

## Summary: Intervention & Options

Department /Agency:

Department of Health

Title:

Impact Assessment of the Statutory Regulation of Acupuncture, Herbal Medicine and Traditional Chinese Medicine

Stage: Partial (for consultation)

Version: Five

Date: 13 May 2009

**Related Publications:** Consultation document and Equality Impact Assessment: "Pittilo" Report to Ministers from the DH steering group on statutory regulation of the three professions - May 2008  
Report of the Working Group on Extending Professional Regulation - February 2009.

Available to view or download at:

<http://www.dh.gov.uk/consultations/liveconsultations>

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### What is the problem under consideration? Why is government intervention necessary?

There is evidence of risk to public health from the unregulated practice of acupuncture, herbal medicine and traditional Chinese medicine. The risks derive from incompetent, unscrupulous or inadequately trained practitioners, and/or practitioners who may be unable to communicate effectively in English. Therefore, for purposes of public protection there may be a need for some form of regulation, statutory or otherwise, for these professions.

However, any regulation should be proportionate to the level of risk and should reflect cross-Government principles of better regulation. The proposed consultation asks whether and if so how these groups of practitioners should be regulated.

### What are the policy objectives and the intended effects?

To ensure public protection by implementing effective and proportionate regulatory measures to promote safe practice within the acupuncture, herbal medicine and traditional Chinese medicine professions.

### What policy options have been considered? Please justify any preferred option.

- To proceed to statutory regulation as recommended in the Pittilo report to Ministers.
- To explore a lighter-touch regulatory regime such as a licensing scheme.
- To rely upon voluntary regulation by recommending that practitioners join a reputable voluntary register, and to explore the possibility of setting up an external accreditation mechanism to quality assure such registers
- To eschew statutory regulation or accreditation and to emphasise client/customer responsibility - "buyer beware", underpinned by voluntary regulation, better information and guidance for the public.

### When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

The policy decision will be made once an analysis of the consultation exercise has been completed around August 2009. It will be reviewed after implementation in the context of continuing reform of professional practitioner regulation.

### Ministerial Sign-off For Consultation Impact Assessments:

*I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.*

Signed by the responsible Minister:



Date:

11/01/09

# Summary: Analysis & Evidence

<b>Policy Option: One</b>	<b>Description: Full statutory regulation</b>
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<b>COSTS</b>	<b>ANNUAL COSTS</b>	Description and scale of <b>key monetised costs</b> by 'main affected groups'	
	<b>One-off</b> (Transition) <b>Yrs</b>	Costs of registration for practitioners with regulatory body; Administration costs for the regulator; Practitioner costs in gaining knowledge of English Language; Loss of business due to burden/language skills provision; Will require secondary legislation.	
	£		
	<b>Average Annual Cost</b> (excluding one-off) <b>Cost</b>		
£	<b>Total Cost (PV)</b>	£	
Other <b>key non-monetised costs</b> by 'main affected groups'			

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>	Description and scale of <b>key monetised benefits</b> by 'main affected groups'	
	<b>One-off</b> <b>Yrs</b>	Possible reduction in costs to NHS resulting from adverse incidents related to practice of these therapies.	
	£	No risk of incurring costs resulting from infraction.	
	<b>Average Annual Benefit</b> (excluding one-off) <b>Benefit</b>	Could permit creation of regulatory arrangements for practitioners to commission unlicensed manufactured herbal medicines under Article 5.1 of Directive 2001/83/EC.	
£	<b>Total Benefit (PV)</b>	£	
Other <b>key non-monetised benefits</b> by 'main affected groups' Patient safety (reduction in untoward events); Will meet requirements of the EU Directive; Increased public confidence in the professions			

Key Assumptions/Sensitivities/Risks

Price Base Year	Time Period Years	Net Benefit Range (NPV) £	NET BENEFIT (NPV Best estimate) £
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What is the geographic coverage of the policy/option?	UK
On what date will the policy be implemented?	2011-2012
Which organisation(s) will enforce the policy?	HPC (probably)
What is the total annual cost of enforcement for these organisations?	£
Does enforcement comply with Hampton principles?	Yes
Will implementation go beyond minimum EU requirements?	No
What is the value of the proposed offsetting measure per year?	£
What is the value of changes in greenhouse gas emissions?	£
Will the proposal have a significant impact on competition?	No
Annual cost (£-£) per organisation	Micro Small Medium Large
Are any of these organisations exempt?	N/A N/A N/A N/A

<b>Impact on Admin Burdens Baseline (2005 Prices)</b>		(Increase - Decrease)
Increase of £	Decrease of £	<b>Net Impact</b> £

# Summary: Analysis & Evidence

<b>Policy Option: Two</b>	<b>Description: Licensing scheme</b>
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<b>COSTS</b>	<b>ANNUAL COSTS</b>	Description and scale of <b>key monetised costs</b> by 'main affected groups'	
	<b>One-off</b> (Transition) <b>Yrs</b>	Administrative costs for licensing body; Licence fees for practitioners; (possibly) practitioner costs in gaining English language knowledge; loss of business due to licensing burden; if statutory, will require primary or secondary legislation.	
	£		
	<b>Average Annual Cost</b> (excluding one-off) <b>Cost</b>		
	£	<b>Total Cost (PV)</b>	£
Other <b>key non-monetised costs</b> by 'main affected groups'			

