



*Regulation of herbal medicine
and acupuncture*

Proposals for statutory regulation

March 2004

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Contents

Foreword by John Hutton MP	3
Introduction – what is statutory regulation?	4
Background to statutory regulation	5
Herbal Medicine Regulatory Working Group	6
Acupuncture Regulatory Working Group	7
Issues for Discussion	
– Devolution	8
– The type of regulatory body	8
– Protection of title	10
– Key functions of the new Council	12
– Composition of the Council	13
– Position of practitioners who are already regulated	14
– Statutory committees	16
– Registration of practitioners	17
– Registration procedures – overseas-qualified practitioners	18
– Registration of practitioners – transitional period	19
– Standards of proficiency	20
– Conduct of practitioners	21
– Continuing professional development (CPD)	21
– Fitness to practise	22
– Appeals	24
– Accountability of the CAM Council	25
– Preparing for statutory regulation	25
Bibliography	26
Summary of consultation questions	27
How to respond	29
Annex A – Regulatory Impact Assessment	30

Foreword by John Hutton MP



This Government is committed to increasing public and patient protection and improving quality in all healthcare settings. As interest in complementary medicine grows, so too must our focus on public safety and ensuring effective standards. It is no longer appropriate for statutory regulation to be restricted to orthodox healthcare professionals such as doctors, nurses and physiotherapists.

The House of Lords Select Committee on Science and Technology recommended in November 2000, in its report on Complementary and Alternative Medicine, that it would be of benefit to both patients and practitioners for the herbal medicine and acupuncture professions to strive for statutory regulation. In its response to the Select Committee's report, this Government accepted this principal recommendation.

We subsequently established, together with the Prince of Wales's Foundation for Integrated Health, two independent regulatory working groups to develop recommendations for the statutory regulation of herbal medicine and acupuncture. Both working groups published their reports in September 2003.

We have considered and built on the working groups' recommendations in developing our proposals for the statutory regulation of the herbal medicine and acupuncture professions. Our proposals are set out in full in this consultation document.

I believe that these proposals will improve the quality of patient care. They will also help reassure patients and the public about the skills and competence of herbal medicine and acupuncture practitioners.

I look forward to receiving comments on our proposals.

A handwritten signature in dark ink that reads "John Hutton". The signature is written in a cursive, flowing style.

John Hutton MP
Minister of State for Health
March 2004

Introduction

What is statutory regulation?

1. Statutory self-regulation of healthcare professionals helps protect patients and the public by ensuring that practitioners meet agreed standards of practice and competence. A statutory regulatory system involves the establishment of a register of practitioners who are qualified and competent to practise. Use of a specified title is then restricted to practitioners who are included on the register. Sanctions, such as suspension or removal from the register, can be applied to any practitioner whose fitness to practise is impaired.

Examples of existing statutory regulatory schemes

Physiotherapists are regulated by the Health Professions Council (HPC). Use of the title “physiotherapist” is restricted to those included on the Register maintained by the HPC.

Osteopaths are regulated by the General Osteopathic Council (GOsC). Use of the title “osteopath” is restricted to those included on the Register maintained by the GOsC.

2. For patients, carers and the public, a modern statutory regulatory framework provides reassurance that a practitioner is not only suitably qualified, but also competent and up-to-date with developments in practice. Lay members are now fully involved in the work of statutory regulatory bodies for healthcare professionals, thereby ensuring that the views of patients and the public are properly represented in the regulatory process.
3. For practitioners, professional self-regulation is about ensuring their competence to treat patients. The matters which concern a regulatory body include education, registration, continuing professional development and, in a small minority of cases, fitness to practise proceedings. Professional self-regulation affects both practitioners’ initial entry into a profession and their continuing development and competence to remain in practice. Statutory regulation can also help other healthcare professionals, who can be confident that regulated practitioners to whom they refer patients will provide an appropriate standard of care.
4. **This paper seeks your views on the statutory professional self-regulation of the herbal medicine and acupuncture professions.** Your views will help frame the provisions to be included in the draft Order establishing the new system, which will be made under section 60 of the Health Act 1999. There will then be a further consultation on the draft Order before it is formally laid before and debated by the UK Parliament and the Scottish Parliament. It will also be open to the Northern Ireland Assembly, subject to the Assembly being restored, and the National Assembly for Wales to debate the proposals, should they wish to do so.

Background to statutory regulation

5. The House of Lords Select Committee on Science and Technology recommended in its report on Complementary and Alternative Medicine, published in November 2000, that the herbal medicine and acupuncture professions should be brought under a statutory regulatory framework.

It is our opinion that acupuncture and herbal medicine are the two therapies which are at a stage where it would be of benefit to them and their patients if the practitioners strive for statutory regulation under the Health Act 1999, and we recommend that they should do so. (paragraph 5.53)

6. The Select Committee report identified three clear advantages of statutory regulation for patients, the public and practitioners.
- Protection of title, which ensures that only practitioners who are registered with the statutory regulatory body are legally entitled to use a particular title;
 - A legal and single register of practitioners, making it easier for the public to find an appropriately qualified and trained practitioner;
 - Legal underpinning of the regulatory body's disciplinary procedures, meaning that a practitioner who has been removed from the Register can no longer use the protected title.

The report stated that while the positive outcomes of statutory regulation are very similar to those achieved under voluntary self-regulation, the key difference is that statutory regulation has a legal underpinning to ensure those outcomes are met.

7. The Government agreed with the Select Committee's recommendation on the statutory regulation of the herbal medicine and acupuncture professions. It stated in its response to the report, published in March 2001, that "it would be desirable to bring both acupuncture and herbal medicine within a statutory framework as soon as practicable" (paragraph 8). In making this statement, the Government took into account the stage of development which the two professions had reached and the public health risks which may be presented by some unregulated herbal medicine and acupuncture practitioners.
8. As a first step towards bringing herbal medicine and acupuncture into statutory regulation, two working groups were charged with developing recommendations for the statutory regulation of the professions. **This paper discusses and draws on the recommendations of both working groups in considering the most appropriate way forward for bringing herbal medicine and acupuncture into statutory regulation.**

Herbal Medicine Regulatory Working Group

9. The Herbal Medicine Regulatory Working Group (HMRWG) was jointly established by the Department of Health, the Prince of Wales's Foundation for Integrated Health and the European Herbal Practitioners Association, the umbrella organisation for the herbal medicine profession, in January 2002. Its terms of reference were to:
 - i) produce a report which examines the options for achieving the successful statutory regulation of the herbal medicine profession as a whole, and makes recommendations which will form a basis for wider consultation by the Government and subsequently for the legislation that will enable the statutory regulation of the herbal medicine profession;
 - ii) in the light of these recommendations for the statutory regulation of the profession and the current Medicines and Healthcare products Regulatory Agency review of Section 12(1) of the Medicines Act 1968, make recommendations for assuring the safety and quality of herbal remedies supplied under Section 12(1).
10. The HMRWG considered a range of options for the statutory regulation of the herbal medicine profession. In doing so it took account of the overall number of practitioners of herbal medicine currently registered with voluntary regulatory bodies, which at 1,300 is relatively small. It also took account of practitioners' associations with particular herbal medicine traditions. These traditions include Western herbal medicine, Chinese herbal medicine/Traditional Chinese Medicine, Tibetan herbal medicine, the Indian and Sri Lankan tradition of Ayurveda and the Japanese tradition of Kampo. Most herbal medicine practitioners practising in the UK work wholly or mainly outside the NHS.
11. The report of the HMRWG, *Recommendations on the Regulation of Herbal Practitioners in the UK*, was published on 19 September 2003 and is available at www.advisorybodies.doh.gov.uk/herbalmedicinergw. The working group's linked report on the reform of section 12(1) of the Medicines Act 1968 forms part of this wider document. A consultation document on the supply of herbal remedies under section 12(1) of the Medicines Act 1968 is being published by the Medicines and Healthcare products Regulatory Agency.

