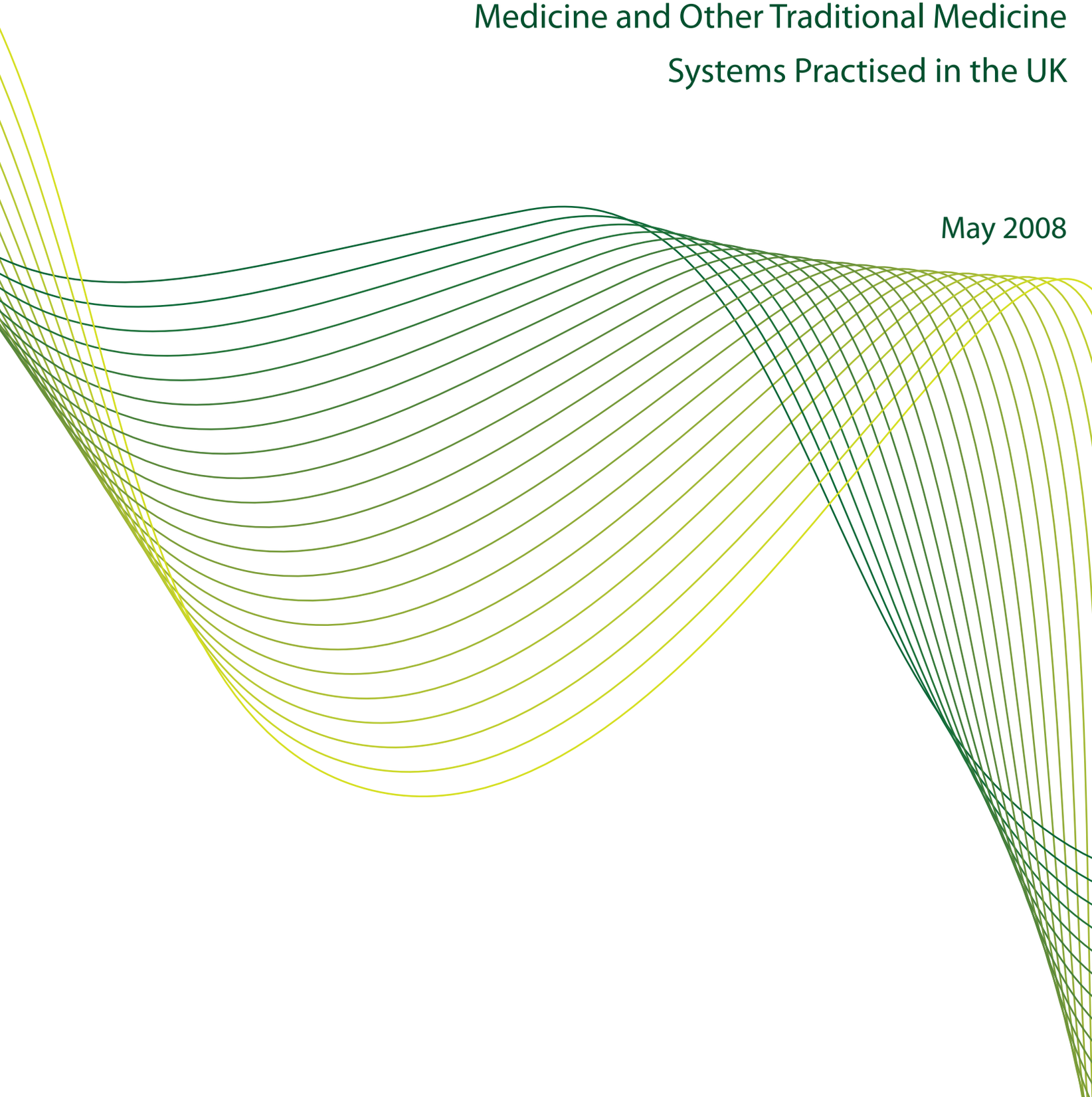
Report to Ministers from The Department of Health Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK

May 2008



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Introduction from the Chair

This report represents a significant milestone in meeting the Government's objectives for the public safely to access acupuncture, herbal/traditional medicine and traditional Chinese medicine. It represents the culmination of many years of work by practitioners, the Prince's Foundation for Integrated Health (PFIH) and the Department of Health in conjunction with the Medicines and Healthcare products Regulatory Agency (MHRA). The stimuli for this were the House of Lords' Select Committee on Science and Technology's report in 2000[1] and the Government response to it in 2001[2]. The recommendations in this report have taken account of emerging health policy over the past decade relevant to protecting patients and new ways of working for healthcare professionals. There has been positive discussion with statutory regulatory bodies, particularly with the Health Professions Council (HPC) which is the proposed new regulator for acupuncture, herbal/traditional medicine and traditional Chinese medicine as well as with professional bodies and practitioners. The report is therefore framed within the context of existing health policy.

In addition, there has also been constructive discussion about regulation of this sector with the home countries of the UK. Given the complexities of parallel medicines legislation and the need to ensure that the public interest is protected through easy movement of health professionals across the UK, and public recognition of regulated professionals, it is to be hoped that the recommendations will lead to UK-wide regulation.

The document consists of the main report that makes specific recommendations for regulation. It is followed by a series of Annexes that in turn explain the nature of herbal/traditional medicine, acupuncture and traditional Chinese medicine and provide further detailed information that will be useful to members of the public and other health professionals as well as to the Department of Health and the future statutory regulatory body. Other Annexes provide information on the development of a research and evidence base for these sectors, on existing training provision and accreditation arrangements as well as the criteria used by the Steering Group to assess the potential of professional practitioner associations to qualify for direct transfer to the chosen regulatory body.

It has been a privilege to chair the Steering Group on behalf of the Department of Health. The report has been informed by expert input from practitioners, orthodox health professionals, statutory regulators and, significantly, by independent lay members of the Steering Group. Lay involvement has been particularly helpful both in ensuring that public safety issues have taken precedence and in resolving contentious issues. It is of the greatest importance that the recommendations in this report are acted upon quickly in order to protect public health and to ensure it remains feasible

under medicines legislation for practitioners and their patients to have continuing access to a wide range of herbal medicines.

I am extremely grateful to all members of the Steering Group for their hard work and commitment to producing this report. In particular I would like to thank the lay members and secretaries to the Steering Group, Amrit Ahluwalia and Christine Black, for their tremendous support.

This report is agreed by all members of the Steering Group. It is important, however, to record that on some matters there were different views and it was not always easy to achieve consensus. Some of the different approaches were relatively minor such as contrasting views on how to describe types of acupuncture through to more serious considerations about the necessity to be able to communicate in English. Colleagues representing traditional Chinese medicine are deeply concerned about the emphasis we have placed upon the need to be able to communicate adequately in both spoken and written English but the overwhelming view of the Steering Group was that this should be a key recommendation. We do however encourage our Chinese-speaking colleagues to work together and enter into discussions with the future statutory regulatory body with regard to English-language comprehension. These discussions will be all the more effective and productive if traditional Chinese medicine practitioners can be represented by a single-body spokesperson.

Professor R. Michael Pittilo
Principal and Vice-Chancellor of The Robert Gordon University, Aberdeen

Chair of the Department of Health Steering Group on the Statutory Regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK.

May 2008

Steering Group Members

Mike Pittilo (Chair and lay member)

Mauroof Athique
Ian Brownhill
Ming Cheng
Peter Conway
Mike Cummings
Deepika Gunawant
Val Hopwood
Mercy Jeyashingham (Stakeholder chair)
Nick Lampert
Michael McIntyre (Stakeholder chair)
Man Fong Mei
Mike O'Farrell (Stakeholder chair)
Ned Reiter
Yilan Shen
Jasmine Uddin
Ken Ward-Atherton
Thomas Scott

Lay Members
Jonathan Coe
Frances Dow
Val McKie
Mee Ling Ng

Also in attendance:

Medicines and Healthcare products Regulatory Agency (MHRA)
Richard Woodfield
Caroline Brennan

Health Professions Council (HPC)
Rachel Tripp

Council for Health Care Regulatory Excellence (CHRE)
Julie Stone (until December 2006 and thereafter as an independent advisor)

National Occupational Standards (NOS)
Tom Lane

Nursing and Midwifery Council (NMC)
Liz Plastow

Department of Health Sponsors
Sharon Corner
Kate Ling

Welsh Assembly Government
Neil James (Observer)

Scottish Government
Professor Bill Scott (Observer)

Secretaries
Amrit Ahluwalia *(to August 2007)*
Christine Black *(from August 2007)*

The Steering Group obtained advice from an external consultant, Ms Catherine Rendell, Director of Academic Quality, Faculty of Law, University of Hertfordshire, on the evidence presented by voluntary organisations with regard to grandparenting.

The Report

1. Establishment of the Steering Group and Terms of Reference

The Department of Health Steering Group for the Statutory Regulation of acupuncture, herbal medicine and traditional Chinese medicine practitioners was established by Jane Kennedy, then Minister of State in the Department of Health, in June 2006 specifically to prepare the ground for the regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK. In addition to traditional Chinese medicine (TCM) these traditional medicine systems include Ayurveda, Unani Tibb (a system of traditional medicine with roots in Greek, Middle-Eastern and Indian Medicine), Kampo (Japanese traditional medicine) and Tibetan Medicine, all of which are currently practised in the UK. The Steering Group was invited to prepare the way for formal regulation by identifying issues and proposing options in relation to education and training, registration, fitness to practise and other aspects of regulation. Although the Steering Group was formed by the Department of Health in England, from the outset the Steering Group has considered the needs of the home countries and its membership has been UK-wide.

2. Background to the Establishment of the Steering Group – The House of Lords' Select Committee on Science and Technology's Report in 2000 and the Government Response

The House of Lords' Select Committee on Science and Technology's report in 2000[1] on complementary and alternative medicine represented a significant milestone in shaping Government policy with regard to complementary and alternative medicine. *Inter alia* it specifically recommended that practitioners of acupuncture and herbal medicine should be statutorily regulated under the Health Act of 1999[3]. The House of Lords' report[1] recommended statutory regulation for herbal medicine and acupuncture because they met key criteria that included risk to the public through poor practice, the existence of a voluntary regulation system and a credible, if incomplete, evidence base. It did not consider that Ayurvedic medicine, Chinese herbal medicine or traditional Chinese medicine should be covered by statutory regulation. However, the Government response proposed that professions using either acupuncture or herbal medicine (thereby also including Chinese herbal medicine, TCM, Ayurveda and other traditional medicine systems mentioned in Section 1) should, in the interests of public safety, be statutorily regulated and that "it would be desirable to bring both acupuncture and herbal medicine within a statutory framework as soon as practicable"[2].

3. Previous Working Groups Supporting the Statutory Regulation of Acupuncture and Herbal Medicine and the Department of Health Consultation and Report

In 2001 the Department of Health, in partnership with the Prince of Wales's Foundation for Integrated Health, established two Working Groups for the regulation of acupuncture and herbal medicine. The Acupuncture and the Herbal Medicine Regulatory Working Groups both reported in 2003[4,5] and, in March 2004, the Department of Health consulted on a set of proposals for the statutory regulation of herbal medicine and acupuncture[6]. In February 2005, the Department of Health reported on the consultation indicating that it expected to publish a draft Section 60 Order for consultation later that year[7].

4. Reviews of "Medical and Non-Medical Regulation", Subsequent Publication of a White Paper and the Consequences for the Steering Group

The delay in establishing the current Steering Group was partly due to the need to await the outcome of two reviews of professional regulation which were not published until July 2006 following which there was a further period of consultation. The first of these reviews, *Good Doctors, Safer Patients*[8], was undertaken by the Chief Medical Officer for England and the second, *The Regulation of the Non-Medical Healthcare Professions*[9], was led by the then Director of Workforce for the Department of Health in England. Following the consultation, a White Paper, *Trust, Assurance and Safety - the Regulation of Health Professionals in the 21st Century*[10], was published in February 2007. Publication of the White Paper several months after the Steering Group had been established had significant impact in informing our recommendations in regard to the future statutory regulatory arrangements for practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK. In particular, the White Paper[10] ruled out the possibility of the formation of new statutory councils to regulate professions aspiring to statutory regulation. It recommended instead that statutory regulation of emerging professions should take place through existing regulatory bodies (see Sections 10 and 11 below).

5. Emerging Health Policy and the Steering Group

In addition to the policy documents referred to above, the Steering Group has also taken account of emerging health policy relating to workforce development. We have framed our recommendations taking cognisance of recent and emerging NHS policy that has impacted upon other health professions[11-15]. Significant policy changes this century have included increased emphasis on inter-professional team working[15], role-extension for existing health professionals including the ability of healthcare professionals to undertake roles customarily carried out by others (in some cases including

the work traditionally undertaken by doctors) and the need to modernise regulation[11-15].

6. Statutory Regulation and the Public Interest

The Steering Group is strongly of the view that the decision to statutorily regulate professions practising herbal medicine and acupuncture is in the public interest. Survey data demonstrates high demand for complementary and alternative medicine[16]. 10.6% of the adult population of England had visited at least one therapist providing any one of the six more established therapies (acupuncture, chiropractic, homoeopathy, hypnotherapy, medical herbalism, osteopathy) during 1998 with an estimated 22 million visits[16]. It is important that those with whom they consult are properly trained, understand the limits of their competence and know when and to whom to refer. There has also been widespread concern about the safety, in particular, of traditional Chinese medicines when inappropriately administered[17] (see Medicines and Healthcare products Regulatory Agency's webpages for examples at www.mhra.gov.uk). Statutory regulation differs from the voluntary registration currently in place for the professions covered by this report and for other complementary and alternative (CAM) therapies including that being extended to other CAM therapies with the support of the Department of Health (DH) and The PFIH. Statutory regulation can more effectively assure the standards of those regulated, protecting the public from poor or bad practice, because legal sanctions exist to remove individuals from a register. Statutory regulatory bodies determine standards of practice and competence. Those who meet the criteria set for determining competence are eligible to be included on a register and to use a protected title.

7. Authorised Health-Professional Status via Statutory Regulation

The Medicines and Healthcare products Regulatory Agency (MHRA) has proposed in its consultation on the reform of Section 12(1) of the Medicines Act 1968[18,19] that *statutorily regulated* herbal practitioners could be regarded as authorised healthcare professionals for the purposes of Article 5.1 of Directive 2001/83/EC (the main European medicines legislation). This is the provision under which a Member State may permit the supply of manufactured unlicensed medicines, if ordered by, and made to the specification of, an authorised healthcare professional, to meet the special needs of an individual patient. After April 2011, transitional protection afforded under the Traditional Herbal Medicinal Products Directive for certain existing unlicensed manufactured herbal products runs out. Subsequently such products would require either a marketing authorisation or a traditional herbal registration - which would not be a feasible process in most cases given the likely small scale of supply where practitioners require a specific formulation for individual patients. The key point is that a scheme to allow the availability of such manufactured herbal products under the Article 5.1 derogation is not regarded by the MHRA as legally viable for herbal

practitioners unless statutory regulation of the profession is in place. The consequence if such arrangements are not established is that after 2011 there is likely to be a significant reduction in the scope and range of herbal medicines that herbal practitioners could use and a resultant loss of consumer choice.

8. The Health Professions Council

Although there are significant differences in the way that acupuncture and herbal medicine is practised, the Steering Group recognises that the creation of several statutory regulatory bodies to accommodate the wide range of professionals that exist is neither practical nor consistent with the recommendations within the White Paper, *Trust, Assurance and Safety - the Regulation of Health Professionals in the 21st Century*[10] and Government policy to reduce the numbers of regulatory bodies. We are mindful that costs are reduced as a statutory regulatory body increases in size. In the case of the professions covered in this report these costs are, in effect, largely borne by the public who for the most part access professionals privately rather than through the NHS. For this reason anything that can be done to reduce costs is in the public interest provided this does not compromise the process. The Steering Group takes the view that effective, safe and cost-effective statutory regulation has been demonstrated by the multi-professional Health Professions Council (HPC) and is convinced that this could be extended to cover practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional-medicine systems practised within the UK. We recognise, however, that given that the HPC was established from professions largely familiar with statutory regulation under the auspices of the Council for Professions Supplementary to Medicine, the workload associated with acupuncture, herbal medicine and traditional Chinese medicine might be greater than that previously experienced in regulating well-established health professional sectors.

9. The Health Professions Council Criteria for Aspirant Professions

The Steering Group was concerned that acupuncture, herbal medicine and traditional Chinese medicine do not meet all the criteria as currently stated for entry into the HPC[20]. These specify that aspirant groups must:

1. Cover a discrete area of activity displaying some homogeneity
2. Apply a defined body of knowledge
3. Practise based on evidence of efficacy
4. Have at least one established professional body which accounts for a significant proportion of that occupational group
5. Operate a voluntary register
6. Have defined routes of entry to the profession

7. Have independently assessed entry qualifications

8. Have standards in relation to conduct, performance and ethics

9. Have Fitness to Practise procedures to enforce those standards

10 Be committed to continuing professional development.

Specifically, currently none of the professions considered in this report has a single voluntary regulatory body representing all of the relevant practitioners. Perhaps more importantly, the evidence base for the effectiveness of acupuncture, herbal medicine and traditional Chinese medicine is not as widely accepted as for many of the other professions regulated by the HPC. Whilst it can be argued that the evidence base should be established in advance of statutory regulation, we are firmly of the view that, in the interest of public safety, statutory regulation should now proceed with all possible speed. We strongly recommend that the various disciplines seeking regulation should simultaneously be encouraged to establish a robust evidence base. The Steering Group recognises that there are significant challenges in developing a strong research and evidence base for much of complementary and alternative medicine (these issues are discussed in Annex 1). Notwithstanding this, the need to demonstrate benefit is essential if credibility with other health professionals is to be realised and NHS resources are to be made available to fund these therapies. We recommend that public funding from the NHS should be used to fund CAM therapies where there is evidence of efficacy, safety and quality assurance.

10. Other Regulatory Options Considered by the Steering Group

As noted above (Section 8), the Steering Group was convinced of the need to achieve efficiencies of scale by being regulated by a larger body. In determining the appropriate statutory regulatory body for acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems, Government policy has been influenced both by previous reviews[8,9] and the White Paper[10] (see Section 4) which have, in turn, influenced our recommendations. Prior to the publication of the reviews of medical[8] and non-medical regulation[9] and then the White Paper[10], the Steering Group did however investigate the advantages and disadvantages of different regulatory arrangements.

One option explored was the concept of a Traditional Medicines Council or Complementary and Alternative Medicine Council. This could have been introduced whilst at the same time reducing the overall number of statutory regulatory bodies as well as distinguishing complementary and alternative medicine from the statutory regulatory arrangements for the orthodox healthcare professions. One possibility we considered in pursuit of this aim was that the General Osteopathic Council (GOsC) and the General Chiropractic Council (GCC) might be amalgamated within this new body thus reducing the overall number of regulators. However, when consulted,

neither of these bodies were interested in creating a Traditional Medicines (or Complementary and Alternative Medicines) Council. In considering these options we noted that, in the case of the manipulative therapies, three different statutory regulatory bodies (the HPC, the GOsC and the GCC) are involved in regulating professions amongst which there is significant overlap of practice. Moreover, the smaller of the statutory regulatory Councils have significantly higher registration costs to individual practitioners which, as noted above, are passed on to patients.

There was some concern that whilst Government policy supports the retention of existing relatively small regulatory bodies - even where there is significant overlap of practice - it does not permit any new ones to be created. We felt there was a missed opportunity to bring about a measure of rationalisation, reducing the number of bodies whilst creating a new statutory regulatory body sympathetic to the nature of complementary and alternative medicine and associated public safety issues. Having made these observations, we accept that the issue raised has now been superseded by the White Paper, *Trust, Assurance and Safety - the Regulation of Health Professionals in the 21st Century*[10]. The Steering Group has every confidence in the ability of the HPC to statutorily regulate practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems effectively and efficiently and thus to protect the public from poor practice.

11. Pharmacy and Herbal Medicine Practice

It should be noted that there was some discussion as to whether practitioners preparing and supplying unlicensed herbal medicines to meet the needs of individual patients might be statutorily regulated alongside pharmacists. Little enthusiasm for this option could be identified amongst both pharmacists and herbalists suggesting that such an arrangement could only be achieved by a level of coercion. As the White Paper determined that the HPC should be the preferred regulator[10], and in view of other doubts which some members of the Steering Group had about the appropriateness of this option, we did not pursue the idea further.

12. Implications for the Health Professions Council Arising from Dealing with a Variety of Traditional-Medicine Systems

It is important to recognise that the fundamental approach and philosophy of complementary and alternative medicine, including acupuncture, herbal medicine, traditional Chinese medicine and other traditional-medicine systems (such as Ayurveda and Tibetan medicine) differ in many ways from the stance taken by orthodox healthcare professions. This has implications for developing a robust research base, underpinning evidence-based practice, and interfacing with other healthcare professionals. The HPC will need to take account of these differences, although they do not impact on its key role of effective protection of the public.

The HPC will also need to devise suitable structures and processes to take account of the different and many traditional-medicine systems that use acupuncture and herbal medicine. There are clearly too many of these to enable representation at all levels within the Council. However, the Steering Group is of the view that the HPC will be able to accommodate the diversity of traditions that exist and ensure that decisions relating to, for example traditional acupuncture, Ayurveda, Western herbal medicine, Tibetan medicine or traditional Chinese medicine are informed by practitioners and experts in the relevant tradition. There will be an ongoing vital role for the professional associations and individual practitioners in providing profession-specific information and input (see also discussion in Sections 22 and 23).

13. Resource Implications for the Health Professions Council

There are likely to be significant resource and organisational issues for the HPC. There is a wide variety of traditions practising acupuncture and herbal medicine. Identifying lead bodies and representatives for complementary and alternative medicine has historically been a challenge and the professions will need to work constructively and effectively to support the HPC. It is likely that the HPC will need additional resources during the early stages of the statutory regulation of these professions to ensure there is effective and efficient implementation. In time, as these professions gain experience, the workload should diminish along with the need for additional pump-priming of financial and administrative support.

14. Use of Acupuncture, Herbal Medicine and Traditional Chinese Medicine by Other Statutorily-Regulated Professions

The Steering Group consulted other statutory regulatory bodies to confirm whether existing statutorily regulated healthcare professionals might wish to be called herbalists or acupuncturists. Whilst protection of title enables appropriately qualified healthcare professionals to extend their scope of practice, it does not allow them to assume a different title, if that title is already protected by another statutory regulator. There is significant use of acupuncture and herbal medicines by a range of health professionals including doctors, physiotherapists and nurses. However, the only existing statutorily regulated professionals that currently seek to be able to describe themselves as acupuncturists are the medical acupuncturists (although at some point physiotherapists and nurses might also wish to have this option open to them). Doctors using acupuncture have expressed concern that protection of the title ‘acupuncturist’ may mean that they are prosecuted for using it.

Discussions with the HPC and the General Medical Council (GMC) have focused on the fact that, under the Health Professions Order 2001, an offence is committed if a title is misused with intent to deceive. It has been suggested therefore that an agreement could be reached by the HPC that other statutorily regulated professionals could use the title 'acupuncturist'

provided that they were clear in providing information to their patients that they were, for example, registered doctors who provided acupuncture as part of their practice, and that their patients were not misled as to the nature of their qualifications or professional background. If there were any difficulties, these could be addressed by their own statutory regulatory body. In discussion, the GMC and the HPC have suggested that one solution would be agreement that doctors qualified in medical acupuncture should be free to describe themselves as acupuncturists without having to be dual registered with the HPC. If there were any difficulties, these could be addressed by their own statutory regulatory body, the GMC, in consultation with the HPC. Doctors wishing to practise traditional acupuncture would need to ensure that they had met the requirements of the HPC with regard to this speciality as the training is quite different from that required for medical acupuncture (see Section 15). Any advice given by the HPC, responsible for the statutory regulation of traditional acupuncture, would need to take account of the significant differences between this tradition and medical acupuncture. This would also apply to advice given to physiotherapists, or to the Nursing and Midwifery Council, or to other statutorily-regulated health professionals using acupuncture.

15. Traditional and Medical Acupuncture

Traditional and medical acupuncture are quite different in terms of their underlying philosophy even though there can be significant overlap with regard to practice. The traditional acupuncturist will rely in part on an energetic diagnosis, whereas the medical acupuncturist will investigate using techniques familiar to those trained in orthodox medicine. It is important that the future regulator identifies these significant differences and that the different approaches (even within traditional acupuncture itself) are recognised without one having precedence over the other.

16. Scope of Professional Practice

We have reached agreement on the scope of professional practice for acupuncture, herbal medicine, and traditional Chinese medicine. From this, standards of proficiency using the HPC template have also been determined and are submitted as Annexes to this report (Annexes 2-4).

17. Standards of Education and Training

Standards of education and training have also been determined and are submitted as Annexes to this report (Annexes 2-4) along with known education and training provision (Annex 5). The criteria that have been agreed by the Steering Group for Accreditation Boards are listed (Annex 6) although at this time it could not be confirmed that all of the voluntary registers operate to this standard. The threshold entry route to the register will normally be through a Bachelor degree with Honours which is comparable to the majority of other professions regulated by the HPC. Entry

to the register may also be possible through possession of an appropriate Masters degree; this is consistent with other professions including physiotherapy, radiography and occupational therapy. Overseas qualifications will need to be considered separately.

18. Standards of Conduct, Performance and Ethics for Registrants

Standards of conduct, performance and ethics for registrants have been agreed and are entirely consistent with those operated by the HPC.

19. Protection of Title

The Steering Group recommends that, consistent with Government policy, for new professions, protection of title is achieved through statutory regulation rather than protection of function. The Steering Group recognises there is an inherent tension in the legal protection of titles. On the one hand, there is a need to minimise the number of titles that are protected, in order to ensure that these titles can be clearly communicated to the public, and are readily understood and seen as credible. On the other hand, it is also important that existing, commonly used and recognised titles should be protected in order to ensure that individuals do not use these titles as a means of avoiding regulation. The group recognised that there is a wide range of titles in use by these practitioners, and that not all of these titles could be protected. The titles that should be protected have been the subject of some debate, notwithstanding that the Steering Group recognises that protecting particular titles would not bar registered practitioners from using a different title should they so wish.

The Steering Group therefore recommends that the titles of 'acupuncturist' and 'herbalist' should be protected, since these are widely used, commonly recognised and simple titles that lend themselves easily to being protected. Registered individuals who wished to add to these titles to show a particular area of practice (for example, 'Medical Herbalist') could do so, whereas those who were not registered could not use these titles, nor any title which contained the words 'acupuncturist' or 'herbalist'. In addition, the Steering Group recommends that the title ‘traditional Chinese medicine practitioner' should be protected. Similarly, those who are not registered will not be allowed to use this title, nor any title which contains the words 'Chinese Medicine Practitioner'. The group recognises that there is a variety of other titles used by traditional Chinese medicine practitioners, along with Ayurveda, Kampo, and Tibetan Medicine, but believes that protecting a large number of further titles would be counter-productive in terms of public protection. It is also unlikely that legislation could protect every individual title that existing practitioners use in this field. Hence the group believes it is more practical to protect a small number of titles, recognising at the same time that this must necessarily represent a compromise, and may not be the preference of all practitioners or all professional associations.

The Steering Group believes that, with the support of professional associations, statutorily regulated practitioners should be encouraged to advertise their services using their preferred title, stating, in addition, that they are HPC registered. The HPC already offers an 'e-kit' for registrants with images that can be downloaded for use in advertising material encouraging users to reinforce their registration with a logo. It also offers other public-facing material for registered professionals to use, including leaflets, posters and window-stickers. This facility may be of particular interest to those practitioners primarily operating in the private sector. It may also help members of the public to identify appropriately qualified practitioners.

20. Control of Function

Although the HPC will be protecting title and not function, the changes to Section 12(1) of the Medicines Act 1968 currently envisaged by the MHRA will regulate function so far as the practice of herbal medicine is concerned[18]. We do not envisage any difficulties for other statutorily regulated healthcare professionals wishing to use acupuncture, herbal medicine or traditional Chinese medicine as part of their practice provided that they ensure they are appropriately qualified.(See Sections 14 and 27). It will be important for the HPC to provide guidance to other statutory regulatory bodies with regard to minimum levels of education and training required for other professionals to practise acupuncture, herbal medicine, traditional Chinese medicine and other traditional-medicine systems.

21. Grandparenting

Whenever a professional title is protected, there is opportunity for individuals who have been using that title safely and effectively to become registered. This process is known as 'grandparenting'. This is a 'one-off' window of time during which individuals can apply to be registered. After this period of time has elapsed, the only way for a UK-trained individual to become registered is to complete a UK regulator-approved course. With regard to grandparenting, there are several aspects to be considered. In addition to individuals making their applications for registration, and being assessed individually, there is also the possibility for *bona-fide* members of voluntary registers to be transferred directly onto the HPC Register without having to go through such individual registration. This has happened in the past with the Operating Department Practitioners, where members of the voluntary register were automatically transferred, becoming registered on the day the Register opened. Subsequently these newly registered practitioners were required to pay their registration fees and renew their registration in order to remain registered. More information about the process of voluntary register transfer is available on the HPC website[21]. There is therefore an option for the grandparenting of complete memberships of voluntary registers as well as of individuals.

With regard to grandparenting of voluntary registers, there are significant challenges. The Steering Group is supportive of grandparenting being inclusive, but without compromising public safety. The Steering Group drew up criteria to judge whether voluntary registers were operating at a level similar to standards applied by the HPC in protecting the public (Annex 7). Based on external peer review and lay-member and stakeholder-chair opinion we are able formally to recommend to the HPC a number of voluntary registers where there is evidence that they have been effectively and rigorously operated to high standards. In these cases, we recommend that registrants should, subject to confirmation by the HPC, automatically transfer to the appropriate HPC register when it is established. It should, however, be made clear that the Steering Group is in no sense mandating that the HPC takes this action but, on the evidence presented, we believe these organisations have operated appropriately under a voluntary code and, in our view, demonstrated over a period of time good practice with regard to protecting the public.

The organisations that meet the criteria are The Acupuncture Association of Physiotherapists, The British Acupuncture Council, The British Dental Acupuncture Society, The British Medical Acupuncture Society, Ayurvedic Practitioners Association, Association of Master Herbalists, The College of Practitioners of Phytotherapy, The National Institute of Medical Herbalists, The Unified Register of Herbal Practitioners and The Register of Chinese Herbal Medicine. It is essential to note that in forming such judgements we have accepted at face value the information submitted to us in support of meeting our criteria and *the Steering Group strongly recommends that this evidence undergoes a further in-depth audit by the HPC before the Regulator agrees any grandparenting exemptions for members of particular professional associations.* There are also voluntary registers for which we have insufficient evidence to be able to recommend such a transfer at this time. Where possible we have indicated what additional steps the organisations hosting these registers should take to ensure they might qualify for the direct transfer of their members to the HPC and encouraged them to enter into discussion with the new statutory regulatory body as soon as practicable.

There remains some concern about the way that some voluntary registers within the traditional Chinese medicine sector determine acceptable levels of English comprehension. It appears that these organisations may operate a somewhat over-lenient policy with regard to the level of English comprehension required to qualify for their membership. Having noted this, The Association of Traditional Chinese Medicine and The Chinese Medicine Council met all other criteria. The British Association of Traditional Tibetan Medicine is a very small organisation but met the criteria through its affiliation to the European Herbal and Traditional Medicine Practitioners Association with its well-established federal arrangements for overseeing quality.

Organisations that have not succeeded in satisfying all the criteria have received confidential feedback from the Chair of the Steering Group and it is hoped they may all be able to satisfy the criteria by the time of the establishment of the statutory regulatory body. It will, of course, be possible for individuals who are not members of a voluntary organisation or who belong to one that does not meet the criteria to apply for registration with the HPC, potentially by the grandparenting route. The precise standards for such individual grandparenting are yet to be determined.

22. The Role of Professional Bodies

Once a profession is subject to statutory regulation, its professional body or bodies continue to play an important role in promoting and developing the profession, representing their members, and offering services. The services professional bodies choose to offer may vary, depending on the organisation's priorities, or resources, but these could include publishing journals or newsletters, running Continuing Professional Development (CPD) training programmes and special interest groups, providing support if a complaint is made, providing some form of trade union or industrial relations function, and others. In relation to regulation, professional bodies may develop their own curriculum framework documents, which education providers may use in order to design a programme of study that meets, and in many cases exceeds, the Standards of Proficiency for their profession.