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>	Description and scale of <b>key monetised benefits</b> by 'main affected groups'	
	<b>One-off</b> <b>Yrs</b>	Possible reduction in costs to NHS resulting from adverse incidents related to practice of these therapies.	
	£	Relatively low risk of incurring costs resulting from infraction.	
	<b>Average Annual Benefit</b> (excluding one-off) <b>Benefit</b>		
	£	<b>Total Benefit (PV)</b>	£
Other <b>key non-monetised benefits</b> by 'main affected groups' Increased public confidence in the professions; Greater patient protection; Likely to meet the requirements of the European Directive			

Key Assumptions/Sensitivities/Risks

Price Base Year	Time Period Years	Net Benefit Range (NPV) £	NET BENEFIT (NPV Best estimate) £
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What is the geographic coverage of the policy/option?	UK		
On what date will the policy be implemented?	2011-2012		
Which organisation(s) will enforce the policy?	NK - possibly HPC		
What is the total annual cost of enforcement for these organisations?	£		
Does enforcement comply with Hampton principles?	Yes		
Will implementation go beyond minimum EU requirements?	No		
What is the value of the proposed offsetting measure per year?	£		
What is the value of changes in greenhouse gas emissions?	£		
Will the proposal have a significant impact on competition?	No		
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium Large
Are any of these organisations exempt?	N/A	N/A	N/A N/A

**Impact on Admin Burdens Baseline (2005 Prices)** (Increase - Decrease)

# Summary: Analysis & Evidence

<b>Policy Option: Three</b>	<b>Description: Accredited voluntary regulation</b>
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<b>COSTS</b>	<b>ANNUAL COSTS</b>	Description and scale of <b>key monetised costs</b> by 'main affected groups'	
	<b>One-off</b> (Transition) <b>Yrs</b>	Administrative costs in setting up accreditation system	
	£	Voluntary registration fees for practitioners (as at present)	
	<b>Average Annual Cost</b> (excluding one-off)		
	£	<b>Total Cost (PV)</b>	£
Other <b>key non-monetised costs</b> by 'main affected groups'			

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>	Description and scale of <b>key monetised benefits</b> by 'main affected groups'	
	<b>One-off</b> <b>Yrs</b>	Admin costs low in comparison with full statutory regulation or licensing.	
	£	Relatively low risk of costs resulting from European infraction.	
	<b>Average Annual Benefit</b> (excluding one-off)		
	£	<b>Total Benefit (PV)</b>	£
Other <b>key non-monetised benefits</b> by 'main affected groups'			
More patient protection and public confidence than status quo.			
Likely to meet the requirements of the European Directive			

Key Assumptions/Sensitivities/Risks

Price Base Year	Time Period Years	Net Benefit Range (£)	(NPV)	NET BENEFIT (£)	(NPV Best estimate)
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What is the geographic coverage of the policy/option?	UK			
On what date will the policy be implemented?	2011-2012			
Which organisation(s) will enforce the policy?	NK at this stage			
What is the total annual cost of enforcement for these organisations?	£			
Does enforcement comply with Hampton principles?	Yes			
Will implementation go beyond minimum EU requirements?	No			
What is the value of the proposed offsetting measure per year?	£			
What is the value of changes in greenhouse gas emissions?	£			
Will the proposal have a significant impact on competition?	No			
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	N/A	N/A	N/A	N/A

**Impact on Admin Burdens Baseline (2005 Prices)** (Increase - Decrease)

# Summary: Analysis & Evidence

<b>Policy Option: Four</b>	<b>Description: Do nothing - No statutory or accredited regulation</b>
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<b>COSTS</b>	<b>ANNUAL COSTS</b>	Description and scale of <b>key monetised costs</b> by 'main affected groups'  Potential loss of business if herbal medicine practitioners are unable to supply unlicensed manufactured herbal medicines legally post-2011. Alternatively, if this activity is not stopped, risk of cost to UK resulting from infraction proceedings owing to non-compliance.
	<b>One-off</b> (Transition) <b>Yrs</b>	
	£	
	<b>Average Annual Cost</b> (excluding one-off)	
	£	
<b>Total Cost (PV)</b>		£
Other <b>key non-monetised costs</b> by 'main affected groups' No additional safeguards for patients/public (except better public information) – continuing (what level of?) risk of damage to public health, as at present.		

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>	Description and scale of <b>key monetised benefits</b> by 'main affected groups' No registration fee for the practitioners or costs associated with meeting English Language requirements.  No costs of administering the system.  No increased financial or administrative regulatory burdens.
	<b>One-off</b> <b>Yrs</b>	
	£	
	<b>Average Annual Benefit</b> (excluding one-off)	
	£	
<b>Total Benefit (PV)</b>		£
Other <b>key non-monetised benefits</b> by 'main affected groups' Public clear that their choice is their responsibility. Clear message that these treatments are not "legitimised" by regulation and that patients access them at own risk.		

**Key Assumptions/Sensitivities/Risks**  
Risk of not complying with European legislation and incurring infraction proceedings.