Acupuncture Regulatory Working Group

12. The Acupuncture Regulatory Working Group (ARWG) was jointly established by the Department of Health and the Prince of Wales's Foundation for Integrated Health in July 2002. Its terms of reference were to produce a report which:
 - i) examines the options to achieve successful statutory regulation of the acupuncture profession as a whole; and
 - ii) makes recommendations that will form the basis for wider consultation by the Government, and subsequently for the legislation that will enable the statutory regulation of the acupuncture profession.
13. The Working Group defined acupuncture as follows:

Acupuncture refers to the insertion of a solid needle into any part of the human body for disease prevention, therapy or maintenance of health. There are various other techniques often used with acupuncture, which may or may not be invasive. (paragraph 1.5)
14. The ARWG considered the options for the introduction of statutory regulation from the point of view of both traditional acupuncture and Western medical acupuncture. The total number of acupuncture practitioners registered with voluntary regulatory bodies in the UK is estimated to be 7,500. Many practitioners of Western medical acupuncture work within the NHS and include doctors, nurses and physiotherapists. In addition, there are a number of practitioners of Traditional Chinese Medicine whose practice includes acupuncture.
15. The report of the Acupuncture Regulatory Working Group, *The Statutory Regulation of the Acupuncture Profession*, was published on 26 September 2003 and is available at www.advisorybodies.doh.gov.uk/acupuncturerwg

Issues for Discussion

Devolution

16. It is open to the Scottish Parliament and the Northern Ireland Assembly to legislate separately for health professions which are not currently regulated, and to the UK Parliament to make separate provision for Wales. However, all four UK Health Departments take the view that it is in the interests of the public and the professions to take as consistent an approach as possible to the regulation of complementary and alternative medicine throughout the UK. A common system will be more straightforward for patients and the public and will ensure ease of mobility of practitioners. It will also be in line with the approach taken to the statutory regulation of most other healthcare professions, which are also regulated on a UK-wide basis.
17. While this is formally a joint consultation exercise on behalf of the Secretary of State for Health and the Scottish Ministers, in line with statutory requirements, it has the support of all four UK Health Departments.

Q1: Do you agree that statutory regulation should apply to herbal medicine and acupuncture practitioners in all four UK countries – England, Scotland, Wales and Northern Ireland?

The type of regulatory body

18. A significant issue for the Herbal Medicine and Acupuncture Regulatory Working Groups was the type of regulatory body which should be established to regulate their respective professions.
19. The HMRWG's preferred way forward was for a shared Complementary and Alternative Medicine Council, or "CAM Council", to be established for herbal medicine and acupuncture. The working group suggested that other complementary and alternative medicine professions could potentially be invited to join the CAM Council at a later stage. In its recommendation for a shared Council, the HMRWG identified the following advantages:
 - i) a larger critical mass of practitioners, which would have a greater degree of influence and be better equipped to protect the interests of patients and practitioners;
 - ii) the ability to promote and regulate interdisciplinary working among herbal medicine and acupuncture practitioners;
 - iii) reduced registration fees for individual practitioners, due to the sharing of central administrative costs and premises.
20. By contrast, the ARWG's preferred option was for the establishment of a single Council for Acupuncture. The working group was unconvinced of any cost benefits to practitioners arising from a shared Council with herbal medicine and suggested that the larger scale and complexity of a shared Council may actually increase costs. The ARWG also took the view that the legislation governing herbal medicine products may place an unequal financial and resource burden on a shared Council, with acupuncture practitioners bearing costs more typically associated with herbal medicine practitioners.

21. Both working groups concluded that seeking membership of the Health Professions Council (HPC) was not the preferred way forward for the herbal medicine and acupuncture professions. The working groups reached this conclusion after considering the entry criteria for the HPC, the relative lack of establishment of the herbal medicine and acupuncture professions in mainstream healthcare and the number of other professions currently seeking membership of the HPC. The Health Departments support the working groups' recommendations that it would not be appropriate for the herbal medicine and acupuncture professions to be regulated by the HPC.
22. The Health Departments have given careful consideration to the recommendations of both working groups. **On balance, the Health Departments favour the establishment of a shared CAM Council (Complementary and Alternative Medicine Council) for herbal medicine and acupuncture.** A shared Council would support practitioners who work across professional boundaries, while preserving and respecting individual traditions within the herbal medicine and acupuncture professions. The CAM Council could potentially be extended to other unregulated complementary and alternative medicine professions¹ in due course, should statutory regulation be considered necessary in order to ensure patient and public safety. A separate Order under section 60 of the Health Act 1999 would be needed to provide for such an extension.
23. In particular, the Health Departments recognise the cost benefits to practitioners of a shared Council for the herbal medicine and acupuncture professions. Representations received by the Departments suggest that the cost of statutory regulation is a key concern for practitioners, particularly those who have not been involved with the two regulatory working groups.
24. Statutory regulatory bodies with large numbers of registered practitioners generally benefit from economies of scale. The table below, which compares a number of existing health regulatory bodies' registration fees with the total number of individuals registered with those bodies, illustrates this principle. This information must of course also be considered in the context of the varying statutory functions of the regulatory bodies.

Regulatory Body	Current annual registration fee (£)	Number of registrants at 20 January 2004
Nursing and Midwifery Council (NMC)	20	650,000
Health Professions Council (HPC)	60	149,242
General Optical Council (GOC)	115	15,730
General Medical Council (GMC)	290	200,000
General Dental Council (GDC)	388	34,000
General Osteopathic Council (GOsC)	750	3,451
General Chiropractic Council (GCC)	1,250	1,950

25. The issue of cost is further illustrated by the costings developed by both working groups. The HMRWG's costings, based on a shared Council for herbal medicine and acupuncture practitioners, produced an annual registration fee of £262 per registered practitioner². The ARWG's costings, based on a separate Council for acupuncture practitioners, produced an annual registration fee of £322 per fully registered practitioner³. Fees paid to regulatory bodies by healthcare professionals are tax deductible.

1 Throughout this document, references to unregulated complementary and alternative medicine professions are to professions which are not subject to statutory regulation in the UK.

2 Based on a shared Council located in London with a total of 3,700 registrants.

3 Based on the sharing of education costs with acupuncture practitioners regulated by other regulatory bodies.

26. In addition, a shared Council would help support and regulate herbal medicine and acupuncture practitioners who work across professional boundaries. In particular, many practitioners of Traditional Chinese Medicine (TCM) practise both acupuncture and herbal medicine and have expressed the view that a shared Council would be better equipped to meet their needs.
27. In recognition of the fact that a shared CAM Council was not supported by the Acupuncture Regulatory Working Group, the Health Departments also seek your views on an alternative option for statutory regulation. This alternative option aims to reflect as far as possible the views of both regulatory working groups.
28. The alternative option is the establishment of separate Councils for herbal medicine and acupuncture, with a shared secretariat function to support both Councils. This would involve the sharing of general and administrative resources by the two Councils, including premises, reception facilities, IT systems and administrative staff. This arrangement would enable the Councils to benefit from economies of scale and would reduce registration fees for individual practitioners, although to a lesser extent than a fully shared CAM Council. It would not however provide the same level of support as a CAM Council to herbal medicine and acupuncture practitioners who work across professional boundaries, such as TCM practitioners.

Q2: Do you agree that a shared Complementary and Alternative Medicine Council (CAM Council) for herbal medicine and acupuncture is the model of statutory regulation which best meets the needs of patients, the public and practitioners?

Q3: If you do not support a CAM Council, what is your preferred model of statutory regulation? Do you favour the alternative model described in paragraph 28?

Q4: Is the name “CAM Council” a suitable name for a shared Council? If you do not agree, what alternative name would you suggest?

Q5: Do you agree that a CAM Council should be capable of being extended to other unregulated CAM professions, where this is considered necessary in order to ensure patient and public protection?

Protection of title

29. The House of Lords Select Committee Report on Complementary and Alternative Medicine identified protection of title as a clear advantage of statutory regulation.

