Statutory Regulation of Herbal Medicine and Acupuncture

Report on the consultation

February 2005

Department of Health

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Introduction

1. On 2 March 2004, the UK Health Departments published a consultation paper, *Regulation of herbal medicine and acupuncture*, setting out their proposals for the statutory regulation of herbal medicine and acupuncture practitioners. Statutory regulation improves public protection by setting clear standards of training and competence for regulated practitioners. It also reassures patients that a regulated practitioner is not only suitably qualified, but also competent and up-to-date with developments in practice.

2. The background to the Health Departments' proposals was a recommendation made by the House of Lords Select Committee on Science and Technology 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 report, published in March 2001, the Government accepted this recommendation.

3. In 2002, the Department of Health and the Prince of Wales's Foundation for Integrated Health jointly established 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. The Health Departments considered and built on the working groups' recommendations in developing the proposals for statutory regulation set out in their consultation document *Regulation of herbal medicine and acupuncture.*

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

Responses to the consultation

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

- educational bodies – 19 responses;
- NHS bodies (including NHS Trusts, Primary Care Trusts and Strategic Health Authorities) – 15 responses;
- Health and Social Services Boards and Trusts in Northern Ireland – 7 responses;
- other complementary and alternative medicine (CAM) organisations – 20 responses;
- patient and consumer organisations – 3 responses;
- professional associations for regulated healthcare professionals – 6 responses;
- Royal Colleges – 9 responses;
- statutory regulatory bodies – 5 responses.

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

6. 237 responses, 34% of the total number received, formed a campaign regarding the regulation of Ayurveda, an Indian and Sri Lankan tradition of herbal medicine. Many of these responses were identical in content. The campaign letters were supportive of the principle of statutory regulation but emphasised that the minimum standard of education and training for practitioners of Ayurveda should be equivalent to the training offered by universities in India and Sri Lanka. The campaign was organised by the British Ayurvedic Medical Council and the letters were mainly submitted by members of the public and students and practitioners of Ayurveda.

General Overview of Responses

7. 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. Full information about the comments submitted on each of these issues is provided under the heading "Detail of responses".

1 Practitioners of Traditional Chinese Medicine usually practise both Chinese herbal medicine and acupuncture.

Detail of Responses

Question 1 – application of statutory regulation to all four UK countries

8. There was strong support for the application of a consistent system of statutory regulation across all four UK countries – England, Scotland, Wales and Northern Ireland. A total of 202 respondents commented on this particular issue, with 199 respondents (98.5%) expressing support for a UK-wide system.

Question 2 – the type of regulatory body

9. Views were sought on the UK Health Departments' preferred approach to statutory regulation – a shared Complementary and Alternative Medicine (CAM) Council for herbal medicine and acupuncture practitioners. The consultation document suggested that a shared Council would support practitioners who work across professional boundaries, while preserving and respecting individual traditions within the herbal medicine and acupuncture professions. It also suggested that a CAM Council could potentially be extended to other unregulated complementary and alternative medicine professions, should statutory regulation be considered necessary in order to ensure patient and public safety.

10. This question led to a significant amount of debate, with a total of 281 respondents commenting on the issue. A slight majority of 147 respondents (52.3%) supported a shared CAM Council for herbal medicine and acupuncture, while 134 (47.4%) were not in favour of this approach.

11. The Prince of Wales's Foundation for Integrated Health (POWFIH) and CAM Forum Scotland both supported a shared CAM Council. They highlighted the advantages of this approach as:

- the existence of a single point of contact for patients and the public;
- the possibility of economies of scale, resulting in lower registration fees for practitioners;
- other benefits resulting from a larger overall income, such as increased capacity to make changes and carry out the Council's functions.

They also referred to experience that, where other professions have come together under a single regulatory body, professional autonomy has been preserved. POWFIH nevertheless emphasised the need for individual disciplines to have sufficient autonomy, control and influence over the education and registration standards of their respective professions under a shared Council. Similarly, the University of Westminster noted the value of each discipline retaining its individual identity, while supporting a shared Council as being more likely to defend minority approaches and to lead to best practice and consistency.

12. The Council for the Regulation of Healthcare Professionals, recently renamed the Council for Health Care Regulatory Excellence, stated that a shared Council would be more likely to have the resources to adequately support the various functions of a fully modern regulatory body and to cope with emerging regulatory demands. This view was shared by the European Herbal Practitioners Association, which pointed out that smaller Councils have a lower income and therefore less capacity to make changes and carry out their functions.

13. Other respondents who supported a shared Council included organisations representing practitioners of Traditional Chinese Medicine, Royal Colleges and the majority of NHS bodies which chose to comment on this issue.

14. Several organisations representing practitioners of acupuncture strongly opposed the proposal for a shared Council for herbal medicine and acupuncture. This view was shared by a large number of individual practitioners of acupuncture and some organisations representing practitioners of other CAM therapies, notably aromatherapy, reflexology, homeopathy and shiatsu.

