# A joint consultation on the Report to Ministers from the DH Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK

# A joint consultation on the Report to Ministers from the DH Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK

**DH INFORMATION READER BOX**

| | |
|---|---|
| Policy | Estates |
| **HR / Workforce** | Commissioning |
| Management | IM & T |
| Planning / | Finance |
| Clinical | Social Care / Partnership Working |

| | |
|---|---|
| **Document Purpose** | Consultation/Discussion |
| **Gateway Reference** | 12173 |
| **Title** | Joint UK-wide consultation on the Report to Ministers from the DH steering Group on the Statutory Regulation of Practitioners of Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK |
| **Author** | DH/Professional Standards Division |
| **Publication Date** | 01 Jul 2009 |
| **Target Audience** | PCT CEs, NHS Trust CEs, SHA CEs, Care Trust CEs, Foundation Trust CEs , Directors of PH, Directors of Adult SSs, Allied Health Professionals, GPs, Communications Leads, Privately Practising Alternative Medicine Practitioners, UK Professional Bodies representing Acupuncture, Herbal Medicine and TCM, NHS bodies (Scottish Health Boards, Local Health Boards in Wales, Community Health Councils in Wales, the NI Ambulance Service, the<br>Health and Social Care Board, Public Health Agency, Patient Client Council, and the Business Services Organisation) Royal Colleges, UK Regulatory Bodies, comsumer representatives, Herbal Industry, NHS Trades Union |
| **Circulation List** | Voluntary Organisations/NDPBs |
| **Description** | Government needs to decide whether to agree to the statutory regulation of Acupuncture, Herbal Medicine and TCM and if so, what form such statutory regulation should take. |
| **Cross Ref** | Pittilo report |
| **Superseded Docs** | N/A |
| **Action Required** | N/A |
| **Timing** | **Consultation launch** |
| **Contact Details** | Sharon Corner/Kelly Suthern/Keith Baggs/Kate Ling<br>Professional Standards Division<br>2N09<br>Quarry House, Quarry Hill<br>LS2 7UE<br>(0113 254) 6765/5719/5791/6786 |
| **For Recipient's Use** | |

# Executive summary

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

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

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

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

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

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

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

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

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

# Contents

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

The report from the DH Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK (view Report) is the culmination of nearly two years' work and of a process which began several years ago with the publication of the House of Lords Select Committee on Science and Technology's report in 2000 on complementary and alternative medicine.

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

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

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

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

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

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

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

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

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

Ann Keen Nicola Sturgeon Michael McGimpsey Edwina Hart

# Introduction

## Why Regulate?

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

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

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

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

## What do we mean by statutory professional self-regulation?

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

## Devolved administrations

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

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

## What do we mean by system regulation?

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

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

## Extending Professional Regulation (EPR)

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

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

Key Principles

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

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

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

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

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

<u>Gatekeeper Role</u>

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

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

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

Scottish Government pilot

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

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

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

## The purpose of this consultation

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

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

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

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

# Background

## Background to each of the three therapies proposing statutory regulation

### Acupuncture

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

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

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

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

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

## Herbal Medicine

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

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

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

It is also important to note that :

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

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

## Traditional Chinese Medicine

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

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

## Background to the establishment of the Steering Group

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

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

## The 2004 consultation exercise

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

## Responses to the 2004 consultation

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

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

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

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

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

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

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

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

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

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

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

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

You can view the report HERE

# Issues for Discussion and Questions

### What are the risks to be managed?

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

There are three broad areas of risk to consider:

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

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

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

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

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

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

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

**Question 1**
**What evidence is there of harm to the public currently as a result of the activities of acupuncturists, herbalists and traditional Chinese medical practitioners? What is its likelihood and severity?**

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

### What are the disadvantages associated with introducing statutory regulation?

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

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

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

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

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

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

**Question 4**
**What do you envisage would be the regulatory burden and financial costs, to the public, to practitioners and to businesses, associated with introducing statutory regulation? Are these costs justified by the benefits and are they proportionate to the risks? If so, in what way?**

## Alternatives to statutory regulation of practitioners

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

Product regulation

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

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

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

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

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

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

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

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

Alternatives to statutory regulation of practitioners include

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

- Voluntary regulation with an accredited register

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

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

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

**Question 5**
**If herbal and TCM practitioners are subject to statutory regulation, should the right to prepare and commission unlicensed herbal medicines be restricted to statutorily regulated practitioners?**

