by upgrading the skills and knowledge of traditional medicine providers.*

Question 3

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

Benefits to the public

According to the Secretary of State for Health, writing in the introduction of the Government White Paper, *Trust, Assurance and Safety –the regulation of health professionals in the 21st century* (2007), the overriding interest of professional statutory regulation should be the safety and quality of the care that patients receive from health professionals. We wholeheartedly support this guiding principle.

The most important benefit to the public is improved safety. The numbers affected should not be under-estimated. The Pittilo Report points out that as long ago as 1998, survey data demonstrated that, over a year, some 10.6 million adults had visited at least one practitioner providing one of six established therapies (including acupuncture and medical herbalism). In total, there had been some 22 million visits to these practitioners. Subsequent surveys and consumer research indicate that the popularity of these therapies continues to increase. By 2007, a survey by market analyst Mintel found that almost half (49%) of the adult population

had used complementary medicine and would do so again, while herbal medicine accounted for 63% of the complementary medicine market. Mintel predicted that total consumer spend on herbal medicine, homeopathy and aromatherapy combined would rise to £250 million by 2011.

Most recently, research carried out by Ipsos Mori for the MHRA found that over the previous two years, 5% of adults in Great Britain (one in twenty) had used herbal medicines obtained from a practitioner of traditional Chinese medicine and 8% (one in twelve) had used herbal medicines obtained from a Western or other traditional practitioner. In total 26% had used herbal medicines in the previous two years and 35% had used herbal medicines at some time in the past, whether bought over the counter or obtained from a practitioner. Around 12.5 million people used herbal medicines 2006 – 2008, and more than six million adults in Great Britain had consulted a herbal practitioner. Asian (17%) and BME groups (15%) were more likely than White groups (7%) to have consulted a practitioner.

It is estimated there are some 3,000 practising herbalists (without a national register, it is not possible to provide an exact number). This represents one herbalist for every three or four GP practices. This again provides an illustration of the popularity of herbal medicine with the public.

Given that such large numbers of people wish to consult practitioners of acupuncture, medical herbalism, traditional Chinese Medicine and other traditional medicine systems, it is imperative to put in place effective action that protects public safety while maintaining consumer choice.

Statutory regulation will allow the public, healthcare bodies and the health insurance industry to recognise those practitioners who are properly trained and regulated, and differentiate them from those who are not.

Furthermore, patient choice would be enhanced by statutory regulation because this would allow medical practitioners to refer patients for treatment.

Benefits to practitioners

Trained, qualified and competent practitioners will be able to identify themselves to the public, healthcare providers and the health insurance industry. The current lack of regulation provides a major obstacle to reputable practitioners.

Under statutory regulation, herbal practitioners will benefit from continued access to products supplied by third parties under Article 5.1 of Directive 2001/83/EC (the main European medicines legislation). This is the provision under which a Member State may permit the supply of manufactured unlicensed medicines, if ordered by, and made to the specification of, an authorised healthcare professional, to meet the special needs of an individual patient.

After April 2011, transitional protection afforded under the Traditional Herbal Medicinal Products Directive (THMPD) for certain existing unlicensed manufactured herbal products runs out. Subsequently such products would require either a marketing authorisation or a traditional herbal registration - which would not be practical given the small scale of supply of specific formulations for individual patients. The availability of such manufactured herbal products and third-party supplied herbal prescriptions under the Article 5.1 derogation will

only be legally viable for herbal practitioners if statutory regulation of the profession is in place.

The consequence, if statutory regulation does not occur, is that after 2011 there is likely to be a severe reduction in the scope and range of herbal medicines that herbal practitioners use and as a result a significant loss of consumer choice.

Statutory regulation would also benefit practitioners by ensuring a common and high standard of training and best practice. It is likely to create an environment where research would be encouraged, improving the evidence base for best practice. In addition, it would allow referrals from medical practitioners as, for example, appears to be envisaged by the National Institute of Clinical Excellence (NICE) in its recent guidance on the treatment of low back pain, where it recommends that all patients should be offered the choice of acupuncture alongside conventional treatment.