Professional bodies also have an important role in the development of standards for best practice, or the development of new areas of their profession. Most professions will have standards for best practice which are exemplary, but are not mandatory requisites in order to be registered, because registration is based on minimum threshold standards necessary for public safety. It may be the case that over time, these standards for best practice become so embedded within education and practice that the case can then be made for these to become part of the threshold standards: at this stage what was once 'desirable' best practice becomes a 'required' threshold standard that individuals must prove they can meet in order to be registered. This organic process of a profession's evolution is often driven by the professional body.

23. Profession-Specific Input

The Steering Group is of the view that the consultation processes used by the HPC to obtain profession-specific input is entirely appropriate for practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems. Currently, the HPC draws on profession-specific input in a variety of ways and the associations representing acupuncture, herbal medicine and traditional Chinese medicine should be encouraged to engage with these processes as soon as possible. One example of professional input informing developments at the HPC is through regular formal and informal liaison with professional bodies, of which the foundation

is an annual meeting between the Chief Executive, President, and representatives of the professional body where information can be exchanged, and any pertinent issues raised and discussed. Professional bodies may also respond and contribute to HPC consultations, where appropriate. In addition to this, there are many projects on which collaboration with professional bodies is welcomed by HPC, or indeed is vital to ensuring success. Current work where professional bodies are being invited to participate at an early stage includes revalidation, the review of the Standards of Education and Training, and post-registration qualifications. Previously, professional bodies have made detailed submissions to the review of the Standards of Proficiency, to guidance for education providers, and to the guidance for registrants on Continuing Professional Development standards.

The HPC depends upon the professional knowledge and expertise from the professions it regulates to provide detailed input, particularly into its standard-setting process. This would normally be done by a Professional Liaison Group which is a working group formed from HPC Council members plus external stakeholders with particular knowledge and expertise to consider a defined project in detail. This provides a way for the HPC to draw on expertise from outside its Council, including membership from professional bodies, and it is anticipated that this mechanism would be used for establishing standards for practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems. It is important therefore that professional associations representing these modalities begin to prepare now to support their practitioners in the move towards statutory regulation and liaise effectively with the HPC.

24. Language Comprehension

The Steering Group is of the view that English-language proficiency is essential for all healthcare professions. We do not believe that public safety is assured through the use of interpreters whether this be in communicating with patients or with other healthcare professionals. We are, however, aware that this could cause a significant difficulty particularly with regard to the traditional Chinese medicine sector and that some practitioners who are very experienced and proficient might no longer be able to practise. Furthermore, there are Chinese-speaking members of the community who might consequentially be denied access to traditional Chinese medicine because their Chinese-speaking practitioner was disbarred from practice due to poor English-language skills. Taking all this into account and after careful consideration, we believe that all those practising acupuncture, herbal medicine, traditional Chinese medicine or other traditional medicine modalities should be able to achieve an International English Language Testing System (IELTS) score of at least 6.5, or utilise other methods of testing to achieve an equivalent standard, by the time these professions are regulated. In the meantime, we urge organisations representing and working with Chinese-speaking practitioners and other practitioners for

whom English is not their first language to work with the HPC to ensure that there is no discrimination against such practitioners whilst at the same time recognising that protection of the public health must be the paramount concern. This is facilitated through excellent communication with patients and other healthcare practitioners to whom referral might be made or who are also responsible for treating shared patients.

25. Statutory Regulation and the Home Countries

Although this report was undertaken on behalf of the Department of Health (England), we have been anxious to ensure wide engagement with the Home Countries. Informal discussion has taken place with representatives from the Welsh Assembly, the Northern Irish Assembly and the, then, Scottish Executive now known as the Scottish Government. In Scotland, the regulation of existing health professions is reserved to Westminster but the Scottish Government does have the power to regulate new health professions. However, the Steering Group is firmly of the opinion that there are many benefits to UK-wide regulation, and our recommendation is that statutory regulation should proceed on this basis, providing that the needs of the devolved administrations are taken account of. We believe that there are benefits for professionals in terms of common standards and education requirements, and benefits for the public in a single, accessible system with, for example, one set of protected titles, and one register to check online.

The Steering Group is concerned that were different arrangements to be adopted for the statutory regulation of herbal and traditional medicine practitioners in Scotland and England, this would be likely to lead to considerable confusion when practitioners migrate from one jurisdiction to another. It could frustrate practitioners working in different parts of the UK amongst which there can be a sharing of good practice, and could limit access by the public to practitioners by restricting their mobility. Anything that made it more difficult for English, Welsh or Northern Irish practitioners to work in Scotland, for example, would not be in the interests of the Scottish people. Differing regulatory arrangements are most unlikely to be in the public interest and the implications for medicines legislation would need careful consideration. Feedback from Scotland, Wales and Northern Ireland has been that public safety should be paramount particularly in relation to the establishment of statutory-regulatory arrangements. Strong views were put forward with regard to the need for commonality in the robustness of grandparenting and English-language comprehension.

26. The Next Steps

The Steering Group is of the view that there is an urgent need to proceed without delay with the statutory regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems. The Department of Health has been working with practitioners from these sectors, in some cases for over a decade, and a timeframe has been

published that has not been adhered to[7]. Given the size of the regulatory reform agenda set by the White Paper, *Trust, Assurance and Safety - the Regulation of Health Professionals in the 21st Century*[10], achieving statutory regulation in time to ensure that it is feasible for medicines legislation to permit registered practitioners to have continuity of access to a wide range of manufactured herbal medicines to meet the needs of individual patients will present a significant challenge. Failure to commit to an early timetable for the statutory regulation of these professions would hinder the achievement of effective regulation of herbal medicinal products prepared for practitioner use. It could adversely impact on consumer and practitioner choice and continue to frustrate the possibilities for referrals to practitioners from orthodox healthcare professionals. It could also frustrate UK-wide regulation. Above all, the public would not be protected from inappropriately qualified practitioners and poor professional practice.

27. Statutory Regulation and Reform of Section 12(1) of the Medicines Act of 1968 - Taking into Account other Complementary and Alternative (CAM) Practitioners who may Prepare and Supply Unlicensed Herbal Medicines to Meet Individual Needs

The MHRA report that during their consultation[18,22] on reforms of Section 12(1) of the Medicines Act of 1968, a number of practitioners from various CAM traditions beyond herbal medicine/traditional Chinese medicine said they made use of Section 12(1): that is, they prepared unlicensed herbal medicines to meet the specific needs of individual patients identified in face-to-face consultation. Respondents in this position were concerned about their continuing ability to practise in their field if, as proposed, Section 12(1) were restricted to statutorily registered practitioners. Examples given in response to the most recent consultation include some homoeopaths prescribing herbal tinctures at material dosage, some naturopaths, aromatherapists, and certain shopkeepers[23]. Historically, the weak Section 12(1) regulatory arrangement has been allowed to operate in a largely uncontrolled way leading to a wide variety of practice. This makes any reform of the regime problematical. Nevertheless, we believe that the following considerations should guide action on this issue providing the basis for fair, consistent and safe reform of Section 12(1).

- Public health protection is best served if there is a consistent approach taken to the competencies, training and experience required to practise herbal medicine safely. Agreed standards of training and practice should be applied across the board to all those wishing to practise under Section (12)1.

- The most clear cut, reliable protection for the public is achieved if those who prepare unlicensed medicines to meet individual needs are subject to statutory regulation. If, to the contrary, practitioners who are not statutorily regulated are allowed to continue to make up unlicensed medicines under Section 12(1) this could create an

incentive for some herbal/traditional medicine practitioners to opt out of statutory regulation while continuing to practise herbal medicine. Such a scenario would undermine the purpose of statutory regulation and compromise public health protection.

- Any change to access to Section 12(1) has to take account of the fact that, as previously mentioned, over time a variety of practitioners and individuals from a range of CAM backgrounds have made use of this provision. On the other hand, it seems unlikely that Government policy will extend statutory regulation to a widening range of CAM practitioners in the foreseeable future simply to reflect the fact that various therapies may include a certain number of practitioners who have been making use of Section 12(1).

- Transitional grandparenting arrangements should permit skills and experience in the practice of herbal medicine acquired through a variety of routes to be recognised. Thus practitioners who can demonstrate a history of safe use of unlicensed herbal medicines via Section 12(1) and who meet agreed standards of practice required of herbalists, e.g. in the knowledge of potential herb/drug interactions, could be accepted onto a section of the statutory register in a way that does not compromise the identity of herbal practice.

- Use of Section 12(1) is a professional activity requiring professional skills and professional accountability. It should not be confused with retail supply of over-the-counter herbal medicinal products and regulatory arrangements should be kept correspondingly distinct.

On the basis of these considerations we recommend that use of Section 12(1) of the Medicines Act of 1968 should be restricted to practitioners who are subject to appropriate statutory regulation.

We also recommend that further consultation should take place with those CAM professions that would be affected by the application of the approach we are recommending.

28. Method of working

The Steering Group met on five occasions. The Steering Group and subsidiary Stakeholder Groups were extremely fortunate to be able to draw on the services of a number of highly experienced lay members who provided invaluable advice throughout the process of formulating this report. Three subsidiary Stakeholder Groups, led by Chairpersons from the main Steering Group, were established to work on matters pertaining to acupuncture, herbal/traditional medicine and traditional Chinese medicine respectively. These Stakeholder Groups met several times during the duration of the Steering Group. In addition, the three Stakeholder-Group Chairs met separately with the Chair of the Steering Group together with lay-member

attendees. The Stakeholder Chairs worked with their colleagues to provide material intended to help the HPC assume responsibility for the statutory regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK (Annexes 2-4).

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ANNEX 1

Developing Research and Providing an Evidence Base for Acupuncture and Herbal/Traditional Medicine Treatment

1. Introduction

This paper introduces the evidence base supporting herbal/traditional medicines and acupuncture and presents some of the challenges which need to be addressed in the development of a rigorous and appropriate research programme for these therapies.

Herbal/traditional medicine and acupuncture have for the most part been practised for hundreds, even thousands of years – a feature which needs to be considered when it comes to building an evidence base. This is recognised in the *European Directive on Traditional Herbal Medicinal Products* which notes that "The long tradition of the medicinal product makes it possible to reduce the need for clinical trials insofar as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience." (Directive 2004/24/EC). Nonetheless, whilst taking into account generations of clinical experience, ongoing experimental research is an essential process to establish further the safety and effectiveness of these forms of intervention.

Acupuncture and herbal/traditional medicine typically involve individualised treatments based on a complex clinical encounter. This suggests that to measure effectiveness in a meaningful way requires a specific programme of research to be developed for these therapies which combines pragmatism with scientific rigour.

2. Current Status

2.1 Western herbal medicine

Western herbal medicine has its roots both in the indigenous practises of the British Isles (Bryce 1988) and in the European and Greco-Roman traditions, and can trace its lineage back to Dioscorides, Hippocrates and Galen. There have been further influences from North America (Cook 1869) and more recently this traditional knowledge has been enriched by a stream of scientific insights and discoveries into the pharmacology of plants and their use as medicines.

There have been numerous *in vitro* and *in vivo* trials on herbal medicine which explore the biological mechanisms at work which have established the benefits of single ingredients such as gingko (*Gingko biloba*) for vascular dementia (Napryeyenko 1997), horse–chestnut seed extract (*Aesculus*

hippocastanum) for chronic venous insufficiency (Pittler 2006) and St John's wort (*Hypericum perforatum*) for mild to moderate depression (Linde 1996). However research has tended to concentrate on over-the-counter (OTC) products rather than investigating the effectiveness and safety of herbal practice within a one-to-one consultation in which prescriptions typically comprise a complex mixture of herbal medicines and treatment is tailored to the individual needs of each patient.

The effectiveness of individualised treatment was recently assessed in a systematic review of randomised herbal medicine in any indication (Guo 2007 *et al*). Somewhat surprisingly, the authors of this study found only three randomised clinical trials that met their criteria. They reported that individualised treatment was superior to placebo in four of the five outcome measures in the treatment of irritable bowel syndrome (IBS) (Bensoussan 1998), but was inferior to standardised herbal treatment in all outcomes. The authors (Guo *et al*,2007;634*)* noted that "Patient BSS (Bowel Symptom Score) at a follow up 14 weeks after the end of the trial favoured the individualised over the standard but this was not statistically significant". Guo *et al* concluded that there is "a sparsity of evidence regarding the effectiveness of individualised herbal medicine and no convincing evidence to support the use of individualised herbal medicine... (introductory abstract **Conclusions** p.633) and "Because of the high potential for adverse effects and negative herb-herb and herb-drug interactions, this lack of evidence for effectiveness means that its use cannot be recommended" (**Conclusion** p.637). This bleak view may be seen as unduly harsh since it is based on only three trials deemed to meet the selection criteria. Absence of evidence is, of course, not evidence of absence and the findings of this study may be perceived as a commentary on the general thrust of research that in the final analysis tends to seek out standardised products that can be patented and marketed – something not achievable with individualised treatments. This is undoubtedly a major reason for the paucity of research into individualised herbal/traditional medicine or acupuncture treatments that have their roots in millennia of human experience. In contrast, recent research has challenged the notion that the quality of the evidence on the effectiveness of herbal medicine is generally inferior to the evidence available for conventional medicine (Nartey 2007).

2.2 Chinese herbal medicine (CHM)

CHM has an unbroken recorded history of use stretching back some 2000 years. Early texts such as Zhang Zhong-jing's *Discussion of Cold Damage* (*Shan Han Lun*) or Shen Nong's *Classic of the Materia Medica* (*Shen Nong Ben Cao Jing*), actually written by anonymous hands probably in 1st Century BCE (Unschuld 1986), demonstrate a sophisticated understanding of herbal medicine which still has clinical relevance today. The written contributions of thousands of herbal doctors over the past two millennia means that there is a vast corpus of recorded information and empirical insights underpinning the contemporary practice of CHM.

In recent decades CHM has been increasingly subjected to investigation using modern methods of research. It has been estimated that over 10,000 randomised controlled trials were conducted in China before 1997 (Tang 1999) and in the past 10 years this process of research has accelerated. A recent ongoing systematic review of CHM for endometriosis (Flower 2007), which revealed 116 Randomised Controlled Trials (RCTs) exploring the treatment of this condition, exemplifies the wealth of clinical trial data available from Chinese journals. This is an important source of research data which was not referred to in previous reviews of CHM (House of Lords 2000).

Although there has been justifiable criticism of the methodological weakness of some of this Chinese research there is increasing emphasis in recent years on improving the rigour and transparency of reported clinical trials. There has been a number of Cochrane reviews of CHM which have indicated the therapeutic potential of CHM for conditions such as dysmenorrhoea (Zhu 2007), hyperthyroidism (Zen 2007) and schizophrenia (Rathbone 2005) while stressing the need for better trial design.

Some rigorous trials have been carried out in the West, and have demonstrated positive benefits from CHM intervention. These include randomised controlled trials of CHM in the treatment of IBS (Bensoussan 1998) and atopic eczema (Sheehan 1992, Sheehan & Rustin 1992).

The challenge for research into CHM is to develop trial designs which combine methodological rigour with a pragmatic approach to the delivery of CHM as it is used in clinical practice. The use of individualised treatments, herbal decoctions, and the importance of the non-specific effects of CHM intervention, present difficulties for double blind RCTs which can only be overcome by careful thought and consideration, as well as appropriate training and funding.

2.3 Ayurvedic medicine

Ayurveda (Sanskrit meaning 'the science of life') is a comprehensive system of health care that originated in India. The earliest literary references to Ayurveda as a medical science are datable to around 500 BCE, probably evolving from older oral traditions. The two most important classical Ayurvedic texts are the *Charaka Samhita* and the *Sushruta Samhita*, compiled between the second century BCE and second century CE.

Today, traditional Ayurvedic medicine and its practice are subject to ongoing scientific assessment by international science establishments. The Indian Government Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH), the Ministry of Health and Family Welfare and the Central Council for Research in Ayurveda & Siddha (CCRAS) have undertaken a range of clinical studies that have yielded encouraging results in reviewing the safety and efficacy of Ayurvedic remedies (Central Council for Research in Ayurveda and Siddha Website).

Internationally there have been many studies on the efficacy of different Ayurvedic preparations such as *kalamegha* (*Andrographis paniculata*) for the treatment of upper respiratory infections (Kligler 2006), *sallai guggulu* (*Boswellia serrata*) for the treatment of ulcerative colitis (Gupta 1997) and osteoarthritis (Kimmatkar 2003), *mandukaparni* (*Centella asiatica*) for assisting micro-circulation (Cesarone 2001), and turmeric (*Curcuma longa*) as a COX-2 inhibiting anti-inflammatory (Kawamori 1999) and also for its positive effects in the treatment of IBS (Bundy 2004).

Although there is variance in the methodological rigour of some Indian studies, research on Ayurveda generally indicates positive outcomes that are a spur to further research of this sector. Scientific enquiry into the efficacy of Ayurvedic medicine has, for the most part, been confined to investigating single traditional medicines to treat specific diseases. As yet, there is a lack of systematic evaluation of Ayurvedic therapeutics that takes into account traditional methods of prescribing personalised treatments for individual patients based on their presenting symptoms and diagnosed humoural imbalances. Future research needs to focus much more on these holistic aspects of Ayurveda, since this will evaluate its essentially patient-centred approach and its value as a health-care system.

2.4 Kampo

Kampo is an ancient system of formulae-based herbal medicine originating in Japan. The practice of Kampo has developed through three roots; commentaries on the Chinese Han Dynasty medical classics, modifications of classical formulae through centuries of Japanese experience, and a uniquely Japanese diagnostic system (Shirota 1996).

Around 75% of Japanese conventional medical doctors prescribe Kampo (Watanabe 2001). The costs of prescribed formulae are supplemented by national-health insurance. Consequently research on efficacy, including large scale RCTs, has not been required for the funding or general availability of Kampo medicines. Kampo research has focused on mechanisms of action and significant work has been done to establish this *in vitro* and *in vivo* (Miyate 2007, Oikawa 2005). Kampo herbal products conform to international standards of GMP and are accepted in the USA for clinical trials as "lawfully marketed botanical products without safety concerns" (Watanabe 2007).

2.5 Traditional Tibetan medicine (TTM)

Traditional Tibetan medicine (TTM) has been a distinct tradition for over 1200 years and has built up a theoretical approach which integrates Chinese, Ayurvedic, Bonpo (Tibet's oldest spiritual tradition) and Persian medical systems with Buddhist understanding of the mind. TTM does not share the Decartian mind/body dichotomy characteristic of the approach of much modern biomedical science.

The translation of medical knowledge across cultures is the domain of medical anthropologists like Adams who has reviewed the interface between TTM and western medical understanding (Adams 2001). Adams (Adams 2005) and Millard (Millard - awaiting publication) have both examined the process of the scientization of Tibetan medicine in Tibet and Europe (in other words, how it has been transformed and evaluated according to the principles of western science and biomedicine). In addition, the recently launched *Journal of Traditional Tibetan Medicine* (http://www.iattm.net/uk/pub.htm) provides information about TTM to a broader audience.

A small number of clinical trials have been conducted into the efficacy of TTM testing out its remedies in the treatment of diseases, classified according to the biomedical model. Clinical trials using PADMA-28, a herbal formula combining 28 ingredients, have demonstrated an anti-atherosclerotic effect (Brunner–La Rocca 2005). In addition, in a randomised controlled trial PADMA-28 has been shown to be effective for treatment of intermittent claudication (Sallon 1998) and the mechanism by which this herbal mixture achieves this anti-atherosclerotic effect has also been explored (Winther 1994). Further research suggests that PADMA-28 may prove beneficial for the prevention of cell damage induced by pro-inflammatory agonists that initiate tissue destruction in inflammatory and infectious conditions (Ginsburg 1999).

Preliminary work has also investigated the potential of TTM in the treatment of diabetes (Chotak 1993, Gompo 1993). In a controlled study, individualised treatment provided by a Tibetan practitioner for type-two diabetes was used as adjunctive treatment alongside standard western dietary and lifestyle management compared to standard western diet and exercise alone. The research team reported "a significant improvement in glycaemic control with the use of Tibetan medicine in patients with a recent onset of type-two diabetes compared with patients treated only with diet and exercise. This improvement in glycaemic control was observed at three and six months following commencement of treatment" (Tenzin 2001).

Further preliminary research has tested TTM in the treatment of arthritis. One study was undertaken in Tibetans in the refugee communities in Northern India. The Tibetan treatment was compared with western orthodox medical treatment in an open randomized controlled trial, and the authors concluded that "the trial demonstrated that for these Tibetans, their indigenous treatment worked better than the western treatment for improved limb mobility" (Tenzin 2001).

TTM has also been evaluated alongside other traditional herbal treatments for the treatment of IBS and a systematic review in the Cochrane database indicates some benefit for the treatment of IBS using TTM remedies (Liu 2006). One of the studies reviewed another TTM formulation, PADMA LAX,

which was effective in treating constipation-dominated IBS when compared with standard western treatments (Sallon 2002).

2.6 Acupuncture

Acupuncture has been used in the Orient to restore, promote and maintain good health for over 2,500 years. An early account of acupuncture was given in *The Yellow Emperor's Classic of Internal Medicine (Huang Di Nei Jing)* which dates from around the second century BCE (Unschuld 1985).

Traditional acupuncture is rooted in the Daoist philosophy of change, growth, balance and harmony, and *The Yellow Emperor's Classic* outlines the principles of natural law and the movements of *Qi* (vital energy), blood, yin and yang, the five elements, the organ system and the meridian network along which acupuncture points are located. The meridian system was mentioned in earlier texts (dating back to the 3rd or 4th century BCE) found during excavations of a Han Dynasty tomb in Hunan Province in 1973 (Qiu Mao-liang 1993).

Acupuncture developed over centuries in China, its theory and practice refined by master-practitioners such as the Han dynasty 'surgeon', Hua Tuo (110-207 CE), the Tang dynasty physician, Sun Si Miao (581-682 CE) and the Ming dynasty herbalist Li Shi Zen (1518-1593 CE). The use of acupuncture and moxibustion (the burning of the dried leaves of *Artemisia vulgaris* to provide local heat over acupuncture points) spread across East-Asia particularly to Korea, Japan, Vietnam, and Malaysia. Centuries of accumulated recorded experience from these sources provides the foundation for traditional acupuncture practice today.

In the last thirty years, medical acupuncture has developed in the UK and elsewhere in the West using neuro-physiological principles based on evidence that acupuncture needles stimulate nerve endings and alter brain function, particularly the intrinsic pain inhibitory mechanisms (Han 1982).

Acupuncture experienced a great resurgence of interest in China after the establishment of the People's Republic in 1949 and has been extensively researched in China since the 1960s, notably in respect of physiological mechanisms and the evaluation of new techniques. Most of this work is restricted to Chinese-language journals and is unknown in the West. This is also the case for the substantial output from countries that were part of the former Soviet Union, which have made important contributions in electro-acupuncture and the use of various related devices. Western medical databases now contain thousands of acupuncture research entries, including clinical trials, laboratory experiments, evidence reviews, surveys of use and attitudes, and qualitative studies.

Acupuncture is a complex intervention and lack of a suitable placebo control has hindered efforts to evaluate efficacy. However, in recent years a number

of rigorous RCTs have established the benefits of acupuncture for knee arthrosis (Berman BM 2004, Vas 2004, Witt C 2005, Scharf 2006, Bjordal 2007, White A 2007), arthritis of the hip (Witt 2006) chronic low-back pain (Furlan 2005, Manheimer 2005, Witt 2006), neck pain (Vas 2006, Trinh 2006,Witt 2006) and migraine headaches (Melchart 2004). To this can be added evidence of efficacy in treating more acute conditions such as post-operative pain (Almi 2003) nausea and vomiting (Dundee 1989, Gan 2004, Lee 1999), anxiety disorders (Pilkington 2007), dysmenorrhoea (Habek 2003, White 2003), and pain control after oral surgery (Lao 1999). Recent studies have also provided evidence of cost-effectiveness for treating conditions such as low-back pain (Thomas 2005, Thomas 2006, Ratcliffe 2006, Witt 2006), headache (Jena 2004, Vickers (two papers) 2004, Wonderling 2004, Herman 2005), knee pain (Manheimer 2007), hip arthritis (Witt C 2005, Reinhold 2007), and neck pain (Willich 2006). The GERAC (**Ger**man **Ac**upuncture trial) trial on low-back pain found acupuncture to be superior to guideline-based standard treatment, though not superior to minimal (superficial non-point) acupuncture. On the basis of this, the German health authorities decided that acupuncture will be included in routine reimbursement by social health insurance funds for the treatment of low-back pain (Molsberger 2006). Clinical-audit data show significant reductions in referral rates (Myers 1991, Lindall 1999, Ross 2001). Properly practised, acupuncture is a relatively safe form of therapy (MacPherson 2001).

In the evaluation of acupuncture interventions, it should be borne in mind that different styles of acupuncture operate with different conceptual frameworks and *modus operandi* and such variables are likely to influence the assessment of outcomes. For this reason, differing styles of acupuncture need to be acknowledged and defined in any research program. In addition, research design needs to be patient-centred to ensure that benefits important to the patient are not overlooked, especially in evaluating the overall benefits of supportive care for some chronic diseases where conventional treatment has relatively little to offer.

3. Appropriate Research

As mentioned above, it is important to acknowledge the long tradition of herbal/traditional medicines and acupuncture, the use of which stretches back hundreds and, in some cases, thousands of years. These traditions have codified detailed accounts of the long-term efficacy and safety of their medicinal products and/or interventions which, as also mentioned above, obviate the need for extensive preclinical testing. Familiarity with this corpus of knowledge should be the starting point for any modern research programme.

A systematic research strategy for assessing acupuncture and herbal/traditional medicine practice should involve a progressive gathering of

increasingly detailed data which grows into a convincing portfolio of evidence that balances rigour (internal validity) and relevance (external validity). Research into these therapies needs to be both appropriate and pragmatic. Whilst the pharmaceutical gold standards of RCTs and systematic reviews have a place in this research, other methods such as outcomes studies, case-controlled studies and qualitative research should play a significant role in validating treatment in the round.

Table 1 (see page 9) adapts a model for a research strategy suggested by the Medical Research Council in *'A framework for development and evaluation of RCTs for complex interventions to improve health'* (MRC April 2000). The various phases of research require different methods of evaluation which, when combined, could provide a systematic research programme to explore these therapies.

4. Problems and Possibilities

Problems that could obstruct research into acupuncture and herbal medicines include economic, methodological and ethical barriers.

4.1 Economic

Research into bio-medical medicine is primarily funded by the pharmaceutical industry. As mentioned, individualised herbal/traditional medicine and acupuncture treatments do not usually utilise marketable medicinal products and consequently struggle to attract research funding because financial returns from the sale of herbal/traditional medicinal products marketed for the treatment of specific ailments are not forthcoming. In addition, there is little support for practitioner researchers in the form of research scholarships.

In future, it is hoped that more Government funding can be allocated to research into traditional/herbal medicines and acupuncture and that grants will become available to encourage practitioners to undertake postgraduate research work.

In March 2007, the Chinese Government pledged to spend over $130 million over the next five years on research into the effectiveness of traditional Chinese medicine (Qiu 2007). It is to be hoped that this money will be targeted effectively to evaluate TCM.

4.2 Methodological

There is a relative lack of research expertise within the CAM practitioner community and, judging from many research trials conducted so far, a failure by researchers to understand the heterogeneity inherent in providing individual treatment that is an essential feature of much herbal/traditional

Table 1: Developing a framework to evaluate acupuncture and herbal medicines.

Research Phase	Research methods
Theoretical development • Practitioner world view • Underlying assumptions • Possible mechanisms involved	Individual case studies Reflective practice Laboratory work Review existing literature
Modelling • Distinguishing key components involved (e.g. herbs, therapeutic relationship etc.) • Defining actual intervention and outcomes • Developing protocol (random/blinding/ eligible criteria etc.)	Delphi process to gain professional consensus on best practice Case series Clinical-outcomes data Qualitative research Quantitative research
Exploratory trial • Testing all aspects of the protocol from recruitment to outcomes assessment. • Treatment effects for power calculations • Adapting trial design	N-of 1 trial Pilot study Small RCT Pragmatic RCT
Definitive RCT	Double blind RCT Pragmatic RCT
Long-term implementation • Real-world implementation • Long-term benefits • Compliance • Safety	Pragmatic RCT Clinical-outcomes data Patient/ practitioner surveys Qualitative research Observational studies

medicine and acupuncture treatment. This has led to poorly designed and inadequately deployed studies, the results of which have little or no meaning for any of the stakeholders involved. Appropriate methods of research need to be employed to measure the effectiveness of these interventions in settings that reflect real-world practice. The complex interaction of specific and non-specific effects from acupuncture and herbal/traditional medicine interventions, together with the individualised treatments that often change

throughout the course of treatment, make considerable methodological demands when it comes to designing valid research programmes.

The recent introduction of research methodologies as a component of acupuncture and herbal/traditional medicine undergraduate training will undoubtedly improve this situation but there needs to be more collaboration between researchers from outside the sector and practitioners within it. In addition, when funding applications are peer reviewed, it would be helpful if the funding panel were experienced in the complexities involved in researching these interventions. It would benefit the public who wish to use these modalities if funding were to be made available to encourage and enable experienced practitioners to research their work.

4.3 Ethical

Ethics committees are generally unaware of the specific nature of these interventions and sometimes have difficulty in granting permission to research this sector because, for example, of unfamiliarity with the individualised nature of much herbal/traditional medicine or acupuncture treatment.

5. Conclusion

The recorded history of traditional use over many years should be evaluated and incorporated into the evidence base supporting the effectiveness and safety of herbal/traditional medicines and acupuncture. In addition, stakeholder needs, including those of the patient, service providers, and the practitioners, require that this corpus of knowledge is subjected to a particular scientific scrutiny that needs to combine methodological rigour with an appreciation of the complex and individualised nature of these forms of medical intervention. The provision of adequate funding, training, institutional support, and collaboration between practitioners and researchers needs to be encouraged to enable this essential process to take place.

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ANNEX 2

ACUPUNCTURE
SCOPE OF PRACTICE

1. Introduction

Acupuncture is one of three professions, along with herbal medicine and Chinese medicine, which are jointly engaged in the process of working towards statutory regulation. The acupuncture profession is a complex mixture of full-time professional acupuncturists, statutorily regulated healthcare professionals who use acupuncture in their day-to-day practice, and a large number of users of clearly defined but limited techniques for specific therapeutic purposes. In the United Kingdom there is as yet no single body representing all acupuncturists, although all of the main associations with histories of thirty or more years representing the profession are now grouped under the aegis of the Acupuncture Stakeholders Group (ASG). This group, which operates by consensus decision, may well develop into a central reference point for the profession and the public after regulation.

Acupuncture is a primary healthcare profession, which emphasises, but is not limited to, the use of holistic traditional East-Asian medical theory, art and science to assess, diagnose and treat illness, injury, pain and other conditions. It makes use of safe and appropriate procedures taking into account individual variations in health status to promote, maintain or restore physical, psychological and social health and wellbeing.

Acupuncturists work in a range of healthcare settings, and operate both as independent practitioners and as members of integrated healthcare teams. The majority of full-time acupuncturists work as self-employed individuals independently or in group practices. Statutory regulated healthcare professionals (e.g. doctors, nurses, physiotherapists and others) and substance-misuse workers, may use acupuncture alongside or within their existing statutorily regulated activity in hospitals, community settings, GP practices or in the private sector. Acupuncturists often operate as independent healthcare professionals, from whom patients may seek direct care without referral from another healthcare professional, but will refer patients on where appropriate or liaise with other healthcare professionals where there is shared responsibility for patients.

A distinctive feature of the practice of acupuncture is the ability of individual practitioners to use solid sterilised needles, which are inserted into specific tissues of the human body for disease prevention, therapy or maintenance of health. Various other techniques, both invasive and non-invasive, are often performed or prescribed with acupuncture. These allied techniques and modalities may include electrical and magnetic stimulation, moxibustion and other forms of heat therapy, sound, light and vibration therapy, cupping techniques, traditional East-Asian massage, lifestyle and dietary counselling,

exercise and breathing routines such as tai ji quan, qi gong, and acupressure.

Acupuncture can be an effective treatment intervention as a sole treatment or as a supportive or adjunctive treatment to other medical treatments. Its practice is characterised by reflective behaviour and systematic clinical reasoning, both contributing to, and underpinning, a problem-solving approach to patient-centred care.