**Question 6**
**If herbal and TCM practitioners are *not* statutorily regulated, how (if at all) should unlicensed herbal medicines prepared or commissioned by these practitioners be regulated?**

**Question 7**
**What would be the effect on the public, practitioners and businesses if, in order to comply with the requirements of European medicines legislation, practitioners were unable to supply manufactured unlicensed herbal medicines commissioned from a third party?**

System regulation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Accreditation of voluntary registration bodies

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

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

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

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

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

Legislation on Health and Safety/Trading Standards/Advertising Legislation

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

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

Local Authority Registration and Licensing

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

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

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

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

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

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

Statutory Licensing Schemes

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

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

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

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

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

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

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

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

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

<u>Voluntary Licensing Schemes</u>

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

**Question 8**
**How might the risk of harm to the public be reduced other than by statutory professional self-regulation? For example, by voluntary self-regulation underpinned by consumer protection legislation and by greater public awareness, by accreditation of voluntary registration bodies, or by a statutory or voluntary licensing regime?**

**Question 9**
**What would you estimate would be the regulatory burden and financial costs to the public, to practitioners and to businesses for the alternatives to statutory regulation suggested at Question 8?**

**Question 10**
**What would you envisage would be the benefits to the public, to practitioners and to businesses, for the alternatives to statutory regulation outlined at Question 8?**

**Question 11**
**If you feel that not all three practitioner groups justify statutory regulation, which group(s) does/do not and please give your reasons why/why not?**

**Question 12**
**Would it be helpful to the public for these practitioners to be regulated in a way which differentiates them from the regulatory regime for mainstream professions publicly perceived as having an evidence base of clinical effectiveness? If so, why? If not, why not?**

**Question 13**
**Given the Government's commitment to reducing the overall burden of unnecessary statutory regulation, can you suggest which areas of healthcare practice present sufficiently low risk so that they could be regulated in a different, less burdensome way or de-regulated, if a decision is made to statutorily regulate acupuncturists, herbalists and traditional Chinese medicine practitioners ?**

## How to statutorily regulate

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

Who should statutorily regulate?

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

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

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

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

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

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

**Question 14**
**If there were to be statutory regulation, should the Health Professions Council (HPC) regulate all three professions? If not, which one(s) should the HPC not regulate?**

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

**Question 16**
**If neither, who should and why?**

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

Dual/distributed regulation

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

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

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

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

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

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

Protection of title

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

**Question 18**

**a) Should the titles "acupuncturist", "herbalist" and "[traditional] Chinese medicine practitioner" be protected?**
**b) If your answer is "No", which ones do you consider should not be legally protected?**

Protection of function

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

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

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

**Question 19**
**Should a new model of regulation be tested where it is the *functions* of acupuncture, herbal medicine and TCM that are protected, rather than the *titles* of acupuncturist, herbalist or Chinese medicine practitioner?**

Grandparenting

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

**Question 20**
**If statutory professional self-regulation is progressed, with a model of protection of title, do you agree with the proposals for "grandparenting" set out in the Pittilo report?**

English language competence

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

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

**Question 21**
**In the event of a decision that statutory or voluntary regulation is needed, do you agree that all practitioners should be able to achieve an English language IELTS score of 6.5 or above in order to register in the UK?**

**Question 22**
**Could practitioners demonstrate compliance with regulatory requirements and communicate effectively with regulators, the public and other healthcare professionals if they do not achieve the standard of English language competence normally required for UK registration? What additional costs would occur for both practitioners and regulatory authorities in this case?**

**Question 23**
**What would the impact be on businesses (financial and regulatory burden) if practitioners unable to achieve an English language IELTS score of 6.5 or above are unable to register in the UK?**

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

# Summary of Consultation Questions

**Question 1**
**What evidence is there of harm to the public currently as a result of the activities of acupuncturists, herbalists and traditional Chinese medical practitioners? What is its likelihood and severity?**

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

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

**Question 4**
**What do you envisage would be the regulatory burden and financial costs, to the public, to practitioners, and to businesses, associated with introducing statutory regulation? Are these costs justified by the benefits and are they proportionate to the risks? If so, in what way?**

**Question 5**
**If herbal and TCM practitioners are subject to statutory regulation, should the right to prepare and commission unlicensed herbal medicines be restricted to statutorily regulated practitioners?**