Benefits to businesses

Businesses who deal with practitioners of acupuncture, herbal medicine and TCM will be able to differentiate between those who are properly qualified and reputable and those who are not.

Statutory regulation would have the effect of improving both public and business confidence in the long term viability of the sectors. This would benefit those small businesses that provide these therapies, and the often larger businesses that supply them, enabling suppliers and manufacturers to invest in essential quality assurance systems.

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?

There would be a one-off cost associated with setting up the regulatory framework and structure. This would be minimised by making the Health Professions Council responsible for regulation rather than setting up a new system. The HPC has mechanisms already in place that could be adapted to serve these new requirements. Following those initial costs, we anticipate the on-going cost to the public purse would be no greater than the costs of regulating other professions allied to medicine, such as speech therapy or occupational therapy.

The costs and regulatory "burden" to practitioners is likely to be manageable for reputable practitioners without increasing fees to patients to a level that would be unaffordable. In the context of public safety, the description of regulation as a "burden" is ill-advised.

What must be considered is the potential cost of failing to introduce statutory regulation. In addition to the costs arising from the closure of many existing independent practitioners' businesses as well as their suppliers, the potential cost should be taken into account of treating patients who have experienced severe adverse effects from treatment provided by less than competent practitioners and/or from poor quality or contaminated herbal products.

It would need only one major incident of the type described by the MHRA in its report: *Public Health Risk with Herbal Medicines: an Overview,* to put a costly and long term burden on the NHS and social care.

In contrast, there is the potential for considerable savings to the public purse from statutory regulation. There is a growing body of evidence that complementary therapies, including acupuncture and herbal medicine systems, are effective in treating long term conditions. In particular, their use has been found to reduce prescribing costs, to reduce GP consultations and to enable a significant proportion of patients to return to work, so reducing welfare payments. At present, some 78% of the costs to the NHS of treating patients is spent on treating long term conditions. One example is the treatment of chronic depression. Research has confirmed the effectiveness of the herbal medicine St John's Wort in the treatment of mild to moderate depression, while initial results suggest it may be effective in the treatment of some cases of severe depression. Its cost is a small fraction of the costs of the most commonly prescribed pharmacological treatments. Similarly, NICE has confirmed that acupuncture is effective in the treatment of low back pain, while its cost per patient treated is considerably less than many conventional treatments.

It is clear, therefore, that there is considerable potential for savings to the public purse by increasing patient access to herbal medicine systems and acupuncture. This should be taken into account when considering the costs involved in statutory regulation.

Question 5

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

Yes. The reasons for this are discussed in detail in the Pittilo Report.

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?

None of the options to statutory regulation proposed within the consultation document will deliver adequate protection for the public with regard to the provision of unlicensed herbal medicines. It is not feasible to regulate effectively the preparation or commissioning of herbal medicines without statutory regulation of herbal and TCM practitioners.

Only statutory regulation can ensure the quality and safety of the herbal products being supplied and make it possible for third-party supply of herbal products and prescriptions to be monitored via the MHRA's licensing of those providing this service under Article 5.1 of Directive 2001/83/EC.

At the same time, it would be unreasonable in the extreme to bar competent herbal medicine and TCM practitioners from preparing or commissioning the medicines their patients require. That would put many practitioners out of business, would undoubtedly lead to a public outcry, damage the economy and contribute to increased levels of unemployment.

Question 7

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

The EU Traditional Herbal Medicinal Products Directive will be fully implemented from April 2011, when it will replace Section 12(2) of the Medicines Act 1968. As explained above, in the absence of statutory regulation, practitioners of herbal/traditional medicine and TCM will neither have access to manufactured unlicensed herbal medicines nor third-party supplied herbal prescriptions for individual patients, as is currently the case. This will have a disastrous regulatory impact on the sector. It will substantially restrict the scope of herbal remedies currently available to practitioners and the patients they serve. There would be a particularly severely effect on patients from ethnic minorities who currently consult practitioners of traditional medicine systems including TCM.