Acupuncture practice is supported and influenced by an increasing body of clinical research some of it of high-quality (see Appendix A). Whilst much of the research has been performed overseas, and may not always meet the rigorous standards of Western research, overall the body of evidence suggests widespread effectiveness of acupuncture in treating many disease states and conditions. Practice is informed by acupuncture-specific research as well as general scientific and medical literature (that includes traditional clinical experience extending back a millennium or more), and also by professional and clinical standards and clinical guidelines. In this way, the acupuncture profession engages in evidence-based practice.

In the assessment, management, treatment and evaluation of an individual's needs, acupuncture practitioners will take into account the current physical, psychological, cultural and social factors and their influence on the individual's functional ability. Practice also takes into account, where appropriate, the needs and perspectives of other healthcare professionals in order to provide a coherent and holistic approach that maximises independence and function.

There are a number of accrediting bodies within the United Kingdom. The range of courses which they accredit is broadly split into three groups: undergraduate degree-level, full-time acupuncture training; postgraduate training in Western medical acupuncture undertaken by regulated healthcare professionals; and short courses in defined uses of ear acupuncture and other micro-system treatment.

Some acupuncture qualifying programmes are validated by independent accrediting bodies such as the British Acupuncture Accreditation Board, which was established in 1991 and singled out as an exemplar of best practice in the House of Lords' Select Committee on Science and Technology's Report on Complementary and Alternative Medicine (House of Lord's 2000). Many programmes are jointly validated by higher education institutions (HEIs) as BSc-degree and diploma programmes. Postgraduate and non-degree level training is also recognised by a variety of accrediting and validating bodies.

The education of acupuncturists takes place within HEIs and in the private sector. HEI programmes are offered at honours-degree and postgraduate levels. Study may be full time or part time and programmes include a

practice component. Opportunities to study acupuncture are offered in at least 20 HEIs throughout the UK.

2. Nature and Extent of Acupuncture

Acupuncture practitioners provide an important source of health and lifestyle advice to the public as well as many patient and client groups. They may also provide mentorship for students and colleagues and utilise a range of communication and teaching skills.

Acupuncture is practised throughout the world and is recognised by the World Health Organization for its use in the treatment of a wide range of problems including muscular, neurological, digestive and respiratory disorders as well as urinary, menstrual, and reproductive problems (Xiaorui Zhang 2002). Acupuncture can be used to ease and resolve physical and psychological problems related to tension, stress and emotional conditions.

The breadth and scope of acupuncture practice encompasses, but is not limited to, the following:

- The age span of human development from neonate to old age (acupressure is often employed in treating infants and young children).
- Individuals with complex and challenging problems resulting from multiple pathologies in chronic illness.
- Health promotion and injury prevention.
- The assessment, management and evaluation of treatment interventions.
- The therapeutic management and treatment of individuals with recovering conditions.
- The symptomatic treatment of individuals with deteriorating conditions such as in the area of palliative care or degenerative neurological disorders to improve the quality of life.
- The supportive management of individuals with stable conditions such as medication-controlled illnesses.
- Working within a wide range of settings including private clinics, healthcare facilities, and peripatetic home visiting
- An understanding of the healthcare issues associated with diverse cultures within society.
- Strengthening the body's resistance against disease – in traditional acupuncture this may be expressed in terms of nourishing and fortifying the individual's qi (vital energy), blood, yin and yang. Medical acupuncturists may express this process in terms of restoring homeostasis and improving the immune function.

The acupuncture profession is a developing profession that operates within an ever changing and evolving healthcare and social environment. This growing profession continues to carry out pioneering work in formulating written practice standards and clinical guidelines for a wide range of specialist areas. These standards make direct reference to evidence at

different levels and are embedded in practice and the curricula of undergraduate and postgraduate training programmes.

Please note all but one of the organisations representing acupuncture endorsed this paper. There was one organisation that does not wish to be named, that had a contrary view about some of the aspects of the Annex.

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Position Summary on
Acupuncture Education in the UK

The seemingly simple task of delineating the current strands of UK acupuncture education is more complicated than first appears to be the case. The situation is not much changed from the 2003 Acupuncture Regulatory Working Group Report (ARWG 2003); there is still a diversity of training and professional application of acupuncture skills in the UK. The current increased membership of the Acupuncture Stakeholders Group has only added to the mix. Outcome standards within this context can only be judged as equivalent educational levels. Thus we have a spectrum ranging from a relatively simple certificate of competence to a Masters Degree. The key phrase in the ARWG executive summary was "*in the professional context within which they work*", indicating that the educational outcomes may not be the best way to understand differences in practice.

There is a clear division between those who wish to become professional traditional acupuncturists and undertake a full UK-degree programme to accomplish this and those who, already trained in one of the regulated health professions within the NHS, wish to add a form of acupuncture as an intervention to be used within their profession's scope of practice. The acupuncture training for the second group will, of necessity, be of a postgraduate nature. The register will need to recognise these discrete groups. It would be possible to count the hours of training but wide variations in the quality, the proportions of taught to self-directed learning and, indeed, the precise aspects of the subjects encompassed makes this at best inaccurate and at worst misleading to members of the public.

The following is a summary of the developing educational situation within the acupuncture profession and reflects the diversity of styles and forms of delivery. It can be divided into three main categories; that of undergraduate provision leading to a recognised BSc in acupuncture offered by several universities in the UK; that offered as a postgraduate Western Medical Acupuncture qualification, presently ranging from Certificate to MSc programmes, for statutory healthcare regulated professionals who hold recognised qualifications in medicine/dentistry/nursing/physiotherapy and other related medical disciplines within the National Health Service; and thirdly, training offered to non-medically qualified persons who have opted to undertake shorter, non-academic courses.

1. BSc Acupuncture Qualification

The undergraduate training validated and supervised by the British Acupuncture Accreditation Board (BAAB) is delivered through a number of UK universities and has thus been validated by both the UK advanced education system and the acupuncture professional body, the British Acupuncture Council (BAcC).

This, clearly, will form the qualification for a high proportion of acupuncture practitioners when the new register is opened and will fit easily with the basic standard required by the HPC.

There is also a smaller group, represented by the Acupuncture Society, which currently runs a professional training course like the combined acupuncture and Chinese herbal course at the College of Chinese Medicine (CCM) which, although at degree level, is not yet linked to or validated by a university.

2. Additional Postgraduate Training

This training is usually undertaken as a post registration qualification and may require different standards. Acupuncture used by these professionals is premised on the scope of practice of the primary discipline and cannot be adequately offered without the basic professional qualification to support it. The appropriate acupuncture qualification, therefore, ranges from a certificate of competence to a university validated MSc.

Most of this group are already working in the NHS and include doctors, physiotherapists, nurses and dentists. Since they are all, of necessity, already regulated by an existing body, the General Medical Council (GMC), the Health Professions Council (HPC), and the Nursing and Midwifery Council (NMC) etc, the fundamental degree educational qualification is already subject to regulation. Another characteristic of the education for this group, particularly that of the doctors, nurses and physiotherapists, is the emphasis on the research base, necessary to justify the use of acupuncture within the NHS.

Recent work undertaken to formulate National Occupational Standards (NOS) has established professional acupuncture competences. Compliance with these is inherent in all the forms of training although it may be supported by different and profession-specific definitions of the knowledge and understanding of acupuncture required to practise.

3. Training Limited by Micro-System or Specific Application

This category includes many of the ear-acupuncture practitioners, particularly those utilising the NADA (National Acupuncture Detoxification Association), five-point protocol for drug withdrawal, who have a limited focus and scope of treatment. The NOS competencies do not yet apply to these practices but there is no reason in principle why they should not eventually do so. Other practitioners, such as those in the Society of Auricular Acupuncture (SAA) or some in the Ear Acupuncture Register (EAR), also offer a more comprehensive system of ear acupuncture involving elements of diagnosis and therefore undergo a more extensive training approaching what might be described as a diploma level.

It has been suggested that the new register could perhaps look at extending the range of primary registrants to cover a category of diploma-level entrants for those whose work embraces elements of diagnosis, and also could establish a committee, or work with a profession-led committee, to accredit the training courses in defined-use acupuncture. The users of defined-use acupuncture could, in theory, operate as a voluntary self-regulating association, one proposal being that such an association might satisfy the criteria for the Prince's Foundation for Integrated Health's (PFIH) proposed federal regulatory structure. (http://www.fih.org.uk - Self-regulation for complementary therapies).

An issue inextricably bound with educational standards is that of protected title. By and large those in the first group of professional acupuncturists require title, since this is their chosen profession, while those in the second group do not necessarily require the title itself but do need to be identified on the register of practitioners of acupuncture. Some may also choose to no longer remain registered with their statutory healthcare professional regulator, in which case they will certainly require title.

A supplementary list for those practising Western Medical Acupuncture could provide an answer, offering information on the professional background of the practitioner and directing a complainant to the appropriate regulating body although this solution is not favoured by either the British Academy of Western Medical Acupuncture (BAWMA) or the British Medical Acupuncture Society (BMAS).

All practitioners consulted would like validation of their standards of practice by inclusion on a register. It has become apparent that the HPC favour a simple title, so "acupuncturist" may still be the best solution with some minimal information on the profession of the registrant included on the register.

Regulation according to practice is equally complex and further complicated by the issue of dual regulation. The new term which has been coined for this is 'distributed regulation.' Current thinking seems to favour the primary regulator retaining jurisdiction over doctors, physiotherapists, nurses, dentists and other regulated healthcare professionals. In the case of physiotherapists, assuming, as seems likely, that the HPC will take on the role of regulatory body, no actual change may be necessary.

In the longer term, this might well see the appearance of specialist lists on primary regulators for those meeting standards of acupuncture training and competence agreed between the primary regulator and a specialist committee within the acupuncture regulator. In the interim, however, if there is to be a register of practitioners using acupuncture, it would still be most logical, in the interests of patient protection, to have all those practising acupuncture, even if only as an adjunctive technique, on the same list with the same title. Provision could be made on the acupuncture register site to

direct the enquiring patient to find appropriate regulatory details of an errant statutorily-regulated healthcare professional. NHS Trusts may ultimately request that all those providing acupuncture seek registration for this skill.

The third group of acupuncture users, the SAA, NADA, EAR and SMART may be encouraged to seek voluntary regulation after consultation with the PFIH as mentioned above. There is a strong desire within the Acupuncture Stakeholder Group that they remain at the 'table', however, in order that standards for the shorter courses are established, it is suggested that perhaps future qualifications could be "kite marked" in association with, or by, the acupuncture regulator.

In conclusion, the following quotation from the ARWG Report, with one small addition, best sums up the current situation -

ARWG Executive summary (ARWG 2003)
…[t]he Working group concluded that equivalence has to revolve around what a professional acupuncturist can be expected to do in the professional context within which they work. This would include the ability to synthesise information using a diagnostic framework and cover a wide scope of application. Comparisons will have to be made between differences in knowledge of areas such as Western medicine, acupuncture, patient management, practical skills and ethics, but always with reference to the independent practice of acupuncture…[and the safety of the patient].

Standards of Proficiency for Acupuncture Practitioners

1a: Professional autonomy and accountability

Registrant acupuncturists must:

1a.1 be able to practise within the legal and ethical boundaries of their profession

- understand what is required of them by the Health Professions Council
- understand the need to respect, and so far as possible uphold, the rights, dignity and autonomy of every patient including their role in the diagnostic and therapeutic process

1a.2 be able to practise in a non-discriminatory manner

1a.3 be able to maintain confidentiality and obtain informed consent

1a.4 be able to exercise a professional duty of care

1a.5 know the limits of their practice and when to seek advice

- be able to assess a situation, determine the nature and severity of the problem and call upon the required knowledge and experience to deal with the problem
- be able to initiate resolution of problems and be able to exercise personal initiative

1a.6 recognise the need for effective self-management of workload and be able to practise accordingly

1a.7 understand the obligation to maintain fitness to practise

- understand the importance of maintaining health and care for themselves

1a.8 understand the need for career-long self-directed learning

1b: Professional relationships

Registrant acupuncturists must:

1b.1 know the professional and personal scope of their practice and be able to make referrals and communicate with other healthcare practitioners with whom they may share responsibility for a patient, client or user.

1b.2 be able to work, where appropriate, with other professionals, support staff, patients, clients and users, and their relatives and carers

- understand the need to build and sustain professional relationships as both an independent practitioner and collaboratively as a member of a team
- understand the need to engage patients, clients, users and carers in planning and evaluating diagnostic processes, treatments and interventions to meet their needs and goals

1b.3 be able to contribute effectively to work undertaken as part of a multi-disciplinary team

1b.4 be able to demonstrate effective and appropriate skills in communicating information, advice, instruction and professional opinion to colleagues, patients, clients, users, their relatives and carers

- be able to communicate in English to the standard equivalent to level 6.5 of the International English Language Testing System, with no element below 6.5
- understand how communications skills affect the assessment of patients, clients and users, and how the means of communication should be modified to address potential barriers such as age, physical and learning disability
- be able to select, move between and use appropriate forms of verbal and non-verbal communication with patients, clients, users and others
- be aware of the characteristics and consequences of non-verbal communication and how this can be affected by culture, age, ethnicity, gender, religious beliefs and socio-economic status
- understand the need to provide patients, clients and users (or people acting on their behalf) with the information necessary to enable them to make informed decisions
- understand the need to use an appropriate interpreter to assist patients whose first language is not English, wherever possible
- recognise that relationships with patients, clients and users should be based on mutual respect and trust, and be able to maintain high standards of care even in situations of personal incompatibility
- *be able to explain the techniques of acupuncture practice and scope to patients, colleagues and carers*[*]

1b.5 understand the need for effective communication throughout the care of the patient, client or user

- recognise the need to use interpersonal skills to encourage the active participation of patients, clients and users
- *recognise the need to provide relevant and appropriate information to patients, clients or users to enable them to make informed choices*

[*] Please Note that the normal text is straight from the HPC and the text in italics are additions by the ASG (but both normal and italicised text apply).

2a: Identification and assessment of health and social care needs

Registrant acupuncturists must:

2a.1 be able to gather appropriate information

- *be able to gather information according to the principles and methodologies of either traditional East-Asian or Western medical acupuncture*
- *be able to apply appropriate diagnostic techniques according to their training in traditional east-Asian or western medical acupuncture*

2a.2 be able to use appropriate assessment techniques

- be able to undertake and record a thorough, sensitive and detailed assessment, using appropriate techniques and equipment

2a.3 be able to undertake or arrange clinical investigations as appropriate

2a.4 be able to analyse and evaluate the information collected

- *be able to analyse and evaluate information collected according to the principles of traditional East-Asian or western medical acupuncture and use it to form an appropriate diagnosis, taking into account sources of information from other healthcare professionals involved in the patient's care*
- *be able to investigate and monitor pathological processes and normal states according to traditional East-Asian or Western medicine*

2b: Formulation and delivery of plans and strategies for meeting health and social-care needs

Registrant acupuncturists must:

2b.1 be able to use research, reasoning and problem-solving skills to determine appropriate actions

- recognise the value of research to the systematic evaluation of practice
- be able to conduct evidence-based practice, evaluate practice systematically,
- and participate in audit procedures
- be aware of methods commonly used in healthcare research
- be able to demonstrate a logical and systematic approach to problem solving
- be able to evaluate research and other evidence to inform their own practice

- *recognise the need to discuss and be able to explain the rationale for acupuncture treatment*
- *be able to form a diagnosis based on traditional East-Asian or Western medical principles of health and disease, using research, reasoning and problem-solving skills*

2b.2 be able to draw on appropriate knowledge and skills in order to make professional judgments

- demonstrate a level of skill in the use of information technology appropriate to their profession

2b.3 be able to formulate specific and appropriate management plans including the setting of timescales

- understand the requirement to adapt practice to meet the needs of different client groups distinguished by, for example, physical, psychological, environmental, cultural or socio-economic factors
- *be able to formulate a comprehensive treatment plan/strategy and a considered prognosis*
- *be able to set goals and agree a treatment plan/strategy and treatment methods with the patient, client or user, according to the patient's needs*

2b.4 be able to conduct appropriate diagnostic or monitoring procedures, treatment, therapy or other actions safely and skilfully

- understand the need to maintain the safety of both patients, clients and users, and those involved in their careensure patients, clients and users are positioned (and if necessary immobilised) for safe and effective interventions
- *be able to evaluate an acupuncture treatment plan and any diagnostic or*
- *monitoring procedures*
- *be able to select and apply safe and effective acupuncture treatment techniques for the alleviation of patient symptoms and signs*
- *be able to use a variety of methods including needles, moxibustion, electrical stimulus, cupping, guasha, qigong and tuina according to the patient's condition and the practitioner's limits to competence*

2b.5 be able to maintain records appropriately

- be able to keep accurate, legible records and recognise the need to handle these records and all other clinical information in accordance with applicable legislation, protocols and guidelines
- understand the need to use only accepted terminology (which includes abbreviations) in making clinical records
- *use accepted East-Asian medicine terminology where appropriate.*

2c: Critical evaluation of the impact of, or response to, the registrant's actions

Registrant acupuncturists must:

2c.1 be able to monitor and review the ongoing effectiveness of planned activity and modify it accordingly

- be able to gather information, including qualitative and quantitative data, that helps to evaluate the responses of patients, clients and users to their care
- be able to evaluate management plans against treatment milestones using recognized health-outcome measures and revise the plans as necessary in conjunction with the patient, client or user
- recognise the need to monitor and evaluate the quality of practice and the value of contributing to the generation of data for quality assurance and improvement programmes
- be able to make reasoned decisions to initiate, continue, modify or cease treatment or the use of techniques or procedures, and record the decisions and reasoning appropriately
- understand that outcomes may not always conform to expectations but may still meet the needs of patients, clients or users

2c.2 be able to audit, reflect on and review practice

- understand the principles of quality control and quality assurance
- be aware of the role of audit and review in quality management, including quality control, quality assurance and the use of appropriate outcome measures
- be able to maintain an effective audit trail and work towards continual improvement
- participate in quality assurance programmes, where appropriate
- understand the value of reflection on clinical practice and the need to record the outcome of such reflection
- recognise the value of case conferences and other methods of review

3a: Registrant acupuncturists must:

3a.1 know the key concepts of the biological, physical, social, psychological and clinical sciences which are relevant to their profession-specific practice

- understand the structure and function of the human body, relevant to their practice, together with a knowledge of health, disease, disorder and dysfunction
- be aware of the principles and applications of scientific enquiry, including the evaluation of treatment efficacy and the research process
- recognise the role of other professions in health and social care

- understand the theoretical basis of, and the variety of approaches to, assessment and intervention
- *understand the following aspects of biological science for the safe practice of traditional East- Asian acupuncture and Western medical acupuncture:*
- *regional and surface human anatomy*
- *normal human physiology*
- *location and depth of internal organs*
- *cardiovascular and blood diseases, respiratory and infectious diseases, urogenital disorders, neurological and musculoskeletal conditions, digestive diseases, skin conditions, gynaecological problems, endocrine diseases and mental and emotional disorders*
- *how the application of acupuncture can influence physiological and structural function*

understand the following aspects of clinical science for traditional East-Asian acupuncture and Western medical acupuncture:

- *pathological changes and related clinical features commonly encountered in acupuncture practice*
- *physiological, structural, behavioural and functional changes that can result from acupuncture intervention and disease progression.*
- *understand the different concepts and approaches that inform the development of acupuncture interventions*

understand the following aspects and concepts for traditional East-Asian acupuncture:

- *yin/yang, /5 elements/phases, eight principles, cyclical rhythms, qi ,blood and body fluids, different levels of qi, pathogenic factors, 12 zang fu and 6 extraordinary fu, jing luo/ meridians, the major acupuncture points, East-Asian medicine disease categorisation, the three burners, the 4 stages/levels and 6 divisions*
- *causes of disharmony/disease causation*
- *the four traditional diagnostic methods: questioning, palpation, listening and observing*

understand the following aspects and concepts for Western medical acupuncture:
- *concepts applicable to the practice of acupuncture based on recognised neurophysiological principles, prior experiential learning and experience in recognized Western medical/clinical sciences and hospital training*

for both traditional East-Asian and Western medical acupuncture:
- *the pathways of the 14 main channels/meridians and the major acupuncture points*

3a.2 know how professional principles are expressed and translated into action through a number of different assessment, treatment and

management approaches and how to select or modify approaches to meet the needs of an individual

3a.3 understand the need for, and be able to establish and maintain, a safe practice environment

- be aware of applicable health and safety legislation, and any relevant safety policies and procedures in force at the workplace, such as incident reporting, and be able to act in accordance with these
- be able to work safely, including being able to select appropriate hazard control and risk management, reduction or elimination techniques in a safe manner in accordance with health and safety legislation
- be able to select appropriate personal protective equipment and use it correctly
- be able to establish safe environments for clinical practice, which minimise risks to patients, clients and users, those treating them, and others, including the use of hazard control and particularly infection control
- *selection of types, lengths and gauges of needles, competent, safe and sensitively performed insertion, manipulation and withdrawal of needles*
- *sterile techniques to avoid cross-infection*
- *minimising/obviating the risk of local trauma, bruising or fainting*
- *appropriate use of, and recognition of contra-indications for, auxiliary techniques such as electro-acupuncture, moxibustion, cupping, ear acupuncture, bleeding and plum-blossom needling*

Please note:
The Acupuncture Stakeholder Group (ASG) has discussed the level of specificity of the Traditional East-Asian Medicine (TEAM) that may be required in this document. While the TEAM practitioner representatives are aware that other standards of proficiency within HPC registered professions are perhaps more generic in style, they do nonetheless each specify what is specific to their particular therapy, and, consequently the level and scope of the acupuncture training required.

Since the majority of registrants for the new acupuncture- and herbal-medicine regulator will probably, in the first instance, be TEAM practitioners, the current draft standards are written to provide a suitable benchmark for them which will not appear elsewhere in HPC documentation. The ASG is aware that the herbal-medicine practitioners have also produced standards of proficiency specific to herbal and traditional medicine.

References

The Statutory Regulation of the Acupuncture Profession: The Report of the Acupuncture Regulatory Working Group, The Prince of Wales's Foundation for Integrated Health, London, 2003.

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ANNEX 3
Report from Herbal/Traditional Medicine Stakeholder Group (H/TMSG)

Annex 3 comprises the work and recommendations of the Herbal/Traditional Medicine Stakeholder Group and includes:

- Statement of intent and achievement to date
- Scope of Practice
- Standards of Proficiency
- Discussion of some relevant points pertaining to Standards of Professional Practice
- Note on the Health Professions Council's Standards of Conduct, Performance and Ethics & HPC Standards of Proficiency
- Note on Health Professions Council's Continuing Professional Development
- Suggested protected titles – still to be determined after further discussion post publication of this report
- National Professional Standards for Herbal Medicine
- European Herbal & Traditional Medicine Practitioners Association Core Curriculum for Herbal and Traditional Medicine

Statement of Intent and Achievement to Date

The Herbal/Traditional Medicine Stakeholder Group endorses the adoption by the Steering Group and, in particular, for its own sector of the Health Professions Council's standards of conduct, performance and ethics as well as its standards and scheme for continuing professional development.

The Herbal/Traditional Medicine Stakeholder Group has developed its own Scope of Practice Document (see below) and has used the generic Health Professions Council's Standards of Proficiency to write further additions to this document to cover herbal/traditional medicine practice (see below).

It has also provided commentaries on the Health Professions Council's standards of conduct, performance and ethics and its standards for continuing professional development. Finally it has provided its ideas for protected titles for the different modalities/traditions in this sector.

SCOPE OF PRACTICE

Introduction

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

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

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

Within this variety there are some important shared characteristics and these are outlined in Part One. Part Two then provides a brief account of those traditions which are currently represented in the UK. Each has a specific body of knowledge and skills, the acquisition of which is essential for competent practice.

It is also important to note that:

- Practitioners typically use other forms of treatment alongside herbal medicines. This is apparent in the Eastern traditions in which the use of medicinal substances appears as one modality amongst others. Here the use of the term traditional (as defined by the World Health Organisation[1]) encompasses not only the use of non-plant ingredients but also a wide range of other treatment options. Likewise, in the field of Western herbal medicine, other forms of intervention such as dietary therapy and the use of essential oils internally and externally are legitimate aspects of the work of the Western herbal practitioner.

[1] WHO defines traditional medicine as follows: "Traditional medicine is a comprehensive term used to refer both to TM systems such as traditional Chinese medicine, Indian ayurveda and Arabic unani medicine, and to various forms of indigenous medicine. TM therapies include medication therapies — if they involve use of herbal medicines, animal parts and/or minerals — and nonmedication therapies — if they are carried out primarily without the use of medication, as in the case of acupuncture, manual therapies and spiritual therapies" Source *WHO Traditional Med. Strategy 2002-2005* available at: http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf.

- There is also an awareness of the importance of developing the evidence-base for herbal and traditional medicine. In one sense there is a wealth of evidence based on traditional use, including a rich literary and folk heritage. In the sense of an orthodox evidence-base, the bulk of research so far has been in the form of laboratory studies. However, there has been an increasing output of clinical research, including randomised controlled trials, and these have generally been encouraging. It is recognised that much more needs to be done in this direction, while bearing in mind that the challenge is to establish research designs that are rigorous yet faithfully reflect herbal and traditional medicine as it is actually practised. See Annex 1 of the Steering Group report for further elucidation of this topic.

- Practitioners of herbal and traditional medicine work in a variety of settings; on their own or in larger group practices, in clinics attached to shops, and occasionally in orthodox settings such as specialist rehabilitation and HIV/AIDS centres. The great majority practise in the private sector, outside the NHS.

Part One: Common Features

Despite the great variety of traditions that have established a presence in the UK, there are a number of similar characteristics. Beyond the obvious one of using plant substances as medicines, there are common themes in the understanding of the *materia medica* and in the approach to health and disease and to treatment. In this section the term '*materia medica*' is used generically, but it should be borne in mind that the *materia medica* of one tradition is to a very large extent distinct from that of others.

Materia Medica

- The *materia medica* may be seen through the prism of traditional use, or through an understanding of the chemistry of the plant (or non-plant) ingredients and its impact on human physiology.

- According to the Directive on Traditional Herbal Medicinal Products (Directive 2004/24/EC[2]), the term 'traditional use' refers simply to usage over a certain time period (at least 30 years). Traditional use may apply to the use of herbal/traditional medicines in accordance with their intrinsically 'energetic' properties, for example, having warming, cooling or drying properties, or specific tastes such as sweet, sour, pungent,

[2] Directive 2004/24/EC of 31 March 2004 (amending Directive 2001/83/EC), http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=607

bitter, salty. They are assessed according to their functional aspect - that is their ability to strengthen or support proper function, for example warding off infection, or correcting imbalances in digestion, respiration or urination, or to treat painful rheumatic conditions, or exercise a calming effect in anxiety disorders.

- Alongside the 'energetic' understanding of the *materia medica* a knowledge and understanding of the biochemistry of herbal and traditional medicines has developed, allowing each tradition to draw on a substantial body of modern pharmacological research to inform treatment decisions.

- Herbal and traditional medicines are complex in their chemical make-up by comparison with pharmaceutical drugs. This complexity may well confer advantages, because of the synergy that occurs between the plant constituents. It is also possible that components which are not active in themselves can function to improve the stability, solubility or bioavailability of others. The presence of multiple constituents can also create a buffering effect which contributes to safety. These sorts of advantage may be increased by the use of formulas containing multiple ingredients, which is the typical practice in every tradition.

- Many practitioners run their own pharmacies and this involves a further range of technical, safety and legal competencies. Some practitioners may also grow, harvest and prepare their own materials, though this is not required.

- Herbal and traditional medicines are administered in a variety of forms, as teas (infusions or decoctions), tinctures (alcohol extracts), powders, tablets or capsules, and in external applications including creams, ointments, plasters and compresses. Other forms of medicine that may be used include fermented substances (medicinal wines) extract preparations such as juices and pastes, fatty preparations such as medicated *ghees* and oils, alkalis, ashes and syrups.

Diagnosis and the Understanding of Disease

- Practitioners of herbal and traditional medicine carry out in-depth consultations, make independent diagnostic judgements and treat patients using prescriptions which are flexibly adjusted in the light of the patient's condition or following a change in diagnosis. Each tradition has, however, developed its own diagnostic framework which needs comprehensive separate study and clinical training.

- Practitioners take detailed case histories and use a variety of assessment methods.

- Good health is viewed as a state in which energy is abundant and physiological functions are unimpeded. 'Energy' here appears in various guises as, for example, *vital force*, *Qi* or *prana*. '*Vitality*' is not tangible in the same way as physical or chemical energy, but there are agreed criteria for assessing it.

- The language of diagnosis, like the language that informs traditional use of the *materia medica*, is often couched in terms derived from the natural world. In energetic terms, pathogens (in the broad sense of disease-causing factors) include, for example, cold, heat, dampness and dryness. The humoural aspect, for example, the presence of excess mucus/catarrh or other forms of pathological dampness, appears as an important element in all traditions. Also, organ pathology tends to be viewed as a disruption of function (digestive, respiratory, urinary etc) rather than in terms of pathological changes in isolated body tissue. The focus of attention is less on disease as a specific entity, but more on the individual patterns of disharmony which can vary from person to person.

- These patterns are understood in a holistic way, resting on the assumption of a web of interconnectedness between physiological processes, and between mind and body.

Treatment

- Treatment with herbal and traditional medicine is typically seen as a way of restoring balance and healthy function.

- Treatment may be aimed at assisting the expulsion of pathogens (understood broadly as disease-causing factors) and/or addressing any underlying weakness which may have contributed to the condition. In some traditions there is a relatively strong emphasis on elimination as a means of restoring balance. In others this is given less prominence. However, all traditions use both eliminative (and 'clearing') and restorative (or 'tonifying') therapy, and attach importance to assessing the patient's constitution before deciding on the appropriate balance between the two.

- The skill of treatment with herbal and traditional medicine is to choose an ingredient, or more commonly a combination of ingredients, which matches the pattern of disharmony of the individual, and to modify this in order to accommodate changes in the course of treatment and, if necessary, make revisions to diagnosis.

- The range of conditions treatable with herbal and traditional medicine is very wide, and practitioners may be consulted about almost any condition that a conventional general practitioner might encounter. However, practitioners are trained to know the limits of their competence and to refer where necessary.

Part Two – Specific Features

While there are important common features, each tradition embodies a large area of specific knowledge and skills, and proper acquaintance with these is essential for competent practice.

2.1 Ayurveda

Ayurveda is a Traditional System of Medicine (TSM), recognised as such by the World Health Organisation (WHO). It originated in India and is today widely practised in India and Sri Lanka as a government-recognised and statutorily regulated medical system.

It is a comprehensive medical system based on a specific approach to anatomy, physiology, pathology and therapy, with classical specialist branches that include internal medicine, ENT, ophthalmology, gynaecology, obstetrics, paediatrics, surgery, psychology and rejuvenation therapy.

The term Ayurveda is derived from two Sanskrit words, *ayus* (meaning life) and *vid* (meaning knowledge). Ayurveda is thus also called the 'Science of Life', and it is as much concerned with preventing ill-health and enhancing quality of life, as it is with the actual treatment of disease. Ayurveda recognises the dynamic interplay of the physical, mental, emotional and spiritual levels in every individual and considers each manifestation of life to be inseparable from all other forms of life in the universe.

Ayurveda is firmly embedded in Indian philosophy and its theory of evolution, according to which the universe is composed of five basic elements. These are ether, air, fire, water and earth, which combine and manifest in living beings as so-called *doshas*.

The three *doshas*, called *vata*, *pitta* and *kapha*, are the primary energetic forces of the human body. Each has its characteristic site and unique functions in the body. They are interrelated and, in their normal state, maintain the integrity of the living organism, conferring strength and assuring normal physiological functioning as well as longevity. Any imbalance of these forces results in ill-health.

Ayurveda places particular emphasis on the individual constitution, *prakriti*, of every being, which is determined by a unique combination of *doshas*, genetic factors as well as the health, nutrition and lifestyle of the parents prior to conception. *Prakriti* determines an individual's susceptibility to different diseases and has an influence on the development and course of a disease as well as on the complications that could arise and the prognosis.

An Ayurvedic practitioner takes a detailed case history and arrives at a diagnosis through a variety of methods, including pulse or tongue reading

and other forms of body examination, an in-depth assessment of diet and lifestyle habits, and an analysis of mental and emotional states.