**Question 6**
**If herbal and TCM practitioners are *not* statutorily regulated, how (if at all) should unlicensed herbal medicines prepared or commissioned by these practitioners be regulated?**

**Question 7**
**What would be the effect on the public, practitioners and businesses if, in order to comply with the requirements of European medicines legislation, practitioners were unable to supply manufactured unlicensed herbal medicines commissioned from a third party, after 2011?**

**Question 8**
**How might the risk of harm to the public be reduced other than by statutory professional self-regulation? For example, by voluntary self-regulation underpinned by consumer protection legislation and by greater public**

**awareness, by accreditation of voluntary registration bodies, or by a statutory or voluntary licensing regime?**

**Question 9**
**What would you estimate would be the regulatory burden and financial costs, to the public, to practitioners, and to businesses, for the alternatives to statutory regulation suggested at Question 8?**

**Question 10**
**What would you envisage would be the benefits to the public, to practitioners, and to businesses, for the alternatives to statutory regulation outlined at Question 8?**

**Question 11**
**If you feel that not all three practitioner groups justify statutory regulation, which group(s) does/do not and please give your reasons why/why not?**

**Question 12**
**Would it be helpful to the public for these practitioners to be regulated in a way which differentiates them from the regulatory regime for mainstream professions publicly perceived as having an evidence base of clinical effectiveness? If so, why? If not, why not?**

**Question 13**
**Given the Government's commitment to reducing the overall burden of unnecessary statutory regulation, can you suggest which areas of healthcare practice present sufficiently low risk so that they could be regulated in a different, less burdensome way or de-regulated, if a decision is made to statutorily regulate acupuncturists, herbalists and traditional Chinese medicine practitioners ?**

**Question 14**
**If there were to be statutory regulation, should the Health Professions Council (HPC) regulate all three professions? If not, which one(s) should the HPC not regulate?**

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

**Question 16**
**If neither, who should and why?**

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

**Question 18**
**a) Should the titles "acupuncturist", "herbalist" and "[traditional] chinese medicine practitioner" be protected?**
**b) If your answer is “No”, which ones do you consider should not be legally protected?**

**Question 19**
**Should a new model of regulation be tested where it is the *functions* of acupuncture, herbal medicine and TCM that are protected, rather than the *titles* of acupuncturist, herbalist or Chinese medicine practitioner?**

**Question 20**
**If statutory professional self-regulation is progressed, with a model of protection of title, do you agree with the proposals for "grandparenting" set out in the Pittilo report?**

**Question 21**
**In the event of a decision that statutory or voluntary regulation is needed, do you agree that all practitioners should be able to achieve an English language IELTS score of 6.5 or above in order to register in the UK?**

**Question 22**
**Could practitioners demonstrate compliance with regulatory requirements and communicate effectively with regulators, the public and other healthcare professionals if they do not achieve the standard of English language competence normally required for UK registration? What additional costs would occur for both practitioners and regulatory authorities in this case?**

**Question 23**
**What would the impact be on the public, practitioners and businesses (financial and regulatory burden) if practitioners unable to achieve an English language IELTS score of 6.5 or above are unable to register in the UK?**

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

# Consultation – Next Steps

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

## Response to the Consultation

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

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

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

You may also respond in writing to:

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

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

## Comments or Complaints about the Consultation Process

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

Consultations Co-ordinator

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

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

## Freedom of Information

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

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

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

# ANNEX A

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

## Summary of White Paper tasks for the Working Group

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

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

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

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

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

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

## Terms of Reference

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

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

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

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

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

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

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

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

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

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

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

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

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

8. To act on recommendations from UK health policy.

# ANNEX B

# Public Health Risk with Herbal Medicines: Summary

The main safety issues are as follows:

### Products

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

For example:

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

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

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

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

**Lack of patient information** (unregulated products only)

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

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

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

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

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

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

### Patients

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

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

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

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

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

### Practitioners

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

**Potential drug-herb interactions,** where practitioner lacks relevant knowledge

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

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

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

# ANNEX C

# Alternatives to Statutory Regulation

### Advantages and Disadvantages

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

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

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

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

# ANNEX D

# System Regulation Arrangements

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

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

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

**ANNEX E**

# Health Professions Council – Licensing Proposals for Healthcare Workers

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

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

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