The advantage most often articulated to us was protection of title, so that only practitioners who are registered with the relevant statutory regulatory body can legally use a particular title. This provision makes it very easy for the public to determine who is, and who is not, a properly qualified practitioner, and gives the relevant professional body the power to determine who can claim to practise the therapy in question. (paragraph 5.26)

30. If existing models of statutory regulation were followed, use of a protected title by a herbal medicine or acupuncture practitioner who is not registered with the CAM Council would be a criminal offence subject to prosecution and a fine at level five on the standard scale. This currently stands at £5,000. An offence would also be committed if an unregistered practitioner did the following:
 - falsely represented him or herself to be registered; or
 - falsely represented him or herself to possess qualifications in the herbal medicine or acupuncture professions.

31. An important consideration for both the Herbal Medicine and Acupuncture Regulatory Working Groups was the titles which should be protected under statutory regulation. The Health Departments have considered the working groups' recommendations in this area and seek your views on the protection of the following titles:
- i) Acupuncturist
 - ii) Herbal practitioner
 - iii) Traditional Chinese Medicine practitioner

The title "Traditional Chinese Medicine practitioner" is suggested in recognition of the fact that many practitioners of Traditional Chinese Medicine (TCM) practise both herbal medicine and acupuncture.

32. While the suggested protected titles are informed by the working groups' recommendations, they are common titles rather than titles which include the term "Registered". The Health Departments' view is that, wherever possible, a healthcare profession should be recognisable by a simple and widely understood designation. Among health professions regulated by the HPC, it is common titles that are to be protected by statute, with the emphasis on simplicity and transparency. In addition, the use of the word "Registered" within protected titles could mislead patients and the public. It would, for example, be an offence for an unregulated practitioner to use the title "Registered Acupuncturist", but not the title "Acupuncturist".

Q6: Do you agree with the suggested titles listed in paragraph 31? If you do not agree, what alternative titles would you suggest?

33. Both regulatory working groups recommended that practitioners' titles should recognise that competence to practise can be attained through different traditions and methods of education and training. In order to recognise the practitioner's tradition or main area of practice and to help ensure informed patient choice, one or more of the following subsidiary designations could be used by a registered practitioner.
- i) Acupuncturist (traditional acupuncture)
 - ii) Acupuncturist (Western medical acupuncture)
 - iii) Acupuncturist (auricular acupuncture)
 - iv) Herbal practitioner (Western herbal medicine)
 - v) Herbal practitioner (Chinese herbal medicine)
 - vi) Herbal practitioner (Ayurvedic medicine)
 - vii) Herbal practitioner (Tibetan herbal medicine)
 - viii) Herbal practitioner (Kampo)
 - ix) Traditional Chinese Medicine Practitioner (herbal medicine and acupuncture)
 - x) Traditional Chinese Medicine Practitioner (herbal medicine)
 - xi) Traditional Chinese Medicine Practitioner (acupuncture)

Q7: Do you agree with the suggested subsidiary designations listed in paragraph 33? If you do not agree, what alternative subsidiary designations would you suggest?

Key functions of the new Council

34. The Government has accepted that a CAM Council, in common with other health regulatory bodies, should have four fundamental functions which cannot be transferred to another body. The Health Act 1999 defines these as including:
- keeping a Register of members admitted to practice (referred to throughout this paper as registered practitioners);
 - determining standards of education and training for admission to practice;
 - giving advice about standards of conduct and performance; and
 - administering procedures (including making rules) relating to misconduct, unfitness to practise and similar matters.
35. The Health Departments propose that the fundamental functions of the CAM Council set out above should be underpinned by an explicit and overarching duty on the Council to:
- first and foremost, safeguard the health and well-being of patients and the public;
 - work in partnership with employers, education providers and other regulatory bodies for health and social care professionals and services;
 - consult registered practitioners, employers, education providers, patients and the public in making or varying policy, standards and rules;
 - have regard to the differing considerations affecting the herbal medicine and acupuncture professions and the individual traditions within the professions;
 - have regard to the interests of patients and practitioners in all four UK countries – England, Scotland, Wales and Northern Ireland;
 - inform and educate practitioners and the public about its work.
36. With specific reference to the particular needs of the herbal medicine profession, the new regulatory body would also advise herbal medicine practitioners on the products they use as medicines in their professional practice.
37. Alongside statutory regulation, a key role will remain for the professional bodies which currently represent herbal medicine and acupuncture practitioners. The professional bodies are and would remain free to:
- promote the herbal medicine and acupuncture professions;
 - advise on the development of the herbal medicine and acupuncture professions as a whole;
 - undertake any other non-regulatory functions they consider appropriate.

While the number and nature of professional bodies may change under the new regulatory system, this will be a matter for the professional bodies themselves to consider, in conjunction with their membership.

Q8: Do you agree with the duties of the new Council set out in paragraphs 35 and 36?

Composition of the Council

38. A key duty of the new Council, as set out in paragraph 35 above, will be to ensure that the interests of patients and the public are fully taken into account in the regulatory process. In addition, the Council must be able to address the needs of herbal medicine and acupuncture practitioners, including those who work across professional boundaries, and the interests of the individual traditions within the herbal medicine and acupuncture professions. It must be small enough to be strategic and flexible, while large enough to ensure that it is fully representative of the professions it regulates.
39. The Herbal Medicine Regulatory Working Group stated in its report that the composition of the Council should be informed by public consultation. It recognised the importance of lay membership and representation from the home countries of Scotland, Wales and Northern Ireland on Council. It also recommended that the NHS Appointments Commission should appoint the Chairperson and lay members, in order to ensure that the process is fair and equitable and conducted in the public interest. The ARWG did not consider the composition of the Council in any detail in its report.
40. Your views are sought on the composition of the CAM Council. To stimulate debate, the Health Departments propose that the Council should include the following members:
- i) twelve practitioner members, who are wholly or mainly engaged in the practice of herbal medicine and/or acupuncture. At least one practitioner member would represent the traditions listed below.
 - Western herbal medicine;
 - Ayurveda;
 - traditional acupuncture;
 - Western medical acupuncture;
 - Traditional Chinese Medicine.
 - ii) ten lay or other members. The lay or other members would include:
 - at least one person who lives or works, wholly or mainly, in each of the countries of England, Scotland, Wales and Northern Ireland;
 - at least two people with educational expertise.

The lay or other members would not include registered herbal medicine or acupuncture practitioners, but may include members of other health or social care professions. All lay or other members will play an important role in determining the Council's policies in the interest of patients and the public.

41. It is proposed that the Chair of the new Council should also be a lay person. This will ensure that the Council is well-equipped to carry out its fundamental function of safeguarding the health and well-being of patients and the public. A lay Chair will also have equal regard for the differing considerations affecting the herbal medicine and acupuncture professions and the individual traditions within the professions. This impartiality will be particularly important if the Council is required to consider any issues on which the individual professions or traditions may not be in agreement.

42. The Health Departments propose that the term of office of each Council member should be four years, with arrangements for staggering the appointments process so that changes in membership do not all take place simultaneously. They support the recommendation of the HMRWG that the Chair and the lay or other members should be appointed by the NHS Appointments Commission. In due course the practitioner members should be appointed by the Council itself, by way of an agreed election scheme. However, in the case of the first Council, the practitioner members should also be appointed by the NHS Appointments Commission.
43. Should, in due course, the CAM Council be extended to any other currently unregulated CAM professions by way of a further Order under section 60 of the Health Act 1999, the Council's membership would need to be varied to reflect its new responsibilities. The number of practitioner members would need to be altered in accordance with the Council's changing circumstances. However, in order to ensure that the Council maintains its strategic focus, the total number of practitioner members should not exceed 14. The number of lay members would need to increase accordingly, so that the practitioner majority does not exceed the starting practitioner majority of two.
44. The arrangements for staffing the new Council, including the number of staff members, will be a matter for the Council itself to consider. A Registrar, Executive Officers and sufficient support staff will need to be appointed.