Price Base	Time Period	Net Benefit Range (NPV)	NET BENEFIT (NPV Best estimate)
Year	Years	£	£

What is the geographic coverage of the policy/option?	UK
On what date will the policy be implemented?	No change to
Which organisation(s) will enforce the policy?	none
What is the total annual cost of enforcement for these organisations?	£
Does enforcement comply with Hampton principles?	Yes
Will implementation go beyond minimum EU requirements?	No
What is the value of the proposed offsetting measure per year?	£
What is the value of changes in greenhouse gas emissions?	£
Will the proposal have a significant impact on competition?	No
Annual cost (£-£) per organisation	Micro Small Medium Large
Are any of these organisations exempt?	N/A N/A N/A N/A

<b>Impact on Admin Burdens Baseline (2005 Prices)</b>	(Increase - Decrease)
Increase of £	Decrease of £
<b>Net Impact £</b>	

Key: Annual costs and benefits: Constant Prices (Net) Present Value

## Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

### **Background to the establishment of the Steering Group**

The House of Lords' Select Committee on Science and Technology's report in 2001 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 the Herbal Medicine Regulatory Working Groups both reported in 2003 and, in March 2004, the Department of Health consulted on a set of proposals for the statutory regulation of herbal medicine and acupuncture.

### **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. Statutory regulation improves public protection by setting clear standards of training and competence for regulated practitioners. It also reassures patients that a regulated practitioner is not only suitably qualified, but also competent and up-to-date with developments in practice.

Over 1000 copies of the consultation document were distributed to interested organisations and individuals by the Health Departments. The consultation document was also made available electronically on the Department of Health's website. To respond to the consultation were asked to submit comments by either e-mail or post. The formal consultation period closed on 7 June 2004.

### **Responses to the consultation**

A total of 698 responses were received. The respondents included nine organisations representing practitioners of acupuncture, 12 organisations representing practitioners of herbal medicine and nine organisations representing practitioners of Traditional Chinese Medicine (TCM)<sup>1</sup>. A number of the other responses can be grouped into the following categories:

- educational bodies – 19 responses;

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<sup>1</sup> Practitioners of Traditional Chinese Medicine usually practise both Chinese herbal medicine and acupuncture.

- NHS bodies (including NHS Trusts, Primary Care Trusts and Strategic Health Authorities) – 15 responses;
- Health and Social Services Boards and Trusts in Northern Ireland – 7 responses;
- other complementary and alternative medicine (CAM) organisations – 20 responses;
- patient and consumer organisations – 3 responses;
- professional associations for regulated healthcare professionals – 6 responses;
- Royal Colleges – 9 responses;
- statutory regulatory bodies – 5 responses.

In addition, a large number of responses were received from individual practitioners of acupuncture, herbal medicine, TCM and other CAM professions, patients and members of the public.

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

In February 2005, the Department of Health reported on the consultation indicating that it expected to publish a draft Section 60 Order for consultation later that year.

### **Establishment of the Steering Group under the Chairmanship of Professor Michael Pittilo.**

Following the 2004 consultation exercise, 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, in June 2006 specifically to prepare the ground for the regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK. In addition to traditional Chinese medicine these traditional medicine systems include Ayurveda, Unani Tibb (a system of traditional medicine with roots in Greek, Middle-Eastern and Indian Medicine), Kampo (Japanese traditional medicine) and Tibetan Medicine, all of which are currently practised in the UK. The Steering Group was invited to prepare the way for formal regulation by identifying issues and proposing options in relation to education and training, registration, fitness to practise and other aspects of regulation. Although the Steering Group was formed by the Department of Health in England, from the outset the Steering Group considered the needs of the home countries and its membership was UK-wide. The Devolved Administrations have indicated that they wish to consider the Steering Group's report on a UK wide basis.

The Steering Group delivered its report to Ministers in May 2008 and the Minister for Health Services (England) decided in June 2008 that the report should be subject to a consultation exercise with the wider healthcare community.

### **Extending Professional Regulation**

Many currently unregulated professions wish to be statutorily regulated. The DH set up a Working Group on Extending Professional Regulation (EPR), which took forward one of the workstreams flowing from the UK White Paper on regulation (published in February 2007), to identify the risks associated with new professional/ occupational roles 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 which

began its work in November 2007 and reported to Ministers in April 2009. This impact assessment takes the work and recommendations of the EPR Report into account, as their work is inextricably linked with the work of the Steering Group for the Statutory Regulation of acupuncture, herbal medicine and traditional Chinese medicine.

## **Better Regulation**

In July 2008, BERR published government-wide principles of “better regulation”: that regulation should be transparent, accountable, proportionate, consistent, and targeted only where action is needed. We have borne these principles in mind in formulating this consultation, and they will underpin the eventual decision on whether and if so how to regulate these groups of practitioners.

## **Proposals to regulate acupuncture, herbal medicine and traditional chinese medicine.**

An equality screening and full equality impact assessment has been undertaken and published at the end of the evidence page of this assessment at Annex A.

A health impact assessment has been carried out and is published at Annex B.

