

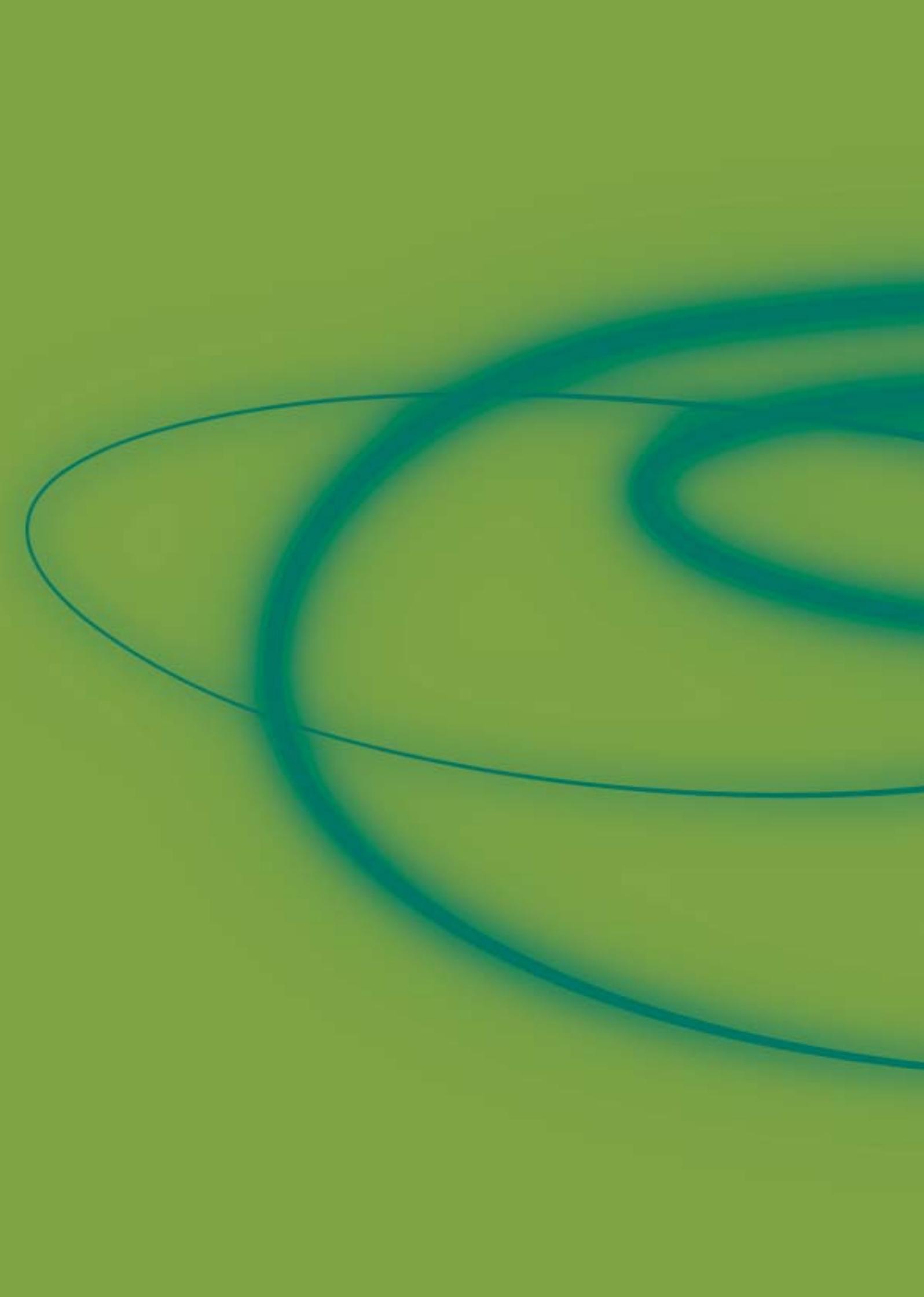
A Report from the Herbal Medicine Regulatory  
Working Group

# Recommendations on the Regulation of Herbal Practitioners in the UK

INCLUDING RECOMMENDATIONS ON THE REFORM  
OF SECTION 12(1) OF THE MEDICINES ACT 1968

September 2003

Commissioned by:  
The Department of Health  
The Prince of Wales's Foundation for Integrated Health  
The European Herbal Practitioners Association



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## INTRODUCTION

### A Preface

This document makes proposals for the regulation of the herbal medicine profession. It recognises that these, which will inevitably be adapted following consultation and debate, need to be compatible with the regulatory systems in place for other health and social care professionals – both conventional as well as complementary and alternative. Professional regulation must be open, responsive and accountable with the emphasis on both the protection of patients and the public rather than being based exclusively on the needs of practitioners.

Regulation will protect the public by setting and monitoring standards, training, conduct and performance for the herbal medicine profession.

*"The professions know that they have to make professional regulation swifter, tougher and more open if it is to regain public support – the essential foundation on which all regulation depends...Patients have a right to expect that the person who treats them is up to the job. Government has a duty to ensure that they are."*

The Prime Minister Right Honourable Tony Blair,  
Address to the NHS, 2 July 1998

### B Foreword

This report makes recommendations for the statutory regulation of practitioners of herbal medicine in the UK. It has been prepared by the Herbal Medicine Regulatory Working Group (HMRWG) which was established by the Department of Health, the Prince of Wales's Foundation for Integrated Health (FIH) and the European Herbal Practitioners Association (EHPA).

The move towards statutory regulation of herbal practitioners originates from the House of Lords' Select Committee on Science and Technology's Report on Complementary and Alternative Medicine (HMSO 2000) and the Government Response (Department of Health 2001) to it. The report recognised that complementary and alternative medicine (CAM) are both widespread and increasing across the developed world and that this has implications for patient safety. The Committee identified that there was considerable diversity of standards amongst the professions and that, for some therapies, the public was at risk from practitioners with inadequate or inappropriate training.

Herbal medicine was identified as posing particular challenges for public health. The statutory regulation of herbal medicine practitioners was supported because this profession meets agreed criteria that make statutory regulation appropriate. These criteria are risk to the public through poor practice; a voluntary regulatory system; and a credible evidence base. Regulation would ensure that appropriate training was established. This would result in competent practitioners with an understanding of the evidence base for their therapy along with an appreciation of the limitations of the treatments they can provide. Safe practitioners would understand when to refer. Effective regulation would therefore seek to safeguard the public from incompetent practitioners. It would identify practitioners suitably qualified to use a range of potent herbal remedies that are not appropriate for over-the-counter sale.

The House of Lords' Select Committee on Science and Technology's Report on Complementary and Alternative Medicine (HMSO 2000) stated that CAM included a large range of therapies and that while some had well-developed regulatory structures, others were fragmented with no consensus about regulation. The evidence base for the various CAM therapies was also variable,

but the majority did not have one. It proposed that CAM therapies should be classified into three groups. Therapies assigned to Group 1 included the most organised CAM professions where NHS provision is increasing and where research into their effectiveness had either already commenced or was likely to be beneficial. The therapies assigned to Group 2 also have support from the NHS but are used in a complementary way alongside conventional medicine. Again they require further research and need to develop their regulatory structures. Those therapies assigned to Group 3 were considered to have no evidence base for clinical effectiveness.

Herbal medicine, or phytotherapy, was defined as "a system of medicine which uses various remedies derived from plants and plant extracts to treat disorders and maintain good health". It was assigned to Group 1 along with acupuncture, chiropractic, homeopathy and osteopathy. Other therapies that also use herbal products, and in some cases acupuncture, in their practice were assigned to Groups 2 and 3. These include Maharishi Ayurvedic Medicine (Group 2), Ayurvedic Medicine (Group 3), Chinese Herbal Medicine (Group 3) and Traditional Chinese Medicine (Group 3). The proposals within this document take account of all traditions using herbal medicine as part of their practice in line with the Government Response to the House of Lords' report.

The Government Response (Department of Health 2001) to the report from the House of Lords recommended that herbal medicine and acupuncture should work towards statutory regulation under the Health Act 1999 and that this was both in the interests of practitioners and patients. Taking account of the public health risks, statutory regulation should be implemented as soon as practicable.

This report from the HMRWG on how the regulation of practitioners of herbal medicine might be achieved, should be read in conjunction with our recommendations on the regulation of herbal remedies made up to meet individual needs and supplied to the public after a personal consultation under the provisions of Section 12(1) of the Medicines Act 1968. Proposals in this latter report aim to ensure that the herbal remedies supplied by practitioners are of the necessary quality to ensure public confidence in herbal treatment. In its response to the House of Lords' report, the Government agreed that future regulatory arrangements relating to the ingredients

and products used by individual herbal practitioners should safeguard quality and safety standards while recognising the diversity of practice. The Government indicated an intention to hold discussions with herbal interest groups on this issue to consider the way forward and said that in the light of this they would consider whether any changes in legislation would be required in order to reach a satisfactory regulatory position. In effect, the work of the HMRWG on the issue of possible reforms to the regime of unlicensed herbal remedies supplied under Section 12(1) of the Medicines Act 1968, represents the first stage in the process of exploration and dialogue envisaged by the Government. It needs to be seen as distinct from, but complementary to, the wider European negotiations on the proposed Directive on Traditional Herbal Medicinal Products which relates to industrially produced traditional herbal remedies sold over-the-counter direct to the public.

I am immensely grateful to members of the HMRWG who have freely given their time and expertise to produce this report. I commend it to you as an important step towards the regulation of practitioners who use herbal products as medicines and as a basis for formal consultation by the Department of Health.

Professor R Michael Pittilo  
Chair  
Herbal Medicine Regulatory Working Group

## C Terms of Reference

The **terms of reference** for the HMRWG were to:

- 1 produce a report which examines the options for achieving the successful statutory regulation of the herbal medicine profession as a whole, and makes recommendations which will form the basis for a wider consultation by the Government and subsequently for the legislation that will enable the statutory regulation of the herbal medicine profession;
- 2 in the light of these recommendations for the statutory regulation of the profession and the current Medicines and Healthcare products Regulatory Agency (formerly the Medicines Control Agency) review of Section 12(1) of the Medicines Act 1968, make recommendations for assuring the safety and quality of herbal remedies supplied under Section 12(1).

The **key objectives** for the HMRWG were to:

- 1 support and promote moves towards unification within a federal structure of the herbal practitioner profession;
- 2 produce a report, as outlined above in the Terms of Reference, by April 2003;
- 3 recommend within the report whether any changes to medicines law relating to the supply of unlicensed herbal remedies following one to one consultation, may be desirable in order to assure the consumer as to the safety and quality of these medicines.

The Chair of the HMRWG was **accountable to** the three organisations that established the group on 1 January 2002. The key stakeholders were:

- 1 The Department of Health
- 2 The European Herbal Practitioners Association
- 3 The Prince of Wales's Foundation for Integrated Health

# D Herbal Medicine Regulatory Working Group Membership and Details of Professional Associations

## List of Members

Professor R Michael Pittilo	Chairman and Lay Member
Andrew Chevallier	Vice Chair
Amrit Ahluwalia	Secretary

## Herbal Professional Representatives and Alternates

Dee Atkinson/Peter Conway	College of Practitioners of Phytotherapy
Jill Davies/Peter Jackson-Main	Association of Master Herbalists
Alison Denham/Trudy Norris	National Institute of Medical Herbalists
Peter Jackson-Main/Jill Davies	European Herbal Practitioners Association
Dr Song Xuan Ke/Geoff Most	British Society of Chinese Medicine
Dr Nick Lampert/Emma Farrant	Register of Chinese Herbal Medicine
Dr Graeme Litchfield/Ifanca James	International Register of Consultant Herbalists
Elizabeth Lyden/Ed Berger	Unified Register of Herbal Practitioners
Dr N Moorthy/Dr Athique	Ayurvedic Medical Association
Professor Huijun Shen/Ji Dong Wu	Association of Traditional Chinese Medicine
Dr S Warriar/Dr D Gunawant	British Association of Accredited Ayurvedic Practitioners and British Ayurvedic Medical Council

## Lay Members

Sally Hornsby	Lay Member
Robert Johnstone	Lay Member
Mee Ling Ng	Lay Member

## Non-Herbal Professional Body Representatives

Professor Bill Dawson	Royal Pharmaceutical Society and Lay Member
Dr Catherine O'Sullivan	Education Committee European Herbal Practitioners Association

## Herbal Medicine Sub-Committee

Michael McIntyre	Chair
Dee Atkinson	Members
Bill Dawson	
Professor H Shen	
Dr S Warriar	
Amrit Ahluwalia	

## Stakeholder Representatives

Gordon Brown	Complementary Therapies Unit Department of Health
Rebecca Sidwell	Health Regulatory Bodies Branch Department of Health (from April 2003)
Pamela Jack	The Prince of Wales's Foundation for Integrated Health
Michael McIntyre	European Herbal Practitioners Association

## Details of Professional Associations Represented on the HMRWG

Name	Registered Address	HMRWG Rep	President At Apr 03	Year Est	Members	Accredited Courses	CPD	EHPA Member
Association of Master Herbalists	Broadgate Walkington HU17 8RW	Jill Davies	P Jackson -Main	1996	82	No	Yes	Yes

The AMH was founded by UK graduates of the School of Natural Healing, based upon the Western, 'eclectic' tradition in herbal medicine. Our materia medica is sourced from the British Isles and Europe as well as from North America and further afield. Members are trained in a vitalistic approach and will invariably offer advice on nutrition and lifestyle, as well as prescribing herbal medicines in individually designed formulae.

Association of Traditional Chinese Medicine	22 Rupert St, London W1D 6DG	Prof H Shen	Ji Dong Wu	1994	242		Yes	No
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The Association of Traditional Chinese Medicine (UK) (ATCM) is a self-regulated professional body which includes the whole Traditional Chinese Medicine (TCM) system mainly including Chinese herbal medicine, acupuncture and Chinese remedial massage. Dedicated to excellence in the practice of TCM, it focuses on professional qualifications and aims to enlarge the sphere of influence of TCM in the UK. The majority of the ATCM members have completed a thorough training of at least five years in TCM and conventional medical science appropriate to the practice of Chinese medicine.

Ayurvedic Medical Association	The Hale Clinic, 7 Park Cres, London W1	Dr M Athique	Dr S Godagama	1996	42	Yes	Yes	Yes
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AMA UK was founded to protect Ayurveda, provide services to the general public and maintain the public confidence. All members have to follow the Code of Conduct, Rules and Regulations issued to all practitioners by the Association. The Association holds Annual General Meetings each year and the executive committee meets regularly. The Association helped to form the Ayurvedic Traders Association and takes an active part in discussions with the Department of Health and other organisations. It publishes a register of Ayurvedic physicians with an introduction to Ayurveda for the general public.

British Accredited Ayurvedic Practitioners and British Ayurvedic Medical Council	81 Wimpole St, London W1G 9RF	Dr S Warriar Wodeyar, the Maharaja of Mysore	HE Sri	1999	35	Yes	Yes	No
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The BAMC was set up in 1999 to promote Ayurveda in the west and to overcome regulatory restrictions and cultural prejudices that prevent its growth. One of its main objectives is to protect patients and members of the public by ensuring that Ayurvedic medicine is only practised by qualified and competent practitioners. BAMC also aims to promote the conduct of high quality research into Ayurvedic therapies and treatment modalities and to ensure that safe and good quality Ayurvedic medicinal products are supplied.

The criterion for Full Membership of BAAAP is a minimum qualification of BAMS (Bachelor of Ayurvedic Medicine and Surgery) from a recognised university in India or Sri Lanka. Individuals with a BA(Hons) degree or equivalent in Ayurveda from an approved university in the UK/Europe will gain full membership status after completing an internship/clinical training of 1,000 hours under the supervision of an Ayurvedic physician (BAMS/MD). Students currently on an undergraduate degree programme in Ayurveda at a recognised university in the UK/Europe will be accepted as Student Members. Full Members of BAAAP currently work as single-handed general practitioners of Ayurveda or as staff doctors in Ayurvedic Therapy Centres which offer classical Ayurvedic treatments. BAAAP consider the practice of Ayurveda by unqualified practitioners and the dilution of the standards of Ayurvedic education and practice to be dangerous, unethical and unprofessional.

Name	Registered Address	HMRWG Rep	President At Apr 03	Year Est	Members	Accredited Courses	CPD	EHPA Member
British Society of Chinese Medicine	Asante Academy Clerkenwell Building, London N19 5LW	Dr Ke	Dr Ke	2001	35	No	Yes	Yes

The BSCM aims to promote and develop high standards of Chinese medicine in the UK, especially in the areas of Education / Training, Practice, Research and Quality of Herbal Medicines. It will promote and develop co-operation and understanding between practitioners and students of Chinese medicine and conventional Western medicine; represent the interests of practitioners and students of Chinese medicine in the UK; work with the Government of the United Kingdom towards Self Regulation of Chinese Medicine by Statute and improve the legal status and recognition of the herbal profession.

College of Practitioners of Phytotherapy	Rutherford Park, Battle, E Sussex TN33 0TY	Dee Atkinson	Peter Conway	1991	108	Yes	Yes	Yes
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The CPP was founded by Hein Zeylstra (former Principal of the College of Phytotherapy) and Kristin Jeffs (former President of the National Institute of Medical Herbalists) to serve as a forum for the development of excellence in the practice of Western herbal medicine. Its main focus from the outset has been on providing high quality continuing professional development seminars; it also publishes the British Journal of Phytotherapy. Phytotherapy is the practice of modern western herbal medicine. It is a rational approach based upon a combination of understanding the contemporary scientific evidence-base for herbal medicine, appreciating the insights that can be gained from traditional herbal medicine texts and records (ethnobotanical sources) and learning from clinical experience by ongoing reflective practice.

International Register of Herbalists	32 King Edward Rd, Swansea SA1 4LL	Graeme Litchfield	Ifanca James	1948	38	No	Yes	Yes
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The IRCH training programme closely follows the traditions of the Open University. The 4 – 6 year part-time distance learning course is exclusively traditional in its approach to Herbal Medicine. A large number of students are University graduates. Graduates are awarded the Diploma of Botano-therapy (DBTh), given a supervisor (a mentor) for one year or longer and a site visit. A Registered Medical Herbalist is entitled to add the letters MIRCH after his/her name. A post-graduate seminar that forms part of CPD, is held annually. The IRCH publishes a Quarterly Journal of Natural Medicine, a Register of Members and a Prospectus.

National Institute of Medical Herbalists	56 Longbrook St Exeter Devon EX4 6AH	Alison Denham	Trudy Norris	1864	550	Yes	Yes	Yes
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NIMH was established in 1864 to develop professional standards and has campaigned notably in the 1880s, 1905-1914, 1923, 1945, 1968 and 1994 to protect and improve the legal status of medical herbalists. NIMH is a company limited by guarantee and run by an elected Council who carry out their duties in a voluntary capacity.

The register of qualified and insured Members has been published annually for over 100 years. All current Members have undertaken three years full-time or four years part-time training on one of six accredited (or in the accreditation process) courses. Members agree to be bound by the published code of ethics. The committees are the Accreditation Board (set up in 1994), the Postgraduate Training Board which organises seminars and the mandatory continuing professional development and new members schemes, the Professional Ethics Working Group, the Policy Group, the Publicity Group and the Quality and Safety Working Group which publishes authoritative guidance on safe prescribing and dispensing procedures and administers the Yellow Card system for notification of adverse events. NIMH publishes the European Journal of Herbal Medicine which reflects the wide range of practice within NIMH and includes current clinical practice, clinical audit, traditional usage, scientific findings and the conservation of medicinal plants. NIMH is funding a pilot study to evaluate the holistic practice of herbal medicine and the policy of NIMH is to combine a solid foundation in clinical skills with encouragement of diversity in practice to encompass both research evidence and use of traditional and energetic sources of knowledge.

Name	Registered Address	HMRWG Rep	President At Apr 03	Year Est	Members	Accredited Courses	CPD	EHPA Member
Register of Chinese Herbal Medicine	Ferndale Business Centre, 1 Exeter St Norwich NR2 4QB	Dr Nick Lampert	Dr Nick Lampert	1987	447	Yes	Yes	Yes

The RCHM was the first organisation set up to regulate the practice of Chinese Herbal Medicine (CHM) in the UK. The RCHM exists to provide access to members of the public seeking a properly qualified practitioner who is bound by Codes of Ethics and Good Practice and who has full indemnity insurance; to assist in setting Chinese herbal medicine standards in the UK (it has established links with approved educational institutions to provide standards for entry to the RCHM); to work towards improved regulation of practitioners and herbs/herbal products in the UK (it has set up a scheme for Approved Suppliers in order to promote Quality Control among suppliers, together with a Dispensary Code for individual practitioners and suppliers, and it has worked closely with the Chinese Medicinal Plant Authentication Centre at the Royal Botanic Gardens, Kew, which was established in order to provide reference samples for the Chinese materia medica) ; to ensure practitioner access to the materical medica while working with consumer and patient organisations to ensure the safety of the public; to provide assistance and information to the media regarding CHM.

Unified Register of Herbal Practitioners	58 Fairmantle St., Truro Cornwall TR1 2EG	Elizabeth Lyden	Edward Thompson	1997	31	Yes	Yes	Yes
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The URHP is unique in that it represents all 3 major traditions of herbal medicine practiced in the UK. Western, Chinese and Ayurveda. Many members practice more than one of these traditions. The cross fertilisation of approaches in discussions & newsletters enriches discussions and broadens our perspectives. Although a relatively new organisation we are likely to double in numbers over the next year due to the number of graduates coming through. We are committed to delivering the highest possible quality of herbal practice and look to supporting newly graduated members in developing their practice. We are a member of the EHPA and are committed to the work of the HMRWG.

# SECTION 1: PROPOSALS FOR THE REGULATION OF HERBAL MEDICINE PRACTITIONERS

## E Background

1 The following recommendations for the regulation of practitioners of herbal medicine are proposed by the Herbal Medicine Regulatory Working Group (HMRWG). These recommendations recognise that there are different traditions within herbal medicine and that individual practitioners utilise a range of treatment modalities within the scope of their practice. The different traditions we have considered include Western Herbal Medicine, Chinese Herbal Medicine, Traditional Chinese Medicine (TCM), Ayurvedic Medicine and Tibetan Herbal Medicine, all of which, Tibetan Herbal Medicine excepted, were represented on the HMRWG. Other herbal medicine traditions, such as Kampo (Japanese traditional medicine), may be covered by the future regulatory body. Within TCM, acupuncture is used alongside herbal medicine in the holistic treatment of patients.

2 An important impetus leading to the setting up of the HMRWG was the House of Lords' Select Committee on Science and Technology's Report on Complementary and Alternative Medicine (CAM) (HMSO 2000) and the Government Response to it (Department of Health 2001). The House of Lords' Report stated that the interests of the public in their use of CAM would be best served by improved regulatory structures for many of the professions concerned. It identified evidence of progress for many therapies but noted that in many cases there was diversity of standards, unacceptable fragmentation and a lack of consensus about how to achieve regulation.

3 The House of Lords' report (HMSO 2000) categorised CAM therapies into three groups. Group 1 therapies were termed the principal disciplines and included osteopathy, chiropractic, acupuncture, herbal medicine and homeopathy. Group 2 therapies were those that complement conventional medicine but do not embrace diagnostic skills and included aromatherapy, the Alexander Technique, Bach and other flower remedies, body

work therapies including massage, counselling stress therapy, hypnotherapy, meditation, reflexology, shiatsu, healing, Maharishi Ayurvedic Medicine, nutritional medicine and yoga. Group 3 therapies were those disciplines in Group 1 which purport to offer diagnostic information as well as treatment, but which, in general, favour a philosophical approach and are indifferent to the scientific principles of conventional medicine, and through which various and disparate frameworks of disease and disease causation and its management are proposed. They were separately sub-categorised into group 3a – long established and traditional systems of healthcare including Anthroposophical Medicine, Ayurvedic Medicine, Chinese Herbal Medicine, Eastern Medicine, Naturopathy and Traditional Chinese Medicine, and group 3b - other alternative disciplines which lack any credible evidence base including Crystal Therapy, Dowsing, Iridology, Kinesiology and Radionics.

4 The terms of reference and objectives of the HMRWG were informed by the Government Response (Department of Health 2001) to the House of Lords' Report, which recommended that traditional therapies using herbal products as medicines but assigned to Group 3 could nevertheless be included within a federal group of therapies in Group 1 under the heading of herbal medicine. However the response document also noted that therapies outside Group 1 were likely to function in a different way and that the statutory regulation of these therapies might be hard to establish. The HMRWG has therefore considered herbal medicine in its entirety regardless of where individual therapies using herbal products were assigned within the House of Lords' report.

5 The HMRWG has been concerned with safe practice by herbal practitioners and the safety and quality of the products they use. It has not had any remit with regard to efficacy. Clearly if herbal medicine is to be funded in the UK by the Department of Health and the NHS, an evidence base and support for clinical effectiveness will need to be established.

6 The ethos of the HMRWG was to build on existing consensus amongst members of the herbal medicine community. The HMRWG was large and inclusive, with the main organisations representing those practising herbal medicine being included in the membership. Organisations who are not represented have been excluded because the numbers of practitioners they represent are very

small (less than 40), or because they have predominantly commercial interests. Notwithstanding this, formal discussions have taken place with organisations not represented on the HMRWG where they are known and their views have indirectly informed the proposals within this document.