Q9: Do you agree with the proposed composition of the CAM Council set out in paragraph 40? If you do not agree, please suggest an alternative.

Q10: Would it be possible for the herbal medicine traditions of Kampo and Tibetan herbal medicine to be individually represented on Council? Should any other herbal medicine or acupuncture traditions be individually represented on Council?

Q11: Do you agree with the term of office and method of appointment of Council members proposed in paragraph 42?

Position of practitioners who are already regulated

45. A growing number of orthodox healthcare practitioners are now practising CAM. Acupuncture, for example, is used by doctors, physiotherapists and nurses working both within and outside the NHS. The House of Lords Select Committee considered the position of such practitioners in its report.

We recommend that if CAM is to be practised by any conventional health care practitioners, they should be trained to standards comparable to those set out for that particular therapy by the appropriate (single) CAM regulatory body. (paragraph 5.83)

All those who deliver CAM treatments, whether conventional health professionals or CAM professionals, should have received training in that discipline independently accredited by the appropriate regulatory body. (paragraph 6.33)

While the Government made clear in its response to the Select Committee report that it supported these particular recommendations, further consideration is needed as to how practitioners of herbal medicine and acupuncture who are already subject to statutory regulation should be treated under the new system. This issue of collaborative regulation is an area in which the Health Departments are particularly interested to seek your views.

46. The ARWG proposed a unique method of addressing this issue. It suggested creating a working distinction between the regulatory functions of the new Council and its registering functions. This proposal would create two distinct groups of potential registrants:
- i) those who are not already statutorily regulated, who would join the Register as their primary regulator. They would be fully regulated by the new Council and would hold one of the protected titles suggested in paragraph 31 above;
 - ii) those who are already statutorily regulated, who would have the option of joining the Register as a registering body only. This would also enable them to hold one of the protected titles suggested in paragraph 31 above. This group would continue to be regulated by their existing regulatory body (primary regulator), under whose jurisdiction they would fall for the purposes of disciplinary procedures and other regulatory matters.

In order for this system to work effectively, the ARWG recognised that there would need to be close liaison and co-operation between the new Council regulating acupuncture and the existing regulatory bodies.

47. The ARWG also suggested that the distinction between the two groups of registrants should be reflected in the fee structure of the new Council, with those regulated elsewhere paying a significantly reduced annual fee. The fee for such registrants would be based on maintaining the elements of the Council's work which are relevant to them, in particular a share of its educational functions.
48. The Health Departments acknowledge the particular significance of this issue to the acupuncture profession, in view of the fact that many practitioners of acupuncture are registered doctors, nurses and physiotherapists. However, they do not support the ARWG's proposals in this area. The Health Departments' preferred approach to collaborative regulation is described in more detail in paragraphs 49 to 51 below.
49. It will be important for the new CAM Council to provide professional leadership to all healthcare professions in the area of standards for the practice of herbal medicine and acupuncture. This will require new ways of working among health regulatory bodies, with greater emphasis on close liaison, co-operation and the sharing of expertise.
50. Practitioners of herbal medicine and/or acupuncture who are registered with existing statutory regulatory bodies, such as the General Medical Council and the Health Professions Council, will continue to be regulated by those bodies. This would mean, for example, that a fitness to practise issue about the use of herbal medicine and/or acupuncture would be resolved by the practitioner's current regulatory body. However, it would be important for the existing regulator's fitness to practise panel to seek input on issues relating to the practice of herbal medicine and acupuncture from the CAM Council. In addition, regulatory bodies will need to work closely with the CAM Council on educational issues. An existing regulator could, for example, support its registrants who wish to follow a specialism in acupuncture by applying the CAM Council's continuing professional development scheme.
51. In theory, a practitioner who is registered with an existing regulatory body could also apply to register with the CAM Council. In practice he or she would be most likely to do so in order to use one of the new protected titles. However, practitioners who choose to follow this approach will need to recognise the risk of creating confusion about which regulatory body would respond if their fitness to practise were called into question. In view of the need to ensure clear accountability for regulated healthcare professionals, the Health Departments do not favour dual registration and will therefore not make it a requirement for healthcare practitioners who work across professional boundaries.

Q12: Do you agree with Health Departments' proposals for collaborative regulation described in paragraphs 49 to 51?

Statutory committees

52. In line with many other statutory regulatory bodies regulating healthcare professionals, the working groups recommended the following committee structure for the new regulatory body:
- the **Education and Training Committee**, dealing with pre-registration qualifications, registration procedures and continuing professional development;
 - the **Investigating Committee**, dealing with all initial complaints about individual practitioners;
 - the **Professional Conduct Committee**, dealing with standards of conduct and disciplinary hearings;
 - the **Health Committee**, dealing with practitioners with health issues.

Further information about the recommendations made by the working groups in this area is available in paragraphs 27-34 of the report of the HMRWG and in sections 4.2 and 4.3 of the report of the ARWG.

53. The Health Departments' view is that, wherever possible, the Council's statutory committees should take a multi-professional approach to their work. The experience of other statutory regulatory bodies demonstrates that the majority of issues relating to education, registration, health, discipline and ethics are common across healthcare professions. Membership of the committees should include practitioners from all the herbal medicine and acupuncture disciplines individually represented on Council, together with lay representation. Each Committee will be formally accountable to the Council.
54. Both working groups also recommended that the Council should be free to establish further committees or sub-committees as it deems appropriate. Examples of possible additional committees identified by the working groups include:
- tradition and/or discipline-specific advisory committees, such as committees on Traditional Chinese Medicine or the use of acupuncture in drug detoxification work;
 - finance Committee.

Q13: Do you agree that the Council should be free to establish additional committees as it considers appropriate?

55. The Health Departments agree that the CAM Council should establish an Education and Training Committee. Its role can be summarised as involving some or all of the following functions:
- advising the Council on the performance of its functions in relation to education;
 - ensuring standards of education and training for herbal medicine and acupuncture practitioners;
 - accrediting educational qualifications;
 - determining in relation to any individual an application for admission to the Register, re-admission to the Register or renewal of registration;
 - continuing professional development (CPD).
56. The composition of the Education and Training Committee will be informed by consultation, but will include both practitioner and lay members. As in the case of all of the Council's statutory committees, as stated in paragraph 53 above, it will include practitioners from each of the herbal medicine and acupuncture disciplines individually represented on Council.

Q14: What are your views on the composition of the Education and Training Committee? What numbers of lay and practitioner members are appropriate? Should the Chair be a lay Chair or a practitioner Chair?

57. An alternative model is for the suggested functions of the Education and Training Committee which concern the registration of individual practitioners to be taken forward by a separate Registration Committee. The Health Departments would particularly welcome your views on this issue. The Registration Committee would operate alongside the Education and Training Committee. It would have specialist expertise in relation to the registration of practitioners, although there may also be advantages in these issues being considered as part of the Council's work on education and training more generally

Q15: Do you consider it appropriate for the CAM Council to establish a Registration Committee, or do you think that matters relating to registration should be addressed by the Education and Training Committee?

58. The role and composition of the other statutory committees is considered in more detail in the section on fitness to practise in paragraphs 81 to 87 below.