The options under consideration are:-

1. To proceed to statutory regulation as recommended in the Pittilo report to Ministers.
2. To explore a lighter-touch regulatory regime such as a licensing scheme.
3. To rely upon voluntary regulation by recommending that practitioners join a reputable voluntary register, and to explore the possibility of setting up an external accreditation mechanism to quality assure such registers
4. To eschew statutory regulation or accreditation and to emphasise client/customer responsibility – “buyer beware”, underpinned by voluntary regulation, better information and guidance for the public.

Health Ministers from the four UK countries have decided, especially in the light of developments since the Pittilo steering group was set up, to hold a consultation to obtain the views of the wider healthcare community before deciding on the way forward.

## **Why Regulate Acupuncture, Herbal Medicine and Traditional Chinese Medicine Practitioners?**

**Public safety:** Unlike other complementary/alternative therapies, these professions involve the use of skin piercing (acupuncture) and/or potentially toxic substances (herbs) and therefore have the potential to cause significant and damaging effects on the body. There is unfortunately quite a large body of evidence amassed by the MHRA indicating substandard and potentially dangerous practice in the area of traditional Chinese medicine, which uses both acupuncture and herbs. With herbal medicines there are a wide range of potential risks. These include: inaccurate diagnosis, (including failing to recognise serious conditions and thereby delaying effective treatment); inappropriate advice to come off important prescribed medicines; provision of ineffective or unsuitable unlicensed medicines which are contraindicated; lack of awareness of the possibilities of interactions between orthodox and herbal medicines; supply of low grade potent unlicensed products adulterated with the wrong, toxic, herb, or with undeclared pharmaceuticals or with heavy metals.

There is a significant body of evidence of substandard and sometimes dangerous practice, in the supply by clinics and practitioners of unlicensed “herbal” products, mainly but not exclusively in the area of traditional Chinese medicine. There is evidence that

some practitioners are treating vulnerable groups such as children, the terminally ill or those with serious conditions. There is repeated evidence found of toxic, adulterated products used by some clinics. On several occasions the MHRA has had to issue general warnings about the prevalence of low grade TCM products on the UK market. There is therefore a strong argument for some form of regulation on the grounds of public health risks.

- **European legislation:** In addition, failure to regulate practitioners could create problems with related legislation about unlicensed herbal medicines supplied by practitioners. Many practitioners (particularly in TCM) commission unlicensed manufactured herbal medicines to meet the special needs of their patients. Linked to the then plans for statutory regulation of herbal practitioners, the MHRA had previously identified and consulted on a way to permit and regulate this unlicensed activity by using a derogation within Art 5.1 Directive 2001/83/EC which permits national regulatory arrangements where an unlicensed manufactured medicine is commissioned by “an authorised healthcare professional” to meet the special needs of the individual patient. In the absence of such arrangements, these manufactured unlicensed herbal medicines would require a full marketing authorisation or traditional herbal registration under Directive 2001/83/EC. Legal advice is that the feasibility of regarding practitioners as “authorised healthcare professionals” is linked to the extent to which proposed regulatory arrangements for herbal practitioners are robust and analogous to those for other regulated healthcare professionals. While statutory regulation would be likely to be a reasonable basis for using the Art 5.1 derogation, the position is less clear cut with lighter touch forms of regulation. The reason the UK faces a particular issue here is that, unlike in most other EU Member States, we have existing (albeit weak) national legislation permitting herbal practitioners to supply unlicensed herbal medicines. We therefore face the issue of ensuring that our regime is compliant with European medicines legislation.
- **Prior commitments:** The Government has made previous commitments to statutorily regulate these professions and a decision not to regulate or to regulate differently would be likely to incur criticism from those in favour of orthodox statutory regulation. Arguably, lack of regulation would limit patient/consumer choice by making NHS referrals for complementary healthcare more difficult and by restricting access to herbal medicines as a result of European legislation.

## **Statutory Regulation and Alternatives to Statutory Regulation**

- a) **Statutory regulation** would mean effective assurance of the standards of the practitioners who are regulated. The public would be protected from poor or bad practice because legal sanctions exist to remove individuals from a register. Statutory regulatory bodies determine standards of practice and competence. Those who meet the criteria set for determining competence are eligible to be included on a register and to use a protected title. In the light of the public health risk, during 2008 both the independent Herbal Medicines Advisory Committee and the Health Professions Council (HPC) recommended that herbal practitioners and TCM practitioners should be subject to statutory regulation. The HPC also recommended that acupuncturists should be subject to such regulation.
- b) **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 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 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.

A key consideration with such a licensing scheme is whether it would provide sufficiently targeted safeguards for the public, including vulnerable groups, in a situation where the practitioner is diagnosing illness, which may be serious, and supplying unlicensed medicinal products, which may be potent.

Such a scheme may require primary legislation.

- c) **Voluntary regulation** would mean that whilst practitioners could choose to register with an organisation which accredits their educational qualifications and requires them to sign up to a code of conduct, there would be no legal sanctions for practitioners who do not register, or who behave disreputably (unless of course their offence were sufficiently severe to merit prosecution). Voluntary regulation also has the disadvantage that members of the public do not have the reassurance afforded by statutory regulation that the practitioner is bona fide: as there is no legal protection of title, anyone can describe themselves as (for example) a herbalist without possessing relevant qualifications and without joining a voluntary register or subscribing to any ethical standards. Since there tends to be a proliferation of professional bodies and associations with which alternative practitioners can register voluntarily, members of the public would be unlikely to know which organisations are reputable and which register people on the basis of very slender evidence.