The skill of the practitioner lies in assessing a patient's constitutional type, in diagnosing the root cause of imbalance that manifests as disease, and in selecting appropriate remedial interventions from an array of therapeutic options. These include:

- nutrition and lifestyle therapy
- pharmacotherapy (use of drugs that are, traditionally, of plant, mineral and animal origin)
- *panchakarma* (detoxification therapy): a series of treatments that aim at deep body cleansing. They include elaborate preparatory procedures, emetic and purgative processes and also enema treatments.[3]
- *rasayana* (rejuvenation therapy): various rejuvenating treatments that increase strength, immunity and overall vitality.
- manual therapy including massage and other forms of hands-on body work
- *marma* therapy (stimulation of energy points with pressure or solid needles)
- psychotherapy and counselling
- yoga and therapeutic exercise
- meditation and breathing techniques
- gem therapy and other forms of subtle energy work and healing.

2.2 Chinese Herbal Medicine

Chinese herbal medicine is one modality within the broad tradition of Chinese medicine, which also includes acupuncture, massage (*tuina*), breathing exercises (*qi gong*) and dietary therapy. In the great majority of cases practitioners of Chinese herbal medicine are also qualified in acupuncture-moxibustion and work with both modalities (as well as often with massage, dietary therapy or breathing exercises).

Good health is seen as a state in which a person has optimum energy or vitality (*Qi*) and in which the functions needed to maintain that vitality are unimpeded. Ill-health is due to a loss of vitality or to some form of impediment to those functions, or both. Good health furthermore requires a balance, represented by the core idea of Yin-Yang, a concept drawn from a school of thought which came to be central to the Chinese medical tradition.

[3] Leeching, venesection and other forms of blood letting (*raktamokshan*) are also traditional practices of *panchakarma* and still performed today by suitably qualified practitioners

Diagnosis is the identification of a pattern of disharmony displayed by the individual patient, based on observation, listening, questioning and palpating. Particular attention is paid to the tongue and pulse in evaluating the patient's condition. A disharmony may be read as a deficiency or dysfunction in one or more of the Organs, in particular the Spleen, Liver, Heart, Lungs or Kidneys (these refer to spheres of function, and are not to be confused with the anatomical organs of modern medicine). Another perspective in diagnosis involves identifying patterns according to the presence of pathogenic factors. Such factors, which are not to be thought of as microbes, are described in terms derived from the natural world, namely heat, cold, dampness, wind, dryness, together with varieties of toxin and disease-causing products of the body described as blood stasis and phlegm. These patterns *may* have an external origin in climate or environment. For example, a damp house or damp working conditions may lead to a damp condition affecting the joints, a hot environment may aggravate a hot condition affecting the skin.

Attention is also given to the origins of disease, broadly categorised as external, internal (relating mainly to the emotional sphere), neither external nor internal (including diet, imbalances of work and rest, and sexual factors) and a miscellany of others (including trauma, burns, bites and parasites). Inherited and congenital factors are also recognised.

The Chinese *materia medica* contains several hundreds of plant species, together with some non-plant ingredients. These are classified according to their 'temperature', flavour, direction of movement, and properties that are related to their ability to supplement or clear impediments to function. The art of treatment with Chinese herbal medicine is to choose a formula (a combination of herbs) which matches the pattern of disharmony of the individual, and to modify the formula to accommodate changes in the course of treatment.

2.3 Traditional Tibetan Medicine

Tibetan medicine is an ancient system of medicine with intricate theories of disease causation, diagnosis and therapeutics.

The medical system itself is founded on the principle of mind, body and environmental factors interdependently creating the conditions for health or disease. Mind, body and external environment are all composed of the same basic five elements at greater or lesser degrees of subtlety. These five elemental principles are traditionally designated as earth, water, fire, air and space and may be interpreted as *matter, bonding, energy, movement* and *space*. This enables the components of the world at large to be used, by the physician, to restore the patient to health as both are of similar nature. The individual is a part of a greater whole.

One major factor believed to trigger disease is the interaction between the person and the world in which (s)he lives - diet, human relationships and climate being typical areas of interaction. Tibetan medical practitioners are also trained to track the elemental characteristics of each moment and hour. The understanding of the timing of symptoms can give clues to the nature of the underlying disorder the person is experiencing. Another factor is the influence of the individual's own mind, feelings and personal history. These factors affect the body and mind in multiple ways, grouped by Tibetan Medicine into three major areas of pathology, known as the *nyes pa gsum.* Each of these three areas includes functions of the body's major sub-systems, such as the cardiovascular system and digestive system. Each *nyes pa* is also related to the psychological makeup and welfare of the individual. The importance of compassion in healing is stressed in Tibetan medicine.

Diagnosis is principally based upon a complex analysis involving the following features: palpation of pulses to ascertain the state of the organs of the body, urine inspection, in-depth questioning to establish predisposing and precipitating causes of imbalance.

Traditional Tibetan Medicine has developed an extensive range of clinical practice spanning psychiatry, paediatrics, gynaecology, obstetrics, geriatrics and endocrinology as well as neurology. The system is complete in itself covering all aspects of health.

Traditional Tibetan medicine makes use of the animal, vegetable and mineral components to restore health and balance and gives advice on how to heal the mind and improve the way in which one lives.

Treatment is offered in the following areas:

- advice on certain behaviours to adopt or avoid, since the way a person behaves can affect the subtle mind and more gross body elements and lead to health or disease
- dietary advice in order to help restore the elemental imbalance, as foods made up of the five elements can affect the body’s balance of the elements
- the prescription of herbal and traditional medicines
- external treatments such as moxibustion

2.4 Western Herbal Medicine

Western herbal medicine in the UK has a number of historical roots:

- The Graeco-Roman tradition
- The indigenous herbal culture of the British Isles
- North American herbal medicine
- Western medical science

The Graeco-Roman tradition is linked to the Hippocratic writings (4-5th century BC), to Dioscorides (1st century AD) and to Galen (2nd century AD), a tradition which laid the foundations for European (and Islamic) medicine until the modern era. The Hippocratic writings included herbal medicine, but they covered a much wider range of methods to encourage health, including diet and what would now be called lifestyle, environmental and psychotherapeutic measures. These writings contain some passages which sing the praises of physicians, but they emphasise the natural healing power of life (*vis medicatrix naturae*). This remains important in the practice of western herbal medicine, associated with an emphasis on gentle encouragement of physiological change as well as the treatment of symptoms.

The influence of botanic medicine practised in North America on traditional herbal practice in the UK manifested particularly through the 19th century Eclectic and Physiomedical movements, which themselves incorporated much of the herbal knowledge and herbs of the Native Americans. As global communication and transportation expanded, plants from other parts of the world have been incorporated into the Western herbal framework.

The American movements had reacted strongly against the remedies of the 'regular physic' of the time (dominated by toxic minerals based on mercury, arsenic, antimony and sulphur), and emphasised the importance of physiological *support* or *enhancement* as well as physiological compensation. In enhancement, the goal is to create a state of active health, an optimum state of vitality. Like practitioners of other traditions, Western herbal practitioners assert the existence of a vital energy or vitality which integrates the normal functioning of the body and maintains homeostasis. This viewpoint gave rise to treatments aimed at increasing vitality by improving the function of individual systems/organs. However, where the pathological process has gone too far, or it is necessary to break a vicious circle of debilitating processes, compensation will be required, for example with the use of anti-inflammatory, antiviral, antiseptic or anti-allergenic remedies.

Western herbalists receive thorough training in many aspects of modern medicine and integrate this knowledge with an understanding of the holistic, constitutional approach which is their heritage.

Some herbalists grow and collect plant material to make their own medicines, and most prepare and dispense their own remedies. This involves running and maintaining dispensaries and thus skills in stock and quality control, health and safety and hygiene are essential, as of course are an in-depth knowledge of plant identification, and an understanding of cultivation methods, harvesting and conservation.

Standards of Proficiency for
Herbal/Traditional Medicine Practitioners Supplementary to HPC[4]

1. Expectations of a Health Professional

1a: Professional autonomy and accountability

Registrant herbal and traditional-medicine practitioners must:

1a.1 be able to practise within the legal and ethical boundaries of their profession

- understand the need to act in the best interests of patients at all times
- understand what is required of them by the Health Professions Council
- understand the need to respect, and so far as possible uphold, the rights, dignity values and autonomy of every patient including their role in the diagnostic and therapeutic process and in maintaining health and wellbeing
- *be aware of current UK and European legislation applicable to the work of their profession.*
- *be aware of any guidance from UK or European bodies that regulate standards and effect herbal medicine practice.*

1a.2 be able to practise in a non-discriminatory manner

1a.3 understand the importance of and be able to maintain confidentiality

1a.4 understand the importance of and be able to obtain informed consent

1a.5 be able to exercise a professional duty of care

1a.6 be able to practise as an autonomous professional, exercising their own professional judgement

- be able to assess a situation, determine the nature and severity of the problem and call upon the required knowledge and experience to deal with the problem
- be able to initiate resolution of problems and be able to exercise personal initiative
- know the limits of their practice and when to seek advice or refer to another professional

[4] Please note italicised text in this Annex is specific to Herbal/Traditional Medicine practice whilst normal black text is generic HPC standards.

- recognise that they are personally responsible for, and must be able to justify, their decisions

1a.7 recognise the need for effective self-management of workload and resources and be able to practise accordingly.

1a.8 understand the obligation to maintain fitness to practice

- understand the need to act in the best interests of patients at all times
- understand what is required of them by the Health Professions Council

1b: Professional relationships:

Registrant herbal and traditional-medicine practitioners must:

1b.1 be able to work, where appropriate, in partnership with other professionals, support staff, patients and their relatives and carers

- understand the need to build and sustain professional relationships as both an independent practitioner and collaboratively as a member of a team
- understand the need to engage patients and carers in planning and evaluating diagnostics, treatments and interventions to meet their needs and goals
- be able to make appropriate referrals

1b.2 be able to contribute effectively to work undertaken as part of a multi-disciplinary team

1b.3 be able to demonstrate effective and appropriate skills in communicating information, advice, instruction and professional opinion to colleagues, patients, their relatives and carers

- be able to communicate in English to the standard equivalent to level 7of the International English Language Testing System with no element below 6.5
- understand how communications skills affect the assessment of patients and how the means of communication should be modified to address and take account of factors such as age, physical ability and learning ability
- be able to select, move between and use, appropriate forms of verbal and non-verbal communication with patients and others
- be aware of the characteristics and consequences of non-verbal communication and how this can be affected by culture, age, ethnicity, gender, religious beliefs and socio-economic status
- understand the need to provide patients (or people acting on their behalf) with the information necessary to enable them to make informed decisions

- understand the need to use an appropriate interpreter to assist patients whose first language is not English, wherever possible
- recognise that relationships with patients should be based on mutual respect and trust, and be able to maintain high standards of care even in situations of personal incompatibility
- *be able to explain the nature, purpose and techniques of herbal and traditional-medicine practice to patients and colleagues*

1b.4 understand the need for effective communication throughout the care of the patient

- recognise the need to use interpersonal skills to encourage the active participation of patients
- be able to communicate the outcome of problem solving and research and development activities
- *understand the need to establish and sustain a positive therapeutic relationship within a caring environment*

2. The skills required for the application of practice:

2a. Identification and assessment of health and social care needs:

Registrant herbal and traditional-medicine practitioners must:

2a.1 be able to gather appropriate information

- *be able to gather information according to herbal and traditional-medicine practice, taking account of personal, mental-emotional, social, cultural, economic, and spiritual factors when taking the case history*
- *be able to apply relevant diagnostic techniques from within their tradition and training, as well as use of appropriate medical assessment techniques*
- *be able to take account of investigations already made by the patient's other healthcare professionals, if any*

2a.2 be able to select and use appropriate assessment techniques

- be able to undertake and record a thorough, sensitive and detailed assessment, using appropriate techniques and equipment
- *be able to investigate and monitor pathological processes and normal states according to herbal or traditional-medicine practise, as well as making use of appropriate orthodox medical techniques*

2a.3 be able to undertake or arrange clinical investigations as appropriate

2a.4 be able to analyse and critically evaluate the information collected

- *be able to analyse and evaluate information collected according to the principles of herbal or traditional medicine and use it to formulate an appropriate diagnosis, taking into account relevant factors from a bio-medical point of view*
- *be able to search and critically evaluate scientific literature and other sources of information relevant to the patient's needs*

2b Formulation and delivery of plans and strategies for meeting health and social care needs

Registrant herbal and traditional-medicine practitioners must:

2b.1 be able to use research, reasoning and problem solving skills to determine appropriate actions *consistent with the principles of herbal and traditional medicine*

- recognise the value of research to the critical evaluation of practice
- be able to engage in evidence-based practice, evaluate practice systematically, and participate in audit procedures
- be aware of a range of research methodologies
- be able to demonstrate a logical and systematic approach to problem solving
- be able to evaluate research and other evidence to inform their own practice

2b.2 be able to draw on appropriate knowledge and skills in order to make professional judgements

- be able to change their practice as needed to take account of new developments
- be able to demonstrate a level of skill in the use of information technology appropriate to their practice

2b.3 be able to formulate specific and appropriate management plans including the setting of timescales

- understand the requirement to adapt practice to meet the needs of different groups distinguished by, for example, physical, physiological, environmental, cultural or socio-economic factors
- *be able to form a diagnosis and plan treatment according to herbal and traditional medicine training*

2b.4 be able to conduct appropriate diagnostic or monitoring procedures, treatment, therapy or other actions safely and skilfully

- understand the need to maintain the safety of patients and those involved in their care
- *be able to assist patients to understand and become committed to self-care habits including diet, exercise and other lifestyle adjustments to support treatment according to the herbal and traditional-medicine system.*

- *be able to work in conformity with standard operating procedures and conditions relevant to herbal medicine preparation and dispensing according to the herbal and traditional-medicine system*

2b.5 be able to maintain records appropriately

- be able to keep accurate, legible records and recognise the need to handle these records and all other information in accordance with applicable legislation, protocols and guidelines
- understand the need to use only accepted terminology in making clinical records

2c Critical evaluation of the impact of, or response to, the registrant's actions

Registrant herbal and traditional-medicine practitioners must:

2c.1 be able to monitor and review the ongoing effectiveness of planned activity and modify it accordingly

- be able to gather information, including qualitative and quantitative data, which helps to evaluate the responses of patients to their care
- be able to evaluate intervention plans using recognised outcome measures and revise the plans as necessary in conjunction with the patient
- recognise the need to monitor and evaluate the quality of practice and the value of contributing to the generation of data for quality assurance and improvement programmes
- be able to make reasoned decisions to initiate, continue, modify or cease treatment or the use of techniques or procedures, and record the decisions and reasoning appropriately
- *be able to implement and use the yellow-card scheme for recording adverse reactions to herbal medicines*

2c.2 be able to audit, reflect on and review practice

- understand the principles of quality control and quality assurance
- be aware of the role of audit and review in quality management, including quality control, quality assurance and the use of appropriate outcome measures
- be able to maintain an effective audit trail and work towards continual improvement
- participate in quality assurance programmes, where appropriate
- understand the value of reflection on practice and the need to record the outcome of such reflection
- recognise the value of case conferences and other methods of review
- *recognise the need to be aware of new developments in understanding and use of herbal medicines*

3. Knowledge, understanding and skills

Registrant herbal and traditional-medicine practitioners must:

3a.1 Know and understand the key concepts of the bodies of knowledge which are relevant to their profession-specific practice

- understand the structure and function of the human body, relevant to their practice, together with knowledge of health, disease, disorder and dysfunction
- be aware of the principles and applications of scientific enquiry, including the evaluation of treatment efficacy and the research process
- recognise the role of other professions in health and social care
- understand the theoretical basis of, and the variety of approaches to, assessment and intervention
- *understand the pharmacological effects of the major groups of plant compounds used in practice*
- *know the concepts underpinning the herbal and traditional-medicine system in which the registrant practises*
- *understand the mode of action of an appropriate range and number of medicinal plants in the materia medica according to the herbal or traditional-medicine system the registrant practises*
- *understand the toxicology of medicinal plants in the materia medica, possible adverse effects, cautions and contraindications*
- *be aware of the potential for herb-drug interactions and formulate treatment accordingly*
- *understand the key concepts of health and of disease pathways according to the herbal or traditional-medicine system and the role of herbal or traditional medicines in preserving health and treating disease*
- *know the relevant regulation and/or guidelines affecting the preparation and dispensing of herbal medicines*
- *know the forms of preparations of herbal medicines and be able to choose among them for appropriate administration*
- *understand research methods appropriate for use in herbal and traditional medicine research and evaluate papers critically*

3a.2 know how professional principles are expressed and translated into action through a number of different approaches to practice, and how to select or modify approaches to meet the needs of an individual, groups or communities

- *understand the rational basis that underpins the use of procedures relevant to the herbal or traditional-medicine system*
- *know and implement the standards of manufacture/preparation and dispensing relevant to herbal and traditional medicine*

3a.3 understand the need to establish and maintain a safe practice environment

- be aware of applicable health and safety legislation, and any relevant safety policies and procedures in force at the workplace, such as incident reporting, and be able to act in accordance with these
- be able to work safely, including being able to select appropriate hazard control and risk management, reduction or elimination techniques in a safe manner in accordance with health and safety legislation
- be able to select appropriate personal protective equipment and use it correctly
- be able to establish safe environments for practice, which minimise risks to patients, those treating them, and others, including the use of hazard control and particularly infection control
- *understand sources of hazard in the workplace, including raw materials, waste and equipment*
- *understand the application of principles of good dispensary practice and preparation of herbal medicines with regard to current guidance from relevant statutory or advisory bodies and professional associations*

Note (August 2007) from the Herbal/Traditional Medicine Stakeholder Group on the relevance to herbal and traditional medicine practitioners of:

a) The Health Professions Council (HPC) Standards of Conduct, Performance and Ethics

b) HPC Standards of Proficiency

The Herbal/Traditional Medicine Stakeholder Group has reviewed the Health Professions Council ***Standards of Conduct, Performance and Ethics***. ***We recommend that it is adopted, as published, for use by herbal/traditional medicine practitioners.*** The emphasis on professional standards in advertising is relevant to herbal/traditional medicine.

1. General features to be taken into account:

- Investigating panels are made up of at least three people, including a chairperson, someone from the relevant profession and a lay person (someone who is not on the HPC register).
- It should be ensured that an appropriate herbal/traditional medicine practitioner should always be representative of the relevant tradition involved in the investigation.
- In regard to dealing with allegations against registrants, the HPC ***Standards of conduct, performance and ethics*** states "We have set standards of conduct, performance and ethics, and also have standards of proficiency, and both of these can be relevant"
- These interdependent documents are relevant to herbal/traditional medicine. Aspects of practice which are specifically referred to in the

current European Herbal and Traditional Medicine Practitioners Association's Code of Conduct e.g. dispensary management would be covered by the ***Standards of Proficiency***.

- It should be noted that the generic ***Standards of Proficiency*** requirement for English and communication skills (1b3) says the following:
    - "be able to demonstrate effective and appropriate skills in communicating information, advice, instruction and professional opinion to colleagues, service users patients, clients, users, their relatives and carers".
    - "be able to communicate in English to the standard equivalent to level 7 of the International English Language Testing System, with no element below 6.5" (see Postscript 2 below).

2. Relevant matters from the HPC Standards of Proficiency:

A. Generic standards are varied according to different professions

The following two examples are taken from the consultation document on ***Standards of Proficiency***. They show how the generic standards are applied to different professions. The profession-specific standard is in italics.

Example 1: The skills required for the application of practice

"2b.4 be able to conduct appropriate diagnostic or monitoring procedures, treatment, therapy or other actions safely and skilfully
Dramatherapist: - *be able to use a range of dramatic concepts, techniques and procedures (including games, activities, styles and structures) competently*
Paramedic: - *ensure patients, clients and users service users are positioned (and if necessary immobilised) for safe and effective interventions*"

Example 2: Knowledge, understanding and skills

"3a.1 know and understand the key concepts of the biological, physical, social, psychological and clinical sciences bodies of knowledge which are relevant to their profession-specific practice
Dramatherapist: - *understand both the symbolic value and intent inherent in drama as an art form, and with more explicit forms of enactment and re-enactment of imagined or lived experience*

3a.2 know how professional principles are expressed and translated into action through a number of different approaches to practice, and how to select or modify approaches to meet the needs of an individual, groups or communities

Paramedic: - *be able to use the following airway management techniques, as well as knowledge of when and how each airway adjunct can be utilised to best effect: endotracheal tube placement, laryngeal mask airway, needle thoracocentesis, needle cricothyroidotomy".*

B. Examples specifically relevant to herbal/traditional medicine practice

Excerpts from the generic ***Standards of Proficiency*** are given below and are followed by copy in italics suggesting some possible additions suitable for herbal/traditional medicine practitioners. These are indicative only and will need modification in the light of the current consultation on proposed changes to s12(1) of the Medicines Act of 1968.

Expectations of a health professional

Professional autonomy and accountability
Registrants must:

1a.1 be able to practise within the legal and ethical boundaries of their profession

- be aware of current UK legislation applicable to the work of their profession
- *the herbal/traditional medicine practitioner should be aware of the relevant provisions of the Medicines Act 1968, 2001/83/EC, 2004/24/EC and any other relevant medicines legislation*
- understand both the need to keep skills and knowledge up to date and the importance of career-long learning
- *the herbal/traditional medicine practitioner should keep his/her knowledge of the safety of herbal medicines up to date*

The skills required for the application of practice
2b: Formulation and delivery of plans and strategies for meeting health and social care needs

2b.1 be able to use research, reasoning and problem-solving skills to determine appropriate actions.

- recognise the research to the systematic evaluation of practice
- be able to conduct evidence-based practice, evaluate practice systematically, and participate in audit procedures
- be aware of methods commonly used in healthcare research
- be able to demonstrate a logical and systematic approach to problem solving
- be able to evaluate research and other evidence to inform their own practice
- *manage the dispensary in order to dispense a range of herbal medicines in a safe and hygienic manner with especial regard to*

ensuring traceability of all ingredients of herbal medicine
- *maintain an adequate knowledge base of the main actions, indications, contraindications and evidence on safety on the herbs within their dispensary*

2b.2 **be able to draw on appropriate knowledge and skills in order to make professional judgements**
- be able to change their practice as needed to take account of new developments
- *maintain an adequate knowledge base of the main actions, indications, contraindications and evidence on safety on the herbs within their dispensary*
- *be aware of changes in guidance on quality assurance with regards to the quality of the herbal medicines dispensed*
- be able to demonstrate a level of skill in the use of information technology appropriate to their practice
- *be able to access e-mail and internet so that information on safety is received promptly*

2b.3 be able to formulate specific and appropriate management plans including the setting of timescales
- understand the requirement to adapt practice to meet the needs of different client groups distinguished by, for example, physical, psychological, environmental, cultural or socio-economic factors

2b.4 be able to conduct appropriate diagnostic or monitoring procedures, treatment, therapy or other actions safely and skilfully
- understand the need to maintain the safety of patients, clients and
- users, and those involved in their care

2b.5 be able to maintain records appropriately
- be able to keep accurate, legible records and recognise the need to handle these records and all other clinical iformation in accordance with applicable legislation, protocols and guidelines
- understand the need to use only accepted terminology (which includes abbreviations) in making clinical records
- *be able to implement procedures for record-keeping in the dispensary so that a full audit trail of all herbal medicines is possible*

2c Critical evaluation of the impact of, or response to, the registrant's actions

Registrant herbal/traditional medicine practitioners must:

2c.1 be able to monitor and review the ongoing effectiveness of planned activity and modify it accordingly

- be able to gather information, including qualitative and quantitative data, which helps to evaluate the responses of service users to their care
- be able to evaluate intervention plans using recognised outcome measures and revise the plans as necessary in conjunction with the service user
- recognise the need to monitor and evaluate the quality of practice and the value of contributing to the generation of data for quality assurance and improvement programmes
- be able to make reasoned decisions to initiate, continue, modify or cease treatment or the use of techniques or procedures, and record the decisions and reasoning appropriately
- understand that outcomes may not always conform to expectations but may still meet the needs of patients, clients or users

2c.2 be able to audit, reflect on and review practice

- understand the principles of quality control and quality assurance
- be aware of the role of audit and review in quality management including quality control, quality assurance and the use of appropriate outcome measures
- be able to maintain an effective audit trail and work towards continual improvement
- participate in quality assurance programmes, where appropriate
- understand the value of reflection on practice and the need to record the outcome of such reflection
- recognise the value of case conferences and other methods of review

Knowledge, understanding and skills

Registrants must:

3a.1 know and understand the key concepts of bodies of knowledge which are relevant to their profession-specific practice

- *have an adequate knowledge of the relevant materia medica*

3a.2 know how professional principles are expressed and translated into action through a number of different approaches to practice, and how to select or modify approaches to meet the needs of an individual, groups or communities

3a.3 understand the need to establish and maintain a safe practice environment

- be aware of applicable health and safety legislation, and any relevant safety policies and procedures in force at the workplace
- *where herbal practitioners manufacture herbal medicines, adequate training in methods of characterization of raw herbal ingredients, cultivation and collection of raw materials*

- be able to work safely, including being able to select appropriate hazard control and risk management, reduction or elimination techniques in a safe manner in accordance with health and safety legislation
- *manage the dispensary with regard to the safety of staff and service users*

Discussion of some relevant points pertaining to Standards of Professional Practice

1. Use of professional code to cover safe prescribing

The 2004 MHRA consultation on *Proposals for the reform of regulation of unlicensed herbal remedies in the United Kingdom made up to meet the needs of individual patients* [1] asks:

• *Do you agree on the central importance of requiring systematic professional accountability for those who wish to benefit from the exemption in s12(1)?*

• *Do you agree that best overall approach to improving s12(1) would be through a combination of updated medicines legislation and agreement with the profession on codes of practice?*

For the herbal/traditional medicine profession, these proposals represent the best scenario as codes of practice would remain profession-led.

Use of the professional code should promote safe practice and it should be possible for practitioners to be regularly updated, and advised to follow guidance promptly when new safety issues emerge. For this reason, a duty to have email access is added under 2b of the ***Standards of Proficiency*** (see above).

Detailed guidance on safe practice via the HPC should be informed by professional associations in regular consultation with the HPC. For reference, the Royal Pharmaceutical Society of Great Britain (RPSGB) has several guidance documents on safe practice published on its website (http://www.rpsgb.org.uk/).

For comparison, the RPSGB code gives more detail than the HPC Code: for example on Extemporaneous Preparation/Compounding (See Postscript 4 below for RPSGB Code on this matter

The RPSGB guidance for prescribing pharmacists states that, as far as possible, the pharmacist should not both prescribe and dispense. However, it is common practice for herbal/traditional medicine practitioners both to prescribe and to dispense or to supervise dispensing and this is unlikely to change. Therefore at 2b5 of the ***Standards of Proficiency*** we have added the phrase *"to implement procedures for record-keeping in the dispensary so*

that a full audit trail of all herbal medicines is possible." The Foster Report states that single-handed or lone practitioners may present more risk in healthcare[2]. Single-handed practice emphasises the need for good record-keeping.

2. Face to face consultation under 12(1)

The MHRA's discussion paper ***Reforms of s12(1) of the Medicines Act 1968: the requirement for a face to face consultation*** (8 Jan 07) suggests retaining the requirement for a face-to-face consultation[3]. Such a consultation and any relevant examination should be conducted in private. The requirement for a consultation should not include a conversation over-the-counter in shop with the possible exception of the arrangement for treatment of minor ailments via specialist outlets described below.

Item 8 of the HPC code for ***Standards of Conduct, Performance and Ethics*** dealing with "duties as a registrant" calls on registrants to "effectively supervise tasks you have asked others to carry out for you." It should also be noted that the current RPSGB code covers pharmacy technicians as well as pharmacists. In the light of these arrangements, it may perhaps be possible to develop codes for supervision by registered herbal/traditional medicine practitioners of staff in specialist outlets providing a service for treating minor, self-limiting ailments going beyond the sale of registered traditional medicinal products (licensed traditional medicine products under the THMPD are designed to be sold directly to the public for the treatment of minor, self-limiting conditions without the need for intervention by a health professional). It should, however, be borne in mind that there are some complex issues to be resolved here including the blurring of boundaries between the professional and retail sectors, the possible undermining of retail outlets marketing traditionally registered or licensed medicinal products and of registered practitioners themselves, and the need to comply with the regulations applying to industrially made products under Directive 2001/83/EC.

Lastly, prescribing arrangements by herbalists/traditional medicine practitioners would also evidently need to include guidance on repeat prescriptions. The MHRA consultation document refers to the General Medical Council guidance on remote prescribing[4]. Another relevant document is the RPSGB Code of Prescribing Pharmacists: "Guidance on remote prescribing via telephone, email, fax, video link or website" (Postscript 4 below).

3. Conclusion

Wording of profession-specific standards is a form of risk management. Risks must be identified, assessed for probability and monitored. Bearing in mind the requirements of the HPC Standards of Proficiency as laid down in 1a8 "understand both the need to keep skills and knowledge up to date and the

importance of career-long learning" the following aspects of herbal practice should be included in this process.

- Consultation, including clinical history, clinical examination and diagnosis (according to specific tradition).
- Appropriate advice and, where necessary, referral to another health professional.
- Prescribing herbal medicines of assured quality, prepared in a clean, orderly dispensary, with accurate labelling. Herbal medicines should be prescribed in the light of current knowledge (both traditional and modern).
- Care of the patient to be maintained throughout the treatment period. Any change of clinical circumstance should be monitored by the responsible herbal/traditional medicine practitioner leading to appropriate changes to prescribing/ advice or referral.
- Where required these aspects of practice can specifically be covered in the ***Standards of Proficiency*** (e.g. Paramedics have a long list of required skills). Particular emphasis is required on prescribing, responsibility for repeat prescribing, dispensary management and preparation of herbal medicines.

For reference:

Postscript 1

The following are a summary within current generic standards laid down by the HPC for

Standards of Conduct, Performance and Ethics

This means that you must always keep high standards of **conduct**. You must always:

1. Act in the best interests of your patients, clients and users;
2. Respect the confidentiality of your patients, clients and users;
3. Maintain high standards of personal conduct; and
4. Provide any important information about conduct, competence or health.

Also, you must always keep high standards of **performance**. You must always:

5. Keep your professional knowledge and skills up to date;
6. Act within the limits of your knowledge, skills and experience and, if necessary, refer on to another professional;
7. Maintain proper and effective communications with patients, clients, users, carers and professionals;
8. Effectively supervise tasks you have asked others to carry out for you;
9. Get informed consent to give treatment (except in an emergency);
10. Keep accurate patient, client and user records;
11. Deal fairly and safely with the risks of infection; and
12. Limit your work or stop practising if your performance or judgement is affected by your health.

Finally, you must always keep high standards of **ethics**. You must always:

13. Carry out your duties in a professional and ethical way;
14. Behave with integrity and honesty;
15. Follow our guidelines for how you advertise your services; and
16. Make sure that your behaviour does not damage your profession's reputation.

Postscript 2
Communication in English (excerpt from the generic HPC *Standards of Proficiency*)

1b: **Professional relationships**

Registrants must:

1b.4 **be able to demonstrate effective and appropriate skills in communicating information, advice, instruction and professional opinion to colleagues, service users patients, clients, users, their relatives and carers**

- be able to communicate in English to the standard equivalent to level 7 of the International English Language Testing System, with no element below 6.5
- understand how communication skills affect the assessment of patients, clients and users, service users and how the means of communication should be modified to address and take account of factors such as age, physical and learning disability
- be able to select, move between and use appropriate forms of verbal and nonverbal communication with patients, clients, service users and others
- be aware of the characteristics and consequences of non-verbal communication and how this can be affected by culture, age, ethnicity, gender, religious beliefs and socio-economic status
- understand the need to provide patients, clients and service users (or people acting on their behalf) with the information necessary to enable them to make informed decisions

Postscript 3
Outtake from RPSGB *Professional Standards and Guidance for the Sale and Supply of Medicines* (section 4) Extemporaneous Preparation or Compounding (Nov 07)

This standard is not intended to cover the reconstitution of dry powders with water or other diluents.
The public is entitled to expect that products extemporaneously prepared in a pharmacy are prepared accurately and are suitable for use. If you wish to be involved in extemporaneous preparation you must ensure that:

4.1 A product is extemporaneously prepared only when there is no product with a marketing authorisation available and where you are able to prepare the product in compliance with accepted standards.