15. The British Acupuncture Council (BAcC) expressed a number of concerns about the Health Departments' proposal for a shared Council for herbal medicine and acupuncture practitioners. The concerns raised included:

- the uniqueness of safety issues to each profession;
- the lack of influence of the former non-statutory Council for Complementary and Alternative Medicine;
- the lack of evidence about the effect of operating under a shared regulator on working across professional boundaries;
- a suggestion that costs would increase with complexity and size;
- a view that the herbal medicine and acupuncture professions should not have to bear the start-up costs of a potentially wider CAM Council.

The BAcC also expressed concern about the costings developed by the Herbal Medicine Regulatory Working Group and quoted in the consultation document, suggesting that a registration fee of £400 may be a more realistic estimate.

16. The BAcC's concerns were reinforced by a number of individual practitioners of acupuncture, several of whom expressed concern that a shared Council could become unwieldy and inefficient. The British Acupuncture Accreditation Board took the view that a shared Council would deny the acupuncture profession the opportunity for professional 'self' regulation and also suggested that the similar model of regulation operated by the Health Professions Council had not yet been proven.

Question 3 – alternative model for statutory regulation

17. In recognition of the fact that a shared Council may not be acceptable to all groups, the consultation document also sought views on an alternative model of statutory regulation – separate Councils for the herbal medicine and acupuncture professions, with a shared secretariat function.

18. A total of 138 responses commented on this alternative model. A minority of 24 responses (17.4%) supported the alternative model and 114 responses (82.6%) were opposed to it. Those who expressed support for the proposal included several organisations representing practitioners of other CAM professions, notably aromatherapy, homeopathy and shiatsu.

19. While stating that a General Acupuncture Council remained its preferred model of statutory regulation, the British Acupuncture Council proposed a second alternative model – a joint Council for the herbal medicine and acupuncture professions, with a governing body whose membership is drawn from both. Under the BAcC's proposal, educational issues would be dealt with by profession-specific committees

and administrative and regulatory issues would be addressed in joint committees. Support for the joint Council model proposed by the BAcC was indicated in a total of 55 responses. 48 responses indicated a preference for fully separate Councils for herbal medicine and acupuncture. Other suggestions made included a separate Council for Ayurveda and a separate Council for Traditional Chinese Medicine.

Question 4 – name of the proposed Council

20. Question 4 sought comments on the suitability of the name "CAM Council". A total of 223 responses commented on this issue, with 103 (46.2%) agreeing with the suggested name and 120 (53.8%) opposing it.

21. A number of respondents felt the name "CAM Council" to be too general and suggested that a more specific name should be chosen to accurately reflect the professions that would be regulated by the proposed Council. The name "Acupuncture and Herbal Medicine Council" was suggested by the British Acupuncture Council and supported by a further 46 respondents.

22. Many of the respondents who were in favour of a more overarching name, in order to reflect a flexibility to extend the proposed Council to other CAM professions in the future, expressed concern about the use of the term "alternative". The Faculty of Homeopathy suggested that the concept of "alternative medicine" is not consistent with the development of a more integrated approach to healthcare. Suggested alternatives to the name "Complementary and Alternative Medicine Council" included "Complementary Medicine Council" (suggested by ten respondents), "Complementary Health Professions Council" (suggested by three respondents), "Complementary Health Council" (suggested by two respondents) and "Traditional Medicine Council" (suggested by two respondents).

Question 5 – extension of the proposed "CAM Council" to other CAM professions

23. The consultation document proposed that a CAM Council should be capable of being extended to other CAM professions, where this is considered necessary in order to ensure patient and public protection. While the Health Departments do not currently plan to bring any other CAM professions under statutory regulation, this approach would provide flexibility for future changes.

24. A total of 202 respondents commented on this issue. 139 respondents (68.8%) supported the ability for a CAM Council to be extended to other CAM professions, while 63 respondents (31.2%) were not in favour of the proposal. Organisations representing other CAM professions which supported the proposal included the General Naturopathic Council, the International Federation of Professional Aromatherapists, the Nutritional Therapy Council, the Reiki Association and the Reiki Regulatory Working Group. By contrast, the Aromatherapy Consortium and the General Shiatsu Council did not consider this to be a suitable way forward.

25. Several responses indicated that their support for the ability to extend the CAM Council to other CAM professions was on condition that the professions concerned could meet the necessary standards of education and training. The Prince of Wales's Foundation for Integrated Health suggested that it might be appropriate to consider extending statutory regulation to homeopathy in the near future, a view which was shared by the European Herbal Practitioners Association (EHPA) and several other respondents. Four respondents, including the EHPA, also suggested that there might be advantages in examining whether the osteopathy and chiropractic professions could be brought within a wider regulatory body at some point in the future.

Question 6 – protected titles

26. The consultation document sought views on three proposed titles to be protected under statutory regulation – acupuncturist, herbal practitioner and Traditional Chinese Medicine practitioner. A total of 214 responses expressed a view on the protected titles, with 121 (56.5%) agreeing with all three proposed titles and 93 (43.5%) expressing concern about one or more titles.