Registration of practitioners

59. As set out in paragraph 34 above, the first key function of the new Council will be keeping a Register of members admitted to practice. Under the Health Departments' preferred model of a shared CAM Council, the Register would be divided into two parts – one part for herbal medicine practitioners and one part for acupuncture practitioners. It would be possible for practitioners who are suitably qualified in and practising both herbal medicine and acupuncture, such as practitioners of Traditional Chinese Medicine, to opt to be registered in both parts of the Register. Should the regulatory functions of the CAM Council be extended to any other statutorily unregulated CAM professions in due course, a separate part of the Register would need to be established for each new profession.
60. The second key function of the Council set out in paragraph 34 above is determining standards of education and training for admission to practice. This will involve the accreditation of educational qualifications, a role which could be delegated by the Council to its Education and Training Committee. Practitioners graduating from or completing courses which have been accredited by the Council will be entitled to apply for automatic entry to the Register. Practitioners applying for registration who did not train on an accredited course, including those qualifying overseas, will need to be assessed individually against national entry requirements by way of a process determined by the Education and Training Committee.
61. A detailed accreditation scheme for educational qualifications in herbal medicine is proposed in Annex II of the Report of the HMRWG. The content and operation of this proposed accreditation scheme will need to be considered by the Education and Training Committee of the new Council, together with a suitable accreditation scheme for qualifications in acupuncture.
62. The HMRWG also recommended the development of a core curriculum for herbal medicine. The core curriculum would provide a framework for education establishments to use in the development of courses, to ensure that those courses provide the necessary level of understanding and competence for registration with the CAM Council. Within the core curriculum, which can be considered in full at Annex I of the report of the HMRWG, there are elements that are specific to the individual herbal medicine traditions. The working group noted that further work is needed to ensure consensus about the appropriate standards for the statutory self-regulation of Ayurveda in the UK.

63. The Health Departments support the HMRWG's recommendations regarding the development of a core curriculum for herbal medicine. Although the ARWG placed greater emphasis on National Occupational Standards (see paragraph 72 below) than on a core curriculum, the Health Departments would welcome views on the development of a core curriculum for acupuncture, with elements that are specific to traditional acupuncture and Western medical acupuncture. This core curriculum could follow the model taken by the British Acupuncture Council Guidelines for Acupuncture Education, which outline a core curriculum in broad inclusive terms and are used by the British Acupuncture Accreditation Board. The ARWG recognised the value of these guidelines with the statement that "diversity is supported within the framework of the standardisation necessary for safe and competent practice" (section 5.3).

Q16: Do you agree that the holding of an accredited qualification should enable herbal medicine and acupuncture practitioners to apply for automatic registration with the CAM Council?

Q17: Do you agree that practitioners who do not hold an accredited qualification should be individually assessed for entry on to the Register?

Q18: Do you agree that a core curriculum, with elements that are specific to traditional acupuncture and Western medical acupuncture, should be developed for acupuncture, or should we move in the direction of National Occupational Standards?

Registration procedures – overseas-qualified practitioners

64. The HMRWG recommended that the new Council should establish reciprocal arrangements with professional registration authorities in countries outside the European Economic Area (EEA). These arrangements would enable overseas-qualified practitioners to be eligible for automatic entry on to the Register, provided they meet certain criteria. The working group stated that these criteria "should relate to identity, character, health, a pass in a suitable qualifying examination, good standing, the production of a certificate of registration, and the completion of a suitable period of experiential work in the UK under the direct supervision of a registered professional" (paragraph 45).
65. The Health Departments recognise the need for overseas-qualified herbal medicine and acupuncture practitioners to be able to gain entry to the Register. This is a particular concern for a number of Traditional Chinese Medicine practitioners, many of whom have trained and qualified in China, and for Ayurvedic practitioners who have trained and qualified in India or Sri Lanka. Practitioners' needs for registration must however be balanced with the need to ensure patient and public protection, which is the primary focus of statutory regulation.
66. It is therefore the Departments' view that herbal medicine and acupuncture practitioners trained outside the EEA who wish to be registered with the CAM Council should be assessed individually. The level of competence required of a newly-qualified UK practitioner will be used as a benchmark for the entry of overseas practitioners on to the Register. The assessment process for overseas practitioners will take account of a number of factors, including the level of training of the practitioner, the content of the training course, the type of practice, the practitioner's post-qualification training and experience and any registration with the Chinese or Indian state registers. Views are particularly invited on whether the Council, in common with the other health regulatory bodies, should be empowered to check that applicants from outside the EEA have sufficient knowledge of English for the practice of their profession in the UK.

Q19: Do you agree with the proposed arrangements for assessing overseas-qualified herbal medicine and acupuncture practitioners for entry on to the Register?

67. In addition, practitioners who are nationals of other EEA States will be entitled to practise in the UK, in accordance with rights of free movement conferred by the EC Treaty and applicable EU Directives on the mutual recognition of qualifications. The CAM Council will therefore need to ensure that such practitioners can practise under the same conditions as UK nationals. Where EEA migrants have relevant qualifications or experience, but there is a substantial difference between these and national requirements, the Council may require them to show that they have made up the shortfall, either by successfully completing an adaptation period or by passing a test of competence.

Registration of practitioners – transitional period

68. The registration procedures described in paragraphs 59 to 67 above will be implemented once the new Council is fully operational. In advance of this, a vehicle is needed for existing herbal medicine and acupuncture practitioners to gain entry on to the new Register. A “grandparenting” scheme for such practitioners was therefore proposed by both working groups. The suggested schemes recognise that practitioners currently in practice have a wide range of training, skills and experience and thereby seek to be inclusive as possible, whilst ensuring a standard of practice that will provide the necessary protection for patients and the public.
69. The Health Departments’ view, based on the recommendations of both working groups, is that the categories of practitioner listed below should be eligible for registration through the “grandparenting” arrangements. In line with the recommendations of the ARWG, the “grandparenting” scheme could operate during a transitional period of two years beginning on the date of opening of the Register.
- i) Herbal medicine and acupuncture practitioners in practice prior to the opening of the Register, regardless of their affiliation to any professional association;
 - ii) Herbal medicine and acupuncture practitioners in training in the UK during the transitional period;
 - iii) Practitioners who trained overseas and wish to begin practising in the UK during the transitional period.

The precise requirements of the scheme will vary according to which of the above groups a practitioner falls into, although standards of training required of UK and overseas-qualified practitioners will be comparable. In all cases practitioners will be required to satisfy the Council that:

- they have been engaged in the lawful, safe and effective practice of the profession/s in respect of which they are seeking registration (herbal medicine, acupuncture or, as in the case of many Traditional Chinese Medicine practitioners, both) for three out of the five years prior to the opening of the Register (or its part-time equivalent);
- where the applicant cannot meet the “three out of five years” test, that he or she has undergone additional training or experience, in the UK or overseas, to satisfy the Council’s standards of proficiency for the relevant profession.

In any individual case the applicant may be required to take a test of competence.

70. A practitioner who began practising prior to the opening of the Register would be free to use his or her current professional title until his/her case had been determined by the Council, provided that he or she applies for registration under the “grandparenting” scheme. Those who begin practising after the Register opens will be unable to use the protected title unless they are included on the Register.

Q20: Do you support the proposed groups of practitioners who would be eligible to join the Register through a grandparenting scheme?

Q21: Do you agree with the proposed two-year transitional period for the registration of existing practitioners on to the new Register?

Standards of proficiency

71. National Professional Standards⁴ for Herbal Medicine have recently been developed by the profession and agreed by the professional associations for the Western, Chinese and Tibetan traditions. The National Professional Standards were published by Skills for Health on 19 September 2003 and are available at www.skillsforhealth.org.uk. A summary of the competences amplified in the National Professional Standards can be found in section N of the report of the HMRWG.
72. The ARWG also identified the need for similar National Occupational Standards (NOS) for acupuncture. The working group concluded that equivalences between acupuncture practitioners could only be established by looking at whether practitioners using traditional and Western medical acupuncture both had the same outcome standards.
73. The ARWG identified a number of different ways in which the future NOS could be used by both organisations and individuals. These included:
- supporting the development of a common language and improving performance by the creation of a nationally agreed specification of good practice;
 - helping define learning outcomes as well as suggesting learning strategies and assisting in the development of curricula;
 - helping an individual identify areas of personal development, thus providing a structure for continuing professional development;
 - being owned by the profession and changed and improved upon as the profession learns to work with them.
74. The Health Departments acknowledge the importance of standards of proficiency, which all practitioners will need to meet and continue to meet in order to gain and maintain registration with the CAM Council. The Council's standards of proficiency for herbal medicine and acupuncture practitioners could be developed by its Education and Training Committee. It is expected that they will take account of the National Professional Standards for herbal medicine and any future National Occupational Standards for acupuncture, including any amendments made to the Standards in the period prior to the establishment of the Council.