7 In establishing the HMRWG it was recognised that the needs of different stakeholders had to be met. Both the House of Lords' Report (HMSO 2000) and the Government Response (Department of Health 2001) recognised the importance of working across all interested groups, including practitioners, The Prince of Wales's Foundation for Integrated Health and the Department of Health to develop clear guidelines on competency and training for CAM disciplines. The importance of working with the Medicines and Healthcare products Regulatory Agency (MHRA) regarding the update of medicines law as it pertains to herbal practice was also recognised. Lay membership of the HMRWG has ensured that the interests of patients and the public have been considered and representation from the Royal Pharmaceutical Society has provided expert advice on the regulation of practitioners as well as guidance on the products they use. In addition, expert opinion was obtained from the Royal College of Physicians (Complementary and Alternative Medicine Committee) with regard to the Core Curriculum.

8 Within the UK, the European Herbal Practitioners Association (EHPA) has, for close to a decade, sought to broker consensus amongst the different herbal medicine communities. The organisations represented on the HMRWG are all members of the EHPA with the exception of the Association of Traditional Chinese Medicine (ATCM) and the British Ayurvedic Medical Council/British Association of Accredited Ayurvedic Practitioners (BAMC/BAAAP). The organisations that are represented on the HMRWG which are affiliated to the EHPA are the Association of Master Herbalists, the Ayurvedic Medical Association, the British Society of Chinese Medicine, the College of Practitioners of Phytotherapy, the International Register of Consultant Herbalists, the National Institute of Medical Herbalists, the Register of Chinese Herbal Medicine and the Unified Register of Herbal Practitioners.

## F The Regulatory Framework

9 The HMRWG has considered and debated a range of submissions including a Core Curriculum, Accreditation Arrangements, a Code of Ethics and a Continuing Professional Development scheme transferred to it by the EHPA.

10 The proposals for regulation recognise that there are other traditions or practitioners using herbal products, beyond those represented on the HMRWG, that members of the public may wish to safely access. These proposals allow for these practitioners to be included within the regulatory framework at a later stage.

11 Regulation of herbal medicine needs to take account of the overall numbers of practitioners and their association with particular traditions. Currently, there are approximately 1,300 herbal medicine practitioners who are members of voluntary registers within the UK. The size of these registers is approximately equal for the traditions of Western Herbal Medicine and Chinese Herbal Medicine/TCM. The numbers of practitioners of Ayurvedic Medicine and Tibetan Medicine are small by comparison. An unknown number of practitioners, mainly in the Chinese herbal medicine sector, do not belong to voluntary registers. Estimates of their number vary but taking them into account, it is likely that the total number of UK herbal practitioners would be at least 2,000.

12 The proposals for regulation have been arrived at having considered other options including seeking membership of the Health Professions Council (HPC) as well as the establishment of separate councils for each of the traditions. The former was rejected for a number of reasons. Firstly, unlike the other disciplines covered by the HPC, herbal medicine is not well established in mainstream healthcare. Furthermore, the size of the HPC would make it difficult to ensure that each of the herbal medicine traditions were properly represented on council. Lastly, the HPC is a new organisation with a heavy developmental agenda and already has a number of disciplines seeking membership. There is potential for overload which would not best serve the interests of the herbal medicine profession or the public in the short term.

13 Separate councils for the traditions were rejected because of the very small numbers of

professionals involved in the UK with herbal medicine in comparison with other regulated professions. The costs to practitioners of supporting separate councils would not make this a feasible option. There are also some disciplines, such as Tibetan Medicine, with a very small number of well-qualified practitioners who use herbal products but would not easily be accommodated if separate councils for the disciplines were established. They could, however, be accommodated in a CAM Council.

14 Two options for the regulation of practitioners of herbal medicine are proposed (see p. 26 for diagrams). The first option is the establishment of a Herbal Council. The advantages are that it is the goal that the majority of practitioners, particularly those from Western Herbal Medicine, have been working towards for almost a decade and that it might be perceived as giving greater status to herbal medicine than a shared council. There are, however, significant disadvantages. The cost of a single Herbal Council would be prohibitive to practitioners if it were to be fully self-funding. Furthermore, many practitioners utilise a range of modalities and, as noted above, in the case of TCM, practitioners use acupuncture as well as herbal medicine. A single Herbal Council potentially might work against interdisciplinary working which is a feature of much complementary and alternative medicine (CAM) practice.

15 The second option, and this was preferred by the HMRWG, is for the establishment of a shared council, the Complementary and Alternative Medicine Council, hereafter referred to as the CAM Council, which would include, at the first stage, both herbal medicine and acupuncture. The option for including other disciplines would be open at a later stage. Within the CAM Council it would be possible to have separate sections of the register for the different herbal medicine traditions and for acupuncture. Having a single regulatory framework would have immediate benefits for practitioners using both herbal medicine and acupuncture. Other benefits would include a larger critical mass of practitioners and it would be possible to be more cost effective by sharing administrative resources. Should there be a move to legislate further CAM practices, such as homeopathy, at a later stage, these could be incorporated in the CAM Council reducing the subscription for individual practitioners accordingly. A larger council would have a greater degree of influence and would be better equipped to protect the interests of both patients and practitioners.

The General Osteopathic Council and the General Chiropractic Council might also consider the possible benefits to practitioners of a single shared council through the promotion and regulation of interdisciplinary working as well as the costs borne by practitioners. We recognise, however, that for these professions to be associated with a CAM Council, reform of recently agreed legislation would be required. The wider implications of the establishment of a CAM Council were outside the terms of reference for the HMRWG and might be the subject of a feasibility study amongst interested professions if this concept were generally supported. Representatives from the Department of Health and Children in the Republic of Ireland, where the regulation of CAM disciplines are also being considered, have advised us that an overarching council is also emerging as the favoured option for that country.

16 Whilst separate councils promote the status and development of individual professions, they militate against interdisciplinary working, which is an important feature of CAM including the practice of herbal medicine. With the orthodox medical professions regulatory change has been implemented to ensure that care is designed around the needs of patients, unencumbered by professional boundaries. Separate councils for CAM run contrary to this and may work against the tradition of interdisciplinary working amongst the professionals being regulated.

17 A further advantage of a CAM Council is that central administrative costs and premises can be shared by a range of professions. This has the obvious advantage of reducing registration fees for individual practitioners. A shared council is also likely to be both more effective and able to exert more authority through the representation of a larger number of CAM practitioners. The number of herbal medicine practitioners is small and it is difficult to see how a separate Herbal Council could be self-funded by them.

18 The CAM Council would have to set criteria that professions aspiring to belong to the Council would need to meet. Professions seeking statutory regulation would need to have a clear understanding of the requirements that would have to be met to satisfy the CAM Council in advance of future legislation. These criteria might be analogous to those established by the HPC.

19 A possible disadvantage of a CAM Council is that, unlike the orthodox healthcare professions, individual CAM professions do not have a long

history of statutory regulation. Historically there have been difficulties in reaching a consensus view within individual CAM professions about minimum levels of competency and the appropriate education and training required to achieve these. The establishment of separate councils would allow individual herbal traditions to develop their profession and foster coherence. Notwithstanding this, for reasons identified above, we do not believe a separate council is a viable option for the herbal medicine profession.

20 Either the Herbal Council or the CAM Council will have responsibility for the statutory regulation of the practice of herbal medicine and will advise on the products used by herbal practitioners, including materials of animal or mineral origin<sup>1</sup>, as medicines in their professional practice. Practitioners will of course be expected to conform to international and national law on the conservation of medicinal plants and animal materials.

21 It is recommended that those who are statutorily regulated may prescribe unlicensed remedies which include animal and mineral materials verifiably used as traditional medicines, where the remedy is made up by the practitioner or to the practitioner's specification, as long as their safety and quality of the remedy can be assured. This would require legislative provision.

22 Statutory regulation will enable legal identification of those practitioners qualified to use potent herbal remedies that are only suitable for sale or supply under adequate professional supervision.

## G Role and Composition of the Regulatory Body

23 The key objectives of the Herbal Council or CAM Council will be to:

- treat the health and welfare of patients as paramount;
- collaborate and consult with key stakeholders;
- ensure openness and accountability to the public and the profession for its work;
- work with the profession to develop best practice.

24 The Herbal Council or CAM Council will have responsibility for establishing and maintaining a Register of practitioners competent to prescribe and use herbal products as medicines. The Herbal Council or CAM Council will advise on special licensing arrangements that might allow other healthcare professionals to use herbal products as medicines and any limitations that might apply to those not eligible for inclusion on the Register.

25 The Herbal Council or CAM Council shall determine minimum levels of education and training along with levels of competence expected for inclusion on the Register. To achieve this the Herbal Council or CAM Council, advised by its Education and Training Committee, will specify a Core Curriculum for herbal medicine which will provide the necessary level of understanding and competence to enable pre-registration students to be included on the Register. The core curriculum will be used as a guide and differing educational institutions will be able to interpret it in different ways provided that the key competences for inclusion on the Register can be achieved. The core curriculum determined by the Herbal Council or CAM Council will identify a body of knowledge and training that will deliver competences that the public will expect all practitioners to demonstrate. However, it will also allow flexibility in the way that these are delivered. Within the curriculum there will be an element that is tradition specific for Western Herbal Medicine, Chinese Herbal Medicine/TCM, Ayurvedic Medicine and Tibetan Herbal Medicine. In the future there might also be a specific element for Kampo (Japanese traditional medicine). Each of these components of the curricula will be approved by the Education and Training Committee of the Herbal Council or CAM Council (which will include representatives from all

<sup>1</sup> Throughout this report 'herbal medicines' includes animal and mineral materials used in several traditions.

traditions and lay membership) advised by tradition specific advisory committees of the Council.

26 The Herbal Council or CAM Council will have responsibility for accrediting educational establishments wishing to offer pre-registration education and training for candidates seeking admission to the Register. The Herbal Council or CAM Council will publish clear and transparent guidelines on the expectations from educational institutions along with details of how standards will be secured and monitored. In framing these guidelines, the Herbal Council or CAM Council will be seeking to ensure that an educational establishment has the expertise and resources to deliver the Core Curriculum. The Herbal Council or CAM Council will have authority to recognise "approved qualifications", the attainment of which will allow for inclusion on the Register.

27 The Herbal Council or CAM Council should have four statutory committees, which parallel those of other statutory healthcare councils. These committees would be an Investigating Committee, a Professional Conduct and Competence Committee, a Health Committee and an Education and Training Committee.

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

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

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

31 The Education and Training Committee will have responsibility for establishing standards and requirements for the education and training required for registration and continuing

professional development. It will have responsibility for all pre-registration programmes and continuing professional development in support of registrants along with the registration of applicants trained in the UK and overseas. It will have responsibility for monitoring the standards of education and training and the accreditation of institutions for this purpose.

32 With a Herbal Council the statutory committees would include practitioners from all traditions but in the case of a CAM Council they would also include acupuncturists with the option of including other therapies that might be eligible for statutory regulation at a later stage. For example, if homeopathy were to be regulated and included within the CAM Council, each committee would include homeopaths.

33 Depending on whether a separate Herbal Council or CAM Council is adopted, there would be minor differences to the committee structure. In addition to the four statutory committees, both would have separate discipline/tradition-specific advisory committees. With a single council, these advisory committees would be for Western Herbal Medicine, Chinese Herbal Medicine/TCM, Ayurveda and Tibetan Herbal Medicine. With the CAM Council, there would also be a separate professional advisory committee for acupuncture. The Council would consist of lay representatives along with representatives of the herbal medicine profession including all traditions. In the case of the CAM Council there would need to be full and proportionate representation for acupuncture. The professional advisory committees would have formal advisory roles to both the Council and the statutory committees.

34 The Herbal Council or CAM Council would be free to establish additional committees, as it deemed appropriate.

35 The composition of the Herbal Council or CAM Council should be informed by public consultation. The number of executive officers and staff have been modelled, for costing purposes, on the General Chiropractic Council and the General Osteopathic Council. There must be a Chairperson, a Chief Executive and a Registrar and sufficient executive, administrative and other support staff to provide satisfactory service to members and the public. Lay representation on all committees is very important. It is expected that forty per cent of Council would include lay members and that there would be at least two lay members on each

statutory committee and professional advisory group established by the Council. With regard to its composition the Council needs to ensure that there is representation from the devolved administrations in the home countries of Scotland, Wales and Northern Ireland. The NHS Appointments Commission should appoint the Chairperson and Lay Members to ensure that the process is fair and equitable and conducted independently in the public interest.

36 In determining minimum levels of education and training to allow practitioners to be included on the Herbal Register, registrants would in turn, subject to medicines legislation being amended, have access to the full range of herbs.

37 The Herbal Council or CAM Council will liaise closely with other statutory regulatory bodies and with those responsible for voluntary regulatory arrangements where these cover modalities that are used by herbal medicine practitioners on the Herbal Register. The purpose of this is to ensure that herbal medicine practitioners are aware of what education and training they should safely have completed to enable them to practise modalities other than the prescription of herbal medicines, or other products used as medicines. These would include, for example, massage and aromatherapy but the most important is acupuncture, which is widely practised by herbal practitioners.

38 With respect to acupuncture, the Government is to receive advice on regulation from a parallel working group, the Acupuncture Regulatory Working Group (ARWG). In the event that it recommends a separate Acupuncture Council, it is proposed that both reciprocity agreements and a shared administration, to include co-location of premises, be explored to reduce costs. If there is consensus about a CAM Council it is proposed that both professions work to establish an administration modelled on the HPC to cover both disciplines and the different traditions.

39 Sharing an administration or working within a CAM Council will promote close working between the herbal and acupuncture professions. It will also reduce costs for practitioners and facilitate mechanisms whereby practitioners using both modalities are not penalised by paying separate registration fees. The three Chinese medicine associations represented on the HMRWG are in full agreement with the recommendation for a shared council which, in addition to registration of practitioners of herbal medicine and acupuncture,

will also include registration of TCM practitioners, indicating competence in both modalities.

40 It will be for the ARWG to make recommendations on the regulatory arrangements for acupuncture and it will make proposals that will inform levels of education and training necessary for practitioners using acupuncture as part of their practice but not as their main discipline. These may range from education and training that allows the use of acupuncture in specific and defined circumstances through to inclusion on the Acupuncture Register. Herbal medicine practitioners using acupuncture as part of their practice will have a responsibility under the Code of Ethics to ensure that they are properly trained according to standards laid down by the ARWG and that their practice presents no risk to patients.

41 The Herbal Council or CAM Council will have responsibility for determining the requirements for Continuing Professional Development (CPD) and ensuring that practitioners on the Register undertake mandatory updating. The Herbal Council or CAM Council will approve criteria for courses for CPD and it is expected that these will be mainly offered through professional associations and further and higher education institutions.

42 The Herbal Council or CAM Council will have responsibility for determining the standards of conduct, performance and ethics of those admitted to the Register and will provide appropriate guidance. It will put in place procedures to protect patients and the public from individuals it deems unfit to practise. In this context, it will determine any additional arrangements for training that should be undertaken by those individuals removed from the Register to allow their re-admittance.

43 The Code of Conduct will give guidance on the conduct expected of a registered practitioner, in particular on issues relevant to the consultation such as confidentiality and informed consent. There will also be a Code of Practice relating to the manufacture, preparation and dispensing of herbal medicines under Section 12(1) of the Medicines Act 1968 and the management of the dispensary by the herbal practitioner.

44 Inclusion on the Register will allow a practitioner the use of a protected title. Possible titles could include Registered Practitioner (Western Herbal Medicine), Registered Practitioner (Traditional Chinese Medicine), Registered Practitioner (Chinese Herbal

Medicine), Registered Practitioner (Tibetan Herbal Medicine) and Registered Practitioner (Ayurvedic Medicine). The differing titles recognise that competence to prescribe herbal, and other products, as medicines can be attained through differing traditions and methods of education and training. If a practitioner were qualified in two or more traditions then these would be included within the bracketed element. For example, Registered Herbal Practitioner (Western Herbal and Chinese Herbal Medicine), would indicate a practitioner competent in both Western Herbal Medicine and Chinese Herbal Medicine whilst Registered Herbal Practitioner (Traditional Chinese Medicine) would signify a practitioner registered to practise both Chinese Herbal Medicine and Acupuncture. The appropriate titles should be determined following consultation amongst practitioners, other health professionals and the public.

45 The Herbal Council or CAM Council should establish arrangements that permit reciprocal arrangements with professional registration authorities in any country or state outside the UK subject to specified conditions. These should relate to identity, character, health, a pass in a suitable qualifying examination, good standing, the production of a certificate of registration, and the completion of a suitable period of experiential work in the UK under the direct supervision of a registered professional. In addition, the applicant should complete a declaration to show that the relevant UK code of practice has been read and understood.

46 For practitioners coming from countries without reciprocal arrangements with the UK, who nevertheless wish to practise in the UK, the Herbal Council or CAM Council could review those individuals' documented training programmes, mapping them against the Common Curriculum agreed for the UK. It is important that the regulatory body is assured that applicant professional herbal practitioners from outside the UK should have the competence expected of healthcare practitioners in the UK.

47 The proposals for regulation have been accepted by all members of the HMRWG with the exception of the representatives from BAMC/BAAAP. The view of these organisations is that there should be separate regulation for Ayurvedic Medicine. They continue to maintain that the curriculum being proposed for Ayurvedic Medicine is unsatisfactory both with regard to

content and the proposed time of study. The Ayurvedic Medical Association who are represented on the HMRWG and the Maharishi Ayurveda Physicians Association, who are not represented on the HMRWG, have both endorsed the Ayurvedic Medicine element of the curriculum as providing satisfactory standards of education and training to deliver threshold competency for inclusion on the Register.

48 The differences amongst the Ayurveda organisations could not be reconciled by the HMRWG. Specific advice was, therefore, sought from both the Sri Lankan High Commission and the Indian High Commission. The latter arranged a meeting between representatives of the High Commission, the HMRWG Chair, the Department of Health and colleagues from the Department of Indian Systems of Medicine and Homeopathy. The Department of Indian Systems of Medicine and Homeopathy have provided a curriculum outline, which they consider appropriate for adoption within the UK and which would allow graduates to practise safely and competently. It includes 1,666 hours of theoretical, practical and clinical activities, with the requirement to supplement these hours with further clinical practice where it is deemed necessary or appropriate. Ayurvedic Medicine, and this is true for other herbal medicine traditions, needs to be taught in an integrated way with students having an opportunity to see patients during their clinical training. The curriculum provided by the Department of Indian Systems of Medicine and Homeopathy has been mapped against the EHPA Core Curriculum and the specific Ayurvedic Medicine component of this. There is considerable overlap and congruity. Practitioner groups recognise that work is needed to harmonise details of practice and some of the *materia medica* to the legislative and healthcare context of the UK. BAMC/BAAAP have accepted that the curriculum provided by the Department of Indian Systems of Medicine and Homeopathy is acceptable to them if supplemented with 60 hours of Sanskrit, 60 hours of Ayurveda philosophy and 1,000 hours of clinical training.

49 It is the opinion of the HMRWG that further work needs to be undertaken by practitioners of Ayurvedic Medicine to agree minimum standards of education and training that will deliver threshold competency. It is hoped that this work can be undertaken well in advance of the establishment of the Herbal Council or CAM Council. There was a strong consensus that the emphasis should be on meeting learning outcomes rather than a rigid

adherence to a prescribed number of hours. The quality of the learning experience was considered to be at least as important as determining the number of hours that should be allocated to a particular topic. In planning curricula, different institutions may wish to vary the time allocated to particular topics and this flexibility should be permitted provided that both learning outcomes and threshold competences are achieved by the students. Institutions are encouraged to recognise that one hour of well structured and delivered academic or clinical education can be worth several where the planning has been less rigorous.

50 A Grandparenting Scheme (Annex V) has been proposed. This will assist the Herbal Council or CAM Council to ensure that herbalists in practice, prior to the introduction of statutory regulation, or who trained through a professional association that was not party to the development of statutory regulation, are given a vehicle through which they can attain State Registration and inclusion on the Register of Herbal Practitioners.

51 Competency in written and spoken English is considered essential for practitioners wishing to practise in the UK where the language is English. It is recognised that this requirement will prove difficult for a number of practitioners and that it may also deny access to safe practitioners by members of the public whose first language is not English. While recognising that lack of competence in English by practitioners is unacceptable, there is nevertheless a need to ensure that many non-English speaking patients have fair access to practitioners.

## H Role of Professional Bodies

52 Professional bodies have an important role to fulfil in the delivery of herbal medicine. Their remit will include representing the interests of practitioners, supporting practitioners in connection with career development or with claims or allegations of malpractice, as well as advising on the development of the herbal profession. We believe that professional bodies representing herbal medicine must work closely and effectively with the Herbal Council or CAM Council to deliver appropriate continuing professional development that will ensure practitioners remain competent and eligible for inclusion on the Register.

53 Close working relationships between professional bodies and statutory regulatory bodies exist for a number of healthcare professions. The partnership is mutually beneficial. The statutory regulatory body ensures protection of the public while the professional body looks after the interest of its practitioners, including the long-term future and development of the profession.

54 Professional bodies will also play a major part in the delivery of continuing professional development. Whilst it will be the responsibility of the Herbal Council or CAM Council to approve programmes which are appropriate for registrants to remain up to date and eligible for continuance on the Register, professional bodies are well placed to understand the future development of the profession, and to both inform the development of appropriate education and training and play a role in its delivery.

55 Professional bodies might also play a role in the accreditation of programmes at pre-registration level. If this happened, it would involve them working alongside education providers and the statutory regulatory body. The educational establishments (universities, FE colleges or private institutions) would be responsible for the validation of, or obtaining of a validation arrangement for, programmes against the criteria for an academic award. The statutory regulatory body (the Herbal Council or CAM Council) would have responsibility for accrediting institutions and programmes of study that would allow graduates to be included on the appropriate register. The professional bodies would have responsibility for confirming the

eligibility of graduates from an approved course, for membership of that same professional body through accreditation of the course. Professional bodies may also assist the statutory regulatory body by identifying appropriately qualified members of their organisation to support the work of course approval.

56 At the time of preparing this report, it is difficult to envisage how the mutually beneficial relationship between a Herbal Council or CAM Council with professional bodies could operate for herbal medicine. This is because of the large number of professional bodies and associations already in existence. It would be impractical for any educational institution, for example, to work with more than one professional body for any given tradition, in determining potential membership of a professional body upon qualification of its graduates.

57 The herbal profession therefore needs to consider how professional associations will work with the Herbal Council or CAM Council. At pre-registration level, there are a number of possibilities. One model is for all the current professional bodies and associations for a given tradition to merge into a single body. An alternative is for the professional bodies to work through a federal organisation, such as the EHPA, to reach a consensus on the criteria for eligibility to join all the professional bodies and associations, following the threshold standards for accreditation defined by the future statutory regulatory body. The existence of multiple associations within one tradition has arisen historically but makes little sense, given the very small numbers of practitioners in all the different herbal traditions considered in this consultation document. The herbal medicine community should consider a rationalisation of the professional bodies and associations prior to the introduction of statutory herbal regulation.

## I Other Professionals Using Herbal Products

58 Section 12(1) of the Medicines Act 1968 permits anyone in the course of a business to make up and supply an unlicensed herbal remedy where they do so after being requested by an individual, and in that individual's presence, to exercise judgement as to the treatment required. The remedy must be manufactured or assembled on the premises occupied by the person carrying out the consultation. This is the legislative provision under which professional herbalists are likely to be operating for much of their activities.

59 Many operators in the CAM sector who supply herbal products to the public do not require the cover of Section 12(1). For example they may supply manufactured over-the-counter (OTC) remedies currently regulated under Section 12(2) or in future via the proposed Directive on Traditional Herbal Medicinal Products; or they may supply the public with herbal products or ingredients that would not be classified as medicinal products. However, in addition to professional herbalists whose statutory regulation is considered in this report, it is apparent that a number of other operators in the CAM sector are currently using Section 12(1) provision to serve the needs of patients and the public. These include some acupuncturists, homeopaths and aromatherapists as well as a probably relatively small proportion of those managing and working in health food stores throughout the UK. While there will be some staff in certain health food stores who hold consultations and make up herbal remedies under Section 12(1), the majority will be operating under Section 12(2) of the Medicines Act 1968, in that they will be responding to customers seeking advice on buying over-the-counter herbal remedies currently sold under Section 12(2). The HMRWG believes that there should be appropriate training and audit of all CAM operators who make up and use herbal remedies under Section 12(1).

60 Educational provision from age 16 is offered by a variety of UK institutions ranging from sixth form colleges through colleges of further education to higher education institutions. A variety of levels of achievement are recognised from Business and Technology Education Council (BTEC) through Higher National Certificate (HNC), Higher National Diploma (HND), National Vocational Qualifications (NVQ), Foundation Degrees, Degrees and Higher

Degrees. The training portfolio available to train the full compass of those using Section 12(1) provision, including fully trained professionals (e.g. herbalists and aromatherapists), herbal dispensers, assistants, and counter staff should utilise these existing educational resources. Levels of responsibility associated with each qualification should be clearly defined and the importance of appropriate referral to a more qualified person be properly explained and audited in practice. The use of the National Professional Standards for Herbal Medicine may help this process.

61 In the same way that the roles, responsibilities and training necessary for herbal practitioners to be registered under the Herbal Council or CAM Council will be defined, it is in the interests of public safety that appropriate levels of training and qualification of herbal dispensers and assistants, as well as those managing health food stores, are similarly clearly defined and provided. The public must be assured that guidance received in the use of herbal remedies at all levels is reliable and safe. For example, a counter assistant in a health food store should be trained to advise a member of the public that they should consult a professional if they are intending to use a variety of herbs as well as over-the-counter and/or prescription medicines. If customers require more professional guidance they should be referred to an appropriately trained health professional.