27. The proposed title "Traditional Chinese Medicine practitioner" attracted the greatest amount of comment. A total of 35 responses, including the British Acupuncture Council and a number of individual BAcC members, expressed concern about this title. It was suggested that there was no commonly agreed definition of Traditional Chinese Medicine and that the public may not therefore understand the title's meaning. Among some organisations which supported the concept of a dedicated title for Traditional Chinese Medicine, including the Chinese Medical Institute and Register, the Chinese Medicine Alliance and the Association of Chinese Medicine Practitioners, there was a suggestion that the term "Chinese Medicine Practitioner" may be a more appropriate alternative. Some organisations representing practitioners of Ayurveda, including the British Ayurvedic Medical Association and the General Council for Ayurveda, also suggested that a dedicated title would be appropriate for Ayurveda. This view was shared by the High Commission of the Democratic Socialist Republic of Sri Lanka.

28. 13 respondents questioned the Health Departments' reasons for proposing the protection of simple titles and suggested that the incorporation of the term "registered" within the protected titles would help public understanding. Nine respondents, including the European Herbal Practitioners' Association, suggested that the commonly used title "Herbalist" should be protected either instead of or as an alternative to the title "Herbal medicine practitioner".

Question 7 – subsidiary designations

29. The consultation document also set out a list of 11 proposed subsidiary designations which could be used by registered herbal medicine and acupuncture practitioners, together with a protected title, in order to recognise their tradition and/or main area of practice and to help ensure informed patient choice.

30. A total of 201 respondents commented on the proposed subsidiary designations. 85 respondents (42.3%) supported the subsidiary designations, while 116 respondents (57.7%) disagreed with them.

31. Concern was expressed about two of the proposed subsidiary designations for acupuncturists – "auricular acupuncture" and "western medical acupuncture". 26 respondents expressed the view that a subsidiary designation was inappropriate for auricular acupuncture, suggesting that it is a technique rather than a tradition or profession and referring to the limited training needed to practise auricular acupuncture. 14 respondents questioned the appropriateness of a separate subsidiary designation for western medical acupuncture, particularly if such practitioners were to continue to be regulated by their existing regulatory bodies under the Health Departments' proposals for collaborative regulation (these proposals are discussed in more detail under question 12).

32. 20 respondents suggested that the proposed subsidiary designations might be confusing for the public. The Council for Healthcare Regulatory Excellence stated that the range of subsidiary designations may be more confusing to patients than it is helpful and pointed out that the overarching protected titles allow for different styles of practice. The British Acupuncture Council suggested that the use of subsidiary designations would contradict the Health Departments' logic for protecting simple titles. By contrast, the General Medical Council stated that, while it might be argued that the use of subsidiary

designations could serve to confuse rather than clarify, the proposed designations would put patients in a better position to make informed choices about the type of care they are seeking.

33. A number of respondents, including the British Acupuncture Council and the British Acupuncture Accreditation Board, suggested that an alternative administrative arrangement, such as an indication on the register, could assist patients in identifying a practitioner's training background and the styles of treatment used. The European Herbal Practitioners Association suggested that the protected title itself, rather than an accompanying subsidiary designation, should indicate the practitioner's tradition or style of practice.

34. Several additional subsidiary designations were suggested by respondents. These included a subsidiary designation for Eastern Medicine/Tibb, suggested by the Eastern Medicine (Tibb) Practitioners Association, a subsidiary designation for Korean Medicine, suggested by the Association of Korean Medicine Practitioners, and subsidiary designations for the Thai and African traditions of herbal medicine.

Question 8 – duties of the proposed Council

35. A total of 196 respondents comment on the duties of the proposed regulatory body set out in the consultation document. There was strong support for the duties suggested by the Health Departments, with 183 respondents (93.4%) commenting favourably and 13 respondents (6.6%) objecting.

36. There was however some concern about the appropriateness of the proposed Council advising herbal medicine practitioners on the use of herbal medicine products in their practice. Several respondents, including the British Acupuncture Council, the Council for the Regulation of Health Care Professionals and the University of Westminster, raised this issue. The Prince of Wales's Foundation for Integrated Health suggested that this function might more appropriately be carried out by a herbal medicine advisory group to the Medicines and Healthcare products Regulatory Agency. There was a general consensus that, should this function be assigned to the proposed regulatory body, the costs to registrants would need to be allocated fairly.

37. An additional suggestion made by the European Herbal Practitioners Association was that the proposed Council should have an explicit duty to work in partnership with professional associations for practitioners, in addition to employers, education providers and other regulatory bodies.

Question 9 – composition of the Council

38. The Health Departments' proposals for the composition of the proposed CAM Council generated considerable debate. 232 respondents commented on this particular issue, with 93 (40.1%) supporting the proposals and 139 (59.9%) disagreeing with them. Those who were not in favour included a number of organisations representing practitioners of herbal medicine and acupuncture.