4.2 You and any other staff involved are competent to undertake the tasks to be performed.
4.3 The requisite facilities and equipment are available. Equipment must be maintained in good order to ensure that performance is unimpaired, and must be fit for the intended purpose.
4.4 You are satisfied as to the safety and appropriateness of the formula of the product.
4.5 Ingredients are sourced from recognised pharmaceutical manufacturers and are of a quality accepted for use in the preparation and manufacture of pharmaceutical products. Where appropriate, relevant legislation must be complied with.
4.6 Particular attention and care is paid to substances which may be hazardous and require special handling techniques.
4.7 The product is labelled with the necessary particulars, including any special requirements for the safe handling or storage of the product, and an expiry date and any special requirements for the safe handling or storage of the product.
4.8 If you are undertaking large-scale preparation of medicinal products, all relevant standards and guidance are adhered to.
4.9 Records are kept for a minimum of two years. The records must include:

- the formula,
- the ingredients,
- the quantities used,
- their source,
- the batch number,
- the expiry date
- where the preparation is dispensed in response to a prescription, the patient's and prescription details and the date of dispensing.
- the personnel involved, including the identity of the pharmacist taking overall responsibility.

Postscript 4
Outtake from RPSGB *Professional Standards and Guidance for Pharmacist Prescribers (*section 3.6) "Guidance on remote prescribing via telephone, email, fax, video-link or website (Nov 07)

"From time to time it may be appropriate to use a telephone or other non face-to-face medium to prescribe medicines and treatments for patients. Such situations may occur where:

- You have responsibility for the care of the patient
- You are providing out of hours or urgent care services
- You are working in remote and rural areas
- You have prior knowledge and understanding of the patient's condition and medical history
- You have authority to access the patient's records and you are working as a supplementary prescriber, but the doctor / dentist

required to authorise the clinical management plan works at a distance

You must carry out an adequate risk assessment for each individual case of remote prescribing. Records of remote prescribing including the reasons for prescribing in this manner should be made."

August 2007

Note from the Herbal/Traditional Medicine Stakeholder Group on the Relevance to herbal and traditional medicine practitioners of The Health Professions Council (HPC) document Continuing Professional Development (CPD)

Definition

The HPC defines CPD as:

> "a range of learning activities through which health professionals maintain and develop throughout their career to ensure that they retain their capacity to practice safely, effectively and legally within their evolving scope of practice"

The Herbal/ Traditional Medicines Stakeholders Group agrees that this seems to be a good definition that the herbal/traditional medicine can adopt.

CPD and Compulsion

CPD is a **compulsory** requirement for ongoing registration with the HPC: *it seems clear that CPD must be compulsory for the Herbal/ Traditional Medicines sector too.*

Requirements of Practitioners

According to the HPC practitioners must:

- maintain a continuous, up-to-date and accurate record of their CPD activities;
- demonstrate that their CPD activities are a mixture of learning activities relevant to current or future practice;
- seek to ensure that their CPD has contributed to the quality of their practice and service delivery;
- seek to ensure that their CPD benefits the service user;
- present a written portfolio containing evidence of their CPD upon request.

Regarding what constitutes "evidence" the HPC says:

A range of evidence can be used, for example, letters from users, personal development plans, course assignments, business plans, learning contacts or guidance material, peer assessment forms, learning packages, workshop attendance and reflections, learning and reflections on dissemination of research/publications.

Further advice from the HPC:
You will be required to complete a portfolio which is a complete record of your CPD activities over a two year period and this should:

- Be updated regularly
- Focus on a two-year period
- Be accurate and reflect the activities undertaken.

Should you be selected for audit, you will be required to submit a profile as a demonstration that your CPD activities have met the Standards.
The profile will consist of:

- A summary of practice history for the last two years (maximum 500 words)
- A statement of how the CPD Standards have been met (maximum 1500 words)
- Evidence to support your statement.

According to the HPC:
Standard 2 – A registrant must demonstrate that their CPD activities are a mixture of learning activities relevant to current or future practice.
Your CPD should include 'a mixture of learning activities'. We do not need you to undertake a certain amount of CPD (for example, to do a number of hours or days). This is because we believe that different people will be able to dedicate different amounts of time to CPD, and also because the time spent on an activity does not necessarily reflect the learning gained from it. Under this standard, your CPD must include a mixture of learning activities – so you should include different types of learning activity in your CPD record.

The full HPC standards for CPD are:
Standard 1

- A registrant must maintain a continuous, up-to-date and accurate record of their CPD activities.

Standard 2

- A registrant must demonstrate that their CPD activities are a mixture of learning activities relevant to current or future practice.

Standard 3

- A registrant must seek to ensure that their CPD has contributed to the quality of their practice and service delivery.

Standard 4

- A registrant must seek to ensure that their CPD benefits the service user.

Standard 5

- A registrant must present a written profile containing evidence of their CPD upon request**.**

How is CPD checked?
According to the HPC:
When you renew your registration, you declare that you have undertaken CPD, maintained a record of that CPD and have met the standards. You must

also sign the declaration that you continue to practise and include the relevant fee. If we find that you have not met the necessary standards, we will give you a further opportunity to meet them within a prescribed time limit so long as you have made a genuine attempt to meet those standards. If you fail to meet those standards within the set time, we may remove you from the Register (although you have a right of appeal).

The onus is on the practitioner to "self-certify". This is an adult approach that empowers the individual. An individual practitioner's CPD profile can be checked at any time.

The HPC randomly sample practitioners to audit CPD (i.e. to check if they have done it). The sample size is between 5 and 2.5% of the membership[5].

Specific Details:
The CPD Standards process
The overall CPD Standards process will operate by:

- each registrant making a self-declaration at each registration renewal that they continue to meet the Council's Standards for CPD;
- sample audits of registrants taken at random from each section of the register;
- submission of a profile of evidence by registrants selected for sample audit;
- iv) assessment of profile against the Standards of CPD using appropriate and experienced partners.

Number of Hours/Points Required
The HPC does not have a set number of hours or points required for CPD. At first sight this seems odd but when one starts to question how exactly you might weight points or how many hours of self-study might be equivalent to a number of hours for attending a seminar (for example) one sees how it can be very hard to quantify.

Essentially the HPC scheme trusts that practitioners are active, responsible and committed to their own professional progress. This is an adult and professional approach that places emphasis on the individual practitioner to take charge of his/her own development.

Consequences of Failing to Meet CPD Requirements
According to the HPC:

> The Education and Training Committee, which is a statutory committee of Council, has the responsibility for registration and re-registration, has the right to refuse to renew a registrant's registration or may direct the

[5] The first HPC CPD audit will not take place until July 2008.

Registrar to remove the registrant's name from the Register. This is under article 10(2) (b) of the Health Professions Order, 2001.

This seems appropriate and something we could accept. Clearly there must be consequences for failing to keep up CPD.

What is Classed as CPD?
The HPC favours an approach to CPD that is flexible and non-prescriptive.

According to the HPC:
The range of CPD learning activity is extensive and includes:

- work-based learning. For example, reflective practice, clinical audit, significant event analysis, user feedback, membership of a committee, journal club;
- professional activity. For example, member of specialist interest group, mentoring, teaching, expert witness, presentation at conferences;
- formal/educational. For example, courses, undertaking research, distance learning, planning or running a course;
- self-directed learning. For example, reading journals/articles, reviewing books/articles, updating knowledge via www/TV/press;
- other activities. For example, public service.

Further guidance from the HPC as examples of CPD activity:

Registrant working in a clinical role

- Attending a short course on new laws affecting your work
- Appraising an article with a group of colleagues
- Giving colleagues a presentation on a new technique

Registrant working in education

- Being a member of a learning and teaching committee
- Doing a review for a professional journal
- Studying for a formal teaching award

Registrant working in management

- Being a member of an occupational group for managers
- Studying management modules
- Supporting the development and introduction of a national or local policy

Registrant involved in research

- Giving a presentation at a conference
- Being a member of a local ethics research committee
- Considering articles for scientific journals

When setting our standards for CPD, we realise that health professionals are already undertaking a wide range of CPD activities as part of their professional life. Our standards are not designed to increase the workload of health professionals registered with us, but to recognise the activities they are already undertaking.

The Herbal/ Traditional Medicine Stakeholder Group appreciate such a broad approach. There is also scope for an individual to include an activity that is not on this list as CPD. This scheme enables practitioners to tailor an individual CPD profile to meet their own learning and practice needs.

How is CPD Measured?
According to the HPC:
In determining the Standards for CPD, the Council recognise that registrants are already engaged in a diverse range of CPD activities as an integral part of their professional life. Some CPD activities are opportunistic and are taken on as an evolving component of working life. Following the response to the 2002 Consultation, the Council decided that the proposed scheme for CPD should not be based simply on the number of hours undertaken each year. The scheme should be based upon on-going learning and development, with a focus on individuals' learning achievements and how these enhance service delivery, either directly or indirectly.

The HPC provides details of how the CPD standards are assessed in their guidebook, *Continuing Professional Development and your Registration.*

CPD assessors
According to the HPC:
CPD assessors play a vital role in making sure the audit process runs smoothly. They are one type of what we call 'partners'. Other types of partner that we currently use include registration assessors, who make decisions about applications from people who trained outside the UK, and panel members who consider allegations and complaints about registrants.
When recruiting our CPD assessors we will:

- make sure we advertise openly for the roles;
- produce a shortlist of those who have the necessary skills, knowledge and experience; and
- interview all those shortlisted to make sure we have an appropriate number of CPD assessors drawn from a range of professional backgrounds.

We will then train CPD assessors to make sure they carry out their jobs fairly (and we will put information about how to become a CPD assessor on our website when we begin recruiting). Once CPD audits are underway, we will review the performance of CPD assessors to make sure decisions are being made consistently as far as possible.

Who Delivers CPD?
The HPC does not "organise, certify or manage CPD activities".

Given the range of activities that can constitute CPD, the number of providers is very broad and includes the practitioner themselves (e.g. they may prescribe a course of reading for themselves).

Clearly CPD providers will also include professional bodies, academic institutions and private CPD providers who might arrange activities such as professional seminars.

Can One Take a Break from CPD?
According to the HPC:

We agreed… to take account of the fact that many registrants need to take a break in their practice in order to, for example, care for children or other relations. From 2008, we will be randomly auditing registrants to ensure that they meet our CPD standards and, if you are on a two year break from practice when you are audited, you can write to us and request that your audit be deferred, if you wish. Then, when you begin practising again, you can re-commence your CPD, and keep a record of it, ready for when you are audited the next time (which would happen automatically after a deferral).

If you are out of practice for more than two years, then we recommend that you should come off the Register, and reapply for registration when you wish to practise again. While you are not registered, there are obviously no CPD requirements for you to fulfill.

When you apply for re-registration, if you have been out of practice for more than two years, you will need to complete an updating period of 30 days before you apply. If you have been out of practice for more than five years, you will need to complete an updating period of 60 days before you apply. This updating period can be made up of any combination of supervised practice, formal study or private study, providing that private study comprises no more than half of the whole period.

The H/TMSG agrees with this approach.

In addition, the H/TMSG makes the following points:

regarding CPD and Competence

- **CPD is not taken as a guarantee of competence. Other activities may need to be engaged in to prove this.**

regarding CPD and Revalidation
The HPC says this:

- The process whereby a registered professional is regularly assessed to make sure that they are fit to practise. (This is not the same as CPD, which is concerned with ongoing development and learning.)

The H/TMSG comments:

- **The probable future requirements for regulated herbal practitioners to be revalidated are still unclear. No detail is**

yet available. It seems certain however that it will be a separate process to CPD.

The Relationship of CPD to Fitness to Practice
The HPC says:

- Although within our legislation (Health Professions Order, 2001) there is no automatic link between CPD and fitness to practise (Part V of the Order), if your actions in relation to CPD amount to misconduct (for example making a false declaration or falsifying CPD records) this will lead to your fitness to practise being investigated. If, as a result, you are struck off the Register, you cannot apply to be registered again for at least five years.

CPD and Professional Bodies
The HPC has this to say (presented in a "Frequently Asked Question" style):

- I do not wish to become a member of my professional body who I know offer their own CPD courses and programmes. What is the best way to meet the HPC requirements for CPD without becoming a member of my professional body?

- **You do not have to be a member of a professional body in order to meet the HPC's Standards for CPD. In terms of the types of CPD activities, we have produced a suggested list (which is not exhaustive) from which you may wish to select those which best meet your needs. You may also choose to be a member of your own professional body and meet those requirements. This is at your own discretion and does not affect or influence your HPC registration.**

We have been told that one of the roles for professional bodies post-regulation will be the provision of CPD. There is no mandatory requirement, however, for practitioners to take up professional body CPD . Clearly it will be down to professional bodies to make their CPD so attractive that practitioners will wish to choose it.

Comparisons
The General Medical Council is much more specific than the HPC as regards the content of CPD – specifying, but not limiting, the kind of areas that CPD should cover.

The HPC CPD scheme is broadly in accordance with the "Ten Principles for Continuing Professional Development" given by the Academy of Medical Royal Colleges (Postscript 1), though they do quantify the amount of CPD credits required (equivalent to 50 hours spent on CPD per year).

CPD and the White Paper: *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century*[5].

There is only one mention of CPD in the Paper:

> 23. The Government recognises the gains to be secured from single oversight of medical education, but believes that change should be introduced in such a way as to preserve the expertise and experience of the present organisations that undertake this role. The Government agrees with the proposal, set out in the GMC's response to consultation, for a three-board model covering undergraduate education, postgraduate education and continuing professional development. The Department will work with the GMC to establish an undergraduate board and a continuing professional development board in the GMC. The Postgraduate Medical Education and Training Board will continue as a separate legal entity, fulfilling the role of the postgraduate board within this three-board.

Conclusion and Recommendations from the H/TMSG

The HPC CPD policy is clear and well supported by documents that effectively explain the process to practitioners. The scheme is innovative and flexible and should easily provide scope for herbal/ traditional medicine practitioners to build a mixed CPD portfolio as the HPC requires. Whilst some of the CPD options might be more readily available for practitioners working in employed NHS settings there remain a wide range of options suitable for self-employed independent practitioners to utilise. There is also scope for practitioners to provide a rationale for any extra CPD activities they can identify which are not already listed.

CPD assessors will need to be sensitive to the work of herbal and traditional medicine practitioners but no significant problems are anticipated since the assessment process is essentially generic.

Attainment of appropriate CPD status would not appear to be at all onerous. In fact some might criticise the scheme for being a little too open and non-prescriptive. Certainly there would seem to be nothing here about which the herbal/traditional medicine sector should have concerns.

CPD does not demonstrate competence and this is a major limitation of the concept. The nature and extent of CPD can vary greatly from one individual to another. The emerging emphasis on revalidation responds to the need to prove ongoing competence – something CPD cannot provide. The relationship between CPD and revalidation will be one to watch as time goes on.

The HPC CPD scheme should not present a major extra workload for herbal/traditional medicine practitioners– for the most part it should be simply a case of recording what is already being done.

The H/TMSG recommends the acceptance of this scheme as it stands.

Resources:

HPC – Continuing Professional Development: Key Decisions, 2006
HPC – Your Guide to Our Standards for Continuing Professional Development
HPC - Continuing Professional Development and your Registration
HPC – Website: Frequently Asked Questions re. CPD
www.gmc-uk.org

Postscript 1

Academy of Medical Royal Colleges

PRINCIPLES FOR COLLEGE/FACULTY CPD SCHEMES

1. An individual's CPD activities should reflect and be relevant to their profile of professional practice and performance. This should include continuing professional development outside narrower specialty interests.
2. CPD should include activities both within and outside the employing institution (where there is one) and a balance of learning methods which include a component of active learning. Participants will need to collect evidence to record this process, normally using a structured portfolio cataloguing the different activities. This portfolio will be available for appraisal and revalidation.
3. College/Faculty CPD schemes should be available to all members and fellows and, at reasonable cost, to non-members and fellows who practise in a relevant specialty.
4. Normally, credits given by Colleges/Faculties for CPD should be based on one credit equating to one hour of participation. The minimum required should be an average of 50 per year. Credits for un-timed activities such as writing, reading and e-learning should be justified by the participant or should be agreed between College/Faculty directors of CPD.
5. Participation in College/Faculty based CPD schemes should be acknowledged by a regular statement issued to participants based on annually submitted returns.
6. In order to quality assure their CPD system, Colleges/Faculties should fully audit participants' activities on a random basis. Such peer-based audit should verify that claimed activities have been undertaken and are appropriate. Participants will need to collect evidence to enable this process.
7. The proportion of participants involved in random audit each year should be of a size to give confidence that it is representative and will vary according to the number of participants in a given scheme.
8. Self-accreditation of relevant activities and documented reflective learning should be allowed and encouraged. Formal approval of the quality of educational activities for CPD by Colleges/Faculties should be

achieved with the minimum bureaucracy and with complete reciprocity between Colleges/Faculties for all approved events.

9. Self-accreditation of events will require evidence. This may be produced as a brief reflective note. Formal CPD certificates of attendance at meetings will not be a requirement. Other evidence of attendance should be provided, as determined by each individual College or Faculty. Signed registers are only necessary where there is no other available evidence of attendance.
10. Failure when challenged to produce sufficient evidence to support claimed credits will result in an individual's annual statement being endorsed accordingly for the year involved and the individual subsequently being subject to audit annually for a defined period. Suspected falsification of evidence for claimed CPD activities may result in referral to the GMC/GDC.

Suggestions for Protected titles: From Herbal/Traditional Medicine Stakeholders Group

The H/TMSG is of the opinion that there are still many matters to be resolved over the question of titles and notes that the European Herbal and Traditional Medicine Association wishes to continue discussions on this subject with the DH and HPC post publication of these Steering Group and Stakeholder Groups' reports. **Table 1** below indicates some possible titles proposed by the H/TMSG for further discussion:

GENERIC	TRADITION	TITLE
Herbal/Traditional Medicine Practitioner	Ayurveda	Ayurvedic Practitioner
	Traditional Chinese Medicine	Traditional Chinese Medicine Practitioner
		Chinese Herbal Medicine Practitioner
	Traditional Tibetan Medicine	Traditional Tibetan Medicine Practitioner
	Unani Tibb	Unani Tibb Practitioner
	Western Herbal Medicine	Herbalist
		Western Herbal Medicine Practitioner
		Medical Herbalist

National Professional Standards for Herbal Medicine

The following are excerpts describing the training, knowledge and activity of professional herbalists/traditional practitioners in the western, Chinese and Tibetan traditions originally published in July 2003.

Element HM1.1 Evaluate and process requests for herbal medicine

Performance criteria

You will need to:

1. evaluate *requests for services* for their appropriateness
2. advise clients to consult other healthcare practitioners where appropriate
3. communicate in a manner which is understandable by the client
4. establish the client's *particular requirements* through sensitive questioning
5. assess the severity of the client's needs or the risk of their condition deteriorating
6. ensure that any fee structures, charges and different methods of payment are clearly understood
7. explain possible outcomes, charges and duration of services to the client
8. arrange a suitable time and location for the consultation and agree those who should be present
9. record arrangements made for the consultation fully and accurately

Scope:

1. *Requests for services from:*
   a) potential or current clients
   b) someone acting on behalf of the client (e.g. a parent, carer or appointed person)
   c) other healthcare practitioners

2. *Particular requirements in relation to:*
   a) the client's personal beliefs and preferences
   b) the client's age, sex and physical condition
   c) communication differences
   d) physical support and access
   e) emotional and psychological support

Element HM1.2 Prepare to assess the client

Performance criteria

You will need to:

1. ensure that the consultation environment is appropriate for the client and their needs
2. present a *professional appearance* and be prepared and fit to carry out the consultation
3. ensure that any equipment, materials, and surrounding *work area* are prepared and meet professional codes of practice, legal and organisational requirements
4. introduce the client to those present, *confirm individual roles* and obtain consent if relevant for others to be present
5. *communicate* effectively and in a manner which maintains client goodwill, trust and confidentiality
6. explain the nature, scope and duration of the consultation and any related interventions
7. encourage the client to ask questions, seek advice and express any concerns about the consultation
8. obtain the consent of the client to any physical examination
9. interact with any companion(s) of the client in ways that are appropriate to the needs of all parties involved

Scope:

1. *Professional appearance:*
   a) own presentation including appropriate dress
   b) personal hygiene

2. *Work area is suitable in terms of:*
   a) ventilation
   b) lighting
   c) heating
   d) level of noise
   e) privacy
   f) space
   g) cleanliness and orderliness

3. *Confirm individual roles in relation to:*
   a) the client's identity
   b) the companion's identity
   c) the role which the client wishes their companion to have and the information the companion should receive
   d) the identity and roles of any practitioners/students present

4. *Communicate using:*
   a) speech
   b) actions, gestures and body language
   c) space and position
   d) the written word or illustrations

Element HM1.3 Assess the client

Performance criteria

You will need to:

1. respect the client's privacy and dignity throughout the consultation and ensure they are as comfortable as possible
2. conduct the consultation in a manner which encourages the effective participation of the client and meets their *particular requirements*
3. support the client to identify significant *aspects of their lives* and use this to inform the consultation
4. determine any *contra-indications or restrictions* to physical examination and investigation and take appropriate action
5. use *examination and investigation methods* which are safe, appropriate to the *client's presenting condition* and comply with professional and legal requirements
6. use systematic questioning and appropriate physical examination to establish a *diagnosis*
7. seek advice and support from an appropriate source when the needs of the client and the complexity of the case are beyond your own remit or capability
8. inform the client when additional information is required and obtain their consent to obtain the information
9. evaluate the information obtained for and during the consultation and determine appropriate action
10. ensure records are signed, dated and include all relevant details and any supporting information

Scope:

1. *Particular requirements in relation to:*
   a) the client's personal beliefs and preferences
   b) the client's age, sex and physical condition
   c) communication differences
   d) physical support and access
   e) emotional and psychological support

2. *Aspects of the client's life to explore:*
   a) history of the client's health, effective functioning and well-being (physical, emotional, psychological) including any particular conditions and treatments

b) lifestyle including diet, exercise and outlook
c) work history
d) social, cultural and family history
e) environmental factors

3. *Contra-indications or restrictions:*
a) where pathology may be present that would put client at risk if an examination was carried out
b) where legislation does not allow
c) where not qualified e.g. to take blood

4. *Examination/investigation methods:*
a) invasive investigative technique e.g. taking blood, scraping skin (where qualified)
b) intimate physical examinations
c) blood pressure
d) general physical examinations

5. *Client's presenting condition:*
a) acute
b) chronic
c) mild
d) severe

6. *Diagnosis in relation to:*
a) balance across physical, psychological, emotional and social condition
b) all the client's signs and symptoms
c) symptoms for which treatment is to be provided with caution
d) factors that predispose to or that aggravate the symptoms

UNIT
HM2 Provide a treatment and management plan to meet the needs of the client
Elements of competence
HM2.1 Negotiate and formulate the treatment and management plan with the client
HM2.2 Evaluate the effectiveness of the herbal medicine treatment
HM2.3 Complete post consultation activities

Unit Summary
This unit again is based on the premise that for effective treatment planning and implementation to take place, you need to understand the context of the client and the holistic nature of health, effective functioning and well-being. You must be able to communicate effectively with clients and any companion(s) of the client and integrate your work with that of other practitioners. Throughout the process, clients and any companion(s) are encouraged and supported to take an active part and this is enhanced by you

using, as far as is possible, interventions which are sustainable by the client in their own context.

1. Element one involves negotiating and formulating a treatment and management plan with the client. This includes giving dietary and lifestyle advice and explaining how to handle positive and adverse outcomes of the treatment.
2. Element two is about evaluating the effectiveness of the herbal medicine treatment. It includes making any adjustments to the treatment to accommodate any changes in the needs of the client and agreeing future treatment sessions.
3. Element three is concerned with completing post-consultation activities such as recording the outcomes of the consultation, writing the prescription and dealing with between consultation communications from clients. It is also concerned with evaluating the effectiveness of the herbal dispensary, which you may or may not run yourself.

Knowledge and Understanding

The knowledge and understanding needed to support competent performance of the standards in this unit are presented further on in this document[6].

Element HM2.1 Negotiate and formulate the treatment and management plan with the client Performance criteria

You will need to:

1. ensure information about the client is sufficient to plan the treatment
2. explain the outcomes of the consultation clearly and in a manner that is *understandable by the client*
3. discuss your initial diagnosis and potential outcomes with the client, check their understanding and support them to make informed choices
4. explain the available treatment *options and methods* which meet the client's circumstances, identified needs and their personal beliefs and preferences
5. obtain the consent of the client to proceed with formulating the treatment and management plan and determine any issues of confidentiality with the client and confirm their agreement
6. balance *potential outcomes* with any inherent risks and the legal duty of care to the client
7. advise the client when herbal medicine is unsuitable and enable them to seek other healthcare where appropriate
8. devise and provide dietary and lifestyle advice in consultation with the client

[6] *where 'client' is referred to, read also 'patient' and 'customer';*
where 'companion' is referred to, read also 'representative', 'partner', 'relative', 'friend of client', 'another healthcare practitioner' and 'appointed chaperone'.

9. discuss with the client the content, level of risk, duration, frequency of visits and projected costs of the proposed action and explain how the treatment will be evaluated and reviewed
10. finalise the treatment and management plan and explain any restrictions to the use of herbal medicines and advise on realistic expectations
11. offer clear and accurate *aftercare advice and support* to the client where needed
12. interact with any companion(s) of the client in ways that are appropriate to the needs of the client and to your needs

Scope:

1. *Understandable by the client taking into account their:*
   a) current state of health, effective functioning and well-being
   b) personal beliefs and preferences
   c) age and level of understanding
   d) cultural and social background
   e) awareness and understanding of their condition

2. *Options and methods:*
   a) internal preparations
   b) external preparations
3. *Potential Outcomes:*
   a) positive
   b) adverse

4. *Aftercare advice and support:*
   a) how to handle positive outcomes of the treatment
   b) how to handle adverse reactions to the treatment
   c) how to communicate with you between consultations

Element HM2.2 Evaluate the effectiveness of the herbal medicine treatment

Performance criteria

You will need to:

1. discuss the *outcomes* of the overall treatment and management plan and its effectiveness in a manner, level and pace suited to the client
2. encourage the client to *evaluate* their herbal medicine treatment and suggest possible modifications
3. encourage clients to take responsibility for their own health, effective functioning and wellbeing
4. advise the client where herbal medicine is unsuitable and enable them to seek other healthcare where appropriate

5. make appropriate adjustments to the treatment to meet the client's changing needs
6. obtain the client's consent to pass on confidential information where appropriate
7. negotiate the duration and frequency of subsequent treatment sessions with the client
8. interact with any companion(s) of the client in ways that are appropriate to the needs of the client and to your needs

Scope:

1. *Outcomes:*
   a) improvement of the client's health, effective functioning and well-being
   b) maintenance and stability
   c) palliation
   d) deterioration in the client's health, effective functioning and well-being

2. *Evaluation includes:*
   a) client's experience of the treatment and management plan
   b) extent to which the treatment and management plan has met the needs of the client
   c) the client's broader needs
   d) your experience and the client's experience of using the dispensary
   e) other factors which may have affected the effectiveness of the treatment and management plan

Element HM2.3 Complete post-consultation activities

Performance criteria

You will need to:

1. record the *outcomes* of the consultation accurately and in sufficient detail to meet professional requirements
2. write the prescription in a form suitable for dispensing
3. provide *written advice* for the client, where necessary
4. respond to requests for *aftercare advice and support* from clients
5. store the records securely
6. evaluate the experience you have gained from treating the client to inform future practice
7. evaluate the effectiveness of Standard Operating Procedures and legal and ethical procedures carried out by the herbal dispensary

Scope:

1. *Outcomes:*
   a) differential diagnosis

b) referral
c) lifestyle change
d) dietary change
e) herbal treatment plan
f) details of future visit
g) adverse events notification 'yellow card scheme'

2. Written advice in relation to:
a) herbal medicine
b) lifestyle
c) diet

3. *Aftercare advice and support:*
a) how to handle positive outcomes of the treatment
b) how to handle adverse reactions to the treatment

UNIT
HM3 Dispense herbal medicines and products
Elements of competence
HM3.1 Receive and validate herbal prescription
HM3.2 Assemble and label required herbal medicine(s) or product(s)
HM3.3 Issue prescribed herbal medicine(s) or product(s)

Unit Summary
This unit details the requirements for activities to be carried out either by you as a herbal practitioner, or a trained dispenser acting on your behalf.
You will at all times work within **Standard Operating Procedures (SOPs)** that relate to the way in which you provide the herbal medicine dispensing service. You will also work within the ethical and legal requirements for the provision of a herbal medicine dispensing service.

1. The first element covers how you, or your dispenser, would receive and validate a herbal prescription.
2. The second element covers the actual preparation of the prescribed items, it also covers extemporaneous dispensing. You will need to accurately calculate the quantities of the ingredients needed, make, pack and label the product correctly taking account of relevant legal requirements. Health and Safety and Control of Substances Hazardous to Health (COSHH*)* regulations are especially important.
3. The third element covers the issuing of the prescribed medicine(s) or product(s) to the client and the giving of information and advice to ensure that the client receives the correct treatment. When reading this unit it is important to bear in mind that some of the criteria will refer to a herbal dispenser's activities and that these may not always be relevant to practitioners making up their own prescriptions.

Knowledge and Understanding
The knowledge and understanding needed to support competent performance of the standards in this unit are presented further on in this document[7].