62 It is also important that other users of Section 12(1) follow professional good practice in ensuring that the ingredients they use for their remedies have been assured as to identity and quality. This is further addressed in the report on reform of Section 12(1).

63 Initial advice on herbal remedies is generally sought from herbal professionals and staff working in both pharmacies and health food stores. It is essential that staff receiving such enquiries, are trained to respond appropriately. Sales of pre-packaged products should be accompanied by guidance on recurrence or continuation of symptoms and include suitable courses of action particularly regarding referral to a trained healthcare professional. Over-the-counter, pre-packaged products are currently provided under the aegis of Section 12(2) of the Medicines Act 1968. However, it is anticipated that appropriate labelling of such industrially produced, pre-packaged herbal products will shortly be regulated by the proposed new EU Directive on Traditional Herbal Medicinal Products designed to

replace this Section 12(2) provision. The proposed directive will require registered traditional herbal medicinal products to carry relevant indications and other information about the safe use of the product.

64 The recognition by all workers in the herbal sector of the limits of their competence when providing guidance to customers and/or patients about the taking of herbal medicines is crucial to the effective provision of primary care in the community. The objective must be to ensure rapid referral of people requiring professional diagnosis and treatment as soon as possible. Training of support staff should be appropriate to their roles and responsibilities, and needs to be considered in the context of both patient care and educational provision. Clear guidelines are required regarding training and ongoing professional assessment and validation so that the public can rely on advice and help received regarding herbal treatment. It would appear sensible for such guidelines to take account of and develop from existing training schemes such as those endorsed by the British Herbal Medicine Association and the Health Food Manufacturers Association. The HMRWG recommends that the current arrangements for Section 12(1) provision of herbal medicines for those staff in health food shops and health professionals such as aromatherapists will continue for the foreseeable future under voluntary self-regulation which has clearly flagged standards of training and validation. In time, it would seem in the public interest that all those using Section 12(1) provision should be brought under the control of the Herbal Council or CAM Council. A working party of the EHPA/Skills for Health has recently finalised National Professional Standards for Herbal Medicine including dispensing and managing the herbal pharmacy. We recommend that any new qualifications be built around these standards. It may well also be seen to be in the public interest for aromatherapists to attain similar statutory regulation to that currently being sought by herbal practitioners. This is a matter currently being considered by the Aromatherapy Regulatory Working Group. In the meantime, the aromatherapists may also find some of the National Professional Standards developed for the herbal profession of value to them as the standards around which their own qualifications can be developed.

## J Consultation

65 The proposals and recommendations within this report have been discussed in detail with the Department of Health in England and with representatives from the devolved administrations of the home countries – Scotland, Wales and Northern Ireland. The recommendations are endorsed by these representatives as a basis for public consultation but with the important caveat that further consultation by the Department of Health in England must be informed by input from these devolved administrations. The HMRWG has also informally consulted with or received advice from the following individuals or representatives of the following organisations although all responsibility for this report rests with the HMRWG.

Acupuncture Regulatory Working Group

Aromatherapy Organisations Council

Aromatherapy Trade Council

British Acupuncture Council

British Association of Traditional Tibetan Medicine

British Herbal Medicine Association

British Medical Acupuncture Society

Chinese Medical Institute and Register

Council of Deans and Heads of UK University Faculties for Nursing, Midwifery and Health Visiting

Council of Organisations Registering Homeopaths

Council of Professions Supplementary to Medicine

Federation of Holistic Therapists

Dr Jacqueline Filshie

General Chiropractic Council

General Council of Traditional Chinese Medicine

General Osteopathic Council

Health Food Manufacturers Association

Health Professions Council

High Commission of India

International Federation of Professional Aromatherapists

Maharishi Ayurveda Physicians Association

Mayway (UK) Ltd

Medicines and Healthcare products Regulatory Agency

Royal Pharmaceutical Society

Scottish School of Herbal Medicine

Sri Lankan High Commission

Dr David St George

State Administration of Traditional Chinese Medicine

David Tredinnick MP

### 66 Possible Questions for Public Consultation

- i. Do you support a separate Herbal Council or a shared CAM Council? (Section 1: Paras 9-20) It would be helpful if you could indicate reasons for your choice.
- ii. If a separate Herbal Council were the preferred option, do you believe the costs of supporting this could be met by practitioners? (Section 1: Paras 9-20; Section 3). If affirmative, please detail how you think this could be sustained.
- iii. Do you believe that the professional benefits for herbal medicine practitioners are greater within a separate Herbal Council or within a shared CAM Council? (Section 1: Paras 9-22). If so please say why.
- iv. Do you consider that the professional issues should take priority over the costs to practitioners if the Council is to be self-funding? (Section 1: Paras 9-22; Section 3)
- v. Do you agree that it is inappropriate for the herbal medicine profession to seek regulation through the Health Professions Council? (Section 1: Para 12)
- vi. Are there other traditions beyond Western Herbal Medicine, Traditional Chinese Medicine/Chinese Herbal Medicine, Ayurvedic and Tibetan Herbal Medicine that should be considered for inclusion within the regulatory framework at this stage?
- vii. How important do you consider interdisciplinary working for the herbal medicine profession? (Section 1: Paras 14-16)
- viii. How important do you feel it is for a separate Herbal Council to achieve a close working relationship with a separate Acupuncture Council? (Section 1: Paras 9-22)
- ix. How far do you feel this relationship (between the Herbal Council and the Acupuncture Council) should be developed? For example, it could be an articulation agreement with reciprocity arrangements through to a sharing of facilities and administration or a relationship just short

of a CAM Council. (Section 1: Paras 37-39)

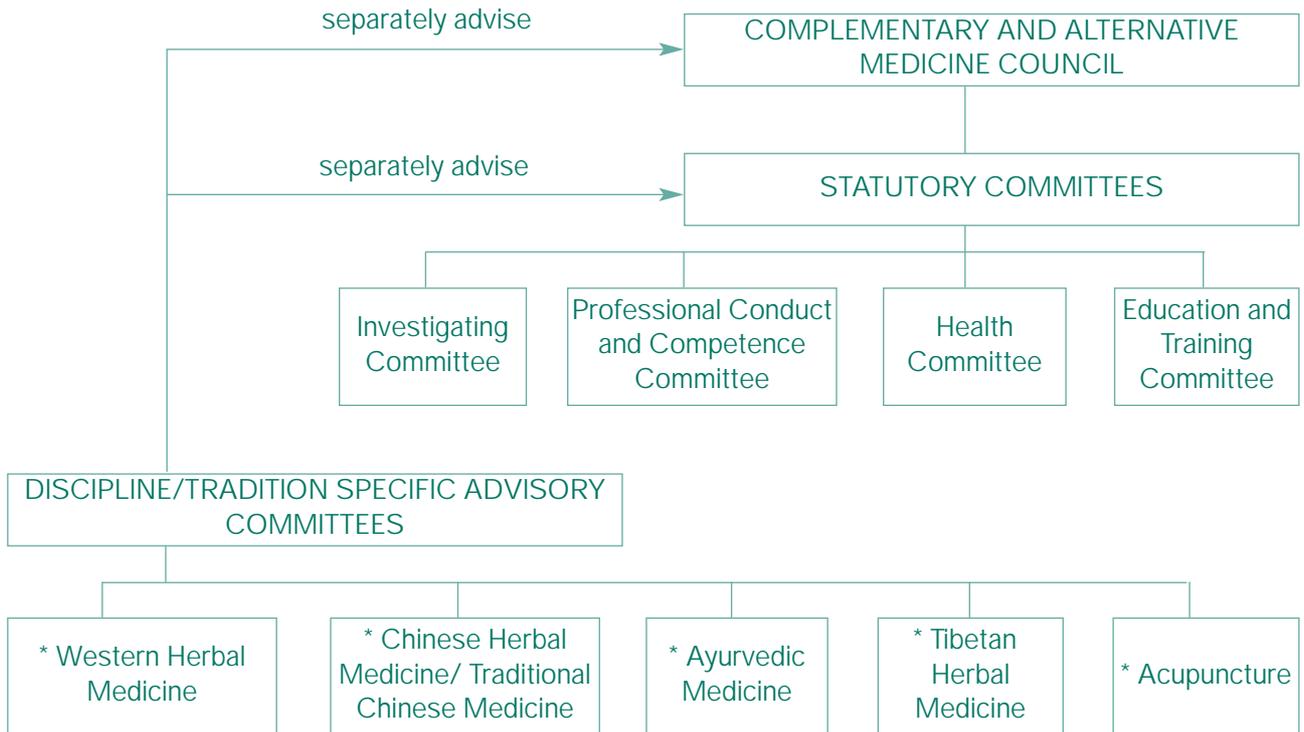
- x. Do you agree that practitioners registered by the Herbal Council or CAM Council should be permitted to use non-herbal products including materials of animal or mineral origin? (Section 1: Para 20)
- xi. Do you agree on the proposed role of the Herbal Council or CAM Council? (Section 1: Paras 23-51)
- xii. Do you consider that the Core Curriculum being proposed is acceptable as a minimum threshold in order to deliver competency to be included on the Herbal Register? (Annex I)
- xiii. Do you consider that the accreditation arrangements being proposed are appropriate? (Annex II)
- xiv. Do you agree with the composition of the proposed Herbal Council or CAM Council? (Section 1: Paras 23-51)
- xv. Do you agree that the scheme for Continuing Professional Development is appropriate? (Annex IV)
- xvi. Do you consider that the role being proposed for professional bodies is appropriate? (Section 1: Paras 52-57)
- xvii. Do you consider that the Code of Ethics is appropriate? (Annex III)
- xviii. What do you feel should be the protected titles for the herbal medicine traditions of Western Herbal Medicine, Chinese Herbal Medicine/TCM, Ayurvedic and Tibetan Herbal Medicine? (Section 1: Para 44)
- xix. Do you consider that the Grandparenting arrangements being proposed are appropriate to safeguard the interests of practitioners as well as safeguarding the public? (Annex V)
- xx. What do you feel should be the title of the shared CAM Council?
- xxi. While recognising that lack of competence in English by practitioners is unacceptable, there is nevertheless a need to ensure that many non-English speaking patients have fair access to practitioners. How could the issues of patient choice, practitioners' right to practice and patient safety be reconciled in traditions where English may not always be used?

## References to Section 1

House of Lords' Select Committee on Science and Technology, Session 1999-2000, 6th Report. *Complementary and Alternative Medicine*. (The Stationery Office, 2000)

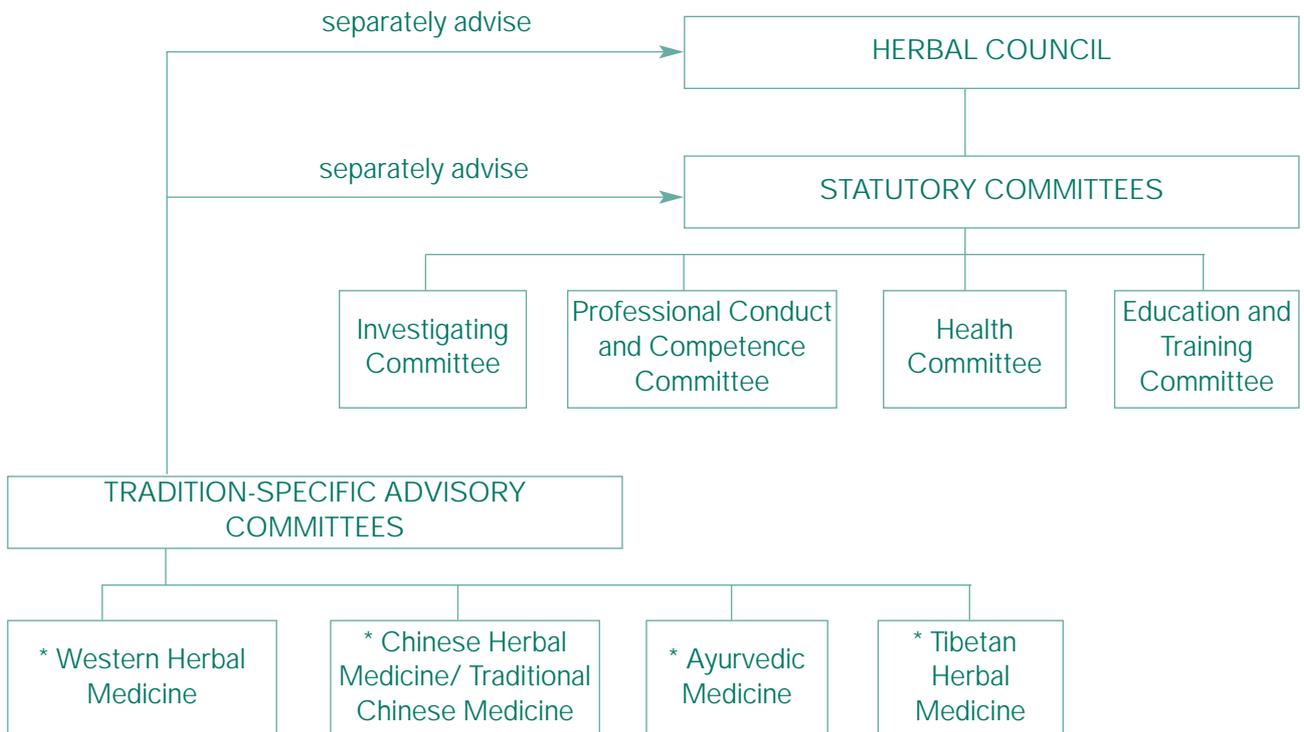
Department of Health. *Government Response to the House of Lords Select Committee on Science and Technology's Report on Complementary and Alternative Medicine*. (The Stationery Office, March 2001)

## Suggested Organisational Structure for the CAM Council



\* All represented on Council and Statutory Committees

## Suggested Organisational Structure for the Herbal Council



\* All represented on Council and Statutory Committees

## SECTION 2: BACKGROUND TO THE REGULATION OF HERBAL MEDICINE

### K Introduction to Herbal Medicine

#### Introduction

67 This section provides background information about herbal medicine, the different traditions that practice using this system of medicine and the work that has been undertaken voluntarily within the sector to achieve regulation and promote patient safety.

#### History

68 Herbal medicine is among the most ancient forms of treatment known and the medicinal use of plants is common to all cultures and peoples of the world. The Egyptian Ebers Papyrus, dating back to 1500 BCE, describes more than 700 herbal remedies including aloes, caraway seeds, castor oil and squill. A medical manuscript, *Wu Shi Er Ming Fang*, dating from second century BCE listing some 224 herbal medicines was discovered in 1973 in a tomb at Ma Huang Dui in Hunan Province, China. The *Atharva Veda* dating from about 1200 BCE is recognised as a major source book laying down the precepts of Ayurveda, the ancient system of medicine from India. There was significant exchange of herbal knowledge in the ancient world. Hippocrates, ‘the father of medicine’, was tutored by Egyptian priest doctors. Dioscorides, a Greek doctor attached to the Roman armies of Claudius and Nero, compiled ancient and contemporary herbal knowledge in his famous herbal *De Materia Medica* that for more than thirteen centuries remained one of the principle medical textbooks throughout the civilised world. The Greek herbal achieved its final form in the work of Claudius Galen who was physician to the Roman Emperor, Marcus Aurelius. The medicine of medieval Europe was significantly advanced by herbal skills brought back to Europe by the Crusaders who learnt their medicine from their Arab adversaries who had themselves synthesised the knowledge of ancient Greek and Persian medicine. For many centuries plant

remedies were the main medicines used to treat disease throughout Europe and many famous herbals were published in English in the sixteenth and seventeenth centuries. Some, like those of Culpepper and Gerard, are still well known today. However, with the dawn of the scientific age came the slow decline of plant-based medicine accelerated by the widespread introduction, in the eighteenth century, of minerals and metal-based remedies into medicine such as arsenic, antimony, lead, mercury, copper, tin and gold. John Waller commented on this trend in his *British Domestic Herbal* published in 1822. “Advantages have accrued to medicine from chemical preparations. It is nevertheless a melancholy truth that the health of thousands and the lives of not a few are yearly sacrificed to the rage for preparations of mercury, arsenic and almost every deleterious mineral under heaven. So far has this rage for poisonous drugs gained ground that scarcely any article from the plant kingdom is thought worthy to enter into the prescription of a modern physician that is not recognised for a dangerous and active poison; hence the daily use of aconite, hemlock, henbane etc.” With the discovery of antibiotics, corticosteroids and other major modern drugs, the vast majority of herbal remedies used by doctors for many centuries became relegated to mere footnotes in the official pharmacopoeias. They remained however the remedies of choice of UK herbalists and the practitioners of other herbal traditions that have recently settled in Britain all of whom have continued these forms of traditional medicine into modern times.

#### The Herbal Medicine Traditions

69 There are a variety of herbal traditions currently practised in the UK. The indigenous tradition, in this document referred to as *Western Herbal Medicine*, has within the last 30 years, been joined by those practising within the Chinese, Japanese, Tibetan Herbal Medicine and Ayurvedic traditions and more recently still, training courses have been set up in the UK for the specific teaching of these traditions. Currently four different traditions are recognised as distinct groupings within the HMRWG. These are Western Herbal Medicine, Chinese Herbal Medicine, Tibetan Herbal Medicine and Ayurveda, introduced from the Indian sub-continent. It is understood, however, that both Traditional Chinese Medicine and Ayurveda are broad systems of medicine that involve practices other than herbalism, such as acupuncture and

massage. Tibetan Herbal Medicine, too, incorporates massage and also uses moxibustion. Western herbal medicine also often includes massage using herbs and/or essential oils. All these systems of medicine incorporate dietary advice as a normal part of treatment. It is usual for each grouping to contain more than one professional association or register, each with its own origin, flavour and emphasis. It is therefore clear that any attempt to group registers and associations together even under the same traditional heading requires lengthy consultation and an administrative framework within which each individual tradition can feel free to express its unique approach to healing and health promotion. Currently, voluntary regulation of Japanese herbal medicine, known as *Kampo*, resides within one of the Chinese herbal medicine associations.

70 Each herbal tradition is based on the transmission of centuries of clinical experience passed on by oral teaching and through ancient and modern texts, and informed in modern times through a variety of papers and articles written for journals by practitioners, physicians and pharmacologists interested in this field. It is the skilful use of knowledge and ability acquired through these means that enables a trained practitioner to design a prescription for the individual patient. Traditions vary in their approach to diagnosis and prescription writing but it is a general feature of herbal practice that prescriptions are written to suit the individual patient rather than to treat a specific disease classified from an orthodox western medical standpoint. In doing this, the practitioner takes account of the patient's presenting signs and symptoms as well as constitutional and other factors.

## Ayurveda

71 Ayurveda is a comprehensive system of healthcare originating in India over 5000 years ago. References to Ayurveda are to be found in the Vedas, the Upanishads and other ancient Hindu sacred texts. Of these, the *Atharva Veda*, dated around 1200 BCE, is widely regarded as the most important source book for this traditional system of healing. Ayurveda is derived from two Sanskrit words: '*Ayus*' meaning life and '*Vid*' meaning knowledge. The 'science of life', Ayurveda, is as much concerned with enhancing the quality of life and the prevention of ill health as it is with treatment of disease. Classical Ayurvedic texts

such as the Charaka Samhita and the Sushruta Samhita, compiled between the second century BCE and the second century CE, took account of the physical, mental, emotional and spiritual aspects of the person in their consideration of health and ill-health, and the complex concepts and theories they embody continue to underpin the modern practice of Ayurvedic medicine. Ayurveda is firmly embedded in the Hindu theory of evolution according to which the universe is composed of five basic elements or **pancha mahabhuta**, namely, ether, air, fire, water and earth. These are present in all things and in the human body they are represented as the **doshas**, **dhatus** and **mala**.

72 The three doshas, **vata**, **pitta** and **kapha**, are the primary and essential components of the human body. Each has its characteristic site in the body and unique function. **Vata** is the strongest of the three doshas and governs all the essential functions of the body. **Pitta** is responsible for digestion, metabolism and energy, while **kapha** gives strength and softness and is the primary force governing all cellular development and reproductive activity within the body. The tridoshas are inter-related and, in their normal state, maintain the integrity of the living human organism, conferring strength and assuring the normal functioning of vital organs and longevity.

73 The **dhatus** form the basic structure of the body. They are seven in number and each has its own function. **Mala** are metabolic end products which serve to support the functions of the body and are then excreted. The tridosha should be in a state of perfect equilibrium for the body to remain healthy. Any imbalance of these bio-energetic forces results in ill health. Ayurveda places particular emphasis on the individual constitution or **prakriti**, which is determined by the unique combination of the tridoshas, genetic factors, the health, nutrition, lifestyle and life experiences of the mother as well as the **pancha mahabhuta** (five elements) that make up the foetus.

74 **Prakriti** determines the individual's susceptibility to different diseases, the course and development of a disease and determining complications that could arise as well as the prognosis. Proper hygiene, diet and lifestyle are essential prerequisites for good health. Ayurvedic classical texts provide detailed directions for a health-promoting daily routine, which must be adapted to individual constitutions and the seasons to ensure optimal balance between body, mind, spirit and the environment. Treatment is

always tailored to the individual in question. The skill of the practitioner lies in assessing the constitutional type and diagnosing the cause of imbalance that manifests as disease as well as selecting appropriate remedial interventions from an array of therapeutic options. In addition the practitioner must be aware of the appropriate time to initiate prophylactic and curative measures.

## Chinese Herbal Medicine

75 Chinese herbal medicine is one modality within a broad tradition, known as traditional Chinese medicine (TCM) that also includes acupuncture, massage (*tuina*), breathing exercises (*qi gong*) and dietary therapy. It has evolved over three millennia and today is practised throughout much of South East Asia. It is state sponsored in hospitals throughout China, where it enjoys equal status and a pragmatic working relationship with orthodox western medicine. Having developed over thousands of years, Chinese medicine has evolved many approaches to diagnosis and treatment yet there is also a strong continuity, with an unbroken written record going back to the third century BCE. Famous texts from the Chinese tradition include the *Yellow Emperor's Inner Classic* (Huang Di Nei Jing) compiled between 200 BCE and 100 CE and the *Divine Husbandman's Classic of the Materia Medica* (*Shen Nong Ben Cao Jing*) from the later Han dynasty (25-220 CE). The *Discussion of Cold-induced Disorders* (*Shang han lun*), written about 220 CE by one of China's most renowned herbal doctors, Zhang Zhong Jing, outlines the treatment of various conditions arising from exterior causes. Several of its formulas are still in use today. Sun Si Miao (581-682 CE), another famous physician and scholar who was versed in both Buddhist and Daoist philosophies, devised in his *Thousand Ducat Formulas* (*Qian Jin Yao Fang*) and his *Supplement to the Thousand Ducat Formulas* (*Qian Jin Yi Fang*) an extensive repertory of prescriptions, which similarly influence Chinese herbal practice to the present day. The *Materia Medica Arranged According to Drug Descriptions and Technical Aspects* (*Ben Cao Gang Mu*) by Li Shi Zhen published in 1596 was the outcome of 40 years work by the author. His book contains 52 chapters describing 1893 medicinal substances. Among other things, Li Shi Zhen demonstrated the connection between sweets and tooth decay and described occupational illnesses such as lead poisoning. In the late Ming and Qing dynasties, new theories concerning the treatment of disease

were developed by five famous doctors, Wu You Ke, Ye Tian Shi, Xue Sheng Bai, Wu Ju Tong and Wang Meng Ying. All these physicians were adherents of the "Warm Diseases Theory" (*Wen Bing Xue*) that addressed the treatment of rapidly transmitted infectious disease. In modern times, Chinese herbal medicine continues to develop as part of Traditional Chinese Medicine alongside conventional western medicine. After taking power in 1949, the Communist Party encouraged the use of Chinese herbs as a cost-effective alternative to expensive western drugs and continued to publish *materia medica*. For example, in 1977, the *Encyclopaedia of Traditional Chinese Medicinal Substances* (*Zhong Yao Da Zi Dian*), representing 25 years of research was published by the Jiangsu College of New Medicine. This monumental work contained 5,767 entries, a compilation of China's herbal tradition to that time.

76 Based on centuries of clinical experience, Chinese herbal medicine has developed practical and effective treatments that are highly effective for many of today's illnesses. These therapeutic strategies are underpinned by a set of core concepts about health and disease that are shared by practitioners of TCM around the world. In the UK, Chinese herbal medicine is a relative newcomer, having developed rather later than acupuncture. However, it has grown rapidly in popularity in recent years.

77 Some effort has gone into understanding the pharmacology of Chinese herbal medicine. But the language of Chinese herbal medicine diagnosis and treatment is quite distinct from that of modern biomedicine, and direct translation from one to the other is not particularly illuminating or meaningful. In the very broadest terms, good health is a state in which a person has optimum vitality (based on adequate supply of Qi and Blood and a healthy balance of Yin nourishment and Yang function), where the various functions needed to maintain that vitality are unimpeded. Ill health is perceived as arising from a loss of that vitality or by some form of impediment to those functions, or both. Precise diagnosis of a patient's illness is achieved by analysis of the presenting symptoms and signs as well as by taking account of dietary and lifestyle factors and evaluating the past medical and family history of the patient. The physician pays special attention to the pulse and tongue in evaluating the patient's condition. The diagnosis identifies the presenting *pattern of disharmony* expressed in TCM terms (e.g. Kidney Yang Deficient, Heart Fire Blazing,

Invasion of Pathogenic Wind-Heat etc.). These pathogenic patterns may relate to dysfunctions of *Organs* (understood as spheres of function rather than in an anatomical sense) or to the presence of pathogenic factors or to a number of other features such as phlegm or blood stasis. The patient's condition may be recognised as an identifiable traditional TCM condition (e.g. Bi - "blockage"- syndrome roughly corresponding to arthritis in western medicine) or further categorised as an excess or deficiency, external or internal, hot or cold condition. In the final analysis all health problems are seen as an imbalance of the two universal polarities, Yin and Yang and may also be expressed in terms of Five-Element imbalance. This is a complex process demanding acute powers of observation and analysis on the part of the practitioner.