This problem could be largely overcome by some form of “meta-regulation” (oversight of regulation) e.g. accreditation of voluntary registers by another body as a mark of quality assurance.

Voluntary regulation is, however, a welcome alternative to no regulation as it provides some minimal protection for the public. The Department has, for the last three years, funded the Prince of Wales’s Foundation for Integrated Health (FIH) to work with a range of complementary and alternative to set up a voluntary “umbrella” regulator, the Complementary and Natural Healthcare Council (CHNC).

An important consideration with this option is whether, given the track record of patchy and sometimes low standards in parts of the TCM sector leading to serious safety concerns, this model of regulation would be sufficiently robust in protecting the public from less responsible and less competent practitioners. One relevant comparison is the extent of regulatory safeguards applying in other situations where orthodox healthcare practitioners are permitted to diagnose and to prescribe unlicensed medicines.

- d) **Do nothing - No regulation.** This is the existing situation, though many practitioners currently choose to join a voluntary register. Given the interface with European medicines legislation which requires that only “authorised healthcare professionals” will be able to supply unlicensed manufactured herbal products after April 2011, there would not be any clear basis for permitting the legal supply of unlicensed manufactured herbal medicines commissioned from a 3<sup>rd</sup> party by practitioners post 2011. Apart from the possible impact on the practitioners, it might also lead to a reduction of choice for patients and the public. There is also the possibility that in the face of a decision not to introduce regulation to the sector this would impact adversely on individual practitioners and practitioners associations that were seeking to behave responsibly in favour of practitioners who were less

scrupulous about patient safety. In the event of continuing evidence of harm to the public, and in the absence of alternative regulatory tools to give assurances about the competence of practitioners, it is likely that the MHRA would need to introduce further restrictions eg on use of potent herbs and on inherently less harmful herbs that were prone to confusion with toxic herbs. It appears that other EU member states are not currently proposing to establish formal professional regulatory arrangements for these practitioners.

## **Knowledge of English Language**

One of the recommendations of the Steering Group is that statutory regulated practitioners from this sector should be able to demonstrate a reasonable standard of English language ability by being able to achieve an International English Language Testing System (IELTS) score of at least 6.5. The Steering Group took the view it is important to safeguard patients and to ensure that practitioners from this sector can communicate effectively with other health professionals.

This recommendation has been controversial within the Chinese Medicine community as there is no doubt that a high proportion would not be able to meet the recommended minimum standard for registration. It is estimated that between 70-85% of the around 2,800 practitioners would fail to meet the standard and this issue is considered in the Equality Impact Assessment.

The Equality Impact Assessment suggests that practitioners might be able to employ an interpreter, undertake language training or strive to get the recommended IELTS score of 6.5 lowered. If any of these factors were taken on board as part of the move towards statutory regulation then

- Practitioners would have to be able to demonstrate compliance and/or act to comply with regulatory requirements, if they are unable to communicate effectively with regulators
- Dealing with non-English speaking practitioners would potentially impose additional costs on regulatory authorities
- It is potentially problematic (and indeed potentially discriminatory) to officially endorse a group of regulated practitioners who can only offer services to one particular ethnic/language group
- A decision to waive (or reduce) English language competencies for this group would obviously set a precedent for other non-English speaking minority practitioners in future. Currently the HPCs IELTS requirements for non-English speaking practitioners on their register is 6.5 – the Pittilo report's recommendation mirrors this requirement.

## **Risks**

The main area of risk to consider results from the activities of unscrupulous or inadequately trained practitioners, or those who may be unable to communicate effectively in English. This could result in incorrect prescribing or the failure to take into account a patient's medical condition (eg diabetes, epilepsy, heart disease) and other medications that the patient may be taking. Patients might also be persuaded not to seek more appropriate treatment from an NHS general practitioner. There is some evidence that some herbal medicines, particularly TCMS, are supplied for use on vulnerable patient groups, such as children and people who have serious illness. UK medicines legislation is weak on unlicensed herbal medicine and is hampered by the absence of assurance that the practitioner (currently undefined in legislation) has any expertise or accountability.

Levels of actual harm are difficult to assess. Sporadic cases continue to be detected in the UK where organ failure or death has resulted from inadvertent supply of toxic remedies. However, in most cases the possible linkage between ill health and consumption of unlicensed herbal products is unlikely to be made; many people do not tell their doctor they are taking a herbal

remedy and even where they do the doctor would usually have no reason to know that the product contained undeclared substances. International evidence, eg from Belgium and Japan, demonstrates the potential for death or serious illness to exceed 100 cases in incidents where there is serious penetration of a supply chain by a widely used product. In the UK, with a pattern of dispersed herbal clinics and practitioners, it would generally be unlikely that problems would be sufficiently concentrated in any particular geographic area for, say, a renal unit to be able to identify an increased incidence in unexplained kidney damage.

The MHRA continues to find examples of low grade unlicensed herbal products on the market supplied by clinics or herbal practitioner that pose a direct risk to public health. The MHRA has produced an overview of the public health risk from herbal medicines (which is reflected in the consultation document).