39. 26 respondents, including the Association of Traditional Chinese Medicine, the British Acupuncture Council, the European Herbal Practitioners Association and the University of Westminster, expressed concern about the inclusion of representatives of other health and social care professions on the Council. It was felt that the use of such professionals as lay members should be limited. The British Acupuncture Council further commented that specific representation among the lay members was needed for patient support groups and consumer groups. A total of 44 responses commented specifically that the membership of the proposed CAM Council should follow the model of the British Acupuncture Accreditation Board, using a lay chair and a high proportion of lay members.

40. The British Acupuncture Council expressed concern about the possible disproportionate representation of small groups on the proposed Council. In this context, a number of respondents suggested that practitioner membership should be proportional to the size of the group represented. The European Herbal Practitioners Association suggested that smaller traditions could have observer status on the Council, receiving automatic representation when registration of an agreed number of practitioners was reached. A number of respondents commented that it would be important not to include a restriction on the overall number of practitioner members in the Council's constitution, in order to allow for such flexibilities.

Question 10 – individual representation of Kanpo and Tibetan herbal medicine

41. 118 respondents commented on the specific issue of whether the herbal medicine traditions of Kanpo and Tibetan herbal medicine should be individually represented on the proposed Council. 57 respondents (48.3%) supported individual representation for Kanpo and Tibetan herbal medicine, while 61 respondents (51.7%) did not consider this to be appropriate.

42. There were concerns that there may not be sufficient practitioners of Kanpo and Tibetan herbal medicine in practice in order to make individual representation possible. A number of respondents suggested that individual traditions could be represented on the Council when the number of registrants reaches an agreed minimum level – levels of 50, 100 and 500 members were suggested. Several respondents expressed concern about the possibility of small groups having a disproportionate influence on the proposed Council and the overall membership becoming too large. Northumbria University suggested that the appointment of a single Council member to represent a group of traditions would be a more practical way forward.

43. Suggestions of other traditions which could potentially be represented on the Council included auricular acupuncture, Japanese acupuncture, Korean acupuncture, Tibetan acupuncture, Eastern Medicine, African herbal medicine, Traditional Korean Medicine, Romany Medicine and Sri Lankan traditional medicine.

Question 11 – term of office and method of appointment of Council members

44. Question 11 sought views on the term of office and the method of appointment of members to the proposed Council. A total of 190 respondents commented on this issue, with 154 respondents (81.1%) supporting the Health Departments' proposals and 36 (18.9%) disagreeing with them.

45. The concerns expressed were predominantly related to the appointment of practitioner members to the proposed Council by the NHS Appointments Commission. A number of respondents questioned the appropriateness of this method of appointment for the complementary and alternative medicine sector. Twelve respondents, including the Chinese Medicine Alliance and the Reiki Regulatory Working Group, suggested that practitioner groups or professional organisations should choose the practitioner members. The European Herbal Practitioners Association suggested a compromise, whereby the appointment of practitioner members to the first Council could be carried out by the NHS Appointments Commission in consultation with the existing professional bodies.

Question 12 – collaborative regulation

46. Question 12 sought views on the Health Departments' proposals for collaborative regulation. Collaborative regulation is the term used to describe the approach taken to the regulation of herbal medicine and acupuncture practitioners who are already regulated by existing statutory regulatory bodies for other healthcare professions. Under the Health Departments' proposals, it was suggested that such practitioners should continue to be regulated by their existing regulatory bodies and that those bodies should work closely with the proposed CAM Council on educational issues. The consultation document also stated that, in view of the need to ensure clear accountability for regulated healthcare professionals, the Health Departments do not favour dual registration and would therefore not make it a requirement for healthcare practitioners who work across professional boundaries.

47. The proposals for collaborative regulation generated a significant amount of discussion and debate, surpassed only by the type of regulatory body proposed. A total of 255 responses commented on this issue, with 93 (36.5%) supporting the Health Departments' proposals and 162 (63.5%) disagreeing with them.

48. Concerns about the collaborative regulation proposals were raised in the following areas:

i) the need for the public to have access to a single list of acupuncture practitioners, which includes those regulated by existing statutory regulatory bodies;

ii) a wish for acupuncture practitioners regulated by existing statutory regulatory bodies to have access to the proposed protected title 'acupuncturist';

iii) the ability of existing regulatory bodies to rule on competence in the practice of herbal medicine and/or acupuncture;

iv) the ability of existing regulatory bodies and the proposed CAM Council to work together on issues relating to education and training;

v) the ability of the proposed CAM Council to advise other regulators on the practice of western medical acupuncture, if western medical acupuncture practitioners are not included among its registrants;

vi) a suggestion that the standard of acupuncture practised by regulated healthcare professionals is lower than that practised by practitioners of traditional acupuncture and therefore requires further regulation.

A large number of members of the British Medical Acupuncture Society wrote to Department of Health Ministers about some or all of concerns (i) to (v). Approximately 50 of these letters were also submitted directly to the Health Departments as consultation responses.