78 The Chinese *materia medica* contains several hundreds of plant species, together with some non-plant ingredients. These are classified according to their 'temperature', flavour, and direction of movement, properties that are related to their ability, in numerous different ways, to supplement energy or clear impediments to function. The art of treatment with Chinese herbal medicine is to choose a formula (a combination of herbs), which matches and redresses the pattern of disharmony of the individual, and to modify the formula in order to accommodate changes occurring in the course of treatment. This allows for considerable therapeutic flexibility, matching the prescription to the needs of the patient throughout a course of treatment. Chinese herbal prescriptions usually comprise a mixture of herbs, each herb playing a specific and significant role to achieve the desired therapeutic effect. Over many centuries, generations of Chinese herbal practitioners have understood and utilised the beneficial synergistic effect obtained by the skilful combining of medicinal herbs (this traditional medicine system also uses some animal and mineral substances) and many famous ancient formulae are still in regular clinical use.

## Western Herbal Medicine

79 Western herbal medicine has its roots both in the indigenous practices of the British Isles (Bryce, 1988), and in the European and Greco-Roman traditions, and can be traced back to prominent physicians such as Dioscorides, Hippocrates and Galen (Acker, 1995). There are also strong links to North America (Cook, 1869), and some

exporting and re-importing of ideas and practices that have taken place particularly over the late nineteenth and early twentieth centuries (Fox, 1932). In North America, the *Eclectic* and *Physiomedical* herbal movements incorporated the herbal lore of the Native Americans, and many North American herbs are still routinely used in western herbal medicine in the UK. The well-known immune stimulant Echinacea (*Echinacea angustifolia*) is a good example of this cross-cultural exchange. Additionally, as global communication and transportation have expanded, plants from all over the world are now found to be in regular use within the Western framework, for example Ginseng (*Panax ginseng*).

80 It is often noted that a significant proportion of orthodox Western medicines were originally derived from herbal medicines. Therefore, it is often assumed that Western herbal medicine is philosophically and theoretically allied to orthodox Western mainstream medicine and modern research into herbal medicine has tended to evaluate herbal medicines as *ersatz* drugs, suited to the treatment of specific diseases (for example St John's Wort (*Hypericum perforatum*)) specifically for the treatment of depression). Whilst this approach has contributed much vital information to the science of herbal medicine, it has by and large failed to highlight the *modus operandi* of western herbal practice and consequently the traditional, holistic elements of western herbal medicine are not widely understood or appreciated.

81 Western herbalism is characterised by a person-centred approach, where the patient rather than the disease is the focus of the practitioner's attention. The background to the patient's condition is assessed through a thorough case history, taking account of family history, personal health history and lifestyle choices, and therapy is directed at the causes, not just the presenting symptoms. The practitioner uses the information obtained during the taking of the case history to make an assessment of the vitality and constitution of the patient. The choice of herbs in the prescription is based on this assessment. The prescription, rather than being based simply on the diagnosis of a disease or condition, is determined by an understanding of the significance of the signs and symptoms in that individual. Prescriptions may vary substantially between individual patients apparently presenting with a similar condition. Herbal treatment is commonly backed up by appropriate advice on lifestyle, particularly nutrition, and the practitioner works at

all times to create an ambience of trust and positivism in the therapeutic relationship.

82 Whilst each association of Western herbal medicine has its own focus or emphasis, some being more 'traditional' in flavour, and others more 'medical', most practitioners these days support a blend of scientific and traditional values. Many incorporate a naturopathic approach in their practices, often, but not always, supplemented by other holistic approaches such as nutritional therapy, massage hydrotherapy, spiritual healing and other techniques aimed at improving the overall vitality and well-being of the patient. The fundamental purpose of such herbal treatment is to support and revive the innate healing process and power of mind, body and spirit. In short, herbal medicines are perceived as ideal tools to harness the *vis medicatrix naturae* to maintain health and treat disease.

## Tibetan Herbal Medicine

83 Tibetan herbal medicine is an ancient system that has many similarities with the other great Asian medical systems: Chinese, Ayurvedic, and Unani. Over the centuries it has developed into a highly complex medical science with intricate theories of disease causation, diagnosis and therapeutics. The similarities with other systems are no coincidence. In the seventh century CE, when the Tibetan empire was the strongest in Asia, the then king, Songtsen Gampo, convened conferences of physicians from what are today China, India and Iran (including a follower of Galen), in order to establish the finest system for his land. The following centuries saw several such conferences. During the eighth to twelfth centuries, hundreds of texts, including many major medical works, were translated from Sanskrit as a basis for teaching.

84 A great milestone in Tibetan medical history came in the eleventh century, when the brilliant scholar physician Yuthogpa drew together all the various strands of Indian, Chinese, Galenic, Mongolian and Tibetan native medical science and made one synthetic overview, based upon the mind-body model of reality found in Northern Buddhism. Since that time, his authoritative work the *rgyud bzhi* or *Fourfold Medical Treatise* has served as the basis for most medical studies within the Tibetan system. It is a highly condensed work consisting of some 600 folio of instructional verse that has been expanded to provide a demanding six-year programme of training.

85 The most famous Tibetan pharmacopoeia is Dilmar Geshe Tenzin Phuntsok's *The Pure Crystal Orb and Crystal Rosary* composed in 1717, which lists 2294 medicinal ingredients. Tibet's first medical school was established in Lhasa in 1696; since that time numerous medical schools have been established in Tibet. Outside of Tibet, the most important Tibetan medical centre is the Tibetan Medical and Astrological Institute, established at Dharamsala, in north India in 1961. In recent years, a number of practitioners trained in Tibet and India have started to work in the UK. Some of these have recently developed a pre-registration programme of study, working with the European Herbal Practitioners Association.

86 The medical system itself is founded on the principle that the human being and the surrounding environment are composed of the same basic five elements: traditionally designated as earth, fire, water, wind and space. These may be interpreted as *matter, energy, bonding, movement* and *space*. This enables the components of the world 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.

87 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. 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 and are grouped by Tibetan Herbal 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 Herbal Medicine.

88 Traditional Tibetan medicine makes use of the animal, vegetable and mineral components of the universe to restore health and balance and gives advice on how to heal the mind and improve the way in which one lives. Tibetan Herbal Medicine, like many traditional medicines, relies primarily upon the doctor's wit when it comes to diagnosis and treatment. Whereas modern Western medicine relies upon the backup of hospital, x-ray and laboratory facilities, there is a great emphasis, in Tibetan Herbal Medicine, on the physician's deductive ability. Diagnosis is principally based

upon a complex analysis involving palpation of the radial pulses, examination of urine and in-depth questioning. Treatment is offered in four areas, behavioural advice, dietary advice, prescription of medication and a series of "external treatments", such as moxibustion. The medications draw upon a vast (several tens of thousands) number of possibilities of formulation in a system that pays close attention to the preparation and purification/detoxification of the raw materials used.

89 The success of Tibetan Herbal Medicine has to a great extent been based upon its pragmatism, adopting whatever was found truly beneficial whilst shedding that found ineffective. For over a thousand years, by including the best of whatever it found in its great neighbours, China, India, Mongolia and Central Asia, Tibetan Herbal Medicine developed into a renowned system of medicine in its own right.

## The Search for Recognition

90 Since the 1960's herbal medicine has made an extraordinary revival throughout the western world. A 2001 IMS market survey estimated sales of herbal products in Europe to be 3.2 billion Euros. In the UK herbal practice has grown to meet this demand. In the place of a handful of herbalists working in the 1950s and 60s, there are now six UK universities offering a BSc in Western Herbal Medicine and four degree courses on offer in Chinese Herbal Medicine, two of which are validated by UK universities. One university offers a degree programme in Ayurvedic Studies. Herbalists of other traditions from outside Europe, in particular Chinese and Ayurvedic, have augmented the numbers of herbalists working in the UK so that there are about 2,000 herbal practitioners currently working in Britain. At present herbalists have no legal status beyond that afforded by Common Law but, with Government backing, are engaged in a process that aims to bring about the statutory self-regulation of herbalists through the 1999 Health Act. However, the progress so far has been long, drawn out and marked by many setbacks.

91 In 1864, UK herbal practitioners organised themselves into the National Association of Medical Herbalists ("Association" has since been replaced by "Institute") in the expectation that herbalists could gain similar professional status as that granted to doctors by the Medical Act of 1858. But the efforts of herbalists to gain

recognition were thwarted. In 1923, over 130 MPs supported the Medical Herbalists Bill through an unopposed first reading, but the Government did not grant time for the Bill to go further. This was no surprise in view of the opinion expressed by Dr Charles Newman, the chief medical officer of England at that time: "*The object is obviously to secure legal recognition for herbalists and the next step would be to claim for registered medical herbalists the rights of registered medical practitioners. No doubt the arguments of the promoters would be that if people wish to be treated by herbalists, it is better to be treated by herbalists who have some kind of training than those with none. I do not know how herbalists are trained, but ... it is at least doubtful whether a trained herbalist is any less dangerous than an untrained one.*" (Saks, 1992).

92 After the war, the new National Health Service (NHS) appeared to offer a further opportunity for the official establishment of the herbal profession. However, once more the hopes of supporters of herbal medicine proved illusory when the then Minister of Health, Mr Bevan, offered herbal practitioners participation in the NHS on meagre financial terms that would also have subordinated them to general practitioners. The herbalists opted to remain outside the NHS and it was not until after a major campaign in support of herbal practice, that the Medicines Act 1968 actually provided a legislative niche for herbal medicines, though it never defined who or what a herbalist might be.

## Current Proposals to Regulate Herbal Practitioners and Herbal Medicines

93 In 1993, the leading associations of UK herbalists came together to form the European Herbal Practitioners Association (EHPA). The EHPA now comprises the majority of herbal organisations representing UK practitioners and has a growing membership throughout the EU. Its work over the last decade has enabled the Government to set up, in early 2002, the independently chaired HMRWG charged with publishing proposals for the statutory self-regulation of herbalists. The HMRWG, together with the Medicines and Healthcare products Regulatory Agency (MHRA), is also engaged in drawing up and publishing new measures regarding the legal arrangements for the one-to-one prescription of herbal medicines for public

discussion. This work complements the proposed EU Directive on Traditional Herbal Medicinal Products which sets out new regulations for the over-the-counter sale of unlicensed herbal products. These proposed changes to medicines law are intended to update the somewhat outmoded current herbal legislation as set out in the Medicines Act 1968. Section 12.1 of this Act specifically addresses one-to-one prescription utilised by the herbal practitioner.

94 It is anticipated that the statutory self-regulation of herbalists and modernisation of the medicines legislation will bring about a number of much needed improvements that will ensure the safety and quality of herbal practice and medicines. Today, there is wide acceptance that herbal medicines are much more than placebo. Herbal practitioners know that many herbal medicines have active pharmacological constituents and support the notion that the most potent of these remedies should be restricted to a well-trained and regulated profession that can play its part in the delivery of healthcare in the UK.

## Quality and Safety of Herbal Medicines

95 It is clear that natural does not always equal safe. Herbal medicines contain a multiplicity of chemical constituents, some of which may have the potential to cause adverse effects. Adverse effects may also be caused by exposure to contaminants present in herbs such as heavy metals or aflatoxins or by misidentification of a herb. There is also a potential for herb-drug interactions, a possibility that has gained wider recognition in recent years. An example of this is the potential interaction of St John's Wort (*Hypericum perforatum*) with a number of prescribed medicines including indinavir, warfarin, cyclosporin, digoxin, theophylline and possibly oral contraceptives. This interaction appears to be mediated via the cytochrome P450 metabolising enzyme system in the liver.

96 Safety concerns should be set in context. It would appear that the incidence of herbal adverse events is rather low given that the EHPA estimates that there are over a million herbal consultations a year in the UK and according to a BBC poll (August 1999) herbal medicines are the most popular form of complementary medicine. In the five-year study into adverse events involving traditional medicines and food supplements

undertaken by the National Poisons Unit (between 1991 and 1995), the NPU received 1297 enquiries. However, a link was identified as probable between exposure and reported adverse effects in just thirty eight of these cases (Shaw, 1997). At the time the Ministry of Agriculture Fisheries and Food press release (326/96) to accompany the report stated that: "*The findings overall are reassuring as they do not indicate any significant health problems associated with most types of traditional remedies and dietary supplements.*"

97 The UK Medicines Control Agency (now renamed the Medicines and Healthcare products Regulatory Agency MHRA) has recently published a report on the safety of herbal products (Medicines Control Agency, July 2002). This too states, "in general most herbal products are unlikely to pose a significant threat to human health". However, there have been a number of significant concerns regarding the safety of herbal medicines in the past two decades. The substitution of the toxic *Aristolochia* species in some traditional Chinese medicines resulted in cases of serious renal toxicity and cancer in Europe, China, Japan and America.

98 The major herbal professional associations in the UK are now, in conjunction with the MHRA, operating a yellow-card Adverse Event Scheme that is designed to pick up adverse herb reactions at an early stage. Doctors have been notified by the MHRA that they should enquire about the use of herbal medicines by their patients and report any side effects via the yellow-card scheme. Herbal practitioners are kept updated of safety issues by their professional bodies and the EHPA as well as their professional journals, newsletters and websites.

99 Proposed new EU and UK medicines legislation referred to in paragraphs 93 and 94 above, will ensure the correct identification of medicinal plants and the adoption of Good Manufacturing Practice by suppliers and manufacturers. The proposed EU Directive on Traditional Herbal Medicinal Products, currently on its way to the statute book, requires that over-the-counter herbal remedies should demonstrate at least thirty years of safe use to qualify for registration under the Directive. Herbal remedies are now being extensively monographed for safety and efficacy. This process is being overseen by the Herbal Medicinal Products Working Party within the European Medicines Evaluation Agency

(EMA) and the proposed Directive anticipates that these monographs will constitute an important feature of the centralised listing of herbs and associated safety and efficacy data by the EMA.

100 There is also useful work on the safety of herbal medicines such as analysis of adverse event reports, drug-monitoring studies, clinical trial reports, *in vitro* work on mechanisms of toxicity (Farah, 2000; Shaw, 1997; Barnes 1998) and more recently, reviews of the safety of herbal medicines and possible drug-herb interactions (Fugh-Berman, 2000; Izzo, Ernst, 2001).

101 The major part of the work on safety refers to over-the-counter usage of standardised herbal medicinal products often purchased by consumers using a concomitant range of drugs, herbs and food supplements (Barnes, 1998) and is of limited relevance to herbal practitioners. It is unfortunate that there has been little or no funding of research into the safety of herbal medicines in clinical usage by herbal practitioners. Since 1998, the National Institute of Medical Herbalists (NIMH) has been working in collaboration with Southampton University and the Drug Safety Research Unit, Southampton on a proposed study using Prescription-Event Monitoring methodology to assess the safety of St John's Wort (*Hypericum perforatum*) in herbal practice. Funding continues to be sought for this joint project. It is unfortunate that the study of plant materials has diminished within pharmacy courses and there remain only four university pharmacognosy departments in Britain. This resource is inadequate to support a healthy research culture and provide for the training needs of the natural products industry.

102 The Foundation for Traditional Chinese Medicine, in partnership with Faculty of Medicine, Sheffield University, the Register of Chinese Herbal Medicine and the Natural Medicines Society, is planning a major study on the safety of Chinese herbal medicine. The study plans to estimate the frequency and type of adverse events associated with Chinese herbal medicine in the everyday practice of practitioners belonging to the RCHM. Funding for such studies continues to be difficult to resource and Government initiatives in this direction are to be welcomed.

## Efficacy and Evidence

103 The shared knowledge base of a profession underpinning professional practice depends upon many sources of evidence. Evaluation of the

original evidence is significant in all health professions and there have been repeated calls to question the assumptions made in practice (Sackett *et al*, 1997). In recent years, there has been more critical evaluation of traditional sources of material (Holland, 1996) and investigation of current prescribing practices (Denham, 1999). Despite a growing worldwide interest in herbal medicines and increasing numbers of published papers exploring the action and efficacy of individual herbal remedies, there is relatively little quality research into the efficacy of herbal medicine as provided within a holistic herbal approach. This is probably due to the fact that a major source of research funding is effectively unavailable because herbs are natural products and cannot be patented and are therefore of little interest to pharmaceutical companies except when a specific active constituent can be isolated and marketed. Herbs often rely for their effect on a multiplicity of chemical constituents that may have a synergistic or buffering effect. In many cases, therefore, a plant that seems a good candidate for drug research fails to yield any significant isolated actives upon analysis.

104 As noted previously, there is a difference between conventional medicines and individualised prescriptions prepared by a herbal practitioner to suit individual needs. Drugs are standardised whilst herbal treatment rarely is. In practice herbs are not usually used as "simples" but are combined for extra effect to suit individual patients. St John's Wort (*Hypericum perforatum*) may be marketed to treat mild to moderate depression but herbalists often combine this remedy to fit each case, for example with Lemon Balm (*Melissa officinalis*) for anxiety and depression, with Wild Oat (*Avena sativa*) and/or Ginseng (*Panax ginseng*) for neurasthenia and with Valerian (*Valeriana officinalis*) for bipolar depressive swings. Herbs often confer a wide spectrum of benefits not usual in conventional medicines. For example, Lemon Balm (*Melissa officinalis*) may be used for anxiety and insomnia but it is also traditionally used for calming a nervous stomach and bowel. In addition, this remedy has also been found to have a significant antiviral effect and may have a role in the treatment of Graves' disease. Herbs comprise an orchestra of biochemical substances that can make the exact mode of action difficult to elucidate. Despite a considerable amount of research into St John's Wort (*Hypericum perforatum*), it still has not yet been satisfactorily established how this remedy is effective in the

treatment of depression. As previously explained, remedies are generally used by herbal practitioners to support and stimulate the body's own natural response to illness rather than to attack a disease head-on as is often the case with conventional medicines. Although there is relatively little research devoted to the evaluation of herbal practice, there is nevertheless an extensive evidence base for the efficacy and safety of western herbal medicines. This can be found mainly in a number of peer-reviewed journals focusing on plant medicines. These include *Economic Botany*, *Fitoterapia*, *Journal of Ethnopharmacology*, *Journal of Natural Products*, *Phytochemical Analysis*, *Phytomedicine*, *Phytotherapy Research*, *Planta Medica*, *Zeitschrift für Phytotherapie*. In addition, there are journals produced by the herbal profession in the UK and elsewhere and working towards Medline citation, including the *British Journal of Phytotherapy* and the *European Journal of Herbal Medicine*. EXTRACT, a dedicated herbal medicine database, has been developed at the University of Exeter. There are also systematic reviews, meta-analyses of randomised controlled trials and textbook summaries. Growing interest in this area is reflected by an increasing number of articles on herbal medicine appearing in mainstream medical journals over recent years. There have, for example, been a number of well-conducted randomised controlled clinical trials of the efficacy of standardised extracts of certain herbs such as St John's Wort (*Hypericum perforatum*) (Linde et al, 1996; Woelk, 2000) and relevant systematic reviews for example on the use of Saw Palmetto (*Serenoa repens*) in benign prostatic hypertrophy (Wilt, 1998). Although this body of work has undoubtedly contributed to our knowledge about plant medicines, the range of active constituents found in most medicinal plants is such that it is impossible to connect constituent with action directly. It is possible that more often than not, a range of related constituents are responsible for the action of medicinal plants (Williamson, 2001).

105 A weakness in current research is the lack of randomised controlled trials or medical outcome studies involving large patient groups. Randomised controlled trials are designed for the measurement of the effect of one variable and can have application to complementary medicine but, as is the case in primary care, many methodological issues are raised (Mason et al, 2002). These have serious limitations when applied to a complex intervention such as the

consultation between patient and practitioner (Lewith et al, 2002). In addition, there are few studies of the whole plant preparations that are actually used in herbal practice, (most research focuses on isolated active constituents rather than whole plant extracts) while many studies do not equate with herbal practice in terms of dosages, preparation forms and administration methods. Finally, there is a relative lack of human studies: *in vitro* and non-human *in vivo* studies cannot be taken as equivalent to human use. All these issues need to be addressed in the future. There is clearly a need for further work and strong support for further research, was given by the House of Lords' Select Committee on Complementary and Alternative Medicine. The herbal community wants to build on the existing evidence base. For example, a pilot study funded by National Institute of Medical Herbalists (NIMH), in cooperation with the University of Central Lancashire is currently underway in Bristol, on the treatment by herbal practitioners of problems associated with the menopause.

106 A large body of research exists for Chinese herbal medicine, including pharmacological studies and clinical trials covering a wide range of conditions. The bulk of it has been undertaken in China and elsewhere in the Far East. A large portion of the Chinese studies takes the form of collected case histories and clinical outcome studies. However controlled trials, in particular comparing the effectiveness of Chinese herbal medicine with placebo or with pharmaceutical drugs, have increasingly become the norm (Dharmananda, 1997).

107 A review of Chinese controlled studies from the 1980s and 1990s revealed a number of problems. First, the uniformity of results showing the superior effectiveness of Chinese herbal medicine in comparison with placebo or western medicine suggests possible biases deriving from defects in study design or publication bias or both. Second, in many trials imbalances of subject numbers between treatment groups raises doubts about the extent of randomisation. Third, few studies had given attention to blinding (Public Health Division, 1996).

108 However those randomised, placebo-controlled trials with Chinese herbal medicine conducted so far have shown very promising results. These include trials on the treatment of non-exudative atopic eczema (Sheehan et al, 1992), hepatitis C (Batey et al, 1998), and irritable

bowel syndrome (Bensoussan et al, 1998). There is also a large body of research into the underlying physiological mechanisms, exemplified by a number of papers (Amano et al, 1996; Chang et al, 1997; Suzuki et al, 1997; Oishi et al, 1998; Yoshida et al, 1997). A recent trial which investigated the effect of prescribing by TCM herbal practitioners in irritable bowel syndrome (Bensoussan et al, 1998) provides an interesting example of the application of the randomised controlled trial to herbal practice.

109 While Chinese herbal medicine has demonstrated enormous popularity around the world (it is provided in state hospitals throughout China and has migrated to the West with great success), and is deeply grounded in traditional use, much remains to be done in meeting internationally agreed research standards. In terms of clinical trial methodology, the challenge is to combine rigorous design with the flexibility required in treating the individual patient. This is a necessary condition of Chinese herbal practice and a challenge that it is possible to meet.

110 Ayurveda is rooted in the Vedas, the sacred Hindu texts which are estimated to be at least 8000 years old. In the *Rig Veda*, the oldest of these texts, there are references to a large number of 'osadhi' or medicinal herbs and plants, as well as cures for various diseases, including heart and circulatory problems, herbal recipes for rejuvenation and procedures for fitting prostheses. The *Atharva Veda* provides detailed anatomical references and describes a number of therapeutic interventions.

111 Knowledge of the healing properties of plants continued to develop in a systematic way and one of the earliest Ayurvedic treatises, the *Charaka Samhita*, dated around second century BCE, provides a detailed typology of medicinal plants according to their action. The substantive content of Dravyaguna Vijnana (Ayurvedic Pharmacology) was influenced by the contributions of other 'acharyas' such as Sushruta (1000 BCE), Vagbhata (7CE) and the authors of various Nighantu (pharmacology tracts and glossaries). Later works, such as *Sarangadhara Samhita* (1226 CE) and *Bhava Prakasa* (mid sixteenth century CE) included new species of plants within the orthodox Ayurvedic Materia Medica. The detailed instructions for preparing an extensive range of dosage forms such as expressed juices, powders, decoctions, pastes, pills, fermented tonics and medicated oils continue to be adhered to by the

manufacturers of authentic Ayurvedic medicines. The recommendations of the classical authors for the cultivation and harvesting of plants for medicinal purposes suggest a strong concern for the preservation and protection of the environment. The respect accorded to plants, however, goes beyond Ayurveda as a system of healthcare, to its roots in Hindu culture and tradition.

112 Over the last 40 years, the Government of India funded Central Council for Research in Ayurveda and Siddha (CCRAS) has been engaged in a wide-ranging programme of research into the effectiveness of traditional Ayurvedic medicines. The findings are reported in various Indian journals such as the *Journal of Research in Ayurveda and Siddha*, *Ayurveda- Science of Life* and *Aryavaidyan* as well as in many international publications. Ayurveda is recognised by the Indian Ministry of Health as a viable form of healthcare alongside Allopathic Medicine, Siddha, Unani and Homoeopathy. Research into Ayurveda undertaken in medical schools and university departments has contributed to the development of a substantial evidence base on the safety and effectiveness of single plants used in Ayurvedic medicines, some compound formulations described in the classical Ayurvedic formulary as well as various therapeutic interventions, such as Pancha karma.

113 Ayurvedic research in recent years has contributed to the compilation of data on all aspects of plants traditionally used in Ayurvedic medicines. Comprehensive pharmacognostic and clinical evaluations of individual herbs and compound formulations have been undertaken and efforts have also been made to standardise the preparation of traditional medicines (Warrier et al, 1991; Tripathi et al, 2000; Ziauddin et al, 1996; Gupta et al, 1984).