Ipsos MORI research for the MHRA (2008) on public perceptions of herbal medicines included findings which may be interpreted as suggesting that those consumers of herbal medicines who are most vulnerable are also most likely to be exposed to products or clinical practise posing the most risk. The research showed that of all groups of users and non users of herbal medicines, users of TCMs are most likely to agree (76%) with the statement that herbal medicines are safe because they natural. This may well mean that they are less likely to exercise caution if a less reputable clinic or practitioner advertises to patients that their products (which may be low grade or even adulterated with undeclared pharmaceutical ingredients) are natural. The qualitative aspect of the Ipsos MORI research also noted: *“Practitioners of traditional Chinese herbal medicine are heavily trusted. Some participants suggested that traditional Chinese herbal medicine was suitable for more serious medical conditions with practitioners regarded by a few participants as similar to conventional doctors.”*

The Medicines and Healthcare Products Regulatory Agency takes the view that the practitioners need to be regulated. This is also the view of the Herbal Medicines Advisory Committee (HMAC), which has written to Ministers to urge them to regulate. This advice did not however consider cost and benefit data and did not consider the relative benefits of potential regulatory regimes.

## **Numbers of practitioners**

**We estimate that in total there are probably less than 8000 practitioners of acupuncture, herbal medicine and TCM who are not already regulated by another statutory regulator.**

Estimates have been obtained from the Chairs of the three professions working groups which in some cases relate to membership of professional bodies/voluntary registers.

Estimates are that there are approximately 3400 acupuncturists who are not already registered with an existing statutory regulator, and a further 9500 who are already regulated (mostly doctors, nurses and physiotherapists).

Similarly there are thought to be around 1500-1700 herbalists who do not practise Chinese medicine.

There is no reliable data on the numbers of Chinese medicine practitioners or the number of Chinese herbal shops in the UK. However, clearly there has been a large increase in the numbers of such shops appearing on the high street over the last few years. The current situation of the shops does give some cause for concern in that 3 of the largest chains have gone into either receivership or administration in the last 3 months (Jan-March 2009). This also causes concern for the public, who in many cases have paid in advance for treatment which they will not be able to receive. The shops represent the public face of Chinese Medicine in the UK and therefore there is an assumption that treatment there will be at the correct and appropriate level. The shops being mainly for retail purposes mainly employ non- practitioners

as retail assistants, but also employ practitioners. The data we have on these numbers comes from the Home Office Work Permits section who received 123 applications for work permits in 2007 of which 26 were refused. It is estimated that around 800 practitioners are currently working within around 2,500 shops and have entered the UK on work permits.

Altogether there are about 2800 Chinese medicine practitioners registered with a range of voluntary professional associations, which presumably includes the 800 mentioned above.

### **Possible effect on small firms/business**

In the case of Options 1 and 2 (statutory regulation, licensing), depending on the English language requirements, a proportion of practitioners might be unable to continue to practise, with the result that some businesses might have to close down if those staff could not be replaced. In the case of any option that did not permit creation of a scheme for practitioners to commission unlicensed manufactured herbal medicines some practitioners/businesses would be at risk of enforcement action by MHRA on account of non compliance with medicines laws.

With any option that did not secure systematic regulation of unlicensed herbal medicines supplied by practitioners there could be an impact on the market in herbal medicinal products. The over the counter (OTC) sector in herbal medicines is currently moving into systematic regulation with many companies, including SMEs, having invested to meet manufacturing and quality standards required by the traditional herbal registration scheme. If poorly regulated unlicensed herbal medicines supplied by practitioners operating within weak professional regulation are explicitly or tacitly permitted this could create an adverse incentive for operators to present activity as being practitioner based within a weak UK regime in order to evade regulatory requirements applying to the OTC sector. Some companies operating in the regulated sector might see some sales and hence profits diverting into the relatively unregulated practitioner sector. In this scenario, asymmetric information available to the consumer would contribute to a degree of market failure. In these circumstances it could also be problematic for MHRA to identify an approach to compliance and enforcement that was transparent, coherent and met Hampton principles. This could give rise to uncertainty in the sector.

Any option that did not deliver effective regulation of the sector could also have a significant effect in shifting the commercial advantage away from practitioners seeking to exercise responsibility (eg in sourcing high quality – more expensive - ingredients/products, avoiding irresponsible advertising, supplying only products to meet patient needs rather than maximising sales) in favour of less responsible and competent practitioners. In addition, any option that did not deliver effective regulation would also mean that responsible operators would be at risk of having their business undermined by continuing scare stories and examples of bad practice emanating from the less responsible end of the sector. A key issues, therefore with any lighter touch regulatory options, such as Option 2 and 3 is to consider whether they could be constructed so as to deliver the kind of regulation that is commensurate with the risks arising from the activity.

### **Potential enforcement costs**

Costs associated with statutory regulation or licensing would be around:-

- Cost of practitioners' registration with e.g. the Health Profession Council 8,000 approx @ £72 per year current rate = £576k (approx) – licences would presumably be cheaper
- Administration costs for the HPC or similar to run statutory registration or a licensing scheme will depend on the need for "grandparenting" but are estimated at £150k maximum
- Costs to practitioners for English language training 2000@ £1,500 = £3m

- Cost to business if practitioners can't register and the need for recruitment. 100@ £250 = £25k

Different costs would apply if any of the other options (voluntary regulation, or no regulation) were approved by Ministers. For example there would be application and registration fees to a voluntary register e.g. CNHC, but most practitioners already belong to a voluntary register anyway. As practitioners would not be obliged to register, those who chose not to would incur nil costs.