49. A number of responses, 35 in total, favoured dual registration and suggested that all practitioners of herbal medicine and/or acupuncture should either be able to, or be required to, register with the proposed Council, regardless of any existing regulatory arrangements. Those in favour of dual registration included the General Council for Ayurveda, the British Academy of Western Medical Acupuncture and the Royal College of General Practitioners. The British Medical Association stated that it favoured some form of dual registration, so that doctors are accountable to the proposed CAM Council for that particular area of their practice and have the right to use a protected title. A further 25 respondents, including the Acupuncture Association of Chartered Physiotherapists, the Council of Organisations Registering Homeopaths and the Prince of Wales's Foundation for Integrated Health,

supported further consideration of the model of dual registration proposed by the Acupuncture Regulatory Working Group.

50. The Council for Healthcare Regulatory Excellence emphasised the importance of considering how successful a collaborative approach would be in practice. It suggested that the success of such an approach would depend on the willingness of existing regulators to consult with and defer to the advice of the proposed CAM Council, particularly with regard to education and training. It also suggested that, if a collaborative approach is preferred, this would need to be kept under regular review to ensure that standards are sufficiently high to protect the public.

Question 13 – ability of the proposed Council to establish additional committees

51. There was strong support for the suggestion of the proposed CAM Council having the freedom to establish additional committees, with 185 respondents (96.9% of those who commented on this issue) supportive of this approach. A Safety Committee was proposed by 25 respondents, including the British Acupuncture Council, while the European Herbal Practitioners Association proposed a Finance Committee and the University of Westminster suggested a Diversity Committee.

52. A number of proposals for tradition or discipline-specific advisory committees were put forward by organisations representing practitioners of auricular acupuncture, Traditional Chinese Medicine and Ayurveda. By contrast, nine respondents raised concerns about the cost and other associated burdens of establishing additional committees. There was a clear view that the right balance needed to be struck between the CAM Council having the freedom to operate effectively and reducing burdens on individual registrants.

Question 14 – composition of Education and Training Committee

53. There was a general consensus that the membership of the proposed CAM Council's Education and Training Committee should include representatives of each of the herbal medicine and acupuncture disciplines or traditions regulated by the Council. In addition, there was strong support for the inclusion of lay members and educationalists on the Committee, which was seen by many respondents as providing an independent method of ensuring standards. The British Medical Association suggested that the membership should include a doctor, in order not to disadvantage medically-qualified CAM practitioners.

54. Some respondents felt that representation of each discipline or tradition on the Committee did not go far enough and suggested that separate profession or even tradition-specific Education and Training Committees would be more appropriate. This view was expressed by, among others, the Chinese Medicine Alliance, the Eastern Medicine (Tibb) Practitioners Association and the Society of Homeopaths. By contrast, the professional representatives from the Acupuncture Regulatory Working Group stated in their response that they did not support the principle of 'one from every group on every committee', a view shared by the British Acupuncture Council, who suggested that the committee should be maintained at the minimum level of members consistent with effective governance.

55. 29 respondents suggested that lay members should form 50% of the membership of the Education and Training Committee. These included the British Acupuncture Council, the Register of Chinese Herbal Medicine and a number of individual practitioners. 18 respondents suggested that the proportion of lay members should be less than 50%, while four respondents were in favour of a majority or slight majority of lay members over practitioner members. Several respondents expressed the view that lay members

should have previous educational expertise and some concerns were raised that the lay membership, as in the case of the Council itself, should not be dominated by orthodox healthcare professionals.

56. A total of 129 respondents commented on whether the Chair of the Education and Training Committee should be a lay person or a practitioner. 83 (64.3%) were in favour of a lay Chair, while 46 (35.7%) felt that a practitioner Chair would be more appropriate. 14 respondents, whether in favour of a lay or practitioner Chair, commented that the most important issue is the Chair's knowledge of matters relating to education and training.

Question 15 – Registration Committee

57. Views were sought on whether the proposed CAM Council should establish a separate Registration Committee, or whether issues relating to registration should be dealt with by the Education and Training Committee.

58. There was general support for the proposal to establish a Registration Committee. Of the 178 respondents who commented on this issue, 123 (69.1%) supported a separate Registration Committee and 55 (30.9%) opposed such a committee. Those who opposed the proposal were generally concerned about cost and suggested that it would be more cost-effective for the Education and Training Committee to take responsibility for issues relating to registration.

59. A number of those who commented in favour of a Registration Committee suggested that such a committee might not need to continue in the long-term. Respondents who expressed this view included the Association of Chinese Medicine Practitioners and the British Acupuncture Council. It was also suggested that any Registration Committee would need to work very closely with the Education and Training Committee, with some sharing of members recommended.

Question 16 – registration of practitioners with an accredited qualification

60. Question 16 sought views as to whether herbal medicine and acupuncture practitioners who hold a qualification accredited by the proposed Council should be able to apply for automatic registration. 191 respondents commented on this issue, with the majority (94.2%) in favour of the proposal.