Element HM3.1 Receive and validate herbal prescription

Performance criteria

You will need to:

1. ensure that client confidentiality is maintained at all times
2. check the client details on the prescription and confirm that they are clear and correct
3. give the *appropriate information* to the client
4. carry out all transactions promptly and correctly
5. forward the prescription for validation and preparation
6. check that prescription is *correctly written*
7. refer the prescriptions to the *relevant person* if you are unsure about any aspect, you must make the appropriate annotation on the prescription
8. handle all queries in a courteous manner
9. confirm that prescriptions are valid and are not a forgery

Scope:

1. *Appropriate information:*
   a) prescription fees
   b) waiting and collection times
   c) alternative delivery services
   d) availability of medicine/product

2. *Correctly written:*
   a) name, address and personal details of the client
   b) dosage, time and frequency of administration
   c) the method of administration
   d) additional instructions to the client
   e) list of contents, with scientific names, using full Latin binomials and/or tradition specific names where relevant
   f) strengths and quantities
   g) form of treatment

3. *Relevant person:*
   a) herbalist

[7] where 'client' is referred to, read also 'patient' and 'customer';
where 'companion' is referred to, read also 'representative', 'partner', 'relative', 'friend of client', 'another healthcare practitioner' and 'appointed chaperone'.

b) client
c) client's representative

Element HM3.2 Assemble and label required herbal medicine(s) or product(s)

Performance criteria

You will need to:

1. ensure that the medicine(s) or product(s) matches the prescription
2. ensure that the medicine(s) or product(s) will remain in date for the course of treatment (as stated on the prescription)
3. ensure the preparation area and equipment is clean and ready for use
4. measure are accurate and meet the prescription requirements
5. and process
6. produce the required labels that meet all the legal and local requirements
7. ensure that the medicine(s) or product(s) is/are checked, packed and labelled appropriately
8. endorse the prescription appropriately
9. complete all relevant records legibly and accurately
10. ensure the work area and equipment is cleaned and maintained ready for use
11. follow the health, hygiene and safety procedures and avoid all distractions whilst fulfilling the prescription

Scope:

1. *Medicine(s) or products:*
   a) solid forms (raw, processed)
   b) liquid forms (oral, topical)
   c) preparations to be taken internally
   d) preparations to be used externally
   e) pre-packed products
   f) restricted herbs

Element HM3.3 Issue prescribed herbal medicine(s) or product(s)
Performance criteria

You will need to:

1. ensure that client confidentiality is maintained at all times
2. confirm the client's identity and that it correctly matches with the prescription
3. provide to the client advice and *information* relating to the use of the prescribed *medicine or product* clearly and accurately and in the most appropriate *format*

4. confirm the client's understanding of any advice or information you give
5. correctly identify any over the counter needs and assess when the client should be referred to a herbalist
6. issue the *medicine or product* correctly, checking it matches the prescription, all details are correct and all the necessary *consumables* are provided

Scope:

1. *Information:*
   a) dosage and usage
   b) contra-indications
   c) storage
   d) side effects
   e) food/drink interactions
   f) repeat supply
   g) expiry date
   h) other medications
   i) outstanding balance of the prescription

2. *Medicine/product:*

   a) raw and processed
   b) internal preparations
   c) external preparations

3. *Formats - in a way that is appropriate for the client and the herbal medicine or product:*

   a) written
   b) oral
   c) demonstration

4. *Consumables:*
   a) client information
   b) spoons/measuring tumblers
   c) syringes/droppers

Knowledge and Understanding

The knowledge and understanding needed to support competent performance of the standards in units HM1 and HM2 is presented under a number of headings as follows:

1 Technical knowledge and understanding

A. Anatomy, physiology and pathology
B. Nutrition and dietary advice

C. Clinical sciences
D. Plant chemistry and pharmacology
E. Pharmacognosy and dispensing
F. Western herbal medicine
G. Traditional Chinese herbal medicine (*materia medica*)
H. Traditional Tibetan herbal medicine
I. Therapeutics

2 Applied technical knowledge and understanding

J. The scope and methods of herbal medicine
K. Assessing the client's needs and the appropriateness of herbal medicine
L. Providing a herbal medicine treatment and management plan
M. Evaluating and reviewing the effectiveness of the herbal medicine treatment and management plan

3 Professional and practice knowledge and understanding

N. Professional standards and codes of practice
O. Legislation
P. Employment and organizational policies and practices
Q. Communication and the professional relationship
R. Work role and practice - reflecting and developing
S. Confidentiality
T. Consent
U. Practice management
V. Health, effective functioning and well-being

Technical knowledge and understanding for units HM1 and 2

You need to know and understand:

A Anatomy, physiology and pathology

1. structure and functions of the cells and their components
2. structure and functions of tissues: epithelium, connective tissue, membranes
3. structure and functions of biomolecules: carbohydrates, lipids, proteins, co-factors, enzymes
4. the metabolism of carbohydrates, lipids and proteins including control and integration
5. structure and functions of the musculoskeletal system: bones, joints, muscles, ligaments
6. structure and functions of the nervous system: central and peripheral systems, autonomic nervous system, sense organs
7. structure and functions of the endocrine system: hypothalamus and the pituitary gland, thyroid gland and adrenal glands, feedback control

8. structure and functions of the lymphatic system: the lymphoid tissues and lymphatic circulation, natural (innate) resistance to disease, immunity
9. structure and functions of the cardiovascular system and components of blood and blood clotting
10. structure and functions of the respiratory system
11. structure and functions of the digestive system
12. structure and functions of the genito-urinary system and prenatal and postnatal growth and development
13. how to recognise conditions:
    - for which herbal medicine is appropriate
    - where herbal medicine must be used with caution
    - for which herbal medicine is contra-indicated
    - for which herbal medicine is inappropriate

B Nutrition and dietary advice

1. the structural characteristics and function of key macronutrients and micronutrients
2. the processes involved in the catabolism of food components
3. terms used in Western dietetics to include RDA, RDI, DRV, EAR, LRNI, RNI, safe intakes, BMR, BMI, PAL and bioavailability
4. the effects of food additives, processing and drugs on nutrition
5. how to evaluate dietary assessment methodologies such as weighed dietary and portion records, questionnaires and surveys, food tables
6. the similarities and differences between different dietary approaches
7. dietary needs at different stages of development
8. the relationships between diet and disease
9. diets for individual specific cases
10. the relationship between herbal medicines and diet

C Clinical Sciences

1. the diagnostic techniques and clinical applications in orthodox medical practice and how to compare and contrast them with your traditional herbal medicine
2. the distribution of disease in the community and the approach to prevention from the orthodox and holistic points of view
3. how normal cell and tissue structure and function can change to produce genetic changes, abnormal cell growths, tissue injury, inflammation and repair
4. the general nervous, endocrine and metabolic responses to ageing, stress and tissue injury
5. the principles of infection and the ways in which alterations in natural and acquired defences (immunity) can lead to disease
6. the consequences of changes in the circulation, resulting from vascular narrowing and obstruction, fluid excess and loss and organ failure
7. diseases leading to the differential diagnosis of common symptoms and signs affecting the covering and support systems of the body (skin, joints and bone), control systems (nervous

8. and endocrine systems) and maintenance systems (cardiovascular, respiratory, gastrointestinal and urinary systems)
9. how to take effective case histories
10. how to perform a clinical examination of the major body systems
11. how to interpret basic pathology laboratory data and results of investigative procedures
12. the major actions and side effects of the major classes of orthodox drugs and how to access drug information (use of National Formularies etc)
13. how to recognise potentially serious signs and symptoms and when to refer clients to orthodox medical practitioners

D Plant chemistry and pharmacology

1. the nature and properties of plant substances
2. the procedures for chemical identification tests
3. the value and uses of chemical identification tests and separation techniques
4. the pharmacological effects of the major groups of plant compounds
5. the mode of action of common medicinal plants
6. the limitations of plant biochemistry as an explanatory model for herb actions
7. how to carry out information searches and evaluate current information on plant biochemistry and phyto-pharmacognosy

E Pharmacognosy and dispensing

1. the processes and issues of quality assurance in relation to herbal medicines
2. the identifying characteristics of commonly used herbs
3. the botanical terms used to describe herbs, including Latin terms and/or tradition specific names where relevant, for parts of plants
4. the legal requirements relating to the storage, labelling and dispensing of herbal medicine
5. the different forms of administering herbs and how to select the most appropriate form
6. the procedures for interacting with pharmacists, licensing authorities, the medical profession and toxicologists

F Western herbal medicine

1. the taxonomy and morphology of medicinal plants. How to recognise and identify a wide range of medicinal plants both growing and dried. How to use botanical reference material
2. how to classify plants according to their actions e.g. as stimulants, astringents etc. How to relate the action of an individual herb to its indications in treatment
3. the pharmacological actions of medicinal plants on the body in health and disease and which specific tissues, organs and physiological systems are affected by the administration of a given medicinal plant.

The influence of plant remedies on the psycho-social and spiritual aspects of a client's being

4. the relative merits of whole plant preparations, standardised extracts and isolated plant constituents for application in holistic treatment
5. the dosage range for a wide range of medicinal plants
6. the contraindications and incompatibilities of a wide range of medicinal plants
7. the role of rationality, intuition and experience in prescribing treatment
8. the relative merits of simple and/or complex herbal prescriptions
9. the debate concerning the use of native versus foreign herbal remedies
10. conservation issues as they relate to herbal medicine. The merits of organic and wildcrafted herbs

G Traditional Chinese herbal medicine

1. the history and fundamental characteristics of Chinese medicine including the stages of development and literary landmarks; holism – seeing patterns of disharmony and the relationship between Traditional Chinese Medicine and Western Medicine in modern China
2. the concept of Yin-Yang, the basic aspects of the Yin-Yang relationship and the medical applications of Yin-Yang
3. the concept of the Five Phases, the Five Phase relationships of engendering (Sheng), restraining (Ke), rebellion (Wu) and overwhelming (Chang) and the medical applications of the Five-Phase concept
4. the fundamental substances in Traditional Chinese Medicine i.e. Qi – as a central concept in Chinese philosophy and medicine; the sources, functions and forms of Qi Blood (Xue) – the sources and functions of blood and the relationship to Qi and to the Zang Fu; Essence (Jing) – the characteristics and functions of essence; Spirit (Shen) – the characteristics and manifestations of spirit; Body Fluids – the characteristics and functions of thinner fluids (Jin) and thicker fluids (Ye)
5. the function of the internal organs including:
    - differences between the Zang Fu in Chinese Medicine and the anatomical organs of Western medicine
    - the Five Yin organs (Wu Zang): the functions of the heart (Xin)/pericardium (Xin bao); the liver (Gan); the spleen (Pi); the lungs (Fei); the kidneys (Shen) and the relationships between the Zang,
    - the Six Yang organs (Liu Fu): the functions of the gall bladder (Dan); stomach (Wei); small intestine (Xiao Chang); large intestine (Da Chang); bladder (Pang Guang); triple burner (San Jiao) and their relationships with the Zang
    - the Extraordinary organs (Qi Heng Zhi Fu): the functions of the brain (Nao); the marrow (Sui); bone (Gu); vessels (Mai); the uterus (Zi Gong) and the gall bladder (Dan)

6. the functuion of the channels (Jing) and network vessels (Luo Mai) i.e. the distinction between channels (Ping) and network vessels (Luo Mai) the channel system: the twelve regular channels (Shi Er Jing Mai); the eight extraordinary channels (Qi Jing Ba Mai); the channel divergences (Jing Bie); the channel sinews (Jing Jin); the cutaneous regions (pi bu); the relationship between the channels and the Zang Fu
7. the causes of diseases (aetiology): external causes: the six pathogenic factors (Liu Xie): wind (Feng), cold (Han), heat (Re) or fire, (Huo), dampness (Shi), dryness (Zao), (summer-) heat (shu) and the relationship between the normal or upright (Zheng) Qi and pathogenic or evil (Xie) Qi. internal causes: the seven emotions (Qi Qing): joy (Xi), anger (Nu), worry (You), pensiveness, (Si), sadness (Bei), fear (Kong), fright (Jing) not external and not internal causes (Bu Nei Wai Yin): diet, imbalances of work and rest, sexual excesses. miscellaneous factors including trauma, burns, bites, parasites.
8. how to identify patterns (Bian Zheng) of disharmony (pathology) according to: the eight principles (Ba Gang): patterns of the interior (Li) and exterior (Biao); cold (Han) and heat (Re); deficiency (Xu) and excess (Shi); Yin and Yang Qi, blood and body fluids: Qi deficiency (Qi Xu), Qi sinking (Qi Xian), Qi stagnation (Qi Yu), Qicounterflow (Qi Ni); blood deficiency (Xue Xu), blood stasis (Xue Yu), blood heat (Xue Re); oedema (Shui Zhong), distinction between thin mucus (Yin) and phlegm (Tan); phlegm patterns (Tan Zheng) including phlegm heat (Tan Re), damp phlegm (Shi Tan), cold phlegm (Han Tan), wind phlegm (Feng Tan), Qi phlegm pathogenic factors: wind patterns (Feng Zheng): wind cold (Feng Han), wind heat (Feng Re),wind dampness (Feng Shi); damp patterns (shi zheng): cold dampness (Han Shi), damp heat (Shi Re); cold patterns (Han Zheng): excess cold (Shi Han), deficiency cold (Xu Han); heat/fire patterns (Re-/Huo Zheng): excess heat (Shi Re), deficiency heat (Xu Re); summer heat pattern(Shu Zheng); dryness patterns (Zao Zheng) the internal organs: patterns of the heart/pericardium, lung, liver, spleen, kidney; patterns of the stomach, small intestine, large intestine, gall bladder, bladder, triple burner the six stages (Liu-Jing): in accordance with the theory of injury by cold: greater yang (Tai Yang), yang brightness (Yang Ming), lesser yang (Shao Yang), greater yin (Tai Yin), lesser yin (Shao Yin), absolute yin (Jue Yin) the four levels: in accordance with the theory pf warm diseases: defence aspect (Wei Fen), Qi aspect (Qi Fen), nutritive aspect (Ying Fen), blood aspect (Xue Fen)
9. methods used to examine clients: looking – the Shen, physical shape and movement, facial colour, tongue, other external manifestations: eyes, nose, ears, mouth/lips/teeth/gums, throat, limbs, skin listening and smelling – sound of the voice; breathing cough; body odours asking about – sensations of cold and hot; sweating; headaches and dizziness; pain/aching/numbness in whole body, in joints, in back, in limbs; chest and abdomen:including epigastric and lower abdominal fullness and pain, oppression of the chest, palpitations, shortness of breath, hypochondriac pain; stools and urine; thirst, appetite and diet,

tastes in the mouth, nausea/vomiting; ears and eyes: including tinnitus, hearing loss, pain or pressure in the eyes, blurred vision, floaters; sleep; vitality; mental-emotional state; gynaecological: cycle, periods, discharges; paediatric: including special events during pregnancy, traumas at birth, breast-feeding and weaning, vaccinations; medical history;medication
touching – the pulse: method of palpation; levels of pressure; pulse positions; pulse qualities including: floating (Fu), sinking or deep (Chen), slow (Chi), rapid (Shuo), empty (Xu), full (Shi), thin or thready (Xi), wiry or stringlike (Xian), slippery (Hua), tight (Jin), flooding (Hong), soggy (Ru) or soft (Ruan), choppy (Se), knotted (Jie), interrupted (Dai), and hurried (Cu); integration of positions and qualities; palpating the skin, the hands and feet, the epigastrium and abdomen

10. the principles (Zhi Ze) and methods (Zhi Fa) of treatment i.e. treating in accordance with the season, the locality, and the individual supporting the upright (Zheng) Qi and expelling the evil (Xie) Qi treating the manifestation (Biao) and the root (Ben) straightforward treatment (Zheng-zhi) and paradoxical treatment (Fan-zhi) the eight methods (ba fa) of treatment: sweating (han), vomiting (Tu), draining downward (Xia), harmonising (He), warming (wen), clearing (Qing), reducing (Xiao), tonifying (Bu), applications, variations, contraindications
11. the differentiation and treatment of common diseases (refer to the list provided by the Regulatory Authority)
12. the identification, harvesting and storage of Chinese herbs
13. the preparation and treatment of Chinese herbs
14. the natures and properties of Chinese herbs i.e. four Qi and five tastes ascending, descending, floating and sinking repairing and draining; targeting of channels, categories of herbs
15. the utilisation of Chinese herbs including: combining herbs contraindications: symptomatic contraindications, contraindicated combinations, contraindications for pregnant women, contraindicated food and drink dosage: as determined by the nature of the herbs, as determined by the combination and the type of prescription, as determined by the disease situation, the constitution and age of the client administration
16. the name, category, properties (four Qi and five tastes), actions and indications, dosage, contraindications, main combinations, differences between members of the same category and appropriate methods of preparations of the Essential Chinese herbs (refer to the list provided by the Regulatory Authority)
17. the name, category, main actions and indications and differences between members of the same category of the Useful Chinese herbs (refer to the list provided by the Regulatory Authority)
18. the general principles of composing and modifying formulae: internal structure of Chinese herbal formulae – the principles of formula building and of herb construction adjustment of formulae to fit the

individual case – adding and deleting herbs and flavours, altering herb combinations and altering dose ratios categories of formula – pre-modern and modern categorisations types of formulation – decoctions, powders, pills, soft extracts, special pills, tinctures preparation and administration

19. the category, ingredients and dosage, indications of dosage, contraindications, major modifications, differences in properties and usage between formulae in the same category of the Essential Model Formulae (refer to the list provided by the Regulatory Authority)
20. the category, main ingredients, indications of usage, differences in properties and usage between formulae in the same category of the Useful Model Formulae (refer to the list provided by the Regulatory Authority)

H Traditional Tibetan herbal medicine

1. The elemental nature of the universe and the five elements i.e. earth, water, fire, air and space
2. The Fourfold Treatise, the relationship between the individual and the environment, mutual dependence and interaction and its use in determining the timing and suitability of treatments
3. The root treatise
    a) normal physical condition viewed as the basis of illness
    b) the diagnosis and symptoms of disorders
    c) treatment, as diet, behaviour, medication and other therapies
    d) the tree metaphor – three roots, nine stems, 47 branches and 224 leaves
4. The explanatory treatise
    a) the object of treatment i.e. the body - formation of the body (embryology); metaphors for the body; nature of the body (quantitative anatomy dealing with the proportion of bodily constituents, nerves and blood vessels and other important channels in the body); characteristics (physiology) of the body; types of physical constitutions; signs of death; illness - causes of illness; contributing factors of illness; mode of inception of illness; characteristics of illness; classification of diseases
    b) the treatment i.e. lifestyle – behaviour including usual, seasonal and occasional behaviour diet - survey of foods and their nutritional value; dietary restrictions; the right amount of food and drink to ingest medicines - 'taste' and 'post-digestive taste'; six basic tastes and eight fundamental' potencies' which give each substance its own properties. What the basis is for compounding medicines, in order to achieve the desired curative effect, and the principles involved in compounding medicines. Instruments used in external treatments - surgical and medical instruments
    c) the means of treatment i.e. health preservation - remaining healthy (preventive medicine) diagnosis - diagnosing the actual condition of the client; diagnosing by indirect questioning:

gaining the client's confidence; four criteria and their use to investigate whether a disease can be treated or not treatment of illness - general method of treatment; specific methods of treatment; common and specific means of treatment

d) the one who treats i.e. the qualities and ethical standards required of a doctor

5. The instruction treatise

a) 'disruption of the three Nyes pa' – diagnosis and treatment of *Rlung* disorders; *Mkhris pa* disorders; *Bad kan* disorders and the combination of all three in diagnosis and treatment

b) 'cold' diseases ('consumptive' disorders) – digestive problems; tumours; 1st , 2nd and advanced stage oedemas; chronic metabolic disorder resulting in wasting of bodily constituents

c) 'hot' disorders (fevers, inflammations, infectious diseases) – hot disorders in general; clarification of possible errors about hot and cold diseases; 'borderline situations' ('Nyespa' reactions following the treatment of a fever); immature fever; fully-developed fever; empty fever; hidden or latent fever; old (chronic) fever; 'turbid' fever; post-traumatic fever; 'disturbing' fever; contagious diseases; pox-type diseases; infectious disease of intestines; infectious disease of throat and of muscle tissues; common cold and influenza

d) diseases of the upper part of the body – head; eyes; ears; nose; mouth; goitre and throat diseases

e) visceral diseases – heart; lungs; liver; spleen; kidneys; stomach; small intestine; large intestine

f) sexual diseases – male genital disorders; female genital disorders

g) miscellaneous diseases – problems of voice production; loss of appetite; intense chronic thirst; hiccups; breathing difficulties; sharp abdominal pains of infectious origin; infections/inflammations; vomiting; diarrhoea; constipation; urinary retention (12 different sorts of disorders); polyuria (20 sorts of disorders); infectious diarrhoea; gout; rheumatic diseases (osteoarthritis); *'Chu-Ser'* disorders (skin affections of various sorts); neurological disorders; dermatological diseases; miscellaneous minor disorders

h) 'endogenous sores/swellings' – swellings, tumours, cysts, growths; haemorrhoids; 'fire heat' (burn-like blisters); 'Surya' swellings (blood clots); swelling of glands; swelling of scrotum and testicles; swelling of lower limbs; anal fistula

i) children's diseases (paediatrics) – child care; children's diseases; disturbances in children caused by negative influences in their environment

j) women's diseases (gynaecology) – general, specific and common disorders

k) disorders due to 'Severe Mental Disturbance' (Neurology and Psychiatry) disruptive influence of negative emotional states

such as hatred and jealousy and their roots in the ultimate demon 'ego fixation' – 'elementals' influence; various patterns of mental disturbance accompanied by physiological manifestations and erratic behaviour; 'insanity makers' – physical signs and disturbed behaviour akin to bipolar affective disorders; 'making one forget' – neurological disorder possibly akin to dementia; 'planetary influence'– neurological disorders including strokes leading to hemiplegia and/or epilepsy; 'naga influence' relating mostly to leprosy

l) wounds and injuries – general, head wounds; neck wounds; abdominal wounds; limb wounds
m) poisons – specially formulated poisons; food poisoning; natural poisons
n) geriatrics – revitalisation treatment
o) virility/fertility treatment – virility; women's fertility treatment

6. The final treatise
   a) diagnosis through examination of pulse and urine
   b) 'calming' medicinal treatment – decoctions; powders; pills; pastes; medicinal butters 'calcinates'; extracts; medicinal brews; preparations based on precious stones or substances; herbal preparations
   c) 'cleansing' medicinal treatment – lubrication (oil therapy); the five works: purgatives; emetics; cleansing via the nose; gentle enema; forceful enema; 'channel' cleansing as a supplement to the five works; five gentle and forceful external treatments: bloodletting; moxibustion; hot/cold applications; baths/steam baths; ointments; minor surgery as a supplement to the five external treatments; conclusion and entrustment

I Therapeutics

1. how to determine a specific treatment strategy, to select appropriate herbal prescriptions and dietary plans for a wide range of conditions and having regard to the pattern of disharmony particular to the individual concerned
2. how to select for any particular scenario or condition a range of possible herbal formulae, and the difference of approach in each case
3. how to adapt a prescription appropriately to respond to changing circumstances in the progress of an individual treatment
4. how to recognise and deal with adverse reactions
5. the factors involved in prognosis
6. the factors involved in selecting appropriate dosages of herbs and treatments for particular individuals and conditions, including dosages for the elderly, children and infants. Schedule III herbs and the contraindications in pregnancy

Applied technical knowledge and understanding for units HM1 and HM2

J The scope and methods of herbal medicine

1. the history, principles and development of herbal medicine and its relationship to other healthcare modalities
2. how to recognise those occasions when herbal medicine may complement other healthcare modalities which the client is receiving
3. how to recognise conditions for which herbal medicine is incomplete in itself and for which the client should seek advice from other sources (discipline specific)
4. the circumstances when you may choose not to accept a client:
    - herbal medicine is unlikely to succeed
    - the client does not want herbal medicine
    - you do not wish to provide herbal medicine
5. the circumstances when you must not accept a client:
    - your specific complementary healthcare discipline is contra-indicated
    - you do not have the requisite experience or expertise

6 the range, purpose and limitations of different methods, which may be used for different clients with different needs

7 how to determine the most appropriate method(s) for different clients and their particular needs

8 how to tailor herbal medicine appropriately for each individual

9 how to judge whether self-care procedure(s) is/are appropriate for the client

K Assessing the client's needs and the appropriateness of herbal medicine

1. how to provide an appropriate assessment environment for the client and the importance of doing so
2. how to select, prepare and use a range of equipment and materials that are needed to assess the client
3. how to prepare and present yourself correctly to carry out assessment
4. why it is important to introduce everyone present and confirm their role within the assessment process
5. how to clarify and confirm the client's (and any companion's) understanding of the assessment process
6. how to interpret the client's initial approach and manner and identify their needs
7. how to select and use different assessment methods effectively
8. the amount of time which each assessment method is likely to take to establish the client's needs
9. the importance of respecting the client's privacy and dignity and affording them as much comfort as possible during assessment
10. how to establish valid and reliable information about the client, determine the priority of need and to formulate your initial hypothesis
11. the information which would confirm or deny initial hypothesis and the reasons for this in particular cases

12. the likely causes of particular conditions and the possibility of changing these
13. the potential risks of various courses of action for the client and how to assess these realistically
14. how to determine the meaning and significance of the information given by the client and how to deal with any inconsistent information gained during assessment
15. why it is important to acknowledge your own limitations and when there may be a need to refer the client on to other healthcare practitioners
16. why it is important to explain the reasons for any delay between requests and assessment
17. the appropriate actions to take on the basis of the assessment to suit the client's condition and identified needs

L Providing a herbal medicine treatment and management plan

1. the importance of explaining treatment/self-care options and methods to meet the needs of the client and what the potential consequences of not doing so may be
2. the role which the client (and others) may take, and may need to take, if the treatment or self-care is to be successful and how to explain and agree them with the client (and any companion)
3. how to support the client to make informed choices
4. the importance of agreeing the location and timing of the herbal medicine sessions with the client, and the factors which may intervene and alter plans
5. why evaluation methods should be determined at the planning stage and what the client's role will be in the evaluation
6. the importance of encouraging the client to be as actively involved as possible and the relationship of this to the promotion of their health, effective functioning and well-being
7. how to monitor and evaluate changes in the client, assess which changes are related to herbal medicine and use this information to inform future practice
8. how to evaluate efficacy and suitability of herbal medicine for a client and how to decide when it should be halted and/or discontinued
9. methods and processes for evaluating information as treatment proceeds and using this to inform future practice
10. the potential risks associated with client self-care and the extent of your responsibilities
11. the importance of giving clear and accurate instructions on self-care and the consequences of not doing so

M Evaluating and reviewing the effectiveness of the herbal medicine treatment and management plan

1. what information is needed for the review to be carried out effectively

2. how to review the effectiveness of the herbal medicine treatment and management plan with the client and evaluate the extent to which their needs have been met
3. the importance of evaluating the herbal medicine treatment and management plan as a whole
4. how and why you should encourage the client (and any companion) to take a full and active part in the review process and offer their views
5. how the client (and any companion) may indicate concerns in the process without making their concerns clear and explicit
6. the importance of active listening in evaluating the herbal medicine treatment and management plan with the client
7. the range of different ways in which the herbal medicine treatment and management plan can be altered to meet the needs of the client and the ways in which their needs may have changed
8. why it is necessary to help and support the client to consider the implications of any changes made to their herbal medicine treatment and management plan
9. how to record the content and outcomes of the review process and what information should be included
10. the variety of reasons there may be for discontinuing the herbal medicine treatment and management plan with the client.

N Communication and the professional relationship

1. how to achieve effective communication through observation, sensitive questioning and listening
2. how to adapt vocabulary, pace and tone of speaking to meet the needs of the client
3. what forms of verbal and non-verbal communication are available and how to use these positively
4. what signals can be used to check the understanding of the client and how to interpret them
5. how to position self and client to encourage communication
6. how to recognise and overcome barriers to communication
7. why certain environments can inhibit communication and how to minimise this
8. why it is important to encourage the client (and any companion(s)) to ask questions, seek advice and express any concerns
9. the nature of a professional relationship and how to develop it with clients
10. how to respond to conflicting advice which clients may receive from different practitioners

O Work role and practice - reflecting and developing

1. why it is important to reflect on your own practice and identify any development needs
2. how to evaluate the effectiveness of your own actions and learn from experience

3. the information available on effective complementary healthcare and how to evaluate and use this information within your own practice
4. how the models and concepts in your area of practice have evolved and developed, how they tend to change with time and the similarities and differences between different versions
5. how to develop links with other healthcare providers and the protocols for doing this
6. how to acknowledge the limits of your own knowledge and competence and the importance of not exceeding these.

Description of knowledge and understanding needed for the standards in unit HM3

You need to know and understand:

A For the whole unit

1. the limits of your own authority and (for a dispenser) when to refer to the herbalist
2. the importance of maintaining dispensary records
3. the current ethical and legal professional requirements that govern the dispensing and issuing of a herbal prescription
4. that some clients will have special needs
5. the different reference sources that are available and when you need to use them
6. the importance of Standard Operating Procedures and reasons for following them
7. the basic principles of modern herbal medicines management

B Receive and validate herbal prescription

1. exactly what client details are required on a prescription and why they are necessary
2. research regulations and procedures
3. the procedures for dealing with clients with special needs
4. the transactional and administration procedures as required by government regulations and those that apply to your workplace
5. how to use herbal reference sources and guidelines for dispensing
6. the procedures for validating prescriptions and reasons for following them
7. how to recognize a possible forged prescription and actions to take
8. the requirements to be satisfied for a complete, unambiguous and valid prescription and actions to take if validity is questionable
9. the prescribing conventions and abbreviations
10. the botanical terms used to describe herbs including Latin terms and/or tradition specific names where relevant, for parts of plants
11. how herbal medicines are administered and the affect they have on basic human physiology
12. different strengths, doses and quantities of medicines and why they are used

13. the actions and use of drugs including different drug interactions and contra-indications
14. why and when Prescription Records are used
15. the regulations relating to the prescription requirements for restricted herbs
16. the current legislation relating to the validity of prescriptions.

C Assemble and label required herbal medicine(s) or product(s)

1. procedures for dispensing prescriptions plus principles underlying these
2. basic hygiene and the importance of maintaining a clean working environment and equipment; personal hygiene and use of protective clothing
3. labelling requirements and conventions; measurement and transfer of medicine from bulk; properties of container types and when to use
4. factors which cause deterioration of stock: microbial contamination, environmental and storage conditions
5. handling and storage of hazardous materials and procedures to minimise risk
6. principles of calculations, weights and measures
7. the correct use and maintenance of dispensing equipment
8. the procedures for preparing products plus principles underlying these
9. chemical, physical and energetic properties of ingredients relevant to formulation and compounding

D Issue prescribed herbal medicine(s) or product(s)

1. the procedures and principles for issuing dispensed medicines and products and the local Standard Operating Procedures that relate to this.
2. why it is important to confirm the client's identity; provide information on use of medicines and products, provide information on storage and maintenance of herbal medicines and products, and provide information on possible side effects to ensure the safe, effective use of treatments.

Element HM11.3 Minimise the risks arising from *health emergencies*

Performance criteria

You will need to:

1. summon assistance immediately for any *health emergency* and initiate appropriate action
2. quickly protect the individual and other people from further risk
3. provide appropriate comfort and reassurance to the individual with the health emergency

4. give the qualified assistance clear and accurate information about the *health emergency* and give appropriate support to assist in the on-going care of the individual, as necessary
5. offer appropriate support to any others involved in the incident once any initial danger has passed
6. record incidents accurately, legibly and completely

E Health emergencies

1. the signs and symptoms of the different emergency conditions and how these may differ in relation to an individual's age and for people from different ethnic groups
2. what you should do and not do for all of the following:
    - severe bleeding
    - cardiac arrest
    - shock
    - faints or loss of consciousness
    - epileptic seizure
    - choking and difficulty with breathing
    - falls: potential and actual fractures
    - burns and scalds
    - poisoning
    - electrocution

European Herbal & Traditional Medicine Practitioners Association

THE CORE CURRICULUM FOR HERBAL & TRADITIONAL MEDICINE

Producing Safe and Competent Practitioners

FOURTH EDITION

May 2007

Written by the Education Committee of the European Herbal & Traditional Medicine Practitioners Association

Edition Two of the Curriculum, May 2007, replaces anything previous and contains changes introduced during recent years. Further revisions have been made following a peer review of Ayurveda and a review undertaken by a sub committee of the Education Committee of clinical outcomes and associated minimum clinical hours.

Next review date: Summer 2009

European Herbal & Traditional Medicine Practitioners Association

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Introduction

This document contains the common-core curriculum of the European Herbal & Traditional Medicine Practitioners Association Education Committee. It is the result of wide consultation between the various herbal traditions to determine the shared components of herbal practice and the content necessary to provide education and training in those components. The core curriculum is applicable to all education/training programmes offering study of herbal medicine.

In addition, there are separate modules which identify the requirements of each specific traditional form of practice, formally referred to as the 8th Elements.

The core curriculum is part of a wider process of accreditation and forms the skeleton around which the delivery of a programme leading to the practice of herbal medicine should take place. As such it delineates the minimum outcomes that should be achieved by students. In terms of content, institutions are encouraged to go beyond those specified here in the detailed delivery of the programmes they offer.

It is recognized that each institution would wish to retain its own identity and unique emphasis. The common curriculum therefore aims at making the requirements specific, while retaining the flexibility for each institute to incorporate the contents into their own curriculum design. The Accreditation Board encourages institutions to develop their programmes within the framework of the core curriculum and to justify their approach against its requirements. Note however, that in all cases, the **majority** of programme content must reflect the specific tradition being accredited.

The demanding of minimum programme-content requirements is part of a process of accreditation by which the EHTPA can ensure competent, safe, effective practitioners aware of the breadth and limitations of herbal medicine practice.

Contents

The core curriculum consists of the following nine modules:

Module 1. Human Sciences
Module 2. Nutrition
Module 3. Clinical Sciences
Module 4. Plant Chemistry and Pharmacology
Module 5. Pharmacognosy and Dispensing
Module 6. Practitioner Development and Ethics
Module 7. Practitioner Research
Module 8. Tradition specific curriculum content *
Module 9. Clinical Practice

* Module 8 identifies tradition specific content which must be included by any given institution into their chosen curriculum. Mandatory curriculum content for each tradition is produced by the appropriate professional body/ies.

Study Time

The following table gives the *minimum* number of hours to be incorporated into the programme to be accredited.

MODULE	**HOURS**
Human Sciences	250
Nutrition	80
Clinical Sciences	350
Plant Chemistry and Pharmacology	80
Pharmacognosy and Dispensing	100
Practitioner Development and Ethics	150
Practitioner Research	150
Clinical Practice (under review)	500
The Specific Herbal Tradition	1,150
TOTAL	**2,810**

Within these minimum totals, the relationship between contact hours and home-study hours will depend on the design of the programme and the previous learning and experience of the students. It is for each Institution to justify in educational terms the hours allocated within modules and teaching/learning approaches used.

In the case of the clinical-practice module, it is required that 50% or more of the module hours will be spent on clinical work in direct proximity to patients. Remaining clinical hours may consist of case discussions, elaborating diagnoses, researching treatments, writing up cases, and other clinically relevant activities. NB. All clinical practice hours must be undertaken in an approved clinical learning environment, under the direction of the Clinic Supervisor and directly relate to the achievement of the clinical module learning outcomes.