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?

None of the alternatives to statutory regulation described in the Joint Consultation document will provide effective protection from risk of harm to the public for the reasons described in our response to questions 2, 6 and 7. We endorse the views of the several expert groups who have examined this issue, from the House of Lords' Science and Technology Committee onwards, all of whom have urged the government to proceed to statutory regulation for these professions.

Question 9

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

We are not aware of any publicly available analysis of the costs relating to these alternatives. However, as we detail in our response to question 4, the costs to the NHS and social care of failing to regulate should be taken into account, as should the cost to the economy of failing businesses brought about by the impact of impending EU legislation on the herbal medicine sector.

Question 10

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

There would be no benefits commensurate with the benefits to be obtained from statutory regulation. On the contrary, failure to proceed to statutory regulation of practitioners of herbal medicine and TCM is likely to lead to growth in the supply of poor quality, adulterated and

contaminated herbal products marketed to the public via unregulated internet sites and mail order. The risk to public would increase rather than diminish.

Question 11

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

All three practitioner groups should be statutorily regulated together. The convergence of these three groups was acknowledged by the Department of Health in the terms of reference for the Working Group chaired by Professor Michael Pittilo and in *Statutory Regulation of Herbal Medicine and Acupuncture* published by the Department in February 2005. This pointed out: "Practitioners of Traditional Chinese Medicine usually practise both Chinese herbal medicine and acupuncture". The regulatory confusion that would occur were all three not to enter statutory regulation together would be considerable and not in the public interest.

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?

There are two significant flaws in this question.

First, it assumes there is no evidence base for the practice of herbal medicine, TCM and acupuncture. That is not the case. We have provided examples in our response to question 4. A search of the literature will provide many more.

Secondly, it assumes that all or most current medical practice is evidence based. The concept of evidence-based medicine is relatively recent and much practice remains based on experience and clinical judgement rather than what is generally meant by "evidence": that is, randomised, double-blind, controlled trials (RCTs) plus systematic reviews and meta-analyses of such trials. It should be noted that an increasing number of experts, including Professor Sir Michael Rawlings, Chairman of NICE, are now questioning the current over-reliance on RCTs, not least because the patients involved are often non-typical. A recent study carried out for the British Medical Journal's *Clinical Evidence* journal found that, of 2,500 commonly used NHS treatments, only 13% were supported by evidence of this sort. Almost half – 46% - were of "unknown effectiveness".

Consequently, the answer to this question is that it would not be helpful to the public for these practitioners to be regulated in a way which differentiates them from the regulatory regime for mainstream professions. On the contrary, the creation of a two-tier system would lead to public confusion. Bringing practitioners of herbal medicine and acupuncture into statutory regulation will facilitate further research into these treatments and enable cross referral and open communication across professional boundaries. That can only be in the best interests of patients and the public.

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 ?

There is here a questionable notion that apparently supposes that there are a finite number of places within statutory regulation, so that as one profession enters another must exit. In fact, as already discussed, statutory regulation is about the protection of the public and the provision of quality care. Consequently the case for each profession being considered for statutory regulation should surely be considered on its own merits independently of other professional groups within this structure.

Question 14

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

The Health Professions Council should regulate all three professions. The reasons why this should be so are clearly set out in the Pittilo report. The HPC has declared itself willing to accept these professions within its regulatory scope, and has written to the Secretary of State for Heath to recommend that that these professions should be brought into statutory regulation under its regulatory remit. (See our response to Question 2.)

Question 15

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

The Health Professions Council should regulate herbal medicine and TCM. This issue was considered but rejected by 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*. Pharmaceutical bodies have no connection with the practice of acupuncture, while many practitioners of traditional Chinese medicine – and some practitioners of Western herbal medicine – practice both herbal medicine and acupuncture.