61. 21 respondents, including the British Acupuncture Council, the European Herbal Practitioners Association and the Prince of Wales's Foundation for Integrated Health, pointed out that additional factors may also need to be taken into account by the proposed Council, such as health, conduct, criminal records and English-language skills. The Council for Healthcare Regulatory Excellence highlighted the need to reach a consensus on training standards for the practice of Ayurveda.

Question 17 – individual assessment of practitioners without an accredited qualification

62. The consultation document sought views on whether herbal medicine and acupuncture practitioners who do not hold an accredited qualification should be individually assessed for entry on to the Register. There was strong support for this proposal, with 185 (92%) of the 201 respondents who commented in agreement. Notable exceptions were CAM Forum Scotland and the Prince of Wales's Foundation for Integrated Health, who took the view that, after the transitional period following the establishment of the statutory register, only applications supported by accredited qualifications should be considered.

Question 18 – core curriculum or National Occupational Standards

63. Question 18 sought views on whether a core curriculum should be developed for acupuncture, or whether it would be more appropriate to move in the direction of National Occupational Standards. A total of 148 respondents indicated a preferred way forward – 65 (43.9%) were in favour of a core curriculum, while 42 (28.4%) preferred National Occupational Standards. 41 respondents (27.7%) pointed out that core curricula and National Occupational Standards are not mutually exclusive and suggested that work be taken forward on both.

64. Several respondents suggested the development of separate core curricula for different acupuncture traditions or disciplines, notably auricular acupuncture and western medical acupuncture . The Association of Chinese Medicine Practitioners and the Association of Traditional Chinese Medicine, among others, suggested a separate core curriculum for Traditional Chinese Medicine. Several respondents noted the importance of clarity of outcomes, regardless of the approach taken.

Question 19 – arrangements for assessing overseas-qualified practitioners

65. Question 19 sought views on the assessment of overseas-qualified practitioners wishing to gain entry onto the register. The Health Departments proposed that herbal medicine and acupuncture practitioners trained outside the European Economic Area (EEA) who wished to be registered with the CAM Council should be assessed individually. Views were particularly invited on whether the Council, in common with 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.

66. There was strong support for the Health Departments' proposals for individual assessment, with 187 (97.4%) of the 192 respondents which commented on this issue supporting such a system. Some exceptions were suggested where individual assessments may not be necessary or appropriate, such as where practitioners hold a qualification accredited by the World Health Organisation or recognised by overseas countries with well-developed systems of statutory regulation.

67. A number of respondents, including the Council for Healthcare Regulatory Excellence, the European Herbal Practitioners Association and the University of Westminster, highlighted the importance of good English-language skills. Other respondents expressed concern that English-language standards must not be set too high. The Unified Register of Herbal Practitioner suggested that the level of English language required should ensure *adequate* communication with patients. A number of alternative approaches for addressing this issue were put forward by organisations representing practitioners of TCM, including the use of an approved interpreter, conditional registration subject to attaining an agreed level of English within a set period of time and an option to register practitioners without the necessary level of English to work only with patients who use the same language.

Question 20 – groups eligible for grandparenting

68. The consultation document set out three proposed groups of practitioners who would be eligible to join the Register through a "grandparenting" scheme and sought views on these groups. There was general support for the proposals – of the 190 respondents who commented on this issue, 154 (81.1%) agreed with the proposals and 36 (18.9%) expressed concern.

69. The most significant area of comment was over the position of newly-qualified practitioners and students in training. 30 respondents, including the European Herbal Practitioners Association and the Prince of Wales's Foundation for Integrated Health, expressed concern about the position of these groups under the proposed grandparenting arrangements. The Prince of Wales's Foundation for Integrated Health and CAM Forum Scotland further commented that the proposals were inadequate to ensure patient protection and that they favoured a programme of individual assessment against clear, agreed competencies. This view was not shared by a number of organisations representing practitioners, including the Chinese Medicine Alliance and the National Institute of Medical Herbalists, with many suggesting that practising members of certain professional bodies should qualify automatically, without being required to take a test of competence.

Question 21 – length of the transitional period

70. Views were sought on a proposed two-year transitional period for the registration of existing practitioners onto a statutory Register. There was strong support for a two-year period, with 170 of the 185 respondents (91.9%) who commented on this issue supporting a transitional period of this length. Among those who did not agree, 11 respondents expressed the view that a longer transitional period would be more appropriate, with periods of between three and six years suggested.

71. On a related issue, the European Herbal Practitioners Association suggested that, during the transitional period following the opening of any statutory register, it should be possible for practitioners who have applied for registration but whose application has not been processed, to hold a provisional registration.

Question 22 – standards of proficiency

72. Question 22 sought views on whether the standards of proficiency maintained by the proposed CAM Council should take account of the National Professional Standards for herbal medicine and any future National Occupational Standards for acupuncture. There was strong support for this proposal, with 169 (93.9%) of the 180 respondents who commented in agreement.