Levels

Each module of the core curriculum is assigned a minimum level using a taxonomy of assessment domains. The use of minimum levels allows institutions some flexibility in curriculum design and in the educational nature of their programmes. The levels refer to the National Qualifications Framework of the Quality Assurance Agency.

Assessment

Each institution is required to present an assessment strategy for the programme as a whole, alongside a detailed account of the assessment process for each module.

The EHTPA does not impose any particular assessment techniques but will seek evidence from the institution to ensure that:

- Module learning outcomes are assessed;
- Assessment techniques reflect the academic level of each module;
- A variety of strategies are used;
- Both formative and summative assessment is incorporated within modules;
- Practice is underpinned by relevant theory;
- Students failing to progress satisfactorily are identified and remedial help given;
- Only safe competent practitioners complete the programme;
- Clinical progression from novice to competent practitioner can be demonstrated;
- Assessment is carried out by suitably qualified and experienced assessors.

Students are expected to develop the ability to deal confidently with the complexities and contradictions that arise in clinical practice. Students must show awareness of the ethical dilemmas which may occur in their work, and must be able to formulate solutions to these.

Documentation for the assessment of practice should clearly demonstrate that clinical skills are performed consistently and with confidence. *Criteria* for success and failure should be made explicit. By the end of their supervised clinical practice students must be able to demonstrate that they are ready to practise herbal medicine independently.

Please note: External Examiners are required to comment upon both academic and clinical outcomes and standards achieved.

1. Human Sciences Minimum Hours 250

Aims

To provide an integrated programme in those aspects of normal anatomy, physiology and biochemistry that are essential for understanding the causes, mechanisms, clinical features and diagnosis of disease as understood by biomedicine.

To provide a foundation for the core syllabus for clinical sciences.

Minimum Level : 4 (HE certificate)

Learning Outcomes

By the end of the programme, the student will be able to:

1. Explain the fundamental biochemical and physical terms related to the human body.
2. Describe the components of normal cells and their functions.
3. Explain the cellular basis of genetics and the patterns of inheritance.
4. Describe the structure and functions of the tissues of the body.
5. Demonstrate knowledge of the underlying concepts of the essential metabolic processes in the body, their integration and control.
6. Explain the structure and function of the physiological systems of the body.

Outline of Syllabus Contents

1. Structure and functions of the cells and their components.
2. Structure and functions of tissues: epithelium, connective, membranes.
3. Structure and functions of biomolecules: carbohydrates, lipids, proteins, co-factors, enzymes.
4. The metabolism of carbohydrates, lipids and proteins including control and integration.
5. Structure and functions of the musculoskeletal system: bones, joints, muscles, ligaments.
6. Structure and functions of the nervous system: central and peripheral systems, autonomic nervous system, sense organs.
7. Structure and functions of the endocrine system: hypothalamus and the pituitary gland, thyroid gland and adrenal glands, feedback control.
8. Structure and functions of lymphatic system: the lymphoid tissues and lymphatic circulation, natural (innate) resistance to disease, immunity.

9. Structure and functions of the cardiovascular system and in addition components of blood and blood clotting.
10. Structure and functions of the respiratory system.
11. Structure and functions of the digestive system.
12. Structure and functions of the genito-urinary system and in addition prenatal and postnatal growth and development.

Indicative Reading

Tortora, Gerard J. et al., 2006. *Principles of Anatomy and Physiology*, 11th edition, + CD Rom. John Wiley and Sons.

Maribe, Elaine, editor, 2005. *Essentials of Human Anatomy and Physiology*, + CD. Addison- Wesley.

Moore Dalley, 2005. *Clinically Oriented Medicine*. Lippincott, Williams, Wilkey.

Edwin R. Chilvers, et al, 2002. *Davidson's Principles and Practice of Medicine* 19th edition. Churchill Livingstone.

Richarson, Haynes, Straus, Glazniou, 2005. *Evidence Based Medicine*. London: Churchill Livingstone.

2. Nutrition — Minimum Hours 80

Aims

To provide a comprehensive understanding of the foundations of nutrition and diet as a means for the maintenance of good health and treating disease. Included in this would be an understanding of the effects of food and diet on specific body systems and disease processes whilst underscoring the holistic aspects of this type of approach.

To provide a perspective on the possible interactions between foods, herb supplements and drugs, with an emphasis being placed on the safe limitations of their usage including nutrient/drug/herb and food interactions.

To allow the herbalist and related practitioners to use an understanding of nutrition as an essential part of their existing discipline.

Minimum Level : 4 (HE certificate)

Learning Outcomes

By the end of the programme the student will be able to:

1. Describe the structural characteristics and function of a range of key macronutrients and micronutrients.
2. Describe processes involved in the catabolism of food components.
3. Explain terms used in Western nutrition and dietetics.
4. Discuss the effects of food additives, processing and drugs on nutrition.
5. Evaluate dietary assessment methodologies.
6. Discuss the similarities and differences between different dietary approach.
7. Demonstrate knowledge of the underlying concepts of dietary needs at different stages of development.
8. Discuss relationships between diet and disease.
9. Recommend and justify suitable diets for individual cases.

Outline of Syllabus Contents

1. Structural characteristics and function of polysaccharides, proteins, enzymes, nucleic acids and lipids. The nature and importance of essential amino and fatty acids in the diet.
2. Metabolic routes used in catabolism of components of foods.
3. Energy value of foods.
4. The importance of physiological systems in nutrition.
5. Terms used in Western dietetics to include: RDA, RDI, DRV, EAR, LRNI, RNI, safe intakes, BMR, BMI, PAL and bioavailability.
6. Government papers on diet and nutrition. Methods for assessing biochemical and clinical nutritional nutritional
7. The nature, occurrence, role and effects of deficiency of micro nutrients.
8. Nutrition at cellular level. The importance of fibre and water in the diet.
9. The effects of drugs, alcohol, smoking and food additives on nutrition.
10. Dietary assessment methodologies such as weighed dietary and portion records, questionnaires and surveys, food tables.
11. Diet as prevention culture and cuisine.
12. Types of food, preparation, storing.
13. Effect of environment, age, work on nutrition.
14. Comparative philosophies of nutrition: Western scientific, naturopathic, macrobiotic, traditional Chinese medicine, Ayurveda, etc.

15.Diets for individual specific cases.

Indicative Reading

Hunt, S.M et al, 1980. *Nutrition: Principles and Clinical Practice*, John Wiley and Sons

Zeman, Frances J., and Nev, Denise, 1990. *Clinical Nutrition and Dietetics*. Macmillan.

Balch, P., and Balch, J., 2001. *Prescription for Nutritional Healing*. Avery (Penguin) New York.

Werbach, Melvyn R , 1996. *Nutritional Influences on Illness, A Sourcebook of Clinical Research.*, Third Line Press.

Pitchford, Paul, 2002 *Healing with Wholefoods, Oriental Traditions and Modern Nutrition*. North Atlantic Books.

Ballentine. Rudolph M.., 2008. *Diet and Nutrition*. Himalayan Institute Press. ISBN 0-89389-048-0

Newman-Turner, R., 1984. *Naturopathic Medicine*. Harper Collins. ISBN 0-7225-0785-2

Lindlahr. Henry, M.D., 1975, 1984, 1997. *Natural Therapeutics*.. (Volume 1: Philosophy ISBN 0-85207-159-0, Volume 2: Practise.. ISBN 0-85207-148-5, Volume 3: Dietetics ISBN 0-85207-154-X.). Saffron-Walden: C.W. Daniel.

Johns, Timothy, 1990. *The Origins of Human Diet and Medicine.* University of Arizona Press

Zimmermann, Michael, 2001. *Burgerstein's Handbook of Nutrition: micronutrients in the prevention and therapy of disease.* Thieme.

3. Clinical Sciences **Minimum Hours 350**

Aims

To provide an integrated programme in clinical sciences aimed at outlining the common diseases, their causes, mechanisms, clinical features and diagnosis.

To provide experience of case-history taking and physical examination.

To provide students with a foundation from which to compare and contrast this knowledge with their own approach to medicine and to communicate effectively with practitioners of orthodox medicine.

To enable students to develop an understanding of the limits of their own medical capabilities and thereby enhance the skills of appropriate referral.

Minimum Level : 5 (HE diploma)

Learning Outcomes

By the end of this programme, the student will be able to:

1. Evaluate the diagnostic techniques and clinical applications in orthodox medical practice and compare and contrast them with their own medical equivalent.
2. Analyse the distribution of disease in the community and the approach to prevention from the orthodox and holistic points of view.
3. Explain how normal cell and tissue structure and function can change to produce genetic changes, abnormal cell growths, tissue injury, inflammation and repair.
4. Demonstrate a knowledge and critical understanding of the general nervous, endocrine and metabolic responses to ageing, stress and tissue injury.
5. Apply the underlying concepts and principles of infection and the ways in which alterations in natural and acquired defences (immunity) can lead to disease.
6. Discuss the consequences of changes in the circulation, resulting from vascular narrowing and obstruction, fluid excess and loss and organ failure.
7. Demonstrate a knowledge and critical understanding of diseases leading to the differential diagnosis of common symptoms and signs affecting the covering and support systems of the body (skin, joints and bone), control systems (nervous and endocrine systems) and maintenance systems (cardiovascular, respiratory, gastrointestinal and urinary systems).
8. Interpret basic pathology laboratory data and results of investigative procedures.
9. Demonstrate a knowledge and critical understanding of the_actions and side-effects of the major classes of orthodox drugs and how to access drug information (use of National Formularies etc.).

Outline of Syllabus Contents

1. **The orthodox medical model**:
   Causes and mechanisms of disease, describing diseases, the principles of differential diagnosis.

2. **Disorders of cells**:
   Genetic diseases. Disorders of cell growth, abnormal growth, benign and malignant tumours.
   Cancer, epidemiology, clinical effects, principles of treatment. Blood-cell disorders.

3. **Local response to tissue injury**:
   Acute and chronic tissue injury, inflammation and its complications.

4. **General response to tissue injury**:
   Fever, neuro-endocrine and metabolic response, role of the immune system, psychological factors, shock, post-operative trauma.

5. **Disturbance of body response**:
   Excessive immune response: hypersensitivity (allergy), auto-immune diseases. Immune deficiency: AIDS, cancer immunology.

6. **Infectious diseases**:
   Principles of infection. Microbial classification. septicemia and pyrexia of unknown origin. common bacterial, viral and fungal diseases.

7. **Circulatory disorders**:
   Atheroma, atherosclerosis, thrombosis, embolism, infarction, shock, haemorrhage, oedema, organ failure, clotting disorders.

8. **Symptoms and signs related to diseases of the various body systems**:
   Common skin signs; eczema/dermatitis, psoriasis, acne, skin infections and infestations, melanoma. Joint pain; rheumatoid arthritis, osteoarthritis, osteomalacia, ankylosing spondylitis, gout. Soft-tissue disorders. Bone pain and fractures; osteoporosis, osteomalacia, Paget's disease, Hypercalcaemia.

9. **Symptoms and signs related to diseases of control systems**:
   Nervous system: paralysis and coma (stroke, cerebral haemorrhage, metabolic disorders), convulsions and epilepsy, disorders of the central nervous system, facial pain and facial weakness (trigeminal neuralgia, shingles, cluster headache, Bell's palsy), motility disorders (Parkinson's disease, cancer, endocrine disorders, peripheral nerve disorders), dementia, Alzheimer's disease.

Special Senses: ageing effects on vision, impaired vision, ageing effects on hearing and balance, ear infection, tinnitus, nasal problems, polyps, sore throat, sinusitis, allergies, tonsillitis, swollen glands.

Endocrine Disorders: underactive and overactive thyroid, adrenal failure, adrenal overactivity (Cushing's disease), pathological effects of steroid therapy, diabetes, hypoglycemia.

10. **Symptoms and signs related to diseases of maintenance systems**:
Heart and lungs: chest pain, breathlessness, wheezing and pleural signs, cough with sputum (with or without haemoptysis), palpitations, cyanosis and clubbing of the fingers.

Gastrointestinal tract: abdominal pain and abdominal obstruction, jaundice, altered bowel habit (diarrhoea and constipation), rectal bleeding, nausea and vomiting, weight loss, difficulty in swallowing, hiatus hernia, peptic ulcer, stomach cancer, inflammatory bowel diseases, irritable-bowel syndrome, diverticular disease, large-bowel cancer, hernias, appendicitis, peritonitis, gall stones, hepatitis, cirrhosis, pancreatitis.

Genito-Urinary tract: urinary frequency and dysuria, increased urine output (polyuria) and decreased urine output (oliguria), haematuria, kidney failure, nephritis, nephrotic syndrome, urinary stones, prostatic enlargement, cancers of the urinary tract and male reproductive organs, impotence, sterility, urinary tract infection.

Heart and blood vessels: angina, myocardial infarction, heart failure, hypertension, abnormal heart rhythms, peripheral vascular diseases.

Lungs: chronic bronchitis and emphysema, asthma, lung cancer, pneumonia, tuberculosis, lung collapse, lung fibrosis, upper-respiratory tract infections.

11. **Disorders of growth and reproduction**:
Abnormalities of menstruation, menopausal problems, pelvic inflammatory disease and vaginal discharges.
Non-malignant conditions: uterine fibroids, cysts, endometriosis.
Cancers of the reproductive system: cervix, endometrium, ovary, testicular, prostate, breast lumps and breast cancer.
Sexually transmitted diseases.

12. **Tests in Clinical Sciences**:
Pathology tests on body fluid: blood, urine, cerebospinal fluid, faeces.
Investigative tests: X-ray, CT, MRI. Physical examination: cardiovascular, respiratory, abdominal, neurological.

13. **Pharmacology and therapeutics**:
Key concepts, major categories of drugs, accessing information on drug actions and side-effects, drug management issues, liaison with patient and GP.

Indicative Reading

Gascoigne, Stephen. 2001. *Clinical Medicine Guide - a holistic perspective.* Jigme Press.

Gascoigne , Stephen. 1995. *Manual of Conventional Medicine for Alternative Practitioners.* Jigme Press.

Hopcroft, Keith and Forte, Vincent, 2003. *Symptom Sorter*. Radcliffe.

Merck Manual of Medicinal Information
Online at: http://www.merck.com/mrkshared/mmanual/sections.jsp

Zatouroff, M.,1996. *General Medicine: Physical Signs in General Medicine*. Mosby.

Epstein, Owen, Perkin, G. David, Cookson, John, de Bono, David P., 2003. *Clinical Examination*. Mosby.

Mims, Cedric A., Dockrell, Hazell, Goering, Richard, and Roitt, Ivan M., 2004. *Medical Microbiology*. Mosby

Bickley Lynn S., 2002. *Bates' Guide to Physical Examination and History Taking.* Lipincottt, Williams, Wilkey.

McGee, S., 2007. *Evidence-based Physical Diagnosis.* W.B. Saunders Co. ISBN – 0721686931 2001

Gascoigne. Stephen, *The Prescribed Drug Guide - a holistic approach.*

Dethlefsen, Thorwald and Dahlke, Rudiger, 2004. *The Healing Power of Illnesss*. New York: Vega Books. ISBN 1-85230-123-6

Seller RH, 2000. *Differential Diagnosis of Common Complaints.* W. B. Saunders Co.

Swartz, M. H., 2002. *Textbook of Physical Diagnosis.* W.B. Saunders Co. ISBN: 072169411X

4. Plant Chemistry & Pharmacology Minimum Hours 80

Aims

To ensure that herbalists are familiar with the main chemical constituents of the most common herbs, the effects they have on the human body, and their reactions with orthodox drugs.

Minimum Level : 5 (HE diploma)

Learning outcomes

By the end of this programme the students will be able to:

1. Have a detailed knowledge of the nature and properties of plant substances.
2. Evaluate simple chemical identification tests and separation techniques and understand the value and uses of more sophisticated techniques.
3. Demonstrate a detailed knowledge and critical understanding of the pharmacological effects of the major groups of plant compounds used in their practice
4. Demonstrate a detailed knowledge and critical understanding of the mode of action of common medicinal plants. Evaluate the limitations of plant biochemistry as an explanatory model for herb actions.
5. Use a range of established techniques to undertake information searches and evaluate current information on plant biochemistry and phytopharmacognosy.

Outline of Syllabus Contents

1. The chemical and physical structure, properties and functions of the main classes of secondary plant chemicals, including:

   terpenes, mono-, sesqui-, di-, tri-terpenes, steroids and carotenoids.
   fatty acids, triglycerides, waxes, alkanes, polyacetylenes.
   alkaloids, non-protein amino acids, amines.
   purines and pyrimidines, chlorophyll.
   carbohydrates - mono-, oligo- and poly-saccharides, gums, sugar alcohols and cyclitols.
   phenols and phenolic acids, phenylpropanoids and coumarins, quinones, flavonoids, tannins.
   sulphur compounds (sulphides, thiophenes, glucosilinates).
   cyanogenic compounds.
2. The dynamics and kinetics of medicinal substances upon the human body - remedy absorption, distribution, metabolism, excretion, and sensitivity.
3. The toxicology of commonly used medicinal plants: side effects, cautions and contraindications.

4. Known and possible comparisons and interactions of orthodox drugs with herbal medicines, dietary modification, etc.
5. Synergistic and reductionist models of medicinal plant activity.

Indicative Reading

Brinker, Francis, 2001. *Herb Contra-indications and Drug Interactions*, 3rd edition. Sandy, Oregon: Eclectic Medical Publications

Bruneton, Jean, 1999. *Pharmacology, Phytochemistry, and Medicinal Plants*. Intercept Scientific. (out of print; for college libraries)

Buhner, Stephen Harrod, *The Secret Teachings of Plants - the intelligence of the heart in the direct perception of nature.*

Buhner, Stephen Harrod, *The lost language of plants - the ecological importance of plant medicines for life on earth.*

Mills, S. and Bone, K., 2005. *The Essential Guide to Herbal Safety.* London: Elsevier/Churchill Livingstone.

New Guide to medicines and drugs. The British Medical Association. ISBN 0-7513-2737-9

Pengelly, A., 2004. *The Constituents of Medicinal Plants*. CABI Publishing

Raney, Dale et al., *Pharmacology*, 5th edition. London: Churchill-Livingstone

Schultes, Richard Evans, et al, edited by William A.R. Thomson , 1978. *Medicines From the Earth, A Guide to Healing Plants*. Maidenhead : Alfred Van Der Marck Editions / MaGraw-Hill.

Waller, D.; Renwick, A.G.; Hillier, K., 2001 *Medical Pharmacology and Therapeutics*. W.B. Saunders Co.

Wohlmuth H, and Leach L., 2001. *Plants and Plant Forms - an illustrated guide*. Lismore. MacPlatypus Productions.

5. Pharmacognosy & Dispensing Minimum Hours 100

Aims

To ensure the safety of herbal practice by enabling herbalists to evaluate quality control and quality-assurance processes for herbal medicines.

To ensure a good understanding of the processes by which herbal medicines are grown, harvested, stored and processed.

To enable herbalists to read and evaluate technical material published on herbal medicines in pharmacopoeias, monographs etc.

To ensure adequate knowledge of the legal requirements relating to herbal practice.

To acquire the necessary skills for the running of a herbal dispensary.

Minimum Level : 5 (HE diploma)

Learning Outcomes

By the end of the programme, students should be able to:

1. Demonstrate a detailed knowledge and critical understanding of the processes and issues of Quality Assurance in relation to herbal medicines.
2. Demonstrate a detailed knowledge and critical understanding of the identifying characteristics of commonly used herbs.
3. Explain the botanical terms used to describe herbs, including Latin terms for parts of plants.
4. Demonstrate a detailed knowledge and critical understanding of dispensary skills.
5. Demonstrate a detailed knowledge and critical understanding of the legislation relating to the sourcing, purchasing, storage, labelling and dispensing of herbal medicine.
6. Compare and contrast the different forms of administration of herbs.
7. Demonstrate a detailed knowledge and critical understanding of the procedures for interacting with pharmacists, licensing authorities, medical profession and toxicologists and the identification, prevention, minimisation and reporting of adverse incidents relating to prescribing.

Outline of Syllabus Contents

Quality Assurance - source and growing environment, harvesting, processing, storage and packaging of herbs. Possible sources of contamination, including aflatoxins, heavy metals and pesticides. Batch numbers and records.

Quality Control - macroscopic identification, microscopic examination, chromatography (TLC, GC, HPLC), spectroscopy, water or ethanol soluble contents, presence of foreign matter and microbial contamination, DNA analysis, volatile oil determination, water content, ash value etc., as

methods for differentiating good quality herbs from poor or substitute herbs and for identifying adulterants. Quality control and standardisation.

Botanical terms used to describe herbs.

Identifying characteristics of commonly used herbs. Common fakes and substitutes.

Dispensary skills – accurate identification of herbs, dispensing (accurate weighing and measuring, containers etc.), labelling of stock and dispensed items (legal requirements, clarity, additional written and verbal advice, patient identification), posology (dosage, contraindications, record keeping, adverse reactions and incompatibilities between herbs), quality control in the dispensary, storage in the dispensary (shelf life, expiry dates, stock rotation, storage conditions, appropriate containers), processing in the dispensary, confidentiality and communication skills for dispensary staff, hygiene, ordering and stock-taking, information and updating on herb regulations.

The law and herbal medicine - relevant UK and European legislation; labelling; adverse event reporting systems; restricted substances; endangered species and CITES; etc.

Health and safety - the practice premises.

Forms of administration of herbs - internal (decoctions, infusions, powders, tinctures, capsules, tablets, etc.) and external (creams, ointments, lotions, liniments, poultices etc.). Choosing between different forms of administration.

Indicative Reading

Bone, Kerry, 2003. *A Clinical guide to blending liquid herbs*. London: Churchill Livingstone.
Green, James, 2000. *Herbal Medicine-Maker's Handbook: A Home Manual*. Berkeley, CA.: Crossing Press

Heinrich, Michel, 2004. *Fundamentals of Pharmacognosy and Phytotherapy*. London: Churchill Livingstone

Mills, S.; Bone, K. 2000. *Principles and Practice of Phytotherapy.* London: Churchill Livingstone.

Tyler, Varro E., Brady, Lynn R.,Robbers, James E. 1981 *Pharmacognosy*. Philadelphia: Lea and Febiger.

Waller, D.; Renwick, A.G.; Hillier, K. 2001 *Medical Pharmacology and Therapeutics*. WB Saunders Co.

Pengelly, A., 2004. *The Constituents of Medicinal Plants*. CABI Publishing.

Evans, William Charles, 2002. *Trease and Evans Pharmacognosy* Edinburgh, New York: W.B. Saunders Co.

6. Practitioner Development & Ethics Minimum Hours 150

Note that until such time as a unified code of ethics and conduct is established for all EHTPA member associations, this module will inevitably need to vary to reflect the specific codes of ethics and conduct for the relevant professional association(s).

Aims

To support student self-development leading to effective communication (including listening and counselling skills, and empathy) within the therapeutic relationship, and within their professional lives as a whole, e.g. in liaising with GPs, etc.

To support the development of reflective practice - the practitioner as a life-long learner; and an understanding of how personal and psychological factors influence the therapeutic relationship.

To ensure that students are familiar with the ethical, legal and professional foundations of good practice, and are able to apply these principles appropriately.

Minimum Level : 6 (HE honours)

Learning Outcomes

By the end of the module students will be able to:

1. Demonstrate a comprehensive knowledge of understanding of the role of self, personality and psychological factors in personal development and in establishing an effective therapeutic relationship and environment.

2. Understand, and evaluate, the fundamental principles of medical ethics. Discuss moral, ethical and legal obligations to patients and the public in general, their profession and fellow practitioners, other health-care professionals, and staff they employ.

3. Practise in accordance with the relevant legal framework, code of ethics , conduct and Health & Safety legislation.

4. Demonstrate a comprehensive understanding of their limits of competence and when and how to make referrals.

5. Investigate and critically evaluate sources of advice, guidance and continuing professional education which will enable them to grow and develop as professional herbal practitioners.

6. Identify and appraise the sources of advice, guidance and continuing professional education to set-up and operate a successful practice.

7 Demonstrate a critical awareness of legal and ethical issues and requirements relating to children and vulnerable adults.

8 Demonstrate a critical awareness of the impact of their practice on the environment.

Outline of Syllabus Contents

1. Individual and cultural prejudices, personal areas of strength and weakness, health beliefs, the ability to give and receive feedback, the ability to self-assess.
2. The patient/practitioner relationship - communication skills to include models of conscious and unconscious communication, building empathy, transference and counter-transference, setting boundaries, proper professional conduct, beginning and endings in a therapeutic relationship, dealing with sensitive issues such as bereavement and loss. Consent (including minors) - justification for treatment and the patient's right to refuse, assault, issues of power and control.
3. Confidentiality - confidentiality and the law, Data-protection Act, situations in which patient information may be disclosed, sources of legal help and advice; confidentiality within the practice, other staff, making and storing case notes, patient access to their own notes
4. Referrals - patient care when the practitioner is absent.
5. Relationships between practitioners: communication, courtesy, professional and ethical conduct; disputes and complaints procedure; transfer and referral of patients, case histories and patient notes.
6. Supervision, mentoring and personal support for the practitioner; continuing professional education; boundaries of the therapeutic space; safeguarding the legitimate needs of the practitioner.
7. Professional misconduct: complaints, disciplinary procedure, advice and guidance, insurance.
8. Prescribed conduct regarding: abortion, venereal disease, notifiable diseases, consent and supervision of minors and vulnerable adults, procedures for the intimate examination of a patient of the opposite sex, notification of adverse events.
9. Small Business and practice management to include producing a Business Plan, advertising standards: methods and wording, creating expectation and making claims; the use of titles "doctor, nurse and medical practitioner". Providing an appropriate environment to practise. Fees,

charges and prescription costs - fairness, clarity and communication. Taxation, insurance and Health & Safety issues

Indicative Reading

Burnard, P., 1997. *Effective Communications Skills for Healthcare Professionals,* 2nd Edition. Cheltenham: Nelson Thorne

Dimond, B. 1998. *The Legal Aspects of Complementary Therapy Practice*. London: Churchill Livingstone.

Wright, S.G., and Adams, J., 2000. *Right Relationship & Spirituality in Healthcare.* London: Churchill-Livingstone.

Annie Mitchell & Maggie Cormack, *The Therapeutic Relationship in Complementary Health Care*. London: Churchill Livingstone.

Dixon M, Sweeney K., 2000. *The Human Effect in Medicine: theory, research and practice*. Radcliffe Medical Press.

Hargie O., Saunders C., Dickson D., 1994. *Social Skills in Interpersonal Communication*. Routledge.

Skovholt, T.M., 2000. *The Resilient Practitioner: burnout prevention and self-care strategies for counsellors, therapists, teachers and health professionals.* Allyn and Bacon. ISBN – 0 205306 11 X

7. Practitioner Research Minimum Hours 150

Aims

To enable practitioners of herbal medicine to develop an orientation towards continuous professional development, recognising that learning is a life-long process, and that part of this process is concerned with the ability to frame enquiry within the context of personal practice, reflecting and analysing in a systematic and critical way

To introduce the principles and practice of research as a system and critical process of enquiry in the context of health care in general and herbal medicine in particular

Minimum Level : 6 (HE diploma/honours)

Learning Outcomes

By the end of the programme the student will be able to:

1. Demonstrate the skills of finding, reviewing and critically analysing relevant research literature.
2. Evaluate research methodology within a range of different research paradigms.
3. Demonstrate practical skills in research design, operation and data analysis.
4. Develop a research proposal, including appropriate methodology and consideration of the ethical and legal issues.
5. Discuss, collaborate on and disseminate research with other herbal practitioners and in the wider healthcare field.
6. Be aware of the value of research for their own practice and understand the importance of audit.

Outline of Syllabus Contents

1. The research culture in herbal medicine - strengths and weaknesses, keeping up with the field, continuous professional development, using research evidence to inform clinical practice. Audit techniques.
2. The epistemology of research: positivist v. interpretative studies, quantitative and qualitative work, co-operative enquiry, action research, ethnography, evidence-based medicine, phenomenology. The value and limitations of a particular approach to a given research
3. Research skills: types of controlled trials, outcome measures, survey and interview techniques, case studies, discourse analysis and personal narrative, introduction to statistics, audit techniques.
4. Designing a research question and develop a research proposal.
5. Ethical and legal issues in research, including negotiating access, informed consent, working with patients within the established health authority.

Indicative Reading

Research Methods in Health, Bowling, Open University Press

Bowling, Ann. 2002 *Research Methods in Health, Investigating Health and Health Services*. Buckingham: The Open University
Bell, Judith. 2005. *Doing your research project : a guide for first time researchers in education, health and social science*. Maidenhead: The Open University.

St George, David, *Research into complementary and alternative medicine, biomedical science or the holistic paradigm*, 2 DVD Presentation. *Journal of Contemplative Science.* http://www.herbalmedicine.org.uk/journal/journal

Lewith G., Jonas W.B., Walach H, 2002. *Clinical Research in Complementary Therapies: principles, problems and solutions.* W.B. Saunders Co. ISBN: 0443063672

8. Tradition Specific Curriculum Content Minimum Hours 1150

Detailed tradition specific module 8 content is available on the EHTPA website. http://www.ehpa.eu/about_us/ehtpa_members/index.html

- Western Herbal Medicine
- Chinese Herbal Medicine
- Ayurvedic Medicine
- Traditional Tibetan Medicine

9. Clinical Practice Minimum Hours 500

Outline of Syllabus Contents

During Clinical Practice students will develop the skills required of a herbal medicine practitioner. At first these skills will be practised with close supervision and support, but increasingly the students will be encouraged to formulate their own decisions regarding the diagnosis and treatment and the progress of the patient's healing and recovery.

Codes of Ethics and Practice

The Codes of Ethics and Practice of the relevant professional body will apply throughout clinical practice. A Clinical Training Handbook must be provided for each student.

Aims

To develop in students the full range of clinical skills under the careful supervision of an experienced herbal practitioner(s), including developing a herbal-medicine treatment strategy, dispensing herbal medicines, dispensary management, health and safety aspects and practitioner development issues.

To motivate students to continue learning and studying by observing beneficial outcomes of treatment.

Minimum Level : 6 (HE honours degree)

Reflective Practice

Reflective Practice Standard 1 Herbal practitioners recognise and understand that they always operate within a set of contexts influenced by legal, political, societal and cultural considerations, which will impact on their practice.

Learning Outcomes

1. Recognises the need to reflect on practical experiences and develop the skills of reflection
2. Competently reflects upon their own practice and demonstrates the ability to learn from reflection in order to identify their practical, personal and professional developmental needs

Diagnosis and Treatment

Diagnosis and Treatment Standard 1. -herbal practitioners gather information from patients using a variety of methods including case history, observation using all the senses, physical examination, constitutional assessment and, where appropriate, laboratory testing.

Learning outcomes

1. Are competent at gathering relevant information, using verbal and non-verbal communication, to build an accurate and holistic picture of the patient.
2. can undertake an accurate physical assessment of the patient.
3. must recognize the relevance of information from other diagnostic systems to their assessment of the patient.

Diagnosis and Treatment Standard 2. Herbal practitioners aim to identify the underlying causes of illness and disease, using one or more of a variety of conceptual frameworks, according to their philosophical and therapeutic standpoint and experience.

Learning outcomes

1. demonstrates the ability accurately to draw on knowledge from a variety of different conceptual frameworks when determining the underlying causes and patterns of disease.
2. can form a valid initial working hypothesis based on their diagnostic framework in order to come to a safe and effective treatment rationale and plan.
3. can demonstrate the ability constantly to develop and modify their working hypothesis in the light of further information and/or changes in the patient's condition.

Diagnosis and Treatment Standard 3. -herbal practitioners formulate and implement, in partnership with the patient, an herbal prescription and treatment plan, which meets the specific needs of the individual patient and aims to support the body's own homeostatic processes and healing ability, alleviate imbalances and restore health as far as is achievable for each patient.

Learning outcomes

1. can formulate safe and appropriate herbal prescriptions and treatment plans which relate to the interpretation and analysis of information gathered during the initial consultation, and the diagnostic hypothesis.
2. formulate a comprehensive herbal prescription and treatment plan and a considered prognosis that takes into account the whole person.
3. can dispense the herbal formula safely and accurately.
4. can communicate their findings with the patient effectively and agree a treatment plan/strategy, for which they obtain informed and valid consent.
5. can change and adapt the prescription and treatment plan appropriately, according to perceived changes and developments in the patient's condition or situation over time.
6. will recommend and promote appropriate self-help strategies in order to support the treatment plan and encourage the most effective improvement for the patient.