Q22: Do you agree that the standards of proficiency maintained by the CAM Council should take account of the National Professional Standards for herbal medicine and any future National Occupational Standards for acupuncture?

⁴ The term "National Professional Standards" is unique to the herbal medicine profession and is used instead of the term "National Occupational Standards".

Conduct of practitioners

75. The third key function of the new Council set out in paragraph 34 above is giving advice about standards of conduct and performance. In line with this statutory requirement, the HMRWG recommended that the Council should have responsibility for determining the standards of conduct, performance and ethics of those admitted to the Register and provide guidance accordingly.
76. The HMRWG recommended that the code of conduct should give guidance on the conduct expected of a registered practitioner, with particular emphasis on issues relevant to consultation with a patient such as confidentiality and informed consent. It also proposed a code of practice relating to the manufacture, preparation and dispensing of herbal medicines under Section 12(1) of the Medicines Act 1968 and the management of the dispensary by the herbal practitioner.
77. Similarly, the ARWG also considered the issue of codes of conduct. It recommended the publication of two codes by the Council – a Code of Professional Conduct and a Code of Safe Practice. These Codes would set minimum requirements for registered acupuncture practitioners. The ARWG recognised in particular that the majority of practitioners who will be regulated by the new Council will be self-employed professionals. As such, it recommended that the Codes are explicit and detailed, and accompanied by ancillary material to guide practitioners and help ensure that they fully understand the responsibilities placed upon them.
78. The Health Departments broadly agree with the recommendations of the working groups in this area. These recommendations will form an important basis for the new Council in taking forward work on standards of conduct and performance.

Q23: Do you agree that the CAM Council should develop and publish codes of conduct for herbal medicine and acupuncture practitioners?

Continuing professional development (CPD)

79. It is important for herbal medicine and acupuncture practitioners to maintain and develop their skills in the interest of public and patient safety and to ensure that they meet the evolving needs of their patients and the NHS. The new Council, through its Education and Training Committee, will play an important role in the development and operation of continuing professional development (CPD) schemes. Registered practitioners who do not adhere to the requirements for CPD drawn up by the Council may be de-registered and thus prevented from using a protected title.
80. Annex IV of the report of the HMRWG contains a core scheme for the continuing professional development of herbal medicine practitioners. This will constitute an important document for the new Council in developing CPD schemes and will need to be considered alongside the specific CPD requirements of acupuncture practitioners.

Q24: Do you agree that the CAM Council should be responsible for determining CPD requirements for herbal medicine and acupuncture practitioners?

Fitness to practise

81. The House of Lords Select Committee report highlighted “legal underpinning of a body’s disciplinary procedures” as a key advantage of statutory regulation (paragraph 5.28). The fourth and final key function of the new Council, as set out in paragraph 34 above, will be dealing firmly and fairly with practitioners whose fitness to practise is impaired. Both working groups considered this issue in some detail and their recommendations are reproduced below.

Scheme proposed by the HMRWG for fitness to practise

The **Investigating Committee** will deal with all initial complaints about individuals on the Register. It will check a complaint or allegation to determine if there is a case and the nature of the case. If there is a case to be answered, then the matter will be referred to the Professional Conduct and Competence Committee or the Health Committee.

The **Professional Conduct and Competence Committee** will have responsibility for dealing with standards of conduct and disciplinary hearings. It will advise the Council on what constitutes appropriate conduct, performance and ethics of all registrants, as well as reviewing cases where these standards are alleged to have been breached. It will ensure that practitioners are able to obtain guidance on any problems that arise in practice.

The **Health Committee** will deal with practitioners experiencing health problems. It will advise the Council when an allegation is made or an investigation suggests that a health professional may be unfit to practise due to ill health.

Scheme proposed by the ARWG for fitness to practise

Preliminary Investigating Committee

- screening and investigation of complaints, allegations and reports about a registrant’s conduct;
- assessing whether matters should be dealt with by the Professional Conduct Committee or the case closed without action.

Professional Conduct Committee

- conducting formal hearings into cases of professional misconduct and incompetence;
- applying a range of sanctions, from admonishments and cautions through to fines, suspensions and removals from the Register.

Health Committee

- reviewing and acting on reports and allegations about a registrant’s health and ability to practise acupuncture safely;
- offering both support and rehabilitation as well as some levels of sanction.

82. The working groups' recommendations on fitness to practise are broadly compatible. There are two key differences – the names of the committees and the role of the Investigating Committee/Preliminary Investigating Committee. The HMRWG recommended that the Investigating Committee should refer cases to both the Professional Conduct Committee and the Health Committee, while under the ARWG's proposals there is no role for the Preliminary Investigating Committee to refer to the Health Committee. If this overall model of fitness to practise is accepted following consultation, the Health Departments support the position of the HMRWG on these points.
83. An alternative model for fitness to practise has been consulted on by the General Medical Council (GMC). The GMC's consultation on these changes closed in October 2003. Your views are sought on whether a similar model of fitness to practise would be appropriate for the herbal medicine and acupuncture professions.
84. Under the model consulted on by the GMC, the two fitness to practise functions, 'investigation' and 'adjudication', will be carried out separately. At both the investigation and adjudication stages all issues relating to a doctor's conduct, health and performance will be considered, thereby enabling fitness to practise to be considered in the round.
85. The investigation stage will be taken forward by an Investigation Committee, which will be composed of GMC members. The Investigation Committee will delegate work to Case Examiners, although the details of this have yet to be decided by the GMC. At the outcome of the investigation stage a single test will be applied to determine whether there is a realistic prospect of establishing that a doctor's fitness to practise is impaired to a degree justifying action on his or her registration with the GMC. If such a prospect is determined, the doctor's case will pass to the adjudication stage.
86. The adjudication stage will determine whether or not the doctor's fitness to practise is impaired to a degree justifying action on his or her registration. The adjudication stage will be taken forward by a panel which is independent of the GMC and does not include any of its members. Guidance will be provided to the panel to enable it to consider the conduct, performance and health elements that may be present in the case. Where the adjudication panel finds that a doctor's fitness to practise is impaired, it will have a range of sanctions available to it. As part of this a new system of warnings is being developed, which may be issued at various stages of the fitness to practise process.

Q25: Do you support the fitness to practise schemes proposed by the working groups, or do you prefer the GMC's model?

Q26a: (If you prefer the fitness to practise model proposed by the working groups.) What are your views on the composition of the fitness to practise committees? What numbers of lay and practitioner members are appropriate? Should the Chair be a lay Chair or a practitioner Chair?

Q26b: (If you prefer the fitness to practise model consulted on by the GMC.) What are your views on the composition of the Investigating Committee and adjudication panel?

87. Your views are also requested on the sanctions that should be available to the Council as part of its fitness to practise powers. It is suggested that where a herbal medicine or acupuncture practitioner's fitness to practise is found to be impaired, the sanctions available should be:

- i) no action;
- ii) the imposition of conditions on the practitioner's registration;
- iii) suspension from the Register;
- iv) erasure from the Register.

The first option of "no action" would only be used in very exceptional circumstances, such as where the practitioner is terminally ill and there is nothing to be gained by the Council in imposing any kind of sanction.

Q27: Do you agree with the suggested sanctions for use in fitness to practise cases?

Appeals

88. Under statutory regulation, it will be possible for herbal medicine and acupuncture practitioners to make appeals against the following decisions:

- decisions of the Registrar in relation to registration or renewal of registration;
- decisions in relation to fitness to practise.

An appeals tribunal will be constituted by the CAM Council to deal with appeals relating to registration or renewal of registration. The usual model is for any subsequent appeals which relate to registration or renewal of registration to be considered by the county court or the sheriff court in Scotland. Appeals against fitness to practise decisions made by the CAM Council would go direct to the High Court.