73. Several respondents expressed a wish to see a stronger statement of linkage between the National Occupational/Professional Standards and the proposed CAM Council's Standards of Proficiency. A number of individual acupuncture practitioners stated a preference for the name "National Professional Standards" and several respondents, including the Association of Traditional Chinese Medicine and the International Ayurveda Foundation, suggested separate National Professional Standards for Traditional Chinese Medicine and/or Ayurveda.

Question 23 – codes of conduct

74. Strong support was also noted in response to question 23 on whether the proposed CAM Council should develop codes of conduct for herbal medicine and acupuncture practitioners. 97.9% of the responses which commented on this issue were in favour of the proposal.

75. The Acupuncture Association of Chartered Physiotherapists pointed out that such codes should only be applied to practitioners who are not already regulated by other regulatory bodies. Several respondents, including CAM Forum Scotland, the Prince of Wales's Foundation for Integrated Health and the General Osteopathic Council, suggested that the codes should focus on what is acceptable practice, rather than on what is not acceptable. By contrast, the Acupuncture Regulatory Working Group

professional representatives did not support the development of such codes, stating that professional practitioners are best placed to determine the detail of the standards required of them.

76. Four respondents suggested the development of a separate code of conduct for practitioners of Chinese Medicine and the establishment of a separate code of conduct for practitioners of Ayurveda was also proposed.

Question 24 – continuing professional development

77. Views were invited on whether the proposed CAM Council should be responsible for determining continuing professional development (CPD) requirements for herbal medicine and acupuncture practitioners. 194 respondents commented on this issue, 176 (90.7%) favourably and 18 (9.3%) against.

78. 22 responses raised the importance of involving professional bodies in the development of requirements for, and the delivery of, CPD. The University of Westminster specifically recommended referring to the systems set in place by the British Acupuncture Council and developed by the Herbal Medicine Regulatory Working Group. Several respondents indicated a wish for CPD requirements to be relevant and unique to individual traditions within the herbal medicine and acupuncture professions. The Acupuncture Association of Chartered Physiotherapists pointed out that such requirements should only be applied to practitioners who are not already regulated by other regulatory bodies.

Question 25 – fitness to practise models

79. Question 25 sought views on the preferred model of the fitness to practise – the schemes proposed by the Herbal Medicine and Acupuncture Regulatory Working Groups or a model which had recently been consulted on by the General Medical Council (GMC). The majority of respondents who expressed a view in favour of one particular option preferred the Working Groups' schemes (70.1%), while 29.9% preferred the GMC's approach. Ten respondents, including the British Acupuncture Council, did not feel in a position to comment.

80. Support for the model consulted on by the GMC was generally found among organisations representing practitioners of Chinese Medicine and other herbal medicine traditions. The European Herbal Practitioners Association described the advantages of this model as including:

- the patient only participates in one set of procedures and hearings;
- conduct, health and performance issues are all considered together;
- practitioners are likely to find it easier to understand;
- one less statutory committee to pay for;
- the process is independent of the Council at the adjudication stage.

Those who opposed the GMC's model suggested that it might be unnecessarily costly and/or burdensome for implementation by smaller professions.

Question 26a – composition of fitness to practise committees – working groups' model

81. Suggestions were sought on the composition of the fitness to practise committees from those who preferred the fitness to practise models developed by the Herbal Medicine and Acupuncture Regulatory Working Groups. There was a general view that practitioner members should include those with the same professional background as the practitioner whose case is being considered, together with appropriate lay representation.

82. A total of 38 respondents, including the British Acupuncture Council and a number of individual practitioners, suggested that lay members should form 50% of the membership of the fitness to practise committees. 20 respondents suggested that the proportion of lay members should or could be less than 50%, while seven respondents were in favour of a majority or slight majority of lay members over practitioner members.

83. 86 respondents commented on the issue of whether the Chair of the fitness to practise committees should be a lay person or a practitioner. The majority (75.6%) were in favour of a lay Chair, while 24.4% felt that a practitioner Chair would be more appropriate

Question 26b – composition of fitness to practise committees – GMC model

84. Views were also sought on the composition of the fitness to practise committees among those who preferred the GMC's model. Again, there was a general view among respondents that practitioner members should include those with the same professional background as the practitioner whose case is being considered, together with appropriate lay representation.

85. Three of the 11 respondents who commented on the issue of lay representation suggested that lay members should form 50% of the membership of the Investigating Committee. Four respondents, including the European Herbal Practitioners Association and the Prince of Wales's Foundation for Integrated Heath, suggested that lay membership of this committee should be substantial, while the British Acupuncture Accreditation Board suggested that it should be sufficient, although not necessarily a majority. With regard to the adjudication panels, nine of the 13 respondents who commented suggested that lay membership should be substantial and/or a majority.

86. A small number of respondents commented on the arrangements for chairing the Investigating Committee. All the respondents, which included the Consumers' Association, were in favour of a lay Chair. Similarly, all the respondents which commented on the arrangements for chairing the adjudication panels favoured a lay Chair.

Question 27 – sanctions for use in fitness to practise cases

87. Question 27 proposed a set of four sanctions for use in fitness to practise cases. 189 respondents comments on the sanctions proposed – 140 (74.1%) agreed with the full set of sanctions while 49 (25.9%) did not agree.