Depending on the option chosen there could be implications for costs of MHRA enforcement in relation to medicines legislation. An initial view is that the cost effectiveness and utility of enforcement may be as much of an issue as actual costs. Any option that does not deliver a clear cut, transparent and credible regulatory position is likely to be difficult to enforce in accordance with Hampton principles

**Stage 1: Initial Scoping assessment and action plan**

**Purpose**

The purpose of this document is –

- Modernisation of the regulation of health care and associated professions.
- The Government needs to decide whether to agree to the statutory regulation of acupuncture, herbal medicine and traditional Chinese medicine practitioners, to look at alternatives to full statutory regulation and to decide what form any such regulation should take.
- The Government needs to seek views from the wider public and other stakeholders on the recommendation from the Pittilo report to proceed to statutory regulation and has decided to do so by a public consultation.

**Promoting equality of opportunity:**

(a) I have prepared an equality screening document which clearly indicates that a full EqlA is required on the ground of racial and age equality. The screening covers all the categories of people that DH are required to consider.

The issue relates to whether the proposal to statutory regulate by either fully regulating, or by a different less stringent model of regulation would discriminate against Chinese Herbal Medicine practitioners and users of their services on grounds of race and age. One of the competences that is recommended to be required of every practitioner seeking to register with the statutory regulator would be to achieve the minimum IELTS score of 6.5 on the knowledge of English language, which will prove very difficult to achieve for a large number of practitioners (see estimated figures below). The older practitioners are more likely to fail to meet the standard, as they will have been practising in the UK for many years without the need to improve their English language knowledge. However, while the working group recommended an IELTS score of 6.5, it could possibly be lowered or there could be agreement to the use of interpreters.

These issues need to be balanced against patient safety which remains paramount and is the driver behind any proposal to statutory regulate a health profession.

**Whether the likely impact is positive or negative**

(b) If some form of statutory regulation is approved by Ministers the impact on the Chinese practitioners and users of their services is likely to be both positive and negative.

On the positive front, it would mean that the MHRA who are required to enforce European Directive 2001/83/EC would be able to accept statutorily regulated practitioners as “authorised healthcare professionals” under Article 5.1. This would enable the UK to permit the supply of manufactured unlicensed medicines, if ordered by, and made to the specification of those authorised practitioners, who would be able to continue practising legally after April 2011. The herbal practitioners including the Chinese medicine practitioners support the move to statutory regulation as they are worried about the effect of the European Directive on Traditional Herbal Medicinal Products on their ability to continue to practise if a form of statutory regulation does not go ahead. Patients would have greater assurance that the services they receive are provided by bona fide, regulated practitioners who comply with certain minimum standards.

However, on the negative side, if Chinese practitioners were required to attain a minimum standard of English in order to gain entry to a statutory register, this could prove a significant barrier to registration for many. The Chinese medicine community have suggested various ways of addressing this problem, for example allowing “provisional” registration while practitioners improve their language skills, during which time they might only be able to practise if using an interpreter when communicating with English-speaking patients. Depending upon the solution adopted, patients might have more difficulty accessing these services as some practitioners might be unable to register and consequently be obliged to cease practising.

**How significant the impact is likely to be: whether it would be proportionate to adjust the policy or practice to increase the positive impact and/or reduce the negative; and if so, how.**

We could decide not to proceed to statutory regulation at all, but this might lead to the European Directive effectively preventing herbal practitioners from practising a significant element of their profession when the Directive takes effect in 2011. Patient safety concerns would also remain and would argue for a campaign to educate the public on the use of herbs.

The Steering Group’s report says that English language proficiency is essential for all healthcare professions and recommended a minimum IELTS score of 6.5 in order to enter the register. The working group did acknowledge that their recommendation of a minimum threshold could cause considerable difficulty especially for some Traditional Chinese Medicine practitioners, who might be prevented from practising if their recommendation were accepted. They further acknowledged that if this were the case some Chinese speaking members of the public might no longer be able to obtain access to traditional Chinese medicine. While the exact numbers of Chinese medicine practitioners working in the UK is not known, we have received an estimate from the chair of the Chinese medicine working group, who suggested that there are approximately 2,800 Chinese medicine practitioners of whom around 70% - 85% might fail to achieve the IELTS score of 6.5.

The working group suggested that organisations representing Chinese herbal practitioners should work with the Health Professions Council to ensure that no discrimination takes place.

Positive action that could be taken in this area is:

1. the use of bilingual English/Chinese speaking interpreters (but it is noted that this proposal was considered and rejected by the joint working group).
2. the professional bodies could work with the HPC to draw up a training programme for non-English speaking practitioners which might allow them to achieve the required standard.
3. consideration could be given to a “grandparenting” clause covering non-speaking chinese practitioners. This might allow for a very short window of opportunity for registration of these practitioners, especially if they only treated non-english speaking Chinese patients. There could be a form of “provisional” registration while practitioners improve their language skills, during which time they might only be able to practise if using an interpreter when communicating with english-speaking patients.
4. there could be a lower threshold than IELTS 6.5 which would allow the practitioners to register with the HPC. Any such reduction would have to be agreed with the professional bodies and the HPC, and would be controversial as it would be lower than the standard set for other professions.