Question 16

If neither, who should and why?

See response to questions 14 and 15.

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?

a) Acupuncture should not be subject to a different form of regulation from that for herbalism and traditional Chinese medicine. As we say in our response to Question 11, many practitioners practice acupuncture with herbal medicine and/or TCM. If the same individual practitioner were subject to two different regulatory regimes for what he or she sees as a single practice, then the confused requirements and responsibilities would not enhance public safety.

b) It is manifestly obvious that existing health and safety legislation, local authority licensing systems and trading standards legislation are wholly inadequate to provide the standards of public protection for which statutory regulation is designed. Health and Safety and Trading Standards Laws are largely reactive, while the agencies involved have neither the resources nor the expertise to ensure professional standards of practice.

   Current local authority registration and licensing of acupuncture rarely involves much in the way of initial scrutiny or annual checks of premises, let alone any system to ensure the expertise of the practitioner. Acupuncture is licensed in the same way, and under the same system, as tattoo parlours and cosmetic piercing – yet it is dealing with the healthcare of patients, providing them with diagnosis and treatment. There is an urgent need to replace this system with statutory regulation of practitioners.

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?

We endorse the recommendation of the Pittilo report which said:

> *". . . the titles 'acupuncturist' and 'herbalist' should be protected, since these are widely used, commonly recognised and simple titles that lend themselves easily to being protected.*
>
> *"Registered individuals who wished to add to these titles to show a particular area of practice (for example, 'Medical Herbalist') could do so, whereas those who were not registered could not use these titles, nor any title which contained the words 'acupuncturist' or 'herbalist'. In addition, the Steering Group recommends that the title 'traditional Chinese medicine practitioner' should be protected. Similarly, those who are not registered will not be allowed to use this title, nor any title which contains the words 'Chinese Medicine Practitioner'".*

Additionally, we recommend that registered health professionals such as doctors, nurses and physiotherapists who have undertaken recognised training in these disciplines should be entitled to use the descriptions 'acupuncturist', 'herbalist' or 'Chinese medicine practitioner' should they so wish.

Question 19

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

We do not believe a new model of regulation that protects the function rather than the title would benefit the public. Indeed, such a model could lead to lower standards of entry to these disciplines. However it is worth noting that, as far as herbal medicine is concerned, the changes to Section 12(1) of the Medicines Act 1968 currently envisaged by the MHRA will, in practice, regulate function.

We endorse the conclusions of the Pittilo report, which said:

> *"We do not envisage any difficulties for other statutorily regulated healthcare professionals wishing to use acupuncture, herbal medicine or traditional Chinese medicine as part of their practice provided that they ensure they are appropriately qualified.(See Sections 14 and 27). It will be important for the HPC to provide guidance to other statutory regulatory bodies with regard to minimum levels of education and training required for other professionals to practise acupuncture, herbal medicine, traditional Chinese medicine and other traditional-medicine systems."*

The Pittilo Report also recommended that:

> *". . . use of Section 12(1) of the Medicines Act of 1968 should be restricted to practitioners who are subject to appropriate statutory regulation."*

This proposal would also have the effect of regulating by function the use of herbal medicines and we support it. In essence, statutory regulation of practitioners of herbal medicine would bring with it regulation by function, whereas a scheme designed purely to regulate function would not regulate practitioners and so not provide the same level of protection to the public.

Question 20

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

Yes.

Question 21

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

Yes. We support the view of the Pittilo Report on this issue, which said:

> *"The Steering Group is of the view that English-language proficiency is essential for all healthcare professions. We do not believe that public safety is assured through*

the use of interpreters whether this be in communicating with patients or with other healthcare professionals. We are, however, aware that this could cause a significant difficulty particularly with regard to the traditional Chinese medicine sector and that some practitioners who are very experienced and proficient might no longer be able to practise.