Diagnosis and Treatment Standard 4 Herbal practitioners maintain an up-to-date knowledge of the uses and effects of the more commonly used drugs; prescribed, over-the-counter (OTC) and recreational, and of the likelihood of interactions with herbal treatment. Herbalists are constantly aware of the potential for herb-drug interactions, and also for adverse reactions to herbal treatment, and document and report any such events, in order to enhance knowledge and awareness in both the herbal and the conventional medical professions.

Learning outcomes

1. Demonstrates an understanding that the potential for herb-drug and other interactions is always present and keeps this always in mind when assessing and prescribing.

Communications and interaction

Standard Communications and Interaction 1 Herbal Medicine practitioners offer empathic, effective and ethical interaction and communication with patients, carers, colleagues and other healthcare professionals.

Learning Outcomes

consistently establish and maintain rapport with patients, carers or

prospective patients and also with colleagues and other healthcare professionals.

communicate and interact ethically with patients, carers, prospective patients and colleagues with clarity, sensitivity and empathy.

recognise, develop, maintain and use their power as an enabler of healing.

Standard Communications and Interaction 2 Herbal Medicine practitioners provide relevant and appropriate information to patients, carers or prospective patients on aspects of diagnosis and treatment to enable informed choices to be made; and also to other healthcare professionals, members of the public, public bodies and organisations.

Learning Outcomes

1. clearly communicate their understanding of the possible combinations of aetiological and pathological factors involved in the development of ill health and disease, and their treatment plans for the patient.

2. inform patients and prospective patients both preceding and after treatment of what to expect in coming for treatment, how to be best prepared for treatment and the effects of treatment(s).

3. are able to inform, instruct, advise and offer professional opinion to patients and /or carers, colleagues and other healthcare professionals about treatments and aspects of lifestyle which may be harmful or beneficial to the health of the patient.

Safety

Safety Standard 1 Herbal Medicine Practitioners generate a safe environment for the patient and themselves.

Learning Outcomes

1. should consistently demonstrate safe practice in all aspects of patient management and treatment
2. interact with other healthcare professional so that the patient's best interests are maintained.
3. keep appropriate accurate and confidential records of their practice and treatments
4. communicate with patients showing awareness of the emotional impact of that interaction on the patient and themselves
5. Maintain patient confidentiality

6. seek to maintain their own health and do so by setting appropriate boundaries and managing the environment in which they work and in the way they work

Operate an effective, legal and professional practice

Professional and legal Standard 1 Herbal Medicine practitioners operate an effective, legally and professionally sound practice

Learning Outcomes

1. consistently practices in compliance with the law and with regulatory and professional body requirements
2. demonstrates a critical awareness of legal and ethical issues and requirements relating to children and vulnerable adults.

Professional and legal Standard 2 Herbal Medicine Practitioners ensure that the dispensing of herbs they prescribe is done in accordance with the current legal and regulatory requirements

Learning Outcomes

1. operates and manages their dispensary in compliance with the law
2. demonstrates and understands the implications of commissioning or purchasing herbal medicine from a third party

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[1] MHRA *Consultation document MLX299: Proposals for the reform of regulation of unlicensed herbal remedies in the United Kingdom made up to meet the needs of individual patients* March 2004, http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=394

[2] Department of Health, *The regulation of the non-medical healthcare professions: A review by the Department of Health.* Department of Health 2006 www.dh.gov.uk/publications

[3] MHRA discussion paper: Reforms of s12(1) of the Medicines Act 1968: the requirement for a face to face consultation. 8 Jan 07 http://www.mhra.gov.uk/home

4 Ibid

5 Department of Health 2007. *Trust, assurance and safety – the regulation of health professionals in the 21st century.* Stationery Office, London

ANNEX 4

Standards of Proficiency for Traditional Chinese Medicine Practitioners

The Chinese Medicine Working Group was set up by the Department of Health as an attempt to draw together the different arms from within the Chinese medical community and develop common standards. This group worked together for nearly three years and produced the following policies which all met with broad acceptance.

(a) Code of professional conduct.
(b) Code of practice.
(c) Standards of conduct, performance and ethics.
(d) Core curriculum for educational institutions.

They also endeavored to find common ground for the membership of different organisations and worked together to develop some clear messages which could eventually be used to help Western medical professionals understand the contribution that TCM could make to public health. The Chinese Medicine Working Group is still going through "growing pains" and it is anticipated that the direction and discipline of statutory regulation will help the members of the group appreciate the need and, more importantly, the value of collective responsibility.

This will ensure that the major efforts all members have made will not be lost but rather will serve as a springboard for the acceptance of this traditional medicine.

It is recognised that the issue of English language standards for practitioners is a major sticking point and the members of the group look forward to the opportunity of discussing with the appropriate regulatory body what options may be available to ensure that the experience of so many Chinese TCM practitioners is not lost.

1. EXPECTATIONS OF A HEALTH PROFESSIONAL

1a: Professional autonomy and accountability

Registrant Traditional Chinese Medicine Practitioners must:

1a.1 be able to practise within the legal and ethical boundaries of their profession

- understand what is required of them by the Health Professions Council (HPC);
- understand the need to respect, and so far as possible uphold, the rights, dignity and autonomy of every patient, client and user including their role in the diagnostic and therapeutic process;

- be aware of the relevant provisions of UK law, e.g. Medicines Act 1968, EU law, e.g. Directives 2001/83/EC, 2004/24/EC, and any other standards that regulate and affect herbal and traditional medicine practice, e.g. guidance from the Herbal Medicines Advisory Committee of the MHRA or the Herbal Medicines Products Committee within the European Medicines Agency.

1a.2 be able to practise in a non-discriminatory manner

1a.3 be able to maintain confidentiality and obtain informed consent

1a.4 be able to exercise a professional duty of care

1a.5 know the limits of their practice and when to seek advice
- be able to assess a situation, determine the nature and severity of the problem and call upon the required knowledge and experience to deal with the problem;
- be able to initiate resolution of problems and be able to exercise personal initiative.

1a.6 recognise the need for effective self-management of workload and be able to practise accordingly

1a.7 understand the obligation to maintain fitness to practise
- understand the importance of maintaining health and care for themselves

1a.8 understand the need for career-long self-directed learning
- understand the need to keep knowledge of the safety of traditional Chinese medicines up-to-date

1b: Professional relationships

1b.1 know the professional and personal scope of their practice and be able to make referrals

1b.2 be able to work, where appropriate, in partnership with other professionals, support staff, patients, clients and users, and their relatives and carers
- understand the need to build and sustain professional relationships as both an independent practitioner and collaboratively as a member of a team;
- understand the need to engage patients, clients, users and carers in planning and evaluating diagnostics, treatments, and interventions to meet their needs and goals

1b.3 be able to contribute effectively to work undertaken as part of a multi-disciplinary team

1b.4 be able to demonstrate effective and appropriate skills in communicating information, advice, instruction and professional opinion to colleagues, patients, clients, users, their relatives and carers

- be able to communicate in English to the standard equivalent to level 7 of the International English Language Testing System, with no element below 6.5;
- understand how communication skills affect the assessment of patients, clients, and users, and how the means of communication should be modified to address and take account of factors such as age, physical and learning disability;
- be able to select, move between and use appropriate forms of verbal and non-verbal communication with patients, clients, users and others;
- be aware of the characteristics and consequences of non-verbal communication and how this can be affected by culture, age, ethnicity, gender, religious beliefs and socio-economic status;
- understand the need to provide patients, clients and users (or people acting on their behalf) with the information necessary to enable them to make informed decisions;
- understand the need to use an appropriate interpreter to assist patients whose first language is not English, wherever possible;
- recognise that relationships with patients, clients and users should be based on mutual respect and trust, and be able to maintain high standards of care, even in situations of personal incompatibility
- be able to explain the nature, purpose and techniques of Traditional Chinese Medicine practice to patients, colleagues and carers

1b.5 understand the need for effective communication throughout the care of the patient, client or user

- recognise the need to use interpersonal skills to encourage the active participation of patients, clients and users

2. THE SKILLS REQUIRED FOR THE APPLICATION OF PRACTICE

2a: Identification and assessment of health and social care needs

Registrant Traditional Chinese Medicine Practitioners must:

2a.1 be able to gather appropriate information

- be able to gather information according to the principles of Traditional Chinese Medicine, taking account of personal, mental-emotional, socio-economic and cultural factors when taking the case history;

- be able to take account of any investigations already made by other healthcare professionals involved in the patient's care

2a.2 be able to use appropriate assessment techniques
- be able to undertake and record a thorough, sensitive and detailed assessment, using appropriate techniques and equipment;
- be able to monitor physiological processes according to Traditional Chinese Medicine principles, as well as make use of appropriate orthodox medical techniques

2a.3 be able to undertake or arrange clinical investigations as appropriate

2a.4 be able to analyse and evaluate the information collected
- be able to analyse and evaluate information collected according to the principles of Traditional Chinese Medicine and use it to formulate an appropriate diagnosis, taking into account relevant factors from an orthodox medical point of view;
- be able to search and critically evaluate scientific literature and other sources of information relevant to the patient's needs

2b: Formulation and delivery of plans and strategies for meeting health and social care needs

Registrant Traditional Chinese Medicine practitioners must:

2b.1 be able to use research, reasoning and problem-solving skills to determine appropriate actions
- recognise the value of research to the systematic evaluation of practice
- be able to conduct evidence-based practice, evaluate practice systematically, and participate in audit procedures
- be aware of methods commonly used in healthcare research
- be able to demonstrate a logical and systematic approach to problem-solving
- be able to evaluate research and other evidence to inform their own practice

2b.2 be able to draw on appropriate knowledge and skills in order to make professional judgements
- demonstrate a level of skill in the use of information technology appropriate to their profession

2b.3 be able to formulate specific and appropriate management plans, including the setting of timescales

- understand the requirement to adapt practice to meet the needs of different client groups distinguished by, for example, physical, psychological, environmental, cultural or socio-economic factors
- be able to form a diagnosis and treatment plan according to Traditional Chinese Medicine principles
- be able to assess when to use a single modality and when to use combinations of two or more modalities (from herbal medicine, acupuncture, tuina massage, acupressure, moxibustion, cupping, qigong techniques)
- understand when it is appropriate to use Traditional Chinese Medicine alone, and when as a support for other treatment

2b.4 be able to conduct appropriate diagnostic or monitoring procedures, treatment, therapy or other actions safely and skilfully

- understand the need to maintain the safety of patients, clients and users, and those involved in their care
- be able to assist patients to understand and become committed to self-care activities including diet, exercise and other lifestyle adjustments to support treatment according to Traditional Chinese Medicine principles
- be able to work in conformity with standard operating procedures and conditions relevant to preparation and dispensing of traditional Chinese medicines

2c: Critical evaluation of the impact of, or response to, the registrant's actions

Registrant Traditional Chinese Medicine Practitioners must:

2c.1 be able to monitor and review the ongoing effectiveness of planned activity and modify it accordingly

- be able to gather information, including qualitative and quantitative data, that help to evaluate the responses of patients, clients and users to their care
- be able to evaluate management plans against treatment milestones using recognised health outcome measures and revise the plans as necessary in conjunction with the patient, client or user
- recognise the need to monitor and evaluate the quality of practice and the value of contributing to the generation of data for quality assurance and improvement programmes
- be able to make reasoned decisions to initiate, continue, modify or cease treatment or the use of techniques or procedures, and record the decisions and reasoning appropriately
- understand that outcomes may not always conform to expectations but may still meet the needs of patients, clients or users

- be able to implement the yellow card scheme for recording possible adverse reactions to traditional Chinese medicines or other medicines

2c.2 be able to audit, reflect on and review practice

- understand the principles of quality control and quality assurance
- be aware of the role of audit and review in quality management, including quality control, quality assurance and the use of appropriate outcome measures
- be able to maintain an effective audit trail and work towards continual improvement – participate in quality assurance programmes, where appropriate
- understand the value of reflection on clinical practice and the need to record the outcome of such reflection
- recognise the value of case conferences and other methods of review

3. KNOWLEDGE, UNDERSTANDING AND SKILLS

3a: Registrant Traditional Chinese Medicine Practitioners must:

3a.1 know the key concepts of the biological, physical, social, psychological and clinical sciences which are relevant to their profession-specific practice

- understand the structure and function of the human body, relevant to their practice, together with a knowledge of health, disease, disorder and dysfunction
- be aware of the principles and applications of scientific enquiry, including the evaluation of treatment efficacy and the research process
- recognise the role of other professions in health and social care
- understand the theoretical base of, and the variety of approaches to, assessment and intervention
- understand key features of gross anatomy relevant to the practice of TCM including the musculo-skeletal, cardiovascular, respiratory, gastro-intestinal, urinary-genital, reproductive, endocrine, neurological, sensory and immune systems
- understand key features of physiology including basic cytology, tissue forms, circulation, respiration, digestion, neurology, endocrinology, immunity, growth, development and reproduction.
- understand key aspects of clinical science relevant to conditions that practitioners of Traditional Chinese Medicine are likely to encounter, including cardiovascular, respiratory, digestive, infectious, urinary-genital, neurological, musculo-skeletal, dermatological, gynaecological/obstetric, endocrine, and mental and emotional disorders

- understand the cultural roots of Traditional Chinese Medicine
- understand the guiding principles of Traditional Chinese Medicine physiology, pathology and diagnosis, including: yin-yang; five phases; eight principle syndrome differentiation; qi-blood-body-fluid syndrome differentiation; visceral syndrome differentiation; the causes of disharmony/disease; nutritional factors and principles
- show competence in the four traditional diagnostic methods: questioning, palpation (including pulse diagnosis), listening and observing (including tongue diagnosis)
- understand the treatment modalities necessary for the competent practice of Traditional Chinese Medicine, including acupuncture and moxibustion, herbal medicine, cupping, and tuina massage
- understand the meridian system and international system of acupuncture point location
- understand the nature and property of a sufficient range of herbs and formulae and their classification
- understand the pharmacological effects of the major groups of plant compounds used in practice
- understand the toxicology of medicinal substances in the *materia medica*, together with possible adverse effects, cautions and contraindications; be aware of the potential for herb-drug interactions and formulate treatment accordingly
- know the forms of preparations of traditional Chinese medicines and be able to choose among them for appropriate administration
- know the relevant regulation and/or guidelines affecting the preparation and dispensing of herbal medicines

3a.2 know how professional principles are expressed and translated into action through a number of different approaches to practice, and how to select or modify approaches to meet the needs of an individual

3a.3 understand the need to establish and maintain a safe practice environment

- be aware of applicable health and safety legislation, and any relevant safety policies and procedures in force at the workplace, such as incident reporting, and be able to act in accordance with these
- be able to work safely, including being able to select appropriate hazard control and risk management reduction or elimination techniques in a safe manner in accordance with health and safety legislation
- be able to select appropriate personal protective equipment and use it correctly

- be able to establish safe environments for clinical practice, which minimises risks to patients, clients and users, those treating them, and others, including the use of hazard control and particularly infection control
- understand sources of hazard in the workplace, including raw materials, waste and equipment
- understand the application of principles of good dispensary practice and preparation of traditional Chinese medicines with regard to current guidance from the regulator, the MHRA and other relevant statutory bodies e.g. Health and Safety Executive, and professional associations

ANNEX 5

EXAMPLES OF EXISTING TAUGHT PROVISION

IN ACUPUNCTURE: VALIDATED BY UK UNIVERSITIES AND ACCREDITED BY THE BRITISH ACUPUNTURE ACCREDITATION BOARD					
Education/Training Provider	**Contact Details**	**Award Title**	**Duration**	**Validating University**	**Accrediting Body**
College of Integrated Chinese Medicine	College of Integrated Chinese Medicine 19 Castle Street Reading Berkshire RG1 7SB	BSc (Hons) Acupuncture and Licenciate in Acupuncture	3.5 years	University of Kingston	BAAB
College of Traditional Acupuncture	The College of Traditional Acupuncture Haseley Manor Hatton Warwickshire CV35 7LU	BA (Hons) Traditional Acupuncture	3 years	Oxford Brookes University	BAAB
International College of Oriental Medicine (UK)	Green Hedges House Green Hedges Avenue East Grinstead West Sussex RH19 1DZ	BSc (Hons) Oriental Medicine - Acupuncture	4 years	University of Brighton	BAAB
London College of Traditional Acupuncture & Oriental Medicine	90 Kingsway North Finchley London N12 0EX	BSc (Hons) Traditional Acupuncture	3 years	University of Portsmouth	BAAB
Northern College of Acupuncture	Northern College of Acupuncture 61 Micklegate York YO1 6LJ	Professional Diploma Acupuncture	3 years	University of Wales	BAAB
University of Salford	School of Community, Health Sciences & Social Care 5th Floor, Allerton Building, Frederick Road Campus Salford, Greater Manchester, M6 6PU	BSc (Hons) Traditional Chinese Medicine (Acupuncture)		University of Salford	BAAB
University of Westminster	Department of Complementary Therapies School of Integrated Health 115 New Cavendish Street London W1W 6UW	BSc (Hons) Traditional Chinese Medicine (Acupuncture)	3 years	University of Westminster	BAAB
University of Lincoln	School of Health and Social Care Brayford Pool Lincoln LN6 7TS	BSc (Hons) Traditional Acupuncture	3 years	University of Lincoln	BAAB
PROGRAMMES IN ACUPUNCTURE VALIDATED BY UK UNIVERSITIES: BAAB ACCREDITATION PENDING					
Leeds Metropolitan University	Leeds Metropolitan University Civic Quarter Leeds LS1 3HE	BSc (Hons) Complementary Therapies (Acupuncture)	3 years	Leeds Metropolitan University	
University of East London	Stratford Campus University House Romford Rd London E15 4LZ	BSc (Hons) Traditional Acupuncture	3 years	University of East London	
PROGRAMMES IN ACUPUNCTURE BAAB ACCREDITATION PENDING: NOT YET VALIDATED BY A UK UNIVERSITY					
College of Naturopathic Medicine	Unit 1, Bulrushes Farm Coombe Hill Road East Grinstead West Sussex RH19 4LZ	Diploma in Acupuncture	3 years		
OTHER PROGRAMMES IN ACUPUNCTURE					
The School of Five Element Acupuncture	57 Harley Street, London, W1G 8QS	Licentiate in Acupuncture	3 years		BAAB
PROGRAMMES IN MEDICAL ACUPUNCTURE					
British Medical Acupuncture Society		Diploma in Medical Acupuncture			
The British Academy of Western Medical Acupuncture	The Liverpool Medical Institution (University of Liverpool) 114 Mount Pleasant Liverpool. L3 5SR	Post Graduate Licentiate	300 hours		
Acupuncture Assn of Chartered Physiotherapists	AACP Accredited trainers, working mostly in NHS hospitals but some in private practice.	AACP Foundation certificate	80 hours		AACP/CSP
Coventry University	HLS, Coventry University Priory Street Coventry CV1 5FB	MSc Acupuncture (Health professionals only)	3 Years P/T	Coventry University	
PROGRAMMES IN AYURVEDA: VALIDATED BY UK UNIVERSITIES					
Middlesex University	Middlesex University Enfield Campus Queensway Enfield, Middlesex EN3 4SA	BSc Complementary Health Sciences (Ayurveda) + MSc Ayurvedic Medicine	4 years	Middlesex University	

Education/Training Provider	Contact Details	Award Title	Duration	Validating University	Accrediting Body
PROGRAMMES IN CHINESE HERBAL MEDICINE: VALIDATED BY UK UNIVERSITIES AND ACCREDITED BY THE EHTPA					
London College of Traditional Acupuncture and Oriental Medicine	90 Kingsway North Finchley London N12 0EX	Licentiate Diploma in Oriental Herbal Medicine/ MSc Oriental Medicine	2 years	University of East London	
Northern College of Acupuncture	Northern College of Acupuncture 61 Micklegate York YO1 6LJ	PGD/Professional Diploma in Chinese Herbal medicine	p/t 3 years	University of Wales	
University of Westminster	Department of Complementary Therapies School of Integrated Health 115 New Cavendish Street London W1W 6UW	PGD in Chinese Herbal Medicine	p/t 3 years	University of Westminster	
PROGRAMMES IN CHINESE HERBAL MEDICINE ACCREDITED BY THE EHTPA: NOT YET VALIDATED BY A UK UNIVERSITY					
College of Integrated Chinese Medicine	College of Integrated Chinese Medicine 19 Castle Street Reading Berkshire RG1 7SB	Diploma in Chinese Herbal Medicine	3.5 years		EHTPA
PROGRAMMES IN WESTERN HERBAL MEDICINE VALIDATED BY A UK UNIVERSITY AND ACCREDITED BY EHTPA OR NIMH					
Middlesex University	School of Health and Social Sciences Enfield Campus Queensway Enfield Middlesex EN3 4SA	BSc Herbal Medicine (Phytotherapy)	3 years	Middlesex University	NIMH
Napier University	Ahnya Plant 10 Colinton Road Edinburgh EH10 5DT	BSc (Hons) Herbal Medicine	4 years	Napier University	NIMH
Scottish School of Herbal Medicine	Alexander Stephen House Unit 20 91 Holmfauld Road Glasgow G51 4RY	BSc(Hons) in Herbal Medicine	4 years	University of Wales	NIMH
University of Central Lancashire	Graeme Tobyn Course Leader Preston United Kingdom PR1 2HE	BSc(Hons) in Herbal Medicine	3 years	University of Central Lancashire	NIMH
University of East London	Barbara Pendry Programme Leader Schl Health and Bioscience Univ E London Romford Road London E15 4LZ	BSc (Hons) Herbal Medicine; Herbal Medicine	3 years	UEL	NIMH
University of Westminster	Department of Complementary Therapies School of Integrated Health 115 New Cavendish Street London W1W 6UW	BSc (Hons) Health Sciences: Herbal Medicine	3 years	University of Westminster	NIMH
University of Lincoln	Andrew Stableford Programme Leader University of Lincoln LN6 7TS	BSc (Hons) Herbal Medicine	3 years	University of Lincoln	EHTPA
PROGRAMMES IN WESTERN HERBAL MEDICINE VALIDATED BY UK UNIVERSITIES: ACCREDITATION PENDING					
Leeds Metropolitan University	Leeds Metropolitan University Civic Quarter Leeds LS1 3HE	BSc(Hons) Complementary Therapies (Western Herbal Medicine)	3 years	Leeds Metropolitan University	EHTPA Pending
PROGRAMMES IN WESTERN HERBAL MEDICINE: ACCREDITATION PENDING NOT YET VALIDATED BY UK UNIVERSITIES					
College of Naturopathic Medicine	Unit 1 Bulrushes Farm Coombe Hill Road East Grinstead West Sussex RH19 4LZ	To be confirmed		To be confirmed	EHTPA Pending
OTHER PROGRAMMES IN WESTERN HERBAL MEDICINE					
International register of Consultant Herbalists Faculty of Herbal Medicne	David Broom c/o IRCH	Dip of Botano Therapy	3 years		
PROGRAMMES IN TRADITIONAL CHINESE MEDICINE: VALIDATED BY A UK UNIVERSITY AND ACCREDITED BY BAAB AND EHTPA					
Middlesex University	School of Health and Social Sciences Enfield Campus Queensway Enfield Middlesex EN3 4SA	BSc Traditional Chinese Medicine	4 years	Middlesex University	BAAB & EHTPA
PROGRAMMES IN TRADITIONAL CHINESE MEDICINE: VALIDATED BY A UK UNIVERSITY AND ACCREDITED BY ATCM					
North East Wales Institute of Higher Education	Plas Coch Campus Mold Road Wrexham LL11 2AW	BSc(Hons) Chinese Medicine	3 years	University of Wales	ACTM
OTHER PROGRAMMES IN TRADITIONAL CHINESE MEDICINE					
Chinese Medical Institute & Register (CMIR) AcuMedic Foundation	Chinese Medical Institute and Register 101-105 Camden High Street London NW1 7JN	PhD/Diplomas for Doctors and Health Care Professionals	3 years		Beijing University of Chinese Medicine *& Guangxi Medical University

NB: For the sake of completeness, information is provided here about a variety of known programmes. It must be emphasised that inclusion does not imply steering group endorsement of academic/professional standards or recognition of all programmes listed here. Whilst every effort has been made to ensure the accuracy of Annex 5, educational development will inevitably mean that at the time of publication some programme details may differ from that shown.

ANNEX 6

Approval of Accreditation Boards

Any proposal to admit practitioners onto the Statutory Register, who have qualified by virtue of completing an accredited education and training programme in herbal/traditional medicine or acupuncture, is based upon the requirement that the accreditation process itself is effective.

Acceptance of this assumption means that it is incumbent upon each Accreditation Board to provide evidence that it has robust and effective procedures in place before transfer of practitioners onto the Statutory Register can occur.

Each Accreditation Board wishing to enable the transfer of herbal/traditional medicine or acupuncture practitioners onto the Statutory Register should provide documented evidence of Accreditation-Board systems and processes and their effectiveness to the Regulator for consideration and approval.

Such documentation should:

- Include organisational structure and reporting mechanisms; constitution; membership and terms of reference; minutes of key meetings for the preceding three years; board annual report for the preceding three years; proof that the Accreditation Board has been operating professionally for three years

- Demonstrate how the independence of the Accreditation Board's decision making process is maintained and undue influence from educational and/or commercial institutions avoided

- Include names of Accreditation Board staff and honorary officers (with procedure for appointment and removal)

- Provide details of all institutions currently accredited, with dates initial accreditation achieved

- Include accreditation criteria/educational standards and evidence of their transparency

- Include three complete documentary audit trails from accredited institutions, each to include the initial stages of scrutiny, eventual accreditation and subsequent annual review

- Include appeal procedures

ANNEX 7

Grandparenting

Criteria for recommending voluntary registers for direct transfer to the Health Professions Council for acupuncture, herbal/traditional medicine and traditional Chinese medicine where there is evidence that the public safety would not be at risk.

This is a copy of the document sent in the summer of 2007 by the Steering Group to Professional Associations representing practitioners using herbal medicines or acupuncture. The document sought information regarding criteria used for recommending voluntary registers to the Health Professionals Council (HPC) for direct transfer of their members to the HPC.

Introduction

The attached criteria have been agreed by the Department of Health (England) Working Group for the statutory regulation of acupuncture, herbal medicine and traditional Chinese medicine for the purposes of recommending that members of a voluntary regulatory body be automatically transferred to the statutory register when it is established. The criteria have deliberately been set to a high level and it is possible that professional associations that do not meet these may, nevertheless, be considered acceptable by the Health Professions Council which is most likely to be the future statutory regulatory body for these professions.

Professional associations are invited to submit evidence to the Working Group that they meet the attached criteria.

Information should be provided no later than **10 July 2007.**

Criteria

1. The register should have been effectively operated for a minimum period of 5 years. Similarly the organisation hosting the register should also have been in existence for at least 5 years prior to the opening of the new statutory register.

2. The organisation hosting the register, whether a single register or a federated organisation should be established and a membership organisation able to speak with a unified voice.

3. The organisation hosting the register should have evidence of (a) a code of ethics informing a code of conduct, (b) clear definitions and expectations of educational standards and outcomes (c) demonstrably effective arrangements for the accreditation of educational programmes, (d) evidence of policies and procedures that would facilitate removal of individuals from a register, (e) evidence that the register recognises the importance of continuing professional development and encourages members to remain professionally up-to-date and (f) involvement of lay members on key committees or have lay input.

4. With regard to accrediting educational programmes, effective procedures should be in place to (a) approve programmes of study, (b) monitor over a period of time their effectiveness against the stated aims and objectives for the programmes taking account of the success of students in attaining these stated, intended learning outcomes and (c) reviewing over time the continuing validity of these aims and objectives.

5. There must be an absolute separation between the financial/business activity of the organisation and those responsible for the accreditation and monitoring of educational programmes. It is acceptable for individuals to act as an accreditor but they should not stand to gain from a successful outcome.

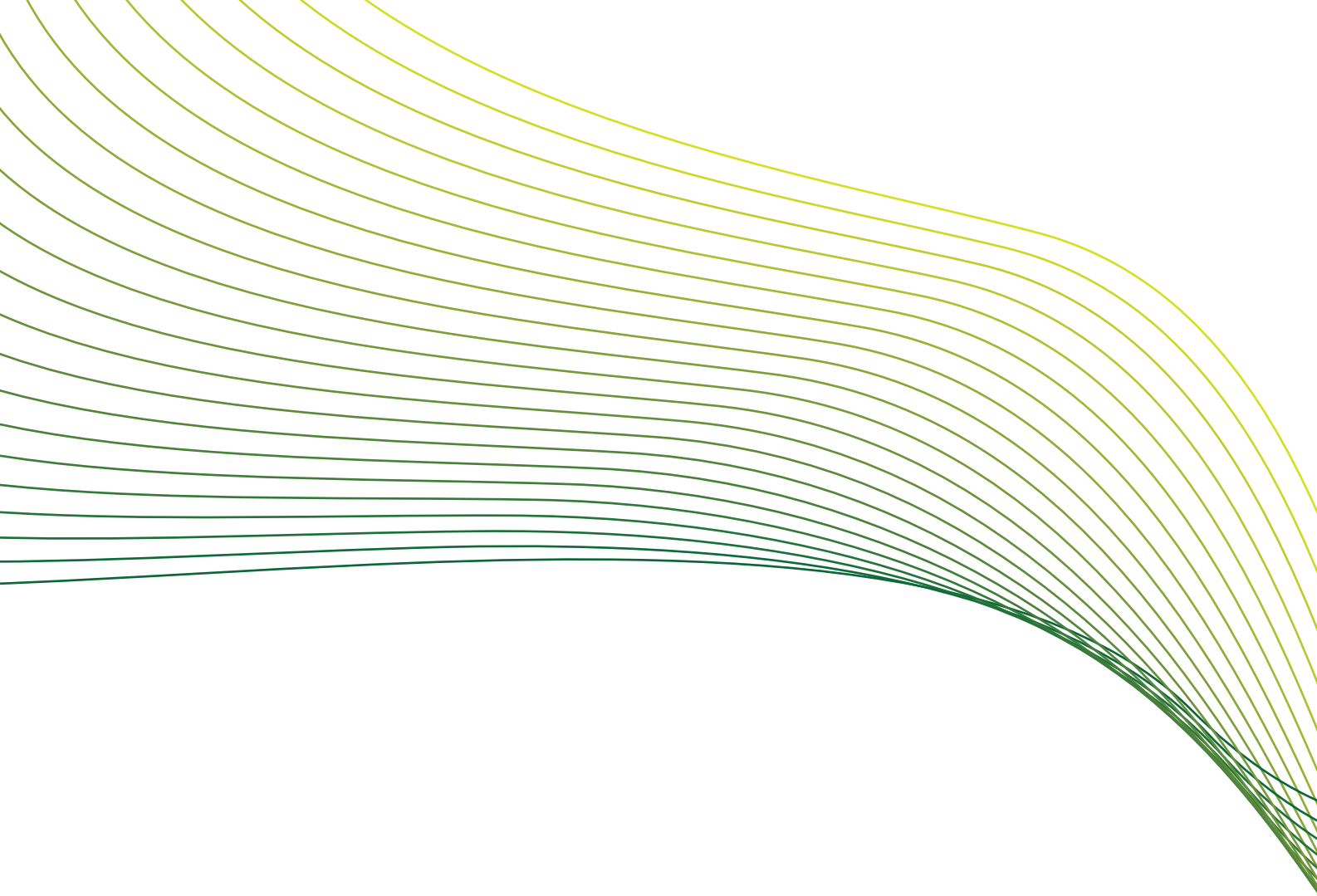
6. The organisational structure and constitution of the body, including the membership and terms of reference of all committees, should be available with evidence of active participation and operation over a minimum of a 5-year period.

7. The minimum size of a viable register will normally be 300 individuals, except where the traditions are extremely small.

8. It should be clear from the organisation that the criteria for inclusion on the professional register include language proficiency, health and fitness to practice, integrity, honesty, comprehension of written and spoken English, conduct and the attainment of minimum educational standards. There needs to be effective disciplinary procedures covering complaints from the public with appropriate separation in determining whether a prima-facie case exists and appropriate procedures for an investigation where necessary.

9. There should be procedures in place covering re-registration of individuals who have been removed from any register for any reason.

10. There should be evidence that the body is aware of the importance of criminal record disclosure and the necessity for this in order to protect the public.



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