Q28: Do you agree that an appeals tribunal should be constituted by the CAM Council to consider appeals relating to registration or renewal of registration?

Accountability of the CAM Council

89. The NHS Plan identified the need for the Council for the Regulation of Healthcare Professionals (CRHP) to be established to co-ordinate the existing professional self-regulatory bodies and improve their accountability to Parliament. CRHP currently covers the following statutory regulatory bodies, each of which appoints a member to the Council.

- General Medical Council
- General Dental Council
- General Optical Council
- General Osteopathic Council
- General Chiropractic Council
- Health Professions Council
- Nursing and Midwifery Council
- Royal Pharmaceutical Society of Great Britain
- Pharmaceutical Society of Northern Ireland

CRHP itself is accountable to Parliament and reports to it every year. Further information about the work of CRHP is available on its website at www.crhp.org.uk

90. The new CAM Council will, in line with the existing statutory regulatory bodies, come under CRHP's responsibility and appoint a member to the Council.

Preparing for statutory regulation

91. Prior to the establishment of the first CAM Council, work will need to be undertaken to prepare for its establishment. The Health Departments favour the creation of a formal working group which, with the agreement of the herbal medicine and acupuncture professions, would have sufficient authority to carry out such preparatory work. This would help the first Council to achieve its aims more rapidly.

Q29: Do you agree with the creation of a formal working group to help prepare for the establishment of the first CAM Council?

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Recommendations on the Regulation of Herbal Practitioners in the UK, The Prince of Wales's Foundation for Integrated Health on behalf of the Herbal Medicine Regulatory Working Group, September 2003

The Statutory Regulation of the Acupuncture Profession, The Prince of Wales's Foundation for Integrated Health on behalf of the Acupuncture Regulatory Working Group, September 2003

Summary of consultation questions

Q1: Do you agree that statutory regulation should apply to herbal medicine and acupuncture practitioners in all four UK countries – England, Scotland, Wales and Northern Ireland?

Q2: Do you agree that a shared Complementary and Alternative Medicine Council (CAM Council) for herbal medicine and acupuncture is the model of statutory regulation which best meets the needs of patients, the public and practitioners?

Q3: If you do not support a CAM Council, what is your preferred model of statutory regulation? Do you favour the alternative model described in paragraph 28?

Q4: Is the name “CAM Council” a suitable name for a shared Council? If you do not agree, what alternative name would you suggest?

Q5: Do you agree that a CAM Council should be capable of being extended to other unregulated CAM professions, where this is considered necessary in order to ensure patient and public protection?

Q6: Do you agree with the suggested titles listed in paragraph 31? If you do not agree, what alternative titles would you suggest?

Q7: Do you agree with the suggested subsidiary designations listed in paragraph 33? If you do not agree, what alternative subsidiary designations would you suggest?

Q8: Do you agree with the duties of the new Council set out in paragraphs 35 and 36?

Q9: Do you agree with the proposed composition of the CAM Council set out in paragraph 40? If you do not agree, please suggest an alternative.

Q10: Would it be possible for the herbal medicine traditions of Kampo and Tibetan herbal medicine to be individually represented on Council? Should any other herbal medicine or acupuncture traditions be individually represented on Council?

Q11: Do you agree with the term of office and method of appointment of Council members proposed in paragraph 42?

Q12: Do you agree with the Health Departments’ proposals for collaborative regulation described in paragraphs 49 to 51?

Q13: Do you agree that the Council should be free to establish additional committees as it considers appropriate?

Q14: What are your views on the composition of the Education and Training Committee? What numbers of lay and practitioner members are appropriate? Should the Chair be a lay Chair or a practitioner Chair?

Q15: Do you consider it appropriate for the CAM Council to establish a Registration Committee, or do you think that matters relating to registration should be addressed by the Education and Training Committee?

Q16: Do you agree that the holding of an accredited qualification should enable herbal medicine and acupuncture practitioners to apply for automatic registration with the CAM Council?

Q17: Do you agree that practitioners who do not hold an accredited qualification should be individually assessed for entry on to the Register?

Q18: Do you agree that a core curriculum, with elements that are specific to traditional acupuncture and Western medical acupuncture, should be developed for acupuncture, or should we move in the direction of National Occupational Standards?

Q19: Do you agree with the proposed arrangements for assessing overseas-qualified herbal medicine and acupuncture practitioners for entry on to the Register?

Q20: Do you support the proposed groups of practitioners who would be eligible to join the Register through a grandparenting scheme?

Q21: Do you agree with the proposed two-year transitional period for the registration of existing practitioners on to the new Register?

Q22: Do you agree that the standards of proficiency maintained by the CAM Council should take account of the National Professional Standards for herbal medicine and any future National Occupational Standards for acupuncture?

Q23: Do you agree that the CAM Council should develop and publish codes of conduct for herbal medicine and acupuncture practitioners?

Q24: Do you agree that the CAM Council should be responsible for determining CPD requirements for herbal medicine and acupuncture practitioners?

Q25: Do you support the fitness to practise schemes proposed by the working groups, or do you prefer the GMC's model?

Q26a: (If you prefer the fitness to practise model proposed by the working groups.) What are your views on the composition of the fitness to practise committees? What numbers of lay and practitioner members are appropriate? Should the Chair be a lay Chair or a practitioner Chair?

Q26b: (If you prefer the fitness to practise model consulted on by the GMC.) What are your views on the composition of the Investigating Committee and adjudication panel?

Q27: Do you agree with the suggested sanctions for use in fitness to practise cases?

Q28: Do you agree that an appeals tribunal should be constituted by the CAM Council to consider appeals relating to registration or renewal of registration?

Q29: Do you agree with the creation of a formal working group to help prepare for the establishment of the first CAM Council?

How to respond

Should you require further copies of this document, it is available electronically at www.dh.gov.uk/Consultations/LiveConsultations/fs/en

Responses should be received no later than **Monday 7 June 2004**. They may be sent:

by e-mail to: HM-AC-Cons@doh.gsi.gov.uk

in writing to: Herbal Medicine and Acupuncture Consultation
Department of Health
Room 2N35B
Quarry House
Quarry Hill
Leeds
LS2 7UE

The information you send to us may need to be passed to colleagues within the UK Health Departments and/or published in a summary of responses to this consultation. We will assume that you are content for us to do so unless you specifically include a request to the contrary in the main body of your reply. If you are replying by email, your consent overrides any confidentiality disclaimer that is generated by your organisation's IT system.

Annex A

Partial Regulatory Impact Assessment

1. Title of the proposed measure

Regulation of herbal medicine and acupuncture

2. Purpose and intended effect

(i) Issue

Herbal medicine and acupuncture practitioners are not currently required to meet specific standards of training, competence, practice or conduct. This means that any individual, regardless of his or her level of training or expertise, may establish him/herself as a herbal medicine and/or acupuncture practitioner. The risks to patients and the public from treatment by untrained or incompetent herbal medicine and acupuncture practitioners are significant.

A large proportion of consultations with herbal medicine and acupuncture practitioners take place outside the NHS. Many patients receiving herbal medicine or acupuncture treatments select their own practitioner. In many cases they do so in the absence of clear information as to whether that practitioner is competent to provide treatment. Other healthcare professionals who wish to refer patients to a herbal medicine or acupuncture practitioner also have no straightforward way of checking whether that practitioner is able to provide an appropriate standard of care.

(ii) Objective

It is necessary to protect patients and the public from untrained or incompetent herbal medicine and acupuncture practitioners. Patients need reassurance that a practitioner who they consult is both competent and suitably qualified. Similarly, other healthcare professionals wishing to refer patients to herbal medicine and acupuncture practitioners need to be able to ensure the competence of those practitioners. These concerns apply equally to England, Scotland, Wales and Northern Ireland.

The House of Lords Select Committee on Science and Technology recommended in its report on Complementary and Alternative Medicine, published in November 2000, that the herbal medicine and acupuncture professions strive for statutory regulation. In considering the need for statutory regulation, the Select Committee's main criterion was whether the therapy was deemed to pose significant risks to the public. It concluded that herbal medicine and acupuncture both carry inherent risk.