114 Brahmi (*Bacopa monniera* Linn), a perennial creeper found throughout India, is referred to as a nerve tonic in Ayurvedic classical literature. Its effectiveness in the treatment of Alzheimer's disease was established in a double blind placebo controlled study. This was part of a larger programme of scientific and clinical investigations of traditional Ayurvedic 'Smriti rasayana' (Agrawal et al, 1990).

115 The anti-inflammatory effect of the gum resin exudate of Salai guggul (*Boswellia serrata*) has been described in classical Ayurvedic texts such as the *Charaka Samhita* and *Sushruta Samhita*. Modern pharmacological studies as well as double

blind randomised controlled trials on Salai guggul, delineate its mode of action to be similar to NSAIDs with the added advantage of being free from side effects such as gastric irritation and ulcerogenic activity (Singh, Atal, 1986; Chandrashekharan et al, 1995; Bichile et al, 2000).

116 Ayurvedic research centres in India have, in recent years, conducted a large number of pharmacognostic, phytochemical and pharmacotherapeutic evaluations of plants traditionally used in Ayurvedic medicines. The adaptogenic properties of six herbs traditionally used in rasayana (rejuvenation therapy), was established in a recent scientific study. After authenticated identification, the parts of the plant were processed in the manner described in the classical texts. In view of the complex nature of the chemical, physical and biological components of a single plant, the researchers opted to use the whole, aqueous, standardised extracts of the selected plants (*Tinospora cordifolia*, *Asparagus racemosus*, *Emblica officinalis*, *Withania somnifera*, *Piper longum* and *Terminalia chebula*). All the plant drugs were found to be safe in both acute and subacute toxicity studies and the first three plants exerted significant anti-stress effects against a battery of stresses (Rege et al, 1999).

117 Clinical trials have established the effectiveness of traditional Ayurvedic treatments for a range of contemporary health problems such as obesity (Kulkarni, Paranjape, 1990), diabetes mellitus (Rajasekharan, Tuli, 1976), stress and anxiety (Lavanya Laxmi et al, 2000). Multi-centric randomised controlled trials have established that Kshara sutra, an Ayurvedic para-surgical technique, offers an effective, ambulatory and safe alternative for the treatment of conditions such as fistula-in-ano and pilonidal sinus (Shukla et al, 1991; Bhaskar Rao, 2001). The clinical effectiveness of Pancha Karma treatments has also been shown in a number of recent studies (Madhavikutty et al, 2000; Gupta et al, 2000; Srikanth et al, 2001)

## L Developing Proposals for the Regulation of Herbal Medicine Practitioners

### Background

118 The House of Lords' Select Committee on Science and Technology's Report on Complementary and Alternative Medicine (HMSO 2000), and the Government Response (Department of Health 2001) stated that the interests of the public in their use of CAM would be best served by improved regulatory structures for many of the professions concerned. It identified evidence of progress for many therapies but noted that in many cases there was diversity of standards, unacceptable fragmentation and a lack of consensus about how to achieve regulation.

119 The terms of reference and objectives of the HMRWG were informed by the Government Response (Department of Health 2001) to the House of Lords' Report. This recommended that traditional therapies using herbal products as medicines, but assigned to Group 3, could nevertheless be included within a federal group of therapies in Group 1 under the heading of herbal medicine. However, the response document also noted that therapies outside Group 1 were likely to function in a different way and that the statutory regulation of these therapies might be hard to establish.

120 The HMRWG has considered herbal medicine in its entirety regardless of where individual therapies using herbal products were assigned within the House of Lords' Report.

The following table provides information on the classification used in the House of Lords' Report.

Group	Group 1	Group 2	Group 3
Characteristics	Principal disciplines, individual diagnostic approach	Complement conventional medicine, do not embrace diagnostic skills	Disciplines in Group 1 which purport to offer diagnostic information as well as treatment which, in general, favour a philosophical approach and are indifferent to the scientific principles of conventional medicine, and through which various and disparate frameworks of disease and disease causation and its management are proposed. Sub-categorised into 3a) long established and traditional systems of healthcare and 3b) other alternative disciplines which lack any credible evidence base.
Disciplines	Osteopathy, Chiropractic, Acupuncture, Herbal Medicine, Homeopathy	Aromatherapy, Alexander Technique, Bach and other flower remedies, Body Work therapies including Massage, Counselling Stress Therapy, Hypnotherapy, Meditation, Reflexology, Shiatsu, Healing, Maharishi Ayurveda Physicians Association, Nutritional Medicine, Yoga	3a) Anthroposophical Medicine, Ayurvedic Medicine, Chinese Herbal Medicine, Eastern Medicine, Naturopathy, Traditional Chinese Medicine  3b) Crystal Therapy, Dowsing, Iridology, Kinesiology, Radionics

House of Lords' Select Committee on Science and Technology's Report on Complementary and Alternative Medicine (The Stationery Office, 2000)

121 The ethos of the HMRWG was to build on existing consensus where that existed amongst members of the herbal medicine community. The group is large and inclusive, with the main organisations representing those practising herbal medicine being included on the membership. Organisations who are not represented have been excluded because the number of practitioners they represent are very small (less than 40), or because they have predominantly commercial interests. Notwithstanding this, formal discussions have taken place with organisations not represented on the HMRWG where they are known and their views have indirectly informed the proposals within this document.

122 The creation of the HMRWG recognised that the needs of different stakeholders had to be met. Both the House of Lords' Report (HMSO 2000) and the Government's Response (The Stationery

Office, 2001) recognised the importance of working across all interested groups, including practitioners, The Prince of Wales's Foundation for Integrated Health and the Department of Health, to develop clear guidelines on competency and training for CAM disciplines. Lay membership of the HMRWG has ensured that the interests of patients and the public are represented and representation from the Royal Pharmaceutical Society has provided expert advice on the regulation of practitioners as well as guidance on the products they use.

123 This section of the report describes the work that has been undertaken voluntarily within the herbal medicine profession to work towards regulation. The EHPA (see above) is referred to within the House of Lords' report as being an umbrella body actively seeking statutory bodies for its members.

124 The organisations represented on the HMRWG are all members of the EHPA with the exception of the Association of Traditional Chinese Medicine (ATCM) and the British Ayurvedic Medical Council/British Association of Accredited Ayurvedic Practitioners (BAMC/BAAAP). The organisations represented on the HMRWG that are affiliated to the EHPA are the:

Association of Master Herbalists  
 Ayurvedic Medical Association  
 British Society of Chinese Medicine  
 College of Practitioners of Phytotherapy  
 International Register of Consultant Herbalists  
 National Institute of Medical Herbalists  
 Register of Chinese Herbal Medicine  
 Unified Register of Herbal Practitioners

125 The largest organisation, that is the EHPA, has over a period of just under a decade prepared a number of documents to support voluntary regulation. The following were transferred to the HMRWG with the endorsement of the organisations affiliated to the EHPA.

- 1 **Core Curriculum** (*Annex I*): this provides for a curriculum determining minimum standards of education and training for herbal medicine practitioners. It has been designed to deliver baseline competency at pre-registration level. Much of the material is core across the disciplines but a tradition-specific element exists.
- 2 **Accreditation Handbook** (*Annex II*): this describes a process of accreditation for organisations, including private colleges, further education and higher education institutions offering courses in herbal medicine.
- 3 **Code of Ethics: Code of Conduct and Disciplinary Procedures** (*Annex III*): this defines a code of ethics for herbal medicine practitioners.
- 4 **Continuing Professional Development** (*Annex IV*): this describes a framework for the continuing professional development of herbal medicine practitioners.

Other documents prepared by the EHPA cover liaison with other professionals, guidelines on admission of members who are not members of the Association, insurance and research. These documents can be found on the EHPA website: [www.euroherb.com](http://www.euroherb.com)

## Philosophy of the European Herbal Practitioners Association Core Curriculum and Accreditation Arrangements

126 A defining characteristic of a profession is that it has a distinctive knowledge base, and that the profession itself takes a leading role in the definition, development and transmission of the knowledge base within the practitioner community. Thus an attention to the knowledge base for herbal medicine has been a cornerstone of the preparation of the practitioner community for a transition to the status of a statutory self-regulated profession. Education, in this context, includes the curriculum for entry into practice, continuing professional education and research.

127 This section of the report is concerned with the education and training processes for initial entry into practice, and the quality assurance processes which have been put into place to ensure that those who deliver programmes of initial training are complying with the standards which have been set. The section begins by describing the processes by which a curriculum and core competences have been identified and described. This includes an explanation of how the individual herbal traditions can maintain their unique identity while working within a common framework. There then follows some detail about the nature of the education and training for initial entry into practice. Finally, the section concludes with a discussion of the processes of accreditation, which provide the quality assurance with regard to educational providers.

128 The development of the common curriculum was a process that took place over an eight-year period, and involved many different interest groups. A core team evolved with representation from the three main traditions of herbal medicine found in the UK (Western, Chinese and Ayurveda), and with support from two traditions less well known in the UK (Tibetan and Kampo). Representatives from higher education, with particular expertise in education and healthcare supplemented this group. The core group engaged in frequent consultation throughout the period of development, culminating in a draft of the Core Curriculum documents being circulated to all known practitioners in the UK and to many other interested groups, in summer 1999. At this point, all the larger registers of herbal practitioners endorsed the curriculum, and agreed to work towards its implementation in their schools.

Many of the courses in the UK are delivered within a university setting, and the course teams involved contributed to the development of the curriculum, ensuring compatibility with the internal university requirements.

129 The emphasis of the common curriculum, and minimum competences for practitioners, is on professional practice. The curriculum integrates academic and technical learning within the context of clinical practice. There is thus no separation of theory and practice, and there is an explicit articulation of the requirement for learning in direct proximity to patients.

130 The published curriculum is in nine sections, one of these being a distinctive and identifiable body of knowledge associated with the specific tradition in which a given practitioner will be working. This is discussed in more detail below. The common elements cover Human Sciences, Nutrition, Clinical Sciences, Plant Chemistry and Pharmacology, Pharmacognosy and Dispensing, Practitioner Development and Ethics, Practitioner Research and Clinical Practice. The minimum total learning hours are 2560, and practitioners will reach at least level six (honours degree level) in the Framework for High Education Qualifications (FHEQ), or its equivalent. It is for the Accreditation Board to assess equivalence in the context of private training providers (see sections 135-138). The community of practitioners who developed the curriculum were anxious to foster the continuance of those smaller schools and colleges that, for so long, have trained herbal practitioners and kept the tradition alive in this country.

131 Thus the curriculum is seen as an enabling framework which sets minimum acceptable levels of knowledge and competence for individuals to enter into practice. The framework supports the maintenance of distinctiveness in individual schools and traditions through encouraging an extended curriculum that goes beyond the minimum prescribed framework. In particular, each of the unique traditions must have an agreed and adopted curriculum that covers the specifics of that tradition, that is the philosophy, the *materia medica* and the distinctive characteristics of the traditional practice. So far, a curriculum has been agreed for Western, Chinese, Tibetan Herbal and Ayurvedic medicine. In the case of the three latter traditions, this is congruent with comparable elements in training in their country of origin. Work is currently being undertaken for Kampo herbal medicine, and it is quite possible for other distinctive traditions to

come forward in future periods and work within the overarching framework of the common curriculum to develop programmes of study for other traditions not currently established in the UK.

132 During the process of developing the curriculum, there was considerable debate about the extent of orthodox medical science to be included in the common curriculum. Some practitioner groups felt that this was not congruent with the historical origins of their tradition. However, after a considerable period of debate, it was decided that the inclusion of a significant amount of orthodox medical science is essential for the healthcare context in which practitioners are working. In communicating both with patients and with other healthcare workers across professional boundaries, it is necessary to have a good command of human and clinical sciences. This is the case also with training in the Asian sub-continent and in China and Tibet where traditional medicine has embraced appropriate training in orthodox medical science alongside the traditional medical training.

133 Having agreed the curriculum, the next task was to develop a description of the values, knowledge, skills and behaviour of a practitioner upon entry to the profession. This is the expected end point for a learner who has followed the curriculum and who is thus assessed as competent to practise. The assessment taxonomy in the curriculum requires learners to show in their practice the following attributes: theory and principles, analysis and reflection, application and reflection, synthesis and evaluation, and creativity. The competences of a qualified practitioner have now been described in the National Professional Standards for Herbal Medicine.

134 Each training establishment can thus take the common curriculum and the minimum competencies for entry into practice and use these as the basis for developing a curriculum that meets the required standard and honours the tradition of that school or university. There are no prescriptive requirements over delivery methods, so courses can be full or part-time, or delivered by distance learning in combination with working alongside a suitably qualified practitioner. What is required is that the training provider can provide a philosophy and rationale for their approach, and show how their programme complies with the minimum standards of the Core Curriculum, to produce practitioners with the required competences.

135 In order to satisfy the public that training providers are meeting these standards, an

Accreditation Board has been established to carry out a quality assurance process. It was decided that one Board should cover the different courses spanning all traditions. Therefore membership of the Board is made up equally from a range of practitioners from different professional associations and lay experts who represent the public interest. These lay people are drawn from education, healthcare and other relevant professional backgrounds (see Annex II for further details).

136 The accreditation process is a blend of documentary reviews combined with visits to the training establishments to meet with students and staff. The process is transparent and documented, and contains the right to appeal. Accreditation can be granted for different periods, depending on the nature and extent of any recommendations for improvement.

137 Many of the existing programmes of study in herbal medicine are within established schools or universities that have already been through rigorous, internal and external, quality assurance. Where possible, the Accreditation Board will work with other bodies to minimise any potential duplication in effort. The Board is particularly keen, where appropriate, to relate professional accreditation very closely to the processes of academic validation.

138 From the start, the Accreditation Board has sought to recognise the diversity of the sector and the roots of practice in traditional origins. This is supported by the inclusion of an internal member of the school or university as part of the accreditation team, in order to ensure the tradition is explored from within. On the site visit team there will also always be a practitioner from the tradition which is being inspected but who is independent of that particular institution. The aim of the accreditation process is to safeguard the public by assuring common standards for the profession, but within a framework that recognises and values the diverse ethnic and cultural philosophies of herbal medicine.

## Divergent Opinion

139 Whilst there is broad consensus about these documents from the organisations affiliated to the EHPA, the individual organisations themselves have in some cases separate procedures specific to themselves for voluntary regulation. These are, however, not inconsistent or in conflict with the documents developed by the EHPA.

140 Similarly, the organisations not affiliated to the EHPA have also been independently working towards voluntary regulation. However, with the British Ayurvedic Medical Council/British Association of Accredited Ayurvedic Practitioners (BAMC/BAAAP), established in 1999, there are both actual and perceived differences between their systems for voluntary regulation and the EHPA proposals. For example, BAMC/BAAAP has developed a Code of Ethics which enshrines many of the values upheld by other health professionals whilst also including the requirements for ethical practice of Ayurveda as stated in the classical texts.

141 BAMC/BAAAP has voluntarily undertaken activity in support of regulation. They have established with Thames Valley University a BA (Hons) Ayurvedic Studies, the only university validated degree programme in Ayurvedic Studies outside India and Sri Lanka. It was launched in 1999 and the first cohort of students has just graduated. The course at Thames Valley does not however confer a licence to practise and graduates are required by BAMC/BAAAP to complete a 1,000 hour internship before they can register with BAAAP. BAMC/BAAAP have also arranged a number of events to inform the public about Ayurveda.

142 In addition, BAMC/BAAAP established the Ayurvedic Charitable Hospital in London in June 2000. The 35 bed in-patient facility accepted self-referrals as well as GP referred patients. The hospital offered treatments for a wide range of chronic and acute disorders. This hospital is temporarily closed whilst a new building to house it is found.

143 BAMC/BAAAP have dissociated themselves from the EHPA primarily because they are opposed to the Common Core Curriculum (see below and Annex I). They consider that the suggested content for the Ayurveda module is limited in its scope and insufficient for the safe practice of Ayurveda. They are of the view that there is an unnecessary emphasis on aspects of biomedicine and the suggested number of hours for these elements of the curriculum are incongruent with the expected learning outcomes.

144 BAMC/BAAAP are firmly resolved that the 5.5 years of education for a Bachelor of Ayurvedic Medicine and Surgery (BAMS) degree should be the minimum standard for the practice of Ayurveda and that institutions providing Higher Education programmes in Ayurveda are accredited by a panel

of Ayurvedic physicians with an MD qualification, experienced educationalists and lay experts. BAMC/BAAAP declare themselves fully committed to protecting public safety and maintaining the authenticity and integrity of Ayurveda. They are prepared to accept the curriculum developed by the Department of Indian Systems of Medicine and Homeopathy provided that the 1,666 hours are taught hours and that there are an additional 60 hours each for the study of Sanskrit and Hindu Philosophy plus 1,000 hours of clinical training. BAMC/BAAAP are concerned that the HMRWG might be persuaded to make recommendations which would defeat these objectives. On the other hand, two other Ayurvedic organisations, the Ayurvedic Medical Association UK and the Maharishi Ayurveda Physicians Association have declared themselves in full support of the Common Core Curriculum (Annex I) and have also given their backing to the EHPA Code of Ethics.

145 Much of the deliberations of the HMRWG have focussed on attempting to reconcile the views of the organisations affiliated to the EHPA with the views of those that are not affiliated to this organisation.

## M Interface with other Health and Social Care Professionals and other Regulatory Bodies

146 In making proposals for the regulation of herbal medicine practitioners, the HMRWG recognised that in the UK new arrangements for the regulation of conventional health and social care disciplines are in the process of being implemented. *The New NHS: Modern, Dependable* (Department of Health 1997) both demonstrated the commitment of the government to giving the people of this country the best system of healthcare in the world and its intention to modernise the NHS. It also placed high priority on integrated care, more control at a local level of NHS organisation, and better working across professional boundaries by those who provide social care, housing, education and employment in order to tackle ill health and inequality. The language of partnership is dominant and driven by performance. Integrated care would be delivered through better understanding of roles across professional boundaries.

147 The White Paper, *The New NHS: Modern Dependable*, (Department of Health 1997) stated that the needs of patients should be paramount in the modern NHS and, instead of being passed amongst different agencies and health and social care professionals, they should have access to an integrated system of care that is quick and reliable. This was further developed in *The NHS Plan* (Department of Health 2000) which was critical of unnecessary boundaries existing between professions that held back staff from fulfilling their true potential. It suggested that some tasks undertaken by medical staff could be better and more effectively undertaken by other health professionals. It identified the need for radical reform of education and training to reshape care around the needs of patients and indicated that it would be mandatory for NHS employers to empower appropriately qualified nurses, midwives and therapists to undertake a wider range of clinical tasks. These include the right to make and receive referrals, admit and discharge patients, order investigations and diagnostic tests, run clinics and prescribe drugs. Almost inevitably the policy pressure to change the way health and social care professionals work has resulted in pressure to review regulation to implement a

consistent approach which will contribute to joint working and help staff to practise their skills more effectively.

148 The theme of working across professional boundaries, along with the fundamental knowledge that the government's objectives for health and social care could only be achieved by delivering a quality workforce, with the right skills and diversity (Department of Health 1997), was reflected in a review by the Department of Health on workforce planning (Department of Health 2000). This review has resulted in widespread change in England to the arrangements that exist for workforce planning and the partnership between universities and the NHS, with a view to achieving a more integrated and flexible workforce, capable of delivering care around the needs of patients (Department of Health 2000).

149 The HMRWG recognised the need to have flexible regulatory arrangements that both protect patients and allow for the flexible working of practitioners across professional boundaries. The HMRWG has therefore taken account of developments affecting conventional health and social care professionals that to some extent run contrary to the creation of separate councils for CAM professions.

150 It was recognised by the working group that herbal medicine practitioners will need to work closely with conventional health and social care professionals regulated by the bodies listed below.

#### **Health Professions Council regulates**

- Arts Therapists
- Chiropodists and Podiatrists
- Clinical Scientists
- Dieticians
- Biomedical Scientists
- Occupational Therapists
- Orthoptists
- Prosthetists and Orthotists
- Paramedics
- Physiotherapists
- Radiographers
- Speech and Language Therapists

#### **Nursing and Midwifery Council regulates**

- Nurses
- Midwives
- Health Visitors

#### **General Medical Council regulates**

- Medical Practitioners

#### **General Dental Council regulates**

- Dentists

#### **Royal Pharmaceutical Society of Great Britain regulates**

- Pharmacists

#### **General Osteopathic Council regulates**

- Osteopaths

#### **General Chiropractic Council regulates**

- Chiropractors

#### **General Social Care Council regulates**

- Social Care Workforce

#### **General Optical Council regulates**

- Dispensing Opticians
- Optometrists

151 Herbal medicine practitioners will need to recognise the limitations of their own expertise and know when to refer patients to other health and social care professionals. Furthermore, referrals from orthodox and complementary health and social care professionals will be facilitated through the establishment of a statutory register for practitioners of herbal medicine. Referrals are complicated at present for two reasons. Firstly, the absence of a statutory register makes it difficult for medical practitioners to be sure that the practitioner to whom they refer is able to offer an appropriate level of care to patients for whom the medical practitioner has responsibility. Secondly, the NHS is working to become cost-effective with a heavy emphasis on clinical effectiveness. Herbal practitioners are only likely to see referrals from the NHS and the transfer of funding if evidence for clinical effectiveness is provided. When this is in place, referrals are likely to increase over time.

152 Many patients seen by herbal practitioners may also be receiving orthodox treatment or treatment from another complementary or alternative therapist. Increasingly, herbal medicine practitioners will be working as part of a multidisciplinary care team.

153 For the above reasons, it will be important for herbal medicine practitioners to understand the responsibilities and regulatory arrangements for the main health and social care professionals with whom they interface on a regular basis.

# N Competences Required for Herbal Practitioners

## Introduction

154 Competencies for the herbal practitioner are defined according to three sets of criteria: professional values and behaviour, knowledge and specific skills. It is expected that the practitioners will maintain and increase competency over time through continuing professional development. Therefore these standards are set at the minimum level for practitioners on entry into the profession. The Competences outlined here have been amplified in the National Professional Standards for Herbal Medicine, which have been agreed by the professional associations for the Western, Chinese and Tibetan traditions. They are being published by Skills for Health at the same time as this report.

## Values and Behaviours

155 A practitioner of herbal medicine is distinguished by a broad ethical understanding that is manifested in practice. As a minimum, the practitioner should demonstrate the following characteristics.

- The integrity of the practitioner is reflected in high standards of personal conduct, supported by compliance with an appropriate Code of Ethics.
- The practitioner will act in accordance with the prescribed Codes of Ethics and Practice of the profession, and be aware of the implications of these to her/his own practice situation.
- The humanity of the practitioner is manifested in her/his ability to see each patient as a unique individual and of equal importance to the practitioner.
- The caring and compassionate practitioner will possess empathy with patients, and demonstrate respect for a patient's autonomy and right of choice over treatment and lifestyle decisions.
- The practitioner will establish trust with patients, and outline clearly the boundaries of the therapeutic relationship.
- The practitioner will take responsibility for professional conduct and the quality of her/his

practice through systematic self, peer and patient evaluation.

- The practitioner must demonstrate confidentiality both verbally and in the way records are maintained and secured.
- The practitioner will manage her/his professional development through a systematic self-assessment of learning needs, supported by a structured programme of continuing reflective personal and professional development, and having regard also to the specific tradition in which s/he practises.
- The practitioner will develop awareness of personal prejudices and opinions that might impact on the therapeutic relationship.

## Knowledge

156 The parameters for entry-level knowledge for the practitioner of herbal medicine are specified in the agreed Core Curriculum for the profession, which has been defined according to the Framework for Higher Education Qualifications (FHEQ).

157 The practitioner will continue to develop his/her knowledge through a systematic self-assessment of learning needs, supported by a structured programme of continuing professional development.

158 The practitioner will keep updated on significant research developments in herbal medicine and contingent topics.

## Skills

159 Herbal medicine is distinguished by its practice, and the practitioner will demonstrate the following skills in the ways in which s/he works.

- The practitioner will be aware of her/his limits of competence, and will be able to refer appropriately.
- The practitioner will be able to assess and document a case history according to the system of medicine in which s/he is working.
- The practitioner will have an appropriate repertoire of diagnostic tools, sufficient for a wide range of clinical conditions.
- The practitioner will be able to modify communications for different patients, recognising that some will not be familiar with the specific tradition of their practice.

- The practitioner will identify and document a treatment strategy appropriate to the patient's condition(s) and dispense herbs in line with the treatment plan.
- The practitioner will maintain her/his dispensary in accordance with the profession's Code of Practice, and in line with all statutory requirements and guidelines.
- The practitioner will offer guidance on lifestyle factors/changes appropriate to the patient's condition.
- The practitioner will comply with all appropriate professional and statutory requirements.

## O Continuing Professional Development

### Need for Continuing Professional Development

160 There is a growing emphasis on the importance of life-long learning as a condition of self-regulation by the professions, and it is accepted that regulatory bodies should concern themselves with the competence and conduct of practitioners at all stages of their careers. In particular, it has been proposed that in future all registered doctors will be periodically required to demonstrate that they are up to date and fit to practise in their chosen field. It is appropriate for the herbal profession to establish similar monitoring of post-registration standards by introducing a mandatory scheme for continuing professional development. It is therefore recommended that continued registration of herbalists should be conditional on continuing professional development. However, in order to allow time for consultation with the membership and to provide a supportive environment in relation to the culture of continuing learning, it is suggested that mandatory arrangements are put into effect one year after the establishment of a statutory Council.