88. The most common reason for disagreement was a suggestion that fines and/or admonishments/cautions should be added to the list of sanctions available to the fitness to practise committees. 45 respondents, including the British Acupuncture Council and the General Osteopathic Council, commented to this effect. The General Medical Council emphasised the need for a means of acknowledging that an individual's practice may be at a minimally acceptable level which is not such to put patients at risk and justify action against registration, but is nevertheless significantly short of good practice. It also suggested that provision was needed for the imposition of interim conditions on, or suspension of, a practitioner's registration prior to any final adjudication.

Question 28 – appeals tribunal

89. There was strong support for the proposal that an appeals tribunal be constituted by the CAM Council to consider appeals relating to registration or renewal of registration. A total of 184 respondents commented on this issue, with 180 (97.8%) in favour of the proposal and just four (2.2%) against.

Question 29 – formal Working Group

90. The final question sought views on the establishment of a formal Working Group to help the herbal medicine and acupuncture professions prepare for statutory regulation. 186 respondents expressed a view on this issue, with 172 (92.3%) commenting in favour and 14 (7.5%) opposed to the suggestion.

91. A number of respondents expressed concern about the cost of establishing a formal Working Group and several, including the National Institute of Medical Herbalists and the European Herbal Practitioners Association, suggested that the Department of Health should provide funding. Five respondents, including the Consumers' Association, highlighted the need for lay representation on such a Working Group.

Other issues raised

92. A large number of respondents commented on further issues which relate to statutory regulation, but were not specifically addressed in the consultation paper. The additional issues raised are summarised below.

Acupuncture

93. There was significant concern about the definition of "acupuncture", with many respondents stating that they considered the definition developed by the Acupuncture Regulatory Working Group (ARWG) and quoted in the consultation document to be unacceptable. A total of 59 respondents, mainly practitioners and students of acupuncture, raised this issue. Many suggested that the following Longman's definition of acupuncture would be an acceptable alternative:

"therapeutic practice of Chinese origin consisting in the introduction of fine needles at certain points in the skin along vital 'lines of force'".

The definition of acupuncture used by the World Health Organisation was also suggested as an alternative to the ARWG's definition, although by a smaller number of respondents. Concern about the standard of training of practitioners of western medical acupuncture was raised by 12 respondents, predominantly practitioners of traditional acupuncture.

Traditional Chinese Medicine

94. Organisations representing practitioners of Traditional Chinese Medicine strongly supported the establishment, under a shared CAM Council, of a dedicated part of the register for TCM practitioners, rather than requiring practitioners to register in both the herbal medicine and acupuncture parts. Those expressing this view included the Association of Traditional Chinese Medicine, the Chinese Medical Institute and Register, the Chinese Medicine Alliance and the General Council of Traditional Chinese Medicine.

Education and training

95. 13 respondents expressed concern about the wide remit of the proposed Council's Education and Training Committee, with the British Acupuncture Accreditation Board suggesting devolving some of the Committee's functions to professional bodies. The Chinese Medicine Alliance went one step further, suggesting that education and training should be the responsibility of the professional bodies. A number of patients of British Acupuncture Council members responded to the consultation emphasising the need to maintain the BAcC's current standards of safety and degree-level education and training.

96. A number of respondents were concerned about the accreditation of educational qualifications and suggested that there should be a single statutory accreditation committee, modelled on the British Acupuncture Accreditation Board, with sub-committees for each discipline. This view was expressed by 44 respondents, mainly practitioners and students of acupuncture. Eight respondents emphasised the need to ensure a thorough assessment of practitioners during the transitional period following the opening of any statutory register.

Cost of statutory regulation and future of professional associations

97. A number of respondents, mainly practitioners and students of herbal medicine and acupuncture, were concerned about the cost of introducing statutory regulation. There were several suggestions that the initial costs of establishing any statutory regulatory body should be borne by the Government. There was some concern among existing professional bodies about their own future, particularly if the cost of statutory regulation were to deter practitioners from continuing with membership of professional associations.

Need for statutory regulation

98. A total of 12 respondents, including the Royal College of General Practitioners, questioned the need to introduce statutory regulation, either due to a preference for voluntary self-regulation or a suggestion that matters of safety and/or efficacy needed to be further considered prior to the establishment of a statutory scheme.

Conclusion

99. The Health Departments are grateful to all those who responded to this consultation exercise on the statutory regulation of herbal medicine and acupuncture practitioners.

Timetable for next steps in regulatory process

Stage	Date
Close of formal consultation period	7 June 2004
Analysis of consultation responses	Summer 2004
Submission to Ministers on policy proposals	Winter 2004
Publication of analysis of consultation responses	Spring 2005
Preparation of draft Order under section 60 of the Health Act 1999	Spring 2005
Clearance of draft s 60 Order by Parliamentary Counsel	Spring 2005
Publication of draft section 60 Order for consultation	Autumn/winter 2005

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