## **Whether there are opportunities to promote equality of opportunity that could be taken if the policy/practice were adjusted**

Statutory regulation could benefit practitioners by conferring “legitimacy” to their practice and increasing public confidence. Whilst initially expensive, investing in improving their communication skills would ultimately benefit both practitioners and their patients.

The actions suggested above would mitigate any negative impact of this policy on equality of opportunity. However this must be balanced against the safety of the public as a whole, which is the overriding rationale behind regulation.

### **Next Steps**

A consultation will be launched in July 2009 to seek views from the public and stakeholders on the recommendations from 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 (known as the Pittilo report). Once the consultation responses have been analysed, Ministers will make a decision on how and which way to move forward.

## **Annex B**

### **Health Impact Assessment**

#### **A. Are the potential positive and/or negative health and well-being impacts likely to affect specific sub groups disproportionately compared with the whole population?**

##### **Proceed to full statutory registration /Proceed to light-touch regulation (licensing)**

Under these options there is potential for both positive and negative impact on the health and well-being of a specific sub-group, namely the Chinese population. Statutory regulation would improve public protection for everyone from incompetent or unscrupulous practitioners. It would certainly comply with the “authorised healthcare professional” requirement of the European Directive and herbalists would be able to continue supplying unlicensed medicines.

The absence of fitness to practise procedures in the case of licensing would reduce the burden on the practitioners but would be less effective in raising standards and promoting patient safety.

However, the conditions for registration are likely to mean that some existing practitioners would not gain registration with the Health Professions Council and therefore would be prevented from continuing to practise their profession. In particular, there is potential for a significant number of traditional Chinese practitioners to fail the English language competency test and therefore be unable to register. Practitioners unable to gain registration with the HPC would effectively lose their livelihoods. This could also lead to a loss of choice for patients, and additional burdens on business in relation to Chinese medicine shops. These changes would have a disproportionate and negative impact on the Chinese community.

These disadvantages must however be balanced against the advantages to the public as a whole, including the Chinese population, of reducing the risk of unsafe practice.

##### **Decision not to statutorily regulate (do nothing) or voluntary regulation only**

There would be no immediate effect on either the practitioners or the population as a whole as the existing situation would be maintained. Chinese only speaking patients who rely on Chinese practitioners would still be able to access services as they currently do. However, on the negative side of the “do nothing option”, this could be seen as giving encouragement to those practitioners who did not wish to follow standards of good professional practice, which could serve to exacerbate existing problems of low standards. In the absence of a legally sound basis for practitioners commissioning unlicensed manufactured herbal medicines it could also lead to a loss of some business for some practitioners. It might also have a disproportionate effect on the local Chinese population who might rely heavily on herbal medicine rather than using general practitioner services.

It is by no means certain that voluntary regulation underpinned by accreditation of registration bodies, or a licensing system could provide sufficient legal certainty to permit the creation of a scheme under Art 5.1 of Directive 2001/83/EC and enable practitioners to continue practising. It appears that other EU member states are not currently proposing to establish formal professional regulatory arrangements for these practitioners.

#### **B. Are the potential positive and/or negative health and well-being effects likely to cause changes in contacts with health and/or care services, quality of life, disability or death rates?**

### **Proceed to full statutory registration or licensing**

The adoption of this option might encourage Primary Care Trusts and general practitioners to commission some services for NHS patients. This is because there would likely to be more confidence in such services if they were being provided by a statutorily regulated practitioner.

### **Decision not to statutory regulate, or voluntary regulation only**

There should be very little change if this option were adopted, as it represents the status quo. However, there is the potential for some patients to lose services they rely upon if there is no regulation and if, as a result, some practitioners are unable to continue practising legally.

## **C. Are there likely to be public or community concerns about potential health impacts of this change of policy?**

### **Proceed to full statutory registration**

Members of the public and organisations who have concerns about the efficacy and safety of these therapies may be concerned that regulation would confer an unwarranted legitimacy on these treatments, which would lead to patients and the public being misled into seeking what they perceive as unproven treatments rather than seeking conventional treatment.

### **Proceed to light-touch (licensing) regulation**

This “middle way” option has not been considered at all by the stakeholders as it has arisen recently as a result of the considerations of the Extending Professional Regulation working group.

### **Decision not to statutory regulate, or voluntary regulation only**

Proponents of regulation will be concerned that voluntary regulation offers insufficient protection of the public from unsafe practitioners.

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

**Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.**

<b>Type of testing undertaken</b>	<b><i>Results in Evidence Base?</i></b>	<b><i>Results annexed?</i></b>
Competition Assessment	No	No
Small Firms Impact Test	Yes	No
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	Yes	Yes
Race Equality	Yes	Yes
Disability Equality	No	No
Gender Equality	No	No
Human Rights	No	No
Rural Proofing	No	No