### Criteria for Continuing Professional Development:

161 It will be for the statutory Council to establish in detail the appropriate criteria for post-registration development. It is recommended that these should allow both for the accumulation of credits through more formal training, and for the flexibility that would enable registered practitioners to define their own needs and to record the activities by which these needs have been met. The research evidence shows that more formal training may highlight what is measurable at the expense of what is really useful. Practitioners also learn in important ways from the problems that face them in relation to their own practice, and from other practitioners who may be more senior to them or at the same level of experience. The latter may be called the 'community of practice', which poses a particular challenge to herbalists (and to other practitioners in complementary/alternative medicine), who are likely to suffer from isolation. A flexible scheme will also benefit those who might

find it difficult to take advantage of formal CPD events, whether for reasons of cost or distance or because of the cultural context (for example practitioners from ethnic minorities, though competent in English, might not be attracted to events that take place within a majority-culture setting).

## New Practitioner Scheme

162 In order to provide post-registration support for recently qualified herbalists, it is suggested that a New Practitioner Scheme be established. For the first two years of membership, newly qualified members would be required to participate in clinical supervision sessions, to attend a certain number of postgraduate seminars, and to present a completion portfolio at the end of the period.

## Administration of the Scheme

163 It is envisaged that the policy for CPD should be decided by the Education Committee of the proposed statutory Council for the herbal profession. It is envisaged that post-graduate courses run by accredited herbal training institutions or by professional associations for herbal medicine would be given automatic approval for CPD, while other courses would need to be sanctioned by the Education Committee.

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## SECTION 3: COSTS OF STATUTORY REGULATION

164 A major concern for herbal medicine practitioners is the costs of statutory self-regulation. The number of practitioners are relatively small, approximately 1,300 being in voluntary registers and perhaps at least some 700 being outside of any register. For this reason, the financial burden likely to be borne by individuals is potentially higher than that for healthcare professionals belonging to larger organisations. This is one of the reasons that the report does not favour the establishment of a separate Herbal Council. It is not in the

interests of either the public or practitioners for members of the herbal medicine profession to be charged disproportionately higher fees than other healthcare professionals.

165 Members of the Herbal Medicine Regulatory Working Group felt that the regulatory body, in whichever form is agreed, should be as financially efficient as possible but sufficiently robust to ensure that public safety is protected and that practitioners are offered an efficient service. The latter is particularly important to practitioners when dealing with registration issues or if they are subject to an investigation. The following table and assumptions provide for an approximate estimate of the costs to practitioners based on different scenarios.

Expenditure Category	Notes	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5	Scenario 6
Office rental, utilities & rate	2	65,840	32,000	87,120	42,000	108,400	52,000
Staffing	3	275,000	247,500	395,000	355,500	445,000	400,500
Phone/fax	4	6,000	6,000	15,000	15,000	20,000	20,000
Postage	5	20,000	20,000	50,000	50,000	120,000	120,000
Stationery	6	40,000	40,000	100,000	100,000	125,000	125,000
Expenses of Committee Members	7	60,000	60,000	80,000	80,000	120,000	120,000
Furniture	8	8,000	8,000	12,000	12,000	15,000	15,000
ICT	9	8,000	8,000	12,000	12,000	15,000	15,000
Publicity	10	50,000	50,000	100,000	100,000	150,000	150,000
Professional Services	11	75,000	75,000	120,000	120,000	150,000	150,000
Total £		607,840	546,500	971,120	886,500	1,268,400	1,167,500
Annual cost £ per practitioner		468	420	262	240	143	131

- Note 1 Assume start up costs including furniture and IT requirements met by DH
- Premises rented on an internal repairing lease with CAT cabling for ICT
- Scenario 1 Single Herbal Council with 1,300 practitioners based in London
- Scenario 2 As above but located in Home Counties
- Scenario 3 Shared with Acupuncture with a total of 3,700 practitioners based in London
- Scenario 4 As above but located in Home Counties
- Scenario 5 Shared with Acupuncture and other disciplines, say a further 5,000 practitioners. Groups that might join at some later date could include Osteopaths, Chiropractors, Aromatherapists and/or Homoeopaths, based in London
- Scenario 6 Shared with Acupuncture and other disciplines, say a further 5,000 practitioners. Groups that might join at some later date could include Osteopaths, Chiropractors, Aromatherapists and/or Homoeopaths, based in Home Counties
- 2 Space modelled on advice from BAMC/BAAAP who currently use a central London location  
All costs are per annum.
- Scenario 1 Assume London office of 150 m<sup>2</sup> at £320/m<sup>2</sup> plus 33% for rates and £2,000 for utilities
- Scenario 2 Assume Home Counties office of 150 m<sup>2</sup> at £160/m<sup>2</sup> plus 25% for rates and £2,000 for utilities
- Scenario 3 Assume London office of 200 m<sup>2</sup> at £320/m<sup>2</sup> plus 33% for rates and £2,600 for utilities
- Scenario 4 Assume Home Counties office of 200 m<sup>2</sup> at £160/m<sup>2</sup> plus 25% for rates and £2,600 for utilities
- Scenario 5 Assume London office of 250 m<sup>2</sup> at £320/m<sup>2</sup> plus 33% for rates and £3,300 for utilities
- Scenario 6 Assume Home Counties office of 250 m<sup>2</sup> at £160/m<sup>2</sup> plus 25% for rates and £3,300 for utilities
- 3 Scenario 1&2 Registrar @ £60k; 4 x Executive Officers @ £35k; 3 x Admin @ £25k, Scenario 1 includes London weighting
- Scenario 3&4 Registrar @ £60k; 6 x Executive Officers @ £35k; 5 x Admin @ £25k, Scenario 3 includes London weighting
- Scenario 5&6 Registrar @ £60k; 6 x Executive Officers @ £35k; 7 x Admin @ £25k, Scenario 5 includes London weighting
- 4 Based on costs provided by General Chiropractic Council and General Osteopathic Council
- 5 Based on costs provided by NIMH, General Chiropractic Council and General Osteopathic Council
- 6 Printer and photocopying costs included in stationery
- 7 Based on costs provided by General Chiropractic Council and General Osteopathic Council
- Assume that professional members receive a fee in partial compensation of lost clinic time and expenses associated with attendance at meetings
- Assume an attendance allowance of £150 per meeting for lay members plus expenses
- 8 Start up costs met by DH and amortised over five years
- 9 Start up costs met by DH and amortised over five years
- 10 Publicity costs include production of annual report and statement of accounts as well as information to inform members of the public
- Assumes initial communication costs of information for members of the public about the new Council would be met by DH
- The communications costs are based on steady state assumptions following start up of the Council
- 11 Professional support assumes that specialist HR support, legal advice, press and publicity liaison and occupational health would be obtained on a consultancy basis to reduce cost

## SECTION 4: ANNEXES TO THE REPORT

166 The following documents are provided to inform discussion on the proposals for the statutory self-regulation of herbal medicine practitioners. Annexes I-V should not be read as definitive statements but rather as a basis to assist the future regulatory body with the setting of standards. It is expected that the annexes will be modified following debate on this report during the consultation period.

167 Annex VI is included because, at the time of submission of this report, differences exist amongst the organisations representing Ayurveda within the UK about appropriate standards for the statutory self regulation of Ayurveda in this country. It should be used during the consultation period to inform further discussion and consensus building amongst the UK representatives of Ayurveda.

- I Core Curriculum
- II Accreditation Handbook
- III Code of Ethics: Code of Conduct and Disciplinary Procedures
- IV Continuing Professional Development
- V Grandparenting Scheme
- VI Proposed Core Curriculum for Ayurvedic Medicine in UK, Prepared by Department of Indian Systems of Medicine and Homeopathy

## ANNEX I: CORE CURRICULUM

### Introduction

This document contains the common core curriculum of the European Herbal Practitioners Association Education Committee. It is the result of wide consultation between the various herbal traditions, to determine the shared elements of herbal practice and the content necessary to provide education and training in those elements. 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.

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

The elements within each module are indicative, not prescriptive. They are presented as sample modules and assessments. This is work in progress and subject to revision.

It is recognised 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 institution to incorporate the contents into their own curriculum of study. The Accreditation Board encourages institutions to develop their courses within the framework of the core curriculum and to justify their approach against its requirements.

The demanding of minimum course-content requirements is part of a process of accreditation by which the EHPA 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:

1. Human Sciences
2. Nutrition
3. Clinical Sciences
4. Plant Chemistry and Pharmacology
5. Pharmacognosy and Dispensing
6. Practitioner Development and Ethics
7. Practitioner Research
8. Module Specific to Each Herbal Tradition\*
9. Clinical Practice

\* The eighth module covers the material specific to the herbal tradition taught by any given institution. A core curriculum for each tradition is produced by the appropriate professional body. The eighth module for Ayurvedic, Chinese, Tibetan and Western medicine are appended here.

## Study Time

The following table gives some guidance as to the length of course expected to be accredited. Again, this is indicative rather than prescriptive.

MODULE	HOURS
Human Sciences	250
Nutrition	80
Clinical Sciences	350
Plant Chemistry and Pharmacology	80
Pharmacognosy and Dispensing	80
Practitioner Development and Ethics	40
Practitioner Research	80
The Specific Herbal Tradition	450
Clinical Practice	1150
<b>TOTAL</b>	<b>2560</b>

The above table gives guidelines for total hours. Within these totals, the relationship between contact hours and home-study hours will depend on the design of the course and the previous learning and experience of the students. An undergraduate course for younger students might have a ratio of one hour of contact time to every hour of directed home study, whilst a course for adult learners, with considerable previous learning and experience, might have a ratio of one hour of contact time to two or three hours of directed

home study. It is for each Institution to present its rationale for the hours allocated to different elements of its curriculum.

In the case of the Clinical Practice module, however, it is expected that on all courses at least half of the time will be spent on clinical work in direct proximity to patients. The remainder can consist of case discussions, clinical supervision, elaborating diagnoses, researching treatments, writing up cases, and other clinically relevant activities.

## 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 courses. The levels refer to the National Qualifications Framework of the Quality Assurance Agency.

## 1 Core Curriculum on Human Sciences

### Aims

To provide an integrated course 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 course, the student will be able to:

1. explain the basic 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. describe the essential metabolic processes in the body, their integration and control
6. describe 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.

### Assessment

Assessment will emphasise students' ability to understand and use the material covered in this module. Typical forms of assessment would include home study questions and essays geared to clinical practice.

### Indicative Reading

*Concise Medical Dictionary.* (Oxford Paperback Reference, 1994)

Tortora G.J., Anagnostakos, N.P. *Principles of Anatomy and Physiology.* (Harper Collins, Sixth Edition, 1990)

## 2 Core Curriculum on Nutrition

### 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. This would include 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 course 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. discuss dietary needs at different stages of development
8. discuss relationships between diet and disease
9. recommend 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.

### Assessment

Assessments will probably be designed to assess students' understanding of the material and their ability to apply it to typical cases. Typical assessments might include home study questions and essays, some of which would probably be based on hypothetical clinical situations.

### Indicative Reading

Davies S.D., Stewart, A. *Nutritional Medicine*. (Pan Books, 1987)

Department of Health, *Dietary Reference, A Guide*. (HMSO, 1991)

Diamon H., Diamond M. *Fit For Life*. (Bantam paperback, 1987)

Erasmus U. *Fats that Heal, Fats that Kill*. (Alive Books, 1993)

Garrow J. James W. *Human Nutrition and Dietetics*. 9th ed. (Churchill Livingstone, 1996)

Grant D., Joyce J. *Food Combining For Health*. (Thorsons 1984)

Griggs B. *The Food Factor*.

Hartvig and Rowley. *You Are What You Eat*. (Platkus, 1996)

Holford P. *The Optimum Nutrition Bible*. (Platkus, 1998)

Murray M., Pizzorna J. *The Textbook of Natural Medicine*. (Churchill Livingstone 2nd ed, 1999)

Pauling L. *How to Live Longer and Feel Better*. (Freeman, 1986)

Pitchford A. *Healing With Whole Foods – Oriental and Modern Traditions*. (North Atlantic Books, California, 1993)

Sharon M. *Complete Nutrition*. (Prion Press, 1989)

Shears C., Curtis. *Orthomolecular Nutrition – the science of self-healing*. (Nutrition Science Research Institute, 1980)

Skypala I. *Healthy Eating*. (Wisebury Publications via Thorsons, 1988)

## 3 Core Curriculum on Clinical Sciences

### Aims

To provide an integrated course 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 course, the student will be able to:

1. describe the diagnostic techniques and clinical applications in orthodox medical practice and compare and contrast them with their own medical equivalent
2. discuss 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. describe the general nervous, endocrine and metabolic responses to ageing, stress and tissue injury
5. describe the principles of infection and the ways in which alterations in natural and acquired defenses (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. describe 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. demonstrate effective case-history taking
9. perform a clinical examination of the major body systems
10. interpret basic pathology laboratory data and results of investigative procedures
11. understand major actions and side-effects of the major classes of orthodox drugs and how to access drug information (use of National Formularies etc.)
12. recognise potentially serious signs and symptoms and recognise when to refer patients to orthodox medical practitioners

### 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, cerebrospinal 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.

books to widen their knowledge. Typical assessments might include home-study questions and essays, some of which would probably be based on hypothetical clinical situations.

#### Indicative Reading

Blaxter M. *Health and Lifestyles*. (Routledge, 1990)

*British National Formulary*. (BMJ Books, 2003)

Browse N. *Introduction to Symptoms and Signs of Surgical Disease*. (Edward Arnold, 1997)

*Concise Medical Dictionary*. (Oxford Paperback Reference, 1994)

Cotran R. S., Kumar V., Collins T. *Robbins Pathologic Basis of Disease*. (Saunders, 1998)

Edwards C.R.W., Bouchier I.A.D, Haslett C., Chilvers E.R. *Davidson's Principles and Practice of Medicine*. (Churchill Livingstone, 1995)

Gascoigne S. *The Manual of Conventional Medicine for Alternative Practitioners*. Vols. I and II (Jigme Press, 1995)

Gascoigne S. *Prescribed Drugs and the Alternative Practitioner*. (Ashgrove Press, 1992)

Kubler-Ross E. *On Death and Dying*. (Routledge, an imprint of Taylor and Francis Books Ltd, 1973)

Kumar P., Clarke M. *Clinical Medicine: A Textbook for Medical Students and Doctors*. (Saunders, 2002)

The Lecture Notes Series (titles include: *General Practice, History Taking and Examination, Cardiology, Gynaecology, Tropical Medicine, Urology, ENT, Obstetrics, Geriatrics, Neurology, Orthopaedics and Fractures, Surgery, Endocrinology, Forensic Medicine, Oncology, Haematology, Paediatrics, Anaesthetics, Psychiatry, Medical Statistics, Clinical Medicine, Sexually Transmitted Diseases, Pathology, Ophthalmology, Occupational Medicine, Clinical Chemistry, Fluid and Electrolyte Balance*) (Blackwell Science (UK))

#### Assessment

Assessments will be designed to assess students' understanding of the material, their ability to apply it to typical cases, and their ability to read relevant

## 4 Core Curriculum on Plant Chemistry and Pharmacology

### 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:** 4/5 (HE certificate/HE diploma)

### Learning Outcomes

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

1. describe the nature and properties of plant substances
2. explain simple chemical identification tests and separation techniques and understand the value and uses of more sophisticated techniques
3. describe the pharmacological effects of the major groups of plant compounds as detailed below
4. describe the mode of action of common medicinal plants. Discuss the limitations of plant biochemistry as an explanatory model for herb actions
5. carry out 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, glucosilicates)
  - 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.

### Assessment

To address the learning outcomes, a possible approach would be to prepare a portfolio on a medicinal plant, based on a search of current published papers, to demonstrate an understanding of the constituents and their actions and modern methods of measurement and analysis of constituents.

In addition an examination could be required to ensure an adequate understanding of herb safety, drug-herb interactions, use of herbs which are "practitioner only" herbs and use of herbs in pregnancy and for children.

### Indicative Reading

Barnes, J. *Herbal Medicine: A Guide for Health Care Professionals*. (Rittenhouse, 2002)

Blumenthal, M., Goldberg, Brinckmann. ed. *The Complete German Commission E Monographs*. (American Botanical Council, 1998)

Bradley, P. (ed) *British Herbal Compendium*. (British Herbal Medicine Association, 1993)

Brinker, F *Herb Contraindications and Drug Interactions*. (Oregon: Eclectic Medical Publications 1998)

*British Herbal Pharmacopeia*. (British Herbal Medicine Association, 1983)

Bruneton, J. *Pharmacognosy, Phytochemistry, Medicinal Plants*. (Paris: Lavoisier Publishing, 1999)

Cupps, M. *Toxicology and Clinical Pharmacology of Herbal Products*. (New Jersey: Humana Press, 2000)

Evans, W., Trease, G. *Pharmacognosy*. (Oxford: Bailliere Tindall, 1995)

Greenwald, J., Brendler, T., Jaenicki, C. (eds) *Physicians Desk Reference for Herbal Medicines*. (New Jersey: Medical Economics Company, 2000)

Miller, L., Murray, W. *Herbal Medicinals*. (Pharmaceutical Press, 1998)

Neal, M. *Medical Pharmacology at a Glance*. (Blackwell, 1997)

Pengelly, A. *Constituents of Medicinal Plants*. (Australia: Sunflower Herbals, 1996)

Robbers, J., Speedie M., Tyler V. *Pharmacognosy and Pharmacobiotechnology*. (Williams and Wilkins, 1996)

Wichtl, M., Bisset, N *Herbal Drugs and Phytopharmaceuticals*. (CRC, 1994)

Williamson, E, et al. *Pharmacological Methods in Phytotherapy Research*. (Chichester, John Wiley & Sons, 1996)

## 5 Core Curriculum on Pharmacognosy and Dispensing

### 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 teach the legal requirements relating to herbal practice.

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

**Minimum Level** : 5 (HE diploma)

### Learning Outcomes

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

1. describe the processes and issues of quality assurance in relation to herbal medicines
2. demonstrate a knowledge 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 knowledge and understanding of a full range of dispensary skills
5. demonstrate knowledge and understanding of the legislation relating to the storage, labelling and dispensing of herbal medicine
6. compare and contrast the different forms of administration of herbs
7. describe procedures for interacting with pharmacists, licensing authorities, the medical profession and toxicologists

### Outline of Syllabus Contents

1. **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.
2. **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.
3. **Botanical terms used to describe herbs.** Identifying characteristics of commonly used herbs. Common fakes and substitutes.
4. **Dispensary skills** 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), 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.
5. **The law and herbal medicine** Relevant legislation; labelling; adverse event reporting systems; restricted substances; endangered species and CITES; etc. (Please note that specifics of the legislation to be covered will vary from country to country, see appendix to this module).
6. **Health and safety** The practice premises
7. **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.

### Addendum

Incompatibilities between herbs should also be covered within the Chinese herbalism, Western medical herbalism, or other specific curricula.

Where preparation methods for crude herbal materials are an integral part of a herbal tradition, this will be covered in the module(s) specific to that tradition, up to the level required for prescription dispensing.

### Appendix

The law and herbal medicine - for the UK this includes:

Restricted substances, Schedule 1, 2 and 3 substances and the requirements of the Medicines Act 1968

The Environmental Protection Act 1991

The Medicines Order 1977

Directive EC 2001/83

Medicines for Human Use (Marketing Authorisations 1994)

### Assessment

To address the learning outcomes, a possible approach would be coursework to demonstrate understanding of quality assurance procedures including stock records and legislation relating to quality assurance and to dispensary management.

Practical assessment could include recognition of samples of dried herbs using pharmacopoeia descriptions; preparation of a compound preparation, production of a draft label for a prescribed medicine.

### Indicative Reading

Bradley, P. (ed) *British Herbal Compendium*. (British Herbal Medicine Association, 1993)

*British Herbal Pharmacopoeia*. (British Herbal Medicine Association, 1983)

Bruneton, J. *Pharmacognosy, Phytochemistry Medicinal Plants* (Lavoisier, 1995)

Evans, W.C. *Trease and Evans' Pharmacognosy*, 14th ed. (Bailliere Tindall, 1996) ISBN 0-7020-1899-6

Hedley C., Shaw, N. *Herbal Remedies*. (Bath: Paragon, 2002)

Heinrich, M. et al. *Fundamentals of Pharmacognosy and Phytotherapy*. (London: Churchill Livingstone, 2003)

Jackson, B.P., Snowdon, D.W. *Powdered Vegetable Drugs, an Atlas of Microscopy in the Identification and Authentication of some Plant Materials Employed as Medicinal Agents*. (Stanley Thornes, 1974)

Painter, G.A., *Herbalist's Medicine-Making Workbook*, (Australia: Painter, 1998)

Priest, A.W., Priest, L.R., *Herbal Medication*. (London: Fowler & Co, 1982)

*Quality control methods for medicinal plant materials*. (World Health Organisation, 1988) ISBN 92 4 154510 0

Wichtl, M. *Herbal drugs and Phytopharmaceuticals, a handbook for practice on a scientific basis*. (Medpharm Publishers 1994) ISBN 3-88763-025-4.

## 6 Core Curriculum on Practitioner Development and Ethics

Please note that until a unified code of ethics and conduct is established for all EHPA member associations, this module will need to vary to reflect the specific codes of ethics and conduct for the professional association with which the course is linked.

### 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** : 4/5/6

(HE certificate/diploma/honours)

### Learning Outcomes

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

1. demonstrate an 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 apply, 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 healthcare professionals, and staff they employ

3. practise in accordance with the relevant code of ethics and conduct
4. demonstrate a clear understanding of their limits of competence and when and how to make referrals
5. identify and access sources of advice, guidance and continuing professional education which will enable them to grow and develop as professional herbal practitioners

### 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, beginnings 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 1998, 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. **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.
6. **Relationships between practitioners** Communication, courtesy, professional and ethical conduct; disputes and complaints procedure; transfer and referral of patients, case histories and patient notes
7. **Supervision** Mentoring and personal support for the practitioner; continuing professional education; boundaries of the therapeutic space; safeguarding the legitimate needs of the practitioner.
8. **Professional misconduct** Complaints,

disciplinary procedure, advice and guidance, insurance.

9. **Prescribed conduct regarding** Abortion, venereal disease, notifiable diseases, consent and supervision of minors and people with learning difficulties, procedures for the intimate examination of a patient of the opposite sex, notification of adverse events.

### 10. Taxation and business issues

#### Assessment

To address the learning outcomes, a possible approach would be short essays on a range of possible scenarios designed to demonstrate an understanding of the practitioner's role in the therapeutic relationship, ethical issues such as informed consent and shared decision-making with patients, consent in treatment of children and child protection, confidentiality, limits of competence and critical incident analysis. A reflective journal could be used as part of the assessment process.

#### Indicative Reading

Dimond, B. *The Legal Aspects of Complementary Therapy Practice: A Guide for Healthcare Professionals*. (Edinburgh: Churchill Livingstone, 1998)

Fletcher, L. *A Legal Framework for Caring: An Introduction to Law and Ethics in Health*. (Basingstoke: Macmillan, 1999)

Holm, S. *Ethical Problems in Clinical Practice: The Ethical Reasoning of Health Care*. (Manchester: Manchester University Press, 1997)

Mitchell, A., Cormack, M. *The Therapeutic Relationship in Complementary Health Care*. (Edinburgh: Churchill Livingstone, 1998)

Seedhouse, D. *Ethics: The Heart of Healthcare*. (Chichester: John Wiley & Sons, 1998)

Stone, J. *Complementary Medicine and the Law*. (Oxford: Oxford University Press, 1996)

## 7 Core Curriculum on Practitioner Research

### 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 healthcare in general and herbal medicine in particular.

**Minimum Level:** 5/6 (HE diploma/honours)

### Learning Outcomes

By the end of the course 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** Identifying an appropriate methodology.
5. **Ethical and legal issues in research** Including negotiating access, informed consent, working with patients within the established health authority.

### Assessment

To address the learning outcomes, a possible approach would be coursework to critically

evaluate a published clinical research paper relevant to the practice of herbal medicine. Candidates would be expected to demonstrate an understanding of the methodology, rationale for the methodology, what the findings were and their relevance to clinical practice in herbal medicine.

Coursework: develop a research proposal for a clinical trial which asks a question relevant to herbal medicine. Candidates would be expected to refer to relevant published material. The proposal would include background, aims, setting, methods, results and possible conclusions. The ethical implications for the patients participating in the trial should be discussed.