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

The practitioner must not only be able to understand the patient – who may be Chinese speaking – but also understand fully his or her professional responsibilities to the patient, other medications the patient may be taking and possible interactions or contraindications. Furthermore, practitioners must be able to keep up to date with changes to legislation, professional practice and the regulatory regime as well as being able to communicate with other healthcare professionals. These requirements would be difficult – if not impossible – for those without an IELTS score of 6.5 or above.

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?

While there should be a reasonable transition period to allow practitioners to achieve English language skills to an IELTS score of 6.5 or above, we do not believe that either compliance or effective communication could be achieved without English language competence.

The costs of achieving such standards should be met by individual practitioners, perhaps with help from their professional bodies such as a reduced membership fee during training in English language skills. Costs incurred by the regulatory body, for instance in any necessary translation, might also be passed on to practitioners.

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?

The impact would depend upon the number of practitioners who are currently not English-speaking. It is known that there are such practitioners, particularly in the Chinese community, but as far as we know, there is no firm estimate of their numbers. Clearly, the impact would be considerable if the majority are not English-speaking. Even so, it would be less than the impact on herbal medicine overall of failing to introduce statutory regulation to coincide with the implementation of changes to EU legislation.

We support the views of the authors of the Joint Consultation document, which said:

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

Question 24

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

a) <u>The implications for ethnic minority communities and race relations of a decision *not* to introduce statutory regulation of herbal medicine</u>

There are many in the South Asian, Chinese and BME communities who regularly use traditional medicine systems, including Ayurvedic medicine, traditional Chinese medicine and traditional Tibetan medicine. No precise quantitative data is available: indeed little research has been carried out to establish usage by these communities and none, so far as we are aware, has been sponsored by the Department of Health. However, the Ipsos Mori research for the MHRA found that 17% of Asian groups, and 15% of BME groups had consulted a herbal practitioner in the previous two years (2006 – 2008). Local information and professional membership associations also suggest relatively high usage by immigrant and ethnic minority communities.

Traditional medicine systems rely upon the prescription of herbal medicines alongside other treatments such as movement therapies, nutrition and acupuncture. Many practitioners of traditional medicine systems depend upon manufactured or pre-prepared herbal formulas. As we describe in our response to Questions 3 and 7, access to these products will be lost if practitioners are not statutorily regulated.

We fear that a decision to deny ethnic minority patients access to herbal products that are intrinsic to their traditional medicine systems – and that they have been accustomed to find freely available – will result in a negative reaction from their communities. Similarly, practitioners from these communities may feel outrage if their practice and livelihood is curtailed because of a decision not to proceed to statutory regulation. Such a decision may be seen as an attack on ethnic minority cultures and as racism.

Policing the activities of practitioners in ethnic minority communities would present considerable problems for the authorities. Alternatively, if the approach were adopted of 'turning a blind eye' so as to avoid offence to ethnic minority communities, then there might

be understandable anger and protest from practitioners of Western herbal medicine and their patients.

b) The purpose of statutory regulation

It has become fashionable among some groups to define statutory regulation as a mark of official recognition: of approval of the professional group to be regulated. That is wholly mistaken. As we discuss in our response to Question 3, the over-riding function of statutory regulation is to ensure the safety and quality of care that the public receives from healthcare practitioners. Public safety must take precedence over all other issues in reaching a decision on statutory regulation.

c) The risk of increasing public use of unregulated medicines

Because of the restrictions in access to herbal medicines that will come about with the implementation of the Traditional and Herbal Medicinal Products Directive (referred to in our response to Questions 3 and 7) there is an additional danger of increasing public use of unregulated internet sites that sell poor quality or contaminated herbal products. Many patients who use herbal medicines have long term conditions and are convinced of the benefits of the remedies they use in relieving symptoms. If these are no longer available from herbalists, it would not be surprising if some patients risk purchasing from unreliable suppliers. There have already been reported instances of inferior or adulterated products sold from internet sites or via mail order companies, some presenting a considerable health risk to users. Without statutory regulation of practitioners of herbal medicine, this risk to public safety can only increase.

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