Statutory regulation involves:

- the establishment of a register of practitioners who meet agreed standards of practice and competence;
- restricting the use of a specified title, such as “herbal medicine practitioner” or “acupuncturist”, to practitioners who are included on the statutory register;

- the ability to apply sanctions, such as suspension or removal from the register, to any practitioner whose fitness to practise is impaired.

Healthcare practitioners who are regulated by existing statutory regulatory bodies, such as the General Medical Council and the Nursing and Midwifery Council, would not be required to register in order to practise herbal medicine and/or acupuncture.

(iii) Risk assessment

There are an estimated 1,300 practitioners of herbal medicine and approximately 2,500 practitioners of acupuncture in the UK who, although not subject to any form of statutory regulation, are registered with voluntary regulatory bodies. Voluntary regulatory bodies vary quite significantly in terms of size and responsibilities, although they generally require practitioners to meet certain standards in order to register. The standards of education and training required by voluntary regulatory bodies also vary, but many practitioners who are registered with voluntary bodies practise herbal medicine and/or acupuncture safely and competently.

Registration with a voluntary regulatory body is by definition voluntary. It is not possible to identify the number of herbal medicine and acupuncture practitioners who are not registered with a voluntary regulatory body. However, it is estimated that there are at least several hundred and more likely several thousand herbal medicine and acupuncture practitioners who are providing direct care to patients and the public without being subject to any kind of regulation.

3. Options

Three options have been identified.

Option 1: To do nothing.

Option 2: To encourage voluntary self-regulation among practitioners of herbal medicine and acupuncture.

Option 3: To introduce statutory regulation for herbal medicine and acupuncture practitioners.

Within Option 3, several sub-options have been considered in order to ensure that the new regulatory system operates effectively in the interests of patients, the public and practitioners. The Health Departments' preferred approach is the establishment of a shared Council for herbal medicine and acupuncture practitioners. This would enable economies of scale that could not be achieved by two separate Councils. A shared Council would also support herbal medicine and acupuncture practitioners who work across professional boundaries.

4. Benefits

Option 1: This option would not meet the objective of protecting patients and the public from untrained or incompetent practitioners.

Option 2: This option may encourage some additional practitioners of herbal medicine and acupuncture to register with voluntary regulatory bodies. There would therefore be some benefits in terms of strengthened public and patient protection. However, significant loopholes would remain within the system. Those who wished to evade voluntary regulation would continue to do so and would thereby continue to pose risks to patients and the public. Furthermore, it is expected that practitioners with less training and/or experience would be more likely to evade voluntary regulation than fully trained and competent practitioners.

Option 3: This would provide the greatest benefit in terms of patient and public protection. It would also:

- provide reassurance for patients seeking a herbal medicine or acupuncture practitioner that a regulated practitioner is not only suitably qualified, but also competent and up-to-date with developments in practice;
- assist other healthcare professionals wishing to refer a patient to a herbal medicine or acupuncture practitioner, by providing a clear means of identifying whether that practitioner is competent to practise;
- increase confidence in the herbal medicine and acupuncture professions among the public and other healthcare professions;
- provide a basis for updating medicines legislation relating to the use of herbal remedies in one-to-one consultations, in the interests of public health.

5. Costs

The proposals would impact on practitioners of herbal medicine and acupuncture and their employers. They would not impact on practitioners who are already registered with statutory regulatory bodies for other healthcare professions, such as doctors, nurses and physiotherapists.

Option 1: As set out above, this option would not meet the objective. It does not carry any additional costs.

Option 2: Herbal medicine and acupuncture practitioners who opt to register with a voluntary regulatory body would incur a registration fee. Registration fees charged by voluntary regulatory bodies for herbal medicine and acupuncture practitioners vary and it is not therefore possible to provide a precise indication of the cost to individual practitioners. Given these varying registration fees and the fact that there is no means of identifying the total number of practitioners who would opt for voluntary regulation, the overall cost of this option cannot be indicated with any degree of accuracy.

Option 3: Herbal medicine and acupuncture practitioners would incur a registration fee in order to register with a statutory regulatory body. The Herbal Medicine Regulatory Working Group, which was established to develop proposals for the statutory regulation of herbal medicine practitioners, produced costings which suggested an annual registration fee of £262 per registered practitioner. For those practitioners who already opt for voluntary self-regulation, the cost of statutory regulation is expected to be broadly comparable with their existing regulatory fees. In addition, fees paid to regulatory bodies by healthcare professionals are tax deductible. In view of the difficulty in identifying the overall number of herbal medicine and acupuncture practitioners who would be affected by statutory regulation, it is not possible to provide an accurate estimate of the total cost of this option.

6. Impact on small business

Most practitioners of herbal medicine and acupuncture are either self-employed or employed by small businesses. The impact of this proposal on individual businesses is directly proportional to the number of herbal medicine and/or acupuncture practitioners employed by those businesses. It is also dependent on whether a business opts to pay the regulatory fees of the practitioners it employs, or whether it expects practitioners to meet the costs of statutory regulation themselves.

Responsible employers of herbal medicine and/or acupuncture practitioners will already encourage or require those practitioners to join voluntary regulatory bodies. As stated in section 5 above, the cost of statutory regulation would be broadly comparable with the cost of voluntary regulation. There is not therefore expected to be any adverse impact on small business as a result of this proposal.

The role of the voluntary regulatory bodies themselves will change under statutory regulation, as they will no longer be responsible for registering practitioners. They will however, as professional bodies for the herbal medicine and acupuncture professions, be free to carry out other duties. These may include promoting the herbal medicine and acupuncture professions and advising on the development of the professions as a whole.

7. Competition Assessment

Whilst the changes proposed will increase barriers to entry into the herbal medicine and acupuncture professions, they will do so in order to provide the necessary level of public and patient protection. The affected markets are characterised by a large number of practitioners who are either self-employed or employed by small businesses, many of whom are already registered with voluntary regulatory bodies. Although the proposals will raise barriers to entry and may cause a small number of unqualified practitioners to exit the market, this is not expected to result in a significant reduction in the effectiveness of competition within the affected markets. No other concerns have been identified which would indicate a need for a detailed competition assessment.

8. Enforcement and Sanctions

Statutory regulation is based around protection of title. The effect of this is that only practitioners who are registered with the statutory regulatory body can legally use a protected title, such as “herbal medicine practitioner” or “acupuncturist”.

If existing models of statutory regulation were followed, use of a protected title by an unregistered herbal medicine or acupuncture practitioner would be a criminal offence subject to prosecution and a fine at level five on the standard scale. This currently stands at £5,000. An offence would also be committed if an unregulated practitioner did the following:

- falsely represented him or herself to be registered;
- falsely represented him or herself to possess qualifications in the herbal medicine or acupuncture professions.

9. Monitoring and Review

This partial regulatory impact assessment will be reviewed following the close of the consultation period outlined below. It will then be re-issued for further consultation alongside the draft Order establishing the new statutory regulatory system.

10. Consultation

A three-month consultation period on the proposals closes on 7 June 2004. The consultation is a joint consultation exercise on behalf of all four UK Health Departments.

Following this initial consultation period, a draft Order under section 60 of the Health Act 1999 will be prepared to establish the new statutory system. There will then be a further consultation on the draft Order before it is formally laid before and debated by the UK Parliament and the Scottish Parliament. It will also be open to the Northern Ireland Assembly, subject to the Assembly being restored, and the National Assembly for Wales to debate the proposals, should they wish to do so.

11. Summary and recommendations

A statutory regulatory system, as described under Option 3 above, is considered necessary in order to ensure patient and public protection and to meet the more detailed objectives described in section 2. The proposals will be further refined as a result of full public consultation. An amended partial regulatory impact assessment, which reflects the outcome of the consultation process, will subsequently be issued for further consultation.



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