### Indicative Reading

- Aldridge, D., Lewith, G.T. *Clinical Research Methodology for Complementary Medicine*. (Hodder and Stoughton, 1993)
- Armstrong, D., Grace, J. *Research Methods and Audit in General Practice*. (Oxford University Press, 2000)
- Bowling, A. *Measuring Disease*. (Open University Press, 1995)
- Furnham, A., Vincent, C. *Complementary Medicine: a research perspective*. (Wiley, 1998)
- Greenhalgh, T. *How to Read a Paper*. (London: British Medical Journal Publishing Group, 1997)
- Kazdin A.E., *Single Case Research Designs*. (Oxford University Press, 1982)
- Lewith, G., Jonas, W., Walach, H. *Clinical Research in Complementary Therapies*. (Churchill Livingstone, 2002)
- Kirkwood, B.R., *Essentials of Medical Statistics*. (Blackwell Scientific Publications, 1988)
- Marshall C., Rossman G.B. *Designing Qualitative Research*. (Sage Publications, 1989)
- Micozzi, M. *Fundamentals of Complementary and Alternative Medicine*. (Churchill Livingstone, 2001)
- Morse, J.M. *Qualitative Health Research*. (Sage, 1992)
- Nettleton, S. *The Sociology of Health and Illness*. (Polity Press, 1995)
- Oppenheim, A.N. *Questionnaire Design, Interviewing and Attitude Measurement*. (Continuum International Publishers, 1992)
- Peters, D. *Understanding the Placebo Effect in Complementary Medicine*. (Churchill Livingstone, 2001)

Pocock, S.J. *Clinical Trials: A Practical Approach*. (Wiley, 1983)

Reason, P., Rowan J. *Human Enquiry: A Sourcebook of New Paradigm Research*. (Wiley, 1981)

Riley. *Getting the Most Out of Your Data*. (Technical and Educational Services Ltd, 1990)

Roth, A.J. *The Research Paper: Process, Form and Content*. (Wadsworth, 1989)

Scambler, G. *Sociology As Applied to Medicine*. (London: W.B. Saunders, 1997)

Strauss, A., Corbin, J. *Basics of Qualitative Research: Grounded Theory Procedures and Techniques*. (Sage, 1987)

Taylor S., Field D. *Sociology of Health and Health Care*. (Oxford: Blackwells, 1993)

van Zwanenburgh, T., Harrison J. *Clinical Governance in Primary Care*. (Oxford: Radcliffe Medical Press, 2000)

## 8 Module specific to each herbal tradition

Some of these are still in preparation and will be published at a later date. The detailed curricula for Ayurvedic, Chinese, Tibetan and Western Herbal Medicine are published in the appendices to this document.

## 9 Core Curriculum on Clinical Practice

### Aims

To promote students' development of the full range of a herbalist's 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)

### Learning Outcomes

By the end of the course the student will be able demonstrate the skills listed below.

#### 1. Develop herbal medicine practical skills

During clinical practice students demonstrate

the development of competence at the following skills:

- dispensary administration, including ordering and stock rotation
- herbal quality assessment and safe storage
- weighing, packaging, labelling and safe dispensing of herbs

#### 2. Practice and extend the theories of herbal medicine and develop diagnostic skills

During clinical practice students will be able to extend their experience of the following aspects of herbal medicine with the guidance of the clinic supervisor(s):

- taking the case history including building rapport, clear questioning, good record-keeping
- making the diagnosis including pathology and aetiology, according to the theories of herbal medicine
- palpation - sensitivity to patient and responsiveness to physical clues
- appropriateness of the patient's condition for treatment with herbal medicine
- analysis of the patient's condition from a herbal medicine perspective and the selection of the most appropriate formulae and herbs
- modification of the herbal strategies used as the patient's condition changes

#### 3. Patient-practitioner relationship skills

Students will progressively develop these skills, with particular attention to:

- establishing good contact and building confidence and trust
- providing information in everyday language
- time management

#### 4. Patient management skills

Students will develop their skills in:

- lifestyle monitoring and advice
- limits to competence
- referrals and recommendations
- drug monitoring and management
- response of the patient to herbal treatment
- ethical considerations

### Outline of Syllabus Contents

During clinical practice students will begin to practise the skills outlined above under learning outcomes. 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. Their judgements must then be checked with the clinical supervisor before action is taken.

### Code of Ethics and Practice

The codes of ethics and practice of the relevant professional body will apply throughout clinical practice.

### Assessment

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 that may occur in their work, and must be able to formulate solutions to these. Clinical skills should be performed consistently and with confidence. By the end of the module students must show that they are ready to practise herbal medicine independently.

Students may be assessed in a variety of ways including writing up case histories of patients seen in clinic, completing competency logs, clinic supervisor's assessment, clinical exams, etc. The assessment process will be designed so that the college is able to satisfy itself that students have developed both the necessary competencies, and an adequate level of global competence in herbal medicine.

### Indicative Reading

Appropriate reading for this module will be determined by the specific tradition of herbal medicine being studied.

## Appendix 1: AYURVEDIC MEDICINE CORE CURRICULUM

These guidelines cover the following areas:

- Aims
- Learning Outcomes
- Curriculum Outline
- Assessment
- Recommended Allocation of Time

### Aims

The aim of professional entry training in Ayurvedic medicine shall be to produce a practitioner who can:

1. display theoretical knowledge and clinical competence sufficient to undertake a professional role as an Ayurvedic physician.
2. utilise the principles and practice of Ayurveda effectively in the promotion of health and alleviation of illness for patients.
3. establish and maintain effective professional relationships with colleagues within the Ayurvedic community and beyond.
4. assume responsibility for own personal and professional growth.
5. participate in defining, maintaining, interpreting, and co-ordinating services within the complementary health care systems.
6. facilitate Ayurvedic research and utilise research findings from multiple disciplines in providing care to patients.
7. utilise a holistic approach in the delivery of patient care based on the philosophy of Ayurveda.
8. reflect upon everyday practice and critically analyse the dynamics of Ayurvedic medicine.

### Learning Outcomes

Upon completion of the prescribed training and subsequent qualification in Ayurvedic medicine, a practitioner shall:

1. be able to obtain and record patient information by performing a complete roga-rogi pariksha (history and physical assessment) in an empathetic fashion, including:
  - a. Prashna and Panchendriya Pariksha (History taking, Inspection, Palpation, Percussion and Auscultation)

- b. Astavidha Pariksha (Eight-point Disease Assessment)
- c. Dasavidha Pariksha (Ten-point Patient Assessment)
- d. Sadanga Pariksha (General Physical Examination)
- e. Sroto Pariksha (Complete Systemic Examination)
2. exhibit proficiency in modifying patient interview and examination based on the circumstances, including the ability to:
  - a. review patient history and physical examination based on laboratory findings
  - b. conduct focused history and physical examination in a timely manner based on a patient's presenting symptoms and signs
  - c. conduct screening examinations for health maintenance
  - d. modify interview technique based on client's interactional style and abilities
  - e. identify patient's diagnosis and make appropriate referrals when necessary
3. apply knowledge in clinical settings to:
  - a. assess acuity of illness:
    - \* recognising patients with life-threatening conditions
    - \* evaluate patients suffering chronic illness
    - \* help manage patients (together with their families) who are facing death
  - b. apply understanding of basic mechanisms of disease processes according to the principles of Ayurveda to analyse data obtained via the history, physical, and laboratory examinations
  - c. present patients case analyses and treatment plans in a well-organised, concise, and effective manner
  - d. where appropriate, present information to other members of the healthcare team, and to the patient's general practitioner
4. suggest a preliminary treatment plan which manifests:
  - a. critical appraisal of the diagnosis
  - b. understanding of natural history of disorders and likelihood that treatment could alter the disease process
  - c. basic understanding of the indications, contraindications, potential adverse reactions, costs and benefits of therapeutic intervention
  - d. basic understanding of mechanisms of herbal actions, pharmacotherapeutics, pharmacodynamics, herb-herb interactions, herb-drug and herb-nutrition interactions
5. evaluate the patient's progress during treatment, assessing compliance with therapy and unexpected deviations, and reassessing both diagnosis and treatment in the light of the treatment outcomes
6. demonstrate responsibility for continuity of care of the whole patient, with regard to factors influencing that care, including:
  - a. psychological factors
  - b. social, economic, and cultural concerns
  - c. potential for substance abuse
  - d. nutrition, health and lifestyle habits
  - e. environmental and occupational concerns
  - f. consideration of long-term as well as short-term goals
7. demonstrate skill in preventative health and health promotion:
  - a. demonstrate disease risk assessment in the areas of:
    - \* nutrition, dietary and life-style management
    - \* tri-doshic imbalance reduction
  - b. promote healthy lifestyles through health behaviour assessment and counselling
  - c. demonstrate awareness of implications of patient's prakruti alterations in disease processes
  - d. appreciate the physician's role in the care of a community's health, including the ability to describe the impact of healthcare systems on community health and how it might be improved
8. record observations, major thought processes, and decision-making considerations in the patient record, including:
  - a. initial consultation, interview and examination, diagnosis and treatment notes
  - b. progress notes, which communicate patient's progress, status, findings, and management options

c. readable, well-organised, and concisely written reports

### Curriculum Outline

#### PART 1 History and Philosophy of Ayurveda (Ayurved Itihias Avum Darshan)

It is very difficult to establish the exact time period of Ayurveda. However, the origin of Ayurveda as an oral tradition is taken to be circa 6000 BC. The history of Ayurveda is closely interwoven with the history and culture of the Indian sub-continent.

Ancient Ayurvedic rishis observed nature for its underlying patterns. Ayurveda has accepted the Vedic hypothesis that there are common principles underlying Microcosm (individual) and Macrocosm (universe). Man and the universe are composed of the same basic elements.

The six philosophies that are at the heart of Ayurveda care are called Shad Darshanas. The creators of these philosophies were enlightened scientists or rishis who had great insight or inner vision. All these philosophies have contributed to the teaching and practice of Ayurveda.

This part covers the history and philosophy of Ayurveda including:

1. a critical examination of the holistic role of mind, body, spirit and environment
2. the spiritual and historical background of Ayurveda
3. the development of Ayurveda in India during the post-mediaeval period
4. the spread and development of Ayurveda in the Asian sub-continent
5. the evolution/creation of the universe according to Sankhya philosophy
6. the relationship between Ayurveda and the Shad Darshanas
7. the role of Ayurveda within the primary healthcare system

#### PART 2 Fundamental Principles of Ayurveda (Moolika Siddhanta)

The human body is an ever-changing organism subject to the same cosmic laws and principles that govern the universe. On the cosmic plane, the three primordial forces or *gunas*, namely, *tamas*, *rajas* and *sattva*, operating through the five energy principles or *pancha-mahabhuta*, namely, *space*, *air*, *fire*, *water* and *earth*, directly interface with human existence. On the physical plane, the

*tri-dosha* (bodily humours), *dhatu*s (tissue elements), and *malas* (metabolic wastes), are the messengers of communication that interface the external with the internal nature.

In addition to these basic concepts, there are several other fundamental principles to be covered such as, *atma*, *prana*, *prakruti*, *agni*, *ama*, *srotas*, *ojas*. The understanding of these concepts is fundamental to the study of Ayurveda.

This part includes the:

1. theory of Panchamaha-bhutas, including a comparison with modern scientific theories
2. principles of the Gunas
3. theory of Tri-doshas
4. theory of Dhatus and Malas, including a comparison with modern anatomy and physiology
5. concept of homeostasis
6. concepts of Atma, prana and manas
7. concepts of agni, ama, srotas and ojas

#### PART 3 Principles of Health and Health Promotion (Swatha Vritta)

Ayurveda is not just a system of medicine but also a science of health promotion designed to increase all aspects of our wellbeing and happiness. It shows us how to live in such a way as to arrive at optimum health and maximum utilisation of our faculties. Maintenance of a healthy lifestyle by one's own right action is called *swastha vritta*, which literally means "the lifestyle of abiding in one's own nature." A lifestyle (regime) that is balanced with a person's constitution type will allow them to enjoy freshness and vitality everyday.

This part includes:

1. a critical examination of the effect of lifestyle activities on the maintenance of health
2. comparison and contrast of modern and Ayurvedic views of lifestyle in the promotion of physical and mental health
3. examination of the cosmos as it affects human development
4. discussion of the effects of the five senses on a person's physical and mental health
5. evaluation of the effects of seasonal variations on the maintenance of health

6. determination of the doshic constitution of an individual
7. prescription of lifestyle changes to manage physical and emotional stress
8. evaluation of the natural rhythms of the body and the environment in the maintenance of health
9. the effects of massage, yoga, meditation and other non-invasive modes of treatment on a person's mental and physical health
10. nutrition and diet
11. maintaining homeostasis
12. promotion of mental health
13. ethical and social aspects of health promotion
14. stress management
15. detoxification

#### **PART 4 Principles of Ayurvedic Aetio-pathology (Vikruti Vijnana)**

The doshas are not simply the dynamic energy within the body; rather they are influenced by various external and internal factors. Knowledge of these factors is essential for balancing the doshas. Each dosha undergoes three basic stages of development, namely (a) increase or accumulation (*sanchaya*) (b) aggravation or provocation (*prakopa*), and (c) decrease or alleviation (*prashama*). Though diseases are of many kinds and pathogens are of many varieties, all are products of disharmonies of the three biological humours, Vata, Pitta, and Kapha. Diseases reflect the predominant dosha, which produces them. When disturbed the doshas undergo six stages (*kriyakalas*) of development.

According to Ayurveda there are basically three types of diseases: a) endogenous (breakdown from within), b) exogenous (attack from without), and c) mental; any of which can subsequently lead to others. Ayurveda also teaches us that there is no single factor, which is wholly responsible for either health or disease; they are the result of the interaction of many factors.

This part provides an integrated approach to the understanding of disease, its causes, mechanisms, clinical features and diagnosis. It will:

1. discuss the factors, which produce a constitutional imbalance or roga
2. critically examine the role of mind and body in the process of disharmony or disease

3. explain the causation of disease according to Ayurveda
4. discuss the concept of disease process according to Ayurveda and modern medicine
5. describe diseases with reference to the differential diagnosis of common symptoms and causes
6. discuss the distribution of disease in the community, and contrast the approach to prevention according to Ayurveda and the modern point of view

In particular it will cover:

- a. causes of disease (Ayurvedic and modern concepts)
- b. Nidana Pancaka
- c. Nidana
- d. Dosha Samya and Vaisamya
- e. Agni Samya and Vaisamya
- f. Dhatu Samya and Vaisamya
- g. Ojas Samya and Vaisamya
- h. Kriyakala
- i. Samprapti
- j. Roga
- k. Arista laksana
- l. Upasaya and Anupasaya
- m. Vikalpa Samprapti

#### **PART 5 Clinical Methods (Roga-Rogi Pariksha)**

This section explores the Ayurvedic methods of examining the patient and the disease, compares the clinical methods of Ayurveda with those of modern medicine, and provides practice in the application of the principles of *trividha*, *astavidha* and *dasavida* pariksha.

In Ayurveda the clinical examination and diagnostic tests investigate a person's "state," the pattern of movement of tissues (*dhatu*), wastes (*malas*), and biological humours (*dosha*) in the body and mind. Direct perception is the best method of discerning a patient's physical and mental state. Whatever cannot be known directly must be elicited through logical inference, analogy and/or the testimony of other experts. Ayurveda uses *drashana* (observation), *sparshana* (palpation and percussion), and *prashna* (interview) as the main clinical barometer. The signs and symptoms elicited from these are then correlated to the

particular Dosha responsible for the disharmony.

The examination of the pulse (*nadi*) is an important measure in the diagnosis. It is a matter of technical skill, subjective experience and intuition. Accuracy depends upon persistent practice and the development of the ability to sense the varied quality of different pulses. The pulse is a subtle manifestation of universal consciousness pulsating through a person's constitution. The experienced Ayurvedic physician will be able to assess *prakruti*, *vikruti*, *doshic* disorders, other subtle observations, and even prognosis of disease through the pulse.

Topics covered include:

1. diagnosis of a patient's physical condition using the clinical methods derived from Ayurvedic and modern western medical techniques
2. comparing and contrasting the clinical diagnostic skills used by Ayurvedic and modern western doctors
3. evaluation of the mental state of a patient and its relationship to his/her somatic condition
4. explanation of how *prakruti*, *vikruti* and *doshic* constitution of an individual can be assessed through the pulse

More specifically it covers:

- a. the concept of clinical examination (Ayurvedic and Modern)
- b. Vyadhi Samprapti
- c. Pariksha Kramas: (i) Tri vidha pariksha (ii) Asta sthana pariksha (iii) Dasa vidha pariksha
- d. Prakruti Pariksha
- e. Sroto Pariksha: (i) Pranavaha srota (ii) Annavaha srota (iii) Purisavaha srota (iv) Udakavaha srota (v) Mutravaha srota (vi) Swedavaha srota (vii) Rasavaha srota (viii) Raktavaha srota (ix) Mamsavaha srota (x) Medovaha srota (xi) Asthivaha srota (xii) Majjavaha srota (xiii) Sukravaha srota (xiv) Manovaha srota (xv) Antahasravi granthi srota

## **PART 6 Principles and Practice of Ayurvedic Medicine (Chikitsa Vigyana)**

Chikitsa (treatment) is the practical use of medications or therapeutic measures to cure an illness. Its goal is to correct disrupted doshas and to preserve the integrity of the doshas, dhatus and malas of the body and mind. Ayurvedic treatment is prophylactic as well as therapeutic, because Ayurveda is primarily a science of health promotion

and only secondarily a science of medicine. The aim of this module is to enable students to acquire an understanding of the application of the principles and practice of Ayurveda in the clinical setting.

Ayurvedic treatments can be either or both general and specific. The goal of general treatment measures is to eliminate toxic substances from the body as quickly as possible and re-establish the natural balance of the doshas. Specific therapies appropriate to specific situations are used, employing the most suitable methods to bring about optimum results.

A distinction is made between treatment methods that are contrary to the cause of the illness, to the illness itself, or to both; and treatment methods that are similar to the cause of the illness, to the illness or to both. Accordingly, this approach includes allopathic (*vishesha*) and homeopathic (*samanya*) principles, as well as other healing methods.

At this stage it will be beneficial if students have an opportunity to observe patients in clinical settings. Supervised clinical practice will complement the theoretical content and skills learned, as well as allowing practice of those skills within a safe environment. It allows students to develop the skills to relate to patients and other healthcare professionals.

This part will:

1. provide an understanding of the practice of Ayurvedic Medicine, allowing an accurate diagnosis of the patient's *vikruti* state based on Ayurvedic pariksha
2. explore the aetiology; pathology and diagnosis of diseases according to Ayurvedic principles, providing a critical examination of the physical and mental disorders related to each of the different *doshic* imbalances
3. explore the different Ayurvedic treatment modalities available for common diseases
4. diagnose and prescribe treatment to a group of patients with uncomplicated pathologies, using Ayurvedic principles
5. evaluate the prognosis of physical disorders related to each of the different *doshic* imbalances
6. compare and contrast the process of treatment according to Ayurveda and other allied therapies including modern medicine
7. compare and contrast the modes of *samana* chikitsa and *sodhana* chikitsa

8. explore the principles of Ayurveda as a preventative health care system
9. provide an opportunity for supervised clinical practice in Ayurvedic clinics
10. prepare students for internship in Ayurvedic hospitals.

The **aetio-pathology and treatment** of the following disorders are to be covered:

1. Jvara (fever)
2. Jvaratisara (fever associated with diarrhoea)
3. Atisara (diarrhoea)
4. Grahani (duodenal disorders)
5. Arsa (piles)
6. Agnimandya (deficient digestion, etc)
7. Krimi (worms)
8. Panduroga (anaemia)
9. Raktapitta (innate haemorrhage)
10. Yaksma (consumption)
11. Kasa (cough)
12. Hikka-svasa (hiccough and dyspnoea)
13. Svarabheda (hoarseness of voice)
14. Arocaka (anorexia)
15. Chardi (vomiting)
16. Trasna (polydypsia)
17. Murccha (fainting)
18. Madatyaya (alcoholism)
19. Daha (burning sensation)
20. Unmada (insanity)
21. Apasmara (epilepsy)
22. Vatavyadhi (vata disorders)
23. Pittavyadhi (pitta disorders)
24. Kaphavyadhi (kapha disorders)
25. Vatarakta (gout)
26. Urustambha (paraplegia)
27. Amavata (arthritis)
28. Sula (colic)
29. Parinamasula (abdominal colic)
30. Udavartta (upward movement of vayu)
31. Anaha (hardness of bowels)
32. Gulma (abdominal lump)
33. Hrdroga (heart disease)
34. Mutrakrcchra (dysuria)
35. Mutraghata (retention of urine)
36. Asmari (calculus)
37. Prameha (diabetes insipidus)
38. Sthaulya (obesity)
39. Udara (abdominal enlargement)
40. Pliha-yakri (spleen-liver disorder)
41. Sotha (oedema)
42. Vrddhi-bradhna (scrotal enlargement)
43. Galaganda (goitre), gandamala (cervical Adenitis), apaci (scrofula), granthi (cyst) and arbuda (tumour)

44. Slipada (filariasis)
45. Vidradhi (abscess)
46. Vranasotha (inflammation)
47. Nadivrana (sinusitis)
48. Bhagandara (anal fistula)
49. Upadamsa (soft chancre)
50. Sukadosa (sprain)
51. Bhangra (fracture)
52. Kustha (skin diseases – leprosy)
53. Udara, kotha and sitapitta (allergic manifestations)
54. Amlapitta (gastritis)
55. Visarpa (erysipelas) and visphota (boils)
56. Masurika (chicken pox)
57. Ksudraroga (minor diseases)
58. Mukharoga (diseases of mouth)
59. Karnaroga (diseases of ear)
60. Nasaroga (diseases of nose)
61. Netraroga (diseases of eye)
62. Sioroga (diseases of head)
63. Asrgdara (menorrhagia, metrorrhagia)
64. Yonivyapad (diseases of female genital tract)
65. Striroga (diseases of women)
66. Balaroga (diseases of children)
67. Visa (poisoning)

## PART 7 Purification and Rejuvenation Theory

Panchakarma is the core of a great number of therapeutic modalities in Ayurveda. It is divided into two main categories - *Shamana* (rejuvenating), and *Shodana* (cleansing) therapies. Shamana encompasses the supporting therapies that are the preparation and post-therapy measures for panchakarma proper. These therapies, Shamana and Shodana are utilised together as panchakarma to form a powerful synergistic means of rejuvenation and revival.

The two main shamana therapies are *snehana* and *abhyanga*. Abhyanga involves the application of medicinal oils that are massaged into the entire body, followed by svedana, the inducing of diaphoresis through the application of fomentation. These treatments prepare the body, mind and spirit for the primary course of elimination (cleansing or detoxifying) therapies. Shodhana (cleansing or detoxifying) refers to panchakarma's five main cleansing and eliminating (detoxifying) procedures.

Panchakarma literally means five actions, and consists of the following activities: *Vamana* - herb induced vomiting, *Virechana* - herb induced purgation, *Niruha vasti* - medicated decoction enemas, *Anuvasana vasti* - medicated oil enema, and *Nasya* - nasal inhalation of medication. The five phases of panchakarma are designed to

penetrate vital tissues of the body in order to uproot the source of aggravation and dislodge unwanted accumulations.

Panchakarma benefits both the healthy and unhealthy and is considered to be the most effective therapy for preventing and curing diseases, as well as for revitalising the entire human body.

This part explores the modes of shodana chikitsa (panchakarma), the different methods of panchakarma, the indications, contraindications and complications of panchakarma, and the use of rasayana krama (rejuvenative therapy).

It will deal with:

1. a critical examination of the different groups of Shamana and Shodana therapies and discuss their therapeutic indications
2. designing a treatment plan using Panchakarma and Rasayana therapies
3. evaluation of the use of Panchakarma therapies in a variety of conditions
4. the use of Panchakarma therapies for a variety of doshic conditions and disorders
5. critical analysis of the advantages and disadvantages of the different groups of Panchakarma and Rasayana therapies
6. the contraindications and limitations of Panchakarma therapies

More specifically it covers:

1. the Principles of Panchakarma Chikitsa
2. the Principles of Rasayana Chikitsa
3. the Phases of Panchakarma: (a) Poorva karma (b) Pradhana karma (c) Paschat karma
4. the Practise of Poorva karma: (a) Snehana karma (oleation therapy) (b) Swedana karma (sudation therapy)
5. indication for Poorva karma
6. contraindications and complications of Snehana karma
7. contraindications and complications of Swedana karma
8. herbs used in Poorva karma
9. the practice of Pradhana karma: (a) Nasya karma (b) Vamana karma (c) Virachena karma (d) Vasti karma (e) Rakta mokshana
10. indications for Pradhana karma

11. contraindications and complications of Nasya karma
12. contraindications and complications of Vamana karma
13. contraindications and complications of Virachena karma
14. contraindications and complications of Vasti karma
15. contraindications and complications of Rakta mokshana
16. herbs used in Pradhana karma
17. principles and practice of Abhyanga
18. principles and practice of Marma therapy
19. the practice of Paschat karma
20. the practice of Sahajana karma
21. the practice of Rasayana Chikitsa

## **PART 8 Ayurvedic Pharmacology and Materia Medica (Dravya-Guna-Vigyana)**

The Ayurvedic study of medicinal herbs is called "*Dravya-guna-karma Vigyana*", which literally means the science (*vigyana*) of substances (*dravya*) and their qualities (*guna*) and actions (*karma*). *Dravya* includes both food and herbs, nourished by the elements. Every tree, plant, shrub, herb, fruit and seed possesses the life-giving essence or *rasa*, undergoing a process of refinement since the beginning of life itself. There are over 2,000 medicinal plants and herbs classified in the Indian Materia Medica.

This part will focus on all aspects of Ayurvedic herbs, and wherever possible compare this tradition with western and Chinese herbal traditions. The concepts of phytochemistry, pharmacology, pharmacognosy, herb-herb and herb-drug interactions will be covered in more detail in separate modules on pharmacology and phytochemistry.

It will:

1. discuss the identification, collection and storage of Ayurvedic herbs
2. discuss the usage, contraindications and precautions of commonly used Ayurvedic herbs
3. describe the processes and issues of Quality Assurance in relation to herbal medicines
4. discuss the issues related to legislation relating to the labelling and dispensing of herbal medicines

5. describe the prescription of herbal medicines according to different doshic imbalances and common disorders
6. explain the rationale for the combination of herbs in certain prescriptions, giving examples of incompatibilities and synergistic enhancement
7. describe the properties and uses of common Ayurvedic compound medicines
8. compare and contrast the traditional uses of Western and Chinese herbs with that of Ayurvedic herbs

It will include:

1. definition, scope and background
2. identification, harvesting and storage
3. absorption, distribution, and excretion of herbs
4. metabolism of herbs
5. herb-herb interactions
6. herb-drug interactions
7. utilisation of Ayurvedic herbs
8. dravya Gana-varga-Misraka-gana (grouping of herbs)
9. groups of morphological, quantitative and pharmacological similarities within commonly used Ayurvedic herbs

### Materia Medica

1. Classification of Herbs
2. Herbal Energetics
  - a. Rasa - Taste
  - b. Guna - Quality
  - c. Veerya - Strength
  - d. Vipaka - Post-digestive effect
  - e. Prabhava - Specific affinity
3. Mutual Relationship of Energetics
4. Karma - Principles of Drug Action
5. Constituents (Hydrocarbons and Derivatives; Carbohydrates; Phenols and Phenolic Glycosides; Volatile Oils and Resins; Saponins and Steroids; Isoprenoids; Glycosides and Glucosylate Compounds; Alkaloids). These will be covered in more detail in other modules.
6. Therapeutic Uses
7. Purification of Toxic Herbs
8. Contraindication and Precautions

The actions of herbs are to be studied according to Charaka's Classification. Representative herbs are to be covered within the following categories.

1. Jivaniya (Vitalising)
2. Brmhaniya (Bulk-promoting)
3. Lekhaniya (Emaciating)
4. Bhedaniya (Laxative)
5. Sandhaniya (Healing)
6. Dipaniya (Appetite stimulant)
7. Balya (Tonic)
8. Varnya (Complexion-promoting)
9. Kanthya (Beneficial for throat)
10. Hrdya (Cordial)
11. Trptighna (Thirst-quencher)
12. Arsoghna (Anti-haemorrhoidal)
13. Kusthaghna (Anti-dermatosis)
14. Kandughna (Anti-pruritic)
15. Krimighna (Anthelmintic)
16. Visaghna (Anti-poison)
17. Stanya-janana (Galactagogue)
18. Stanya-sodhana (Galacto-depurant)
19. Sukra-janana (Semen promoting)
20. Sukra-sodhana (Semen depurant)
21. Snehopaga (Moisturising)
22. Swedopaga (Diaphoretic)
23. Vamanopaga (Emetic)
24. Virecanopaga (Purgative)
25. Asthanopaga (Corrective enemata)
26. Anuvasanopaga (Unctuous enemata)
27. Sirovirecanopaga (Errhines)
28. Chardi-nigrahana (Anti-emetic)
29. Trsna-nigrahana (Anti-dyspeptic)
30. Hikka-nigrahana (Anti-hiccough)
31. Purisa-samgrahaniya (Intestinal astringent)
32. Purisa-virajaniya (Faecal depigmenter)
33. Mutra-sangrahaniya (Anti-diuretic)
34. Mutra-virajaniya (Urinary depigmentor)
35. Mutra-virecaniya (Diuretic)
36. Kasa-hara (Antitussive)
37. Swasa-hara (Anti-dyspneic)
38. Swayathu-hara (Anti-phlogistic)
39. Jwara-hara (Anti-pyretic)
40. Srama-hara (Energy compensator)
41. Daha-prasamana (Refrigerent)
42. Sita-prasamana (Calefacient)
43. Udara-prasamana (Anti-allergic)
44. Angamarda-prasamana (Pain relieving)
45. Sula-prasamana (Intestinal antispasmodic)
46. Sonita-sthapana (Haemostatic)
47. Vedana-sthapana (Analgesic)
48. Sanjna-sthapana (Energising)
49. Praja-sthapana (Anti-abortionificient)
50. Vayah-sthapana (Rejuvenating)

## PART 9 Ayurvedic Formulae and Preparations

1. Nama-Rupa-Jnana
  - a. Classification
  - b. Storage
  - c. Shelf-life
  - d. Dispensing
  - e. Weights and measures
2. Pharmaceutical Processing
  - a. Purification
  - b. Detoxification
  - c. Compounding
  - d. Incompatibilities
3. Pharmaceutical Preparations
  - a. Kasayas
  - b. Fatty preparations
  - c. Fermented preparations
  - d. Other preparations
4. Administration of drugs
  - a. Mode of administration
  - b. Time of administration
  - c. Posology
  - d. Anupana
  - e. Observation

### Common Preparations, Main Ingredients and Main Indications

These are to be studied according to the following classification.

1. Avalehas
2. Gutika/vati
3. Churnas
4. Ghritas
5. Guggulu
6. Taila
7. Kwatha
8. Asava and arishta
9. Kalka

### Assessment

Continuous assessment, including both formative and summative assessments, is recommended. It

is suggested that methods be chosen from the following:

1. portfolio-based formative assessment
2. theory examination
3. practical examination
4. case studies
5. clinical portfolios
6. essays
7. dissertation
8. viva-voce examination based on case studies

### Recommended Allocation of Time

Following the recommendations of the EHPA, the total minimum course length should be 2560 hours. A minimum of one third of this should be teacher/student contact time.

Clinical practice should be no less than 400 hours, of which at least 200 hours should be spent on supervised clinical practice in proximity to patients (which incorporates the diagnosis and treatment of patients and planning of treatment strategies in the clinic). The remainder could consist of case discussions and supervision of students outside the immediate clinical setting, researching treatments, writing up cases and other clinically relevant activities.

It is recommended that clinical practice should combine clinical rotation within the United Kingdom and hospital rotations based on a guru-sishya (teacher-student) scholarly interaction, in India and/or Sri Lanka, or at an alternative approved location.

The objective of the sishya-guru interaction is to provide a platform for the student to deepen the study and practise of Ayurveda in a traditional Ayurvedic medical setting. This activity could be carried out in any country where experienced Ayurvedic physicians and researchers offer training. These training centres need to be attached to a clinical base or hospital dedicated to inpatient care based on the principles of Ayurveda, permitting trainees to engage in a wide variety of clinical experience.

### Indicative Reading

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## Appendix 2: CHINESE HERBAL MEDICINE CORE CURRICULUM

These guidelines cover the following areas:

- Aims
- Learning outcomes
- Curriculum content
- Assessment
- Recommended allocation of time
- Notes on terminology

### Aims

The aim of professional entry level training shall be to produce a practitioner of Chinese herbal medicine who can practise independently and who is safe, competent, and effective. Training should encourage the development of a reflective, research-minded practitioner with qualities of integrity, humanity, caring, trust, responsibility, respect and confidentiality.

### Learning Outcomes

Upon completion of the prescribed training and subsequent qualification, a practitioner shall:

1. be capable of taking and interpreting a patient's case history. This should include:
  - i) information about the patient's presenting condition
  - ii) information about predisposing, precipitating and maintaining factors
  - iii) information about the patient's medical, psychological, social and family history
2. be capable of conducting and interpreting the necessary diagnostic procedures, including:
  - i) pulse reading
  - ii) tongue examination
  - iii) body palpation

The practitioner should have sufficient knowledge of anatomy, physiology, pathology and clinical medicine in order to carry out these procedures safely and interpret them competently.
3. be capable of making an appropriate differential diagnosis based upon their findings. This should be based upon knowledge of current and traditional Chinese medical knowledge.
4. be capable of integrating patterns of disharmony with aetiological factors and pathological processes, identifying how these different aspects interconnect.
5. be aware of limitations with regard to competence. In the context of knowledge of the medical sciences the practitioner should be able to recognise clinical situations where:
  - i) herbal treatment may be inappropriate
  - ii) herbal treatment may be contraindicated
  - iii) herbal treatment may be inadequate when used on its own
6. be able to communicate (see 5. above) with, and make the appropriate referral to, registered medical or other health care practitioners
7. be capable, if treatment is appropriate, of elucidating a treatment principle and methods, and design an appropriate treatment based upon the use of Chinese herbal medicine
8. have the appropriate practical skills to dispense Chinese herbal medicine. This includes knowledge pertaining to the safe storage of herbs and legal requirements related to this
9. be capable of succinctly and clearly communicating their findings, diagnosis, treatment plan and prognosis to the patient in such a way that the patient's own needs, expectations and culture are taken into consideration
10. be able to identify key lifestyle factors which are:
  - i) causing the patient's condition
  - ii) limiting their potential for recovery

The practitioner should be able to discuss these factors with the patient and where possible encourage the patient to help himself/herself.

11. understand the roles of all forms of prescribed medication in the overall management of a patient's condition, knowing:
  - i) which medications should be maintained at constant levels
  - ii) which medications can be reduced slowly
  - iii) which medications can be stopped immediately without risk to the patient

With regard to any proposed changes in the management of the medication, the practitioner should liaise with the patient and where appropriate with the patient's medical practitioner.
12. understand that they are required to:
  - i) systematically and accurately record all relevant information and details of herbal formulae prescribed at every session
  - ii) maintain and store these records for future reference and in accordance with statutory requirements
  - iii) make these records available to their patients
13. be able to monitor a patient's condition as a result of treatment, re-evaluate diagnostic information and differential diagnosis as necessary, and modify and implement new treatment strategies as the patient's condition changes over time
14. be able to evaluate any ethical considerations which might affect the practitioner/patient relationship. Such considerations include:
  - i) issues relating to age, gender or race
  - ii) issues arising out of prejudice or ignorance
  - iii) issues relating to confidentiality
  - iv) the impact of the practitioner's personality and circumstances (both physical and emotional)
  - v) issues of a financial nature
15. be aware of the potential for rare but sometimes serious adverse events when using herbal medicines. This includes:
  - i) knowledge of previous occurrences
  - ii) the debates about their causes
  - iii) knowledge of the role of liver function testing

iv) the ability to identify signs and symptoms of possible adverse reactions and respond appropriately

v) compliance with requirements of notification of adverse events

16. be aware of the requirements of the professional Codes of Ethics and Practice of the European Herbal Practitioners Association, and the legal framework governing the practice of herbal medicine in the UK
17. have acquired the attitudes and skills which are necessary for life long learning and professional development, and be aware that they are essential to continuing effective practice of Chinese herbal medicine
18. be aware of significant research issues

### Curriculum Content

The Chinese herbal medicine core curriculum content comprises:

Section A: Theories, methods, diagnosis, treatment

Section B: Materia Medica

Section C: Formulae

#### Section A: Theories, Methods, Diagnosis, Treatment

##### PART 1 General Background

1. History and Fundamental Characteristics of Chinese Medicine
  - (a) Stages of development and literary landmarks; the importance of an historical understanding of Chinese medicine and the relationship between TCM and Western medicine in modern China
  - (b) Holism: seeing patterns of disharmony
  - (c) Medicine East and West: key contrasts
2. The Philosophical Setting
  - (a) Yin-Yang Theory
    - i. The concept of Yin-Yang and the basic aspects of the Yin-Yang relationship: Yin and Yang are divisible but inseparable (*yin yang ke fen er bu ke li*), rooted in each other (*yin yang hu gen*), mutually counterbalancing (*yin yang zhi yue*)
    - ii. The medical applications of Yin-Yang.
      - (b) Five Phase or Five Elements (Wu Xing) Theory
        - i. The concept of the Five Phases/Elements; the Five Phase relationships of engendering

(*sheng*)<sup>1</sup>, restraining (*ke*)<sup>2</sup>, rebellion (*wu*)<sup>3</sup> and overwhelming (*cheng*)<sup>4</sup>

ii. The medical applications of the Five Phase concept

## PART 2 Physiology

### 1. The Fundamental Substances

(a) Qi: Qi as a central concept in Chinese philosophy and medicine; the sources of Qi; the functions of Qi; the forms of Qi: Organ (*zang fu*), Channel (*jing*), Nutritive (*ying*)<sup>5</sup>, Protective (*wei*), Gathering (*zong*)<sup>6</sup>

(b) Blood (*xue*): sources and functions; relationship to Qi and to the Zang Fu

(c) Essence (*jing*): characteristics and functions

(d) Spirit (*shen*)<sup>7</sup>: characteristics and manifestations

(e) Body Fluids (*jin ye*): comprising thinner fluids (*jin*) and thicker fluids (*ye*); characteristics and functions

### 2. The Internal Organs (*zang fu*)

(a) Differences between the *Zang Fu* in Chinese medicine and the anatomical organs of Western medicine

(b) 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*); the relationships between the Zang

(c) 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*); their relationships with the Zang.

(d) The Extraordinary Organs (*qi heng zhi fu*)<sup>8</sup>: the functions of the Brain (*nao*); Marrow (*sui*); Bone (*gu*); Vessels (*mai*); Uterus (*zi gong*); Gall Bladder (*dan*)

### 3. The Channels (*jing*)<sup>9</sup> and Network Vessels (*luo mai*)<sup>10</sup>

(a) The functions of the channels; the distinction between channels (*jing*) and network vessels (*luo mai*)

(b) 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

## PART 3 Aetiology

### 1. External: the Six Pathogenic Factors (*liu xie*)<sup>11</sup>:

Wind (*feng*), Cold (*han*), Heat (*re*) or Fire (*huo*), Dampness (*shi*), Dryness (*zao*), Summer Heat (*shu*); the relationship between the Normal or Upright (*zheng*) Qi and Pathogenic or Evil (*xie*) Qi

### 2. Internal: the Seven Emotions (*qi qing*)<sup>12</sup>:

Joy (*xi*), Anger (*nu*), Worry (*you*)<sup>13</sup>, Pensiveness (*si*)<sup>14</sup>, Sadness (*bei*)<sup>15</sup>, Fear (*kong*), Fright (*jing*)

### 3. Not External, not Internal (*bu nei wai yin*):

(a) diet

(b) imbalances of work and rest

(c) sexual excesses

### 4. Miscellaneous factors

Trauma, burns, bites, parasites, etc.

## PART 4 Pathology: Patterns of Disharmony

Identifying patterns (*bian zheng*) according to:

### 1. The Eight Principles (*ba gang*)

Patterns of the Interior (*li*) and Exterior (*biao*); Cold (*han*) and Heat (*re*); Deficiency (*xu*)<sup>16</sup> and Excess (*shi*)<sup>17</sup>; Yin and Yang.

### 2. Qi, Blood, Body Fluids

(a) Qi: Qi Deficiency (*qi xu*), Qi Sinking (*qi xian*)<sup>18</sup>, Qi Stagnation (*qi yu*)<sup>19</sup>, Qi Counterflow (*qi ni*)<sup>20</sup>

(b) Blood (*xue*): Blood-Deficiency (*xue xu*), Blood Stasis (*xue yu*), Blood Heat (*xue re*)

(c) Body Fluids (*jin ye*): oedema (*shui zhong*)<sup>21</sup>; distinction between Thin Mucus (*yin*)<sup>22</sup> 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 (*qi tan*).

### 3. Pathogenic Factors

(a) Wind Patterns (*feng zheng*): Wind-Cold (*feng han*), Wind-Heat (*feng re*), Wind-Dampness (*feng shi*)

(b) Damp Patterns (*shi zheng*): Cold-Dampness (*han shi*), Damp-Heat (*shi re*)

(c) Cold Patterns (*han zheng*): Excess Cold (*shi han*), Deficiency Cold (*xu han*)

(d) Heat/Fire Patterns (*rehuo zheng*): Excess Heat (*shi re*), Deficiency Heat (*xu re*)

(e) Summer Heat Patterns (*shu zheng*)

(f) Dryness Patterns (*zao zheng*)

#### 4. 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.

5. 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*)<sup>23</sup>.

6. The Four Levels in accordance with the theory of Warm Diseases

Defense aspect (*wei fen*), Qi aspect (*qi fen*), Nutritive aspect (*ying fen*), Blood aspect (*xue fen*)

### PART 5 Methods of Examination

#### 1. Looking

(a) The *Shen* (including facial expression, look and shine of the eyes, clarity of thought)

(b) Physical shape and movement

(c) Facial colour

(d) Tongue

(e) Other external manifestations: eyes, nose, ears, mouth/lips/teeth/gums, throat, limbs (including index finger in infants), skin

#### 2. Listening and Smelling

(a) Sound of the voice; breathing; cough

(b) Body odours (including stools, urine and other discharges)

#### 3. Asking

(a) Sensations of cold and hot

(b) Sweating

(c) Headaches and dizziness

(d) Pain/aching/numbness: in whole body, joints, back, limbs

(e) Chest and abdomen: including epigastric and lower abdominal fullness and pain, oppression of the chest, palpitations, shortness of breath, hypochondriac pain

(f) Stools and urine

(g) Thirst, appetite and diet, tastes in the mouth, nausea/vomiting

(h) Ears and eyes: including tinnitus, hearing loss; pain or pressure in the eyes, blurred vision, floaters

(i) Sleep

(j) Vitality

(k) Mental-emotional state

(l) Gynaecological: cycle, periods, discharges

(m) Paediatric: including special events during pregnancy, traumas at birth, breast-feeding and weaning, vaccinations

(n) Medical history

(o) Medication

#### 4. Touching

(a) 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 Threadlike (*xi*), Wiry or Stringlike (*xian*), Slippery (*hua*), Tight (*jin*), Flooding (*hong*), Soggy (*ru*) or Soft (*ruan*), Choppy (*se*), Knotted (*jie*), Interrupted (*da*), and Hurried (*cu*); integration of positions and qualities.

(b) Palpating the skin, the hands and feet, the epigastrium and abdomen.

### PART 6 Principles and Methods of Treatment

#### 1. Principles of Treatment (*zhi ze*)

(a) Treating in accordance with the season, the locality, and the individual

(b) Supporting the Upright (*zheng*)<sup>24</sup> Qi and expelling the Evil (*xie*) Qi.

(c) Treating the manifestation (*biao*)<sup>25</sup> and the root (*ben*)

(d) Straightforward treatment (*zheng-zhi*) and paradoxical treatment (*fan-zhi*)

#### 2. Methods of Treatment (*zhi fa*)

The Eight Methods (*ba fa*)<sup>26</sup>: Sweating (*han*), vomiting (*tu*), Draining Downward (*xia*), Harmonising (*he*), Warming (*wen*), Clearing (*qing*), Reducing (*xiao*), Tonifying (*bu*); applications, variations, contraindications

### PART 7 Differentiation and Treatment of Common Diseases

The differentiation of diseases adopted here is

based mainly on categories used in the Chinese medicine tradition. In all cases where these are employed, the Pinyin version is added in order to remove any uncertainty about which Chinese term is being translated.

The Chinese medicine categories are generally distinct from modern biomedical concepts. At the same time, an understanding of those concepts and how they relate to the categories of Chinese medicine is an essential element in professional entry training in Chinese herbal medicine. They are brought together here in two ways:

(a) by listing a number of biomedical disease categories in brackets after the Chinese medicine category. Due to the lack of direct correspondence, this procedure is bound to be more or less artificial. For example, irritable bowel syndrome is placed in brackets after 'abdominal pain'. IBS is not of course characterised simply by abdominal pain, but also by abnormality in the bowel pattern. The point of the reference is only to indicate the context in which it might be appropriate to study IBS. Some Chinese medicine disease categories (for example 'cough', 'epigastric pain', 'painful obstruction') are very broad. They incorporate many Chinese medicine differentiations, and may be associated with a range of biomedical disease concepts.

(b) by adopting modern terms as the headings for broad sub-categories of disease in most cases.

Two important further points should be made. First, the purpose in drawing up this list is not to suggest that there is only one appropriate way of categorising diseases, but to indicate the range of common diseases that educational institutions are expected to cover. The outline here provides one possible structure, but we recognise that this is provisional in nature and that it will be subject to future refinement in the light of continuing debate about the development of Oriental medicine in the West.

Second, it is understood that in the case of some of the disorders listed (eg diabetes, epilepsy, HIV) Chinese herbal medicine may not be regarded as a first line treatment but as a supportive one.

#### INTERNAL MEDICINE (*nei ke*)

##### Respiratory

- Common cold (*gan mao*)
- Cough (*ke sou*)
- Wheezing (*xiao*) and dyspnoea (*chuan*) (including asthma, bronchitis, emphysema)

- Pulmonary consumption (*fei lao*)

##### Gastro-Intestinal

- Epigastric pain (*wei tong*) (including gastritis, gastric and duodenal ulcer)
- Vomiting (*ou tou*)
- Stomach reflux (*fan wei*)
- Constipation (*bian bi*)
- Abdominal pain of digestive origin (*fu tong*) (including Irritable Bowel Syndrome)
- Diarrhoea (*xie xie*) (including Crohn's and ulcerative colitis)
- Haemorrhoids (*zhi chuang*)
- Hiccough (*e ni*)
- Oesophageal constriction (*ye ge*)

##### Liver and Gall Bladder

- Jaundice (*huang dan*)
- Lateral costal pain (*xie tong*) (including gall stones and cholecystitis)
- Hepatitis B and C

##### Neurological

- Headache (*tou tong*)
- Dizziness and vertigo (*xuan yun*)
- Wind Stroke (*zhong feng*) (including CVA, Bell's Palsy)
- Facial pain (*mian tong*)
- Epilepsy (*xian*)
- Multiple sclerosis

##### Cardiovascular

- Chest pain (*xiong tong*) and painful chest obstruction (*xiong bi*) (including angina)
- Coronary heart disease
- Arrhythmia
- Hypertension
- Varicose veins

##### Urinary and Genital

- Painful urination patterns (*lin zheng*)
- Urinary blockage (*long bi*)
- Impotence (*yang wei*)
- Male infertility

##### Musculo-skeletal and rheumatological

- Low back pain (*yao tong*)
- Painful obstruction patterns (*bi zheng*) (including osteoarthritis and rheumatoid arthritis)
- Atrophy syndrome (*wei*) (including myasthenia gravis)
- Trauma

##### Ear, Nose and Throat

- Tinnitus and deafness (*er ming er long*)
- Purulent ear (*ting er*) (including otitis media)
- Nasal congestion (*bi yuan*) (including sinusitis, rhinitis)
- Nosebleed (*bi niu*)

- Sore swollen throat (*yan hou zhong tong*) (including tonsillitis, pharyngitis)
- Loss of voice (*shi yin*)

#### Eye Disorders

- Sore, red and swollen eyes (*mu chi zhong tong*)
- Stye (*zhen yan*)
- Tearing patterns (*liu lei zheng*)

#### Fluid and Blood Disorders

- Water swelling (*shui zhong*) (including oedema of various aetiologies)
- Sweating (*han*)
- Phlegm (*tan*) disorders (the role of Phlegm in a broad range of diseases)
- Blood stasis (*yu xue*) (the role of Blood stasis in a broad range of diseases)

#### Mental and Emotional

- Insomnia (*bu mei*)
- Palpitation (*xin ji*) (including anxiety states)
- Depression patterns (*yu zheng*)
- Mania and withdrawal (*dian kuang*)

#### Oncology

- Basic theory
- Supportive treatments

#### Metabolic disorders

- Diabetes
- Thyroid disease

#### Immune deficiency and auto-immune disorders

- Chronic fatigue syndrome
- Lupus erythematosus
- HIV and AIDS

#### GYNAECOLOGY (*fu ke ji bing*)

- Menstrual irregularity (*yu jing bu tiao*)
- Uterine bleeding (*beng lou*)
- Amenorrhoea (*bi jing*)
- Dysmenorrhoea (*tong jing*)
- Leukorrhoea (*dai xia*)
- Pre- and post-menopausal patterns (*jing jue qian hou zhu zheng*)
- Infertility (*bu yun*)
- Abdominal masses (*zheng jia*)
- Uterine prolapse (*zi gong tuo chi*)
- Premenstrual syndrome
- Endometriosis
- Pelvic inflammatory disease
- Polycystic ovaries

#### Obstetrics

- Precautions in using herbs during pregnancy
- Morning sickness (*ren chen e zhu*)
- Threatened miscarriage (*xian zhao liu chan*)
- Difficult delivery (*nan chan*)
- Insufficient lactation (*ru shao*)

- Postnatal depression

#### PAEDIATRICS (*xiao er za bing*)

- Infantile diarrhoea (*xiao er xie xie*)
- Infantile convulsions (*xiao er jing feng*)
- Enuresis (*yi niao*)
- Mumps (*zha sai*)
- Measles (*ma zhen*)
- Respiratory infections
- Catarrh
- Ear infections
- Abdominal pain

#### DERMATOLOGY (*pi fu ke*)

- Eczema
- Psoriasis
- Seborrhoeic dermatitis
- Acne vulgaris
- Herpes zoster
- Herpes simplex
- Rosacea
- Urticaria
- Alopecia
- Discoid lupus

### Section B: Materia Medica

#### PART 1 General Background

1. The Historical Development of Chinese Herbal Knowledge
2. The Identification, Harvesting and Storage of Chinese herbs  
This will be dealt with in detail in the module on 'Pharmacognosy and Dispensing'
3. The Preparation and Treatment of Chinese Herbs  
This will be dealt with in detail in the module on 'Pharmacognosy and Dispensing'
4. The Natures and Properties of Chinese Herbs
  - (a) Four Energies and Five Flavours
  - (b) Ascending, Descending, Floating and Sinking
  - (c) Tonifying and Draining
  - (d) Targeting of Channels
  - (e) Categories
5. The Utilisation of Chinese Herbs
  - (a) Combining herbs
  - (b) Contraindications
    - (i) Symptomatic contraindications
    - (ii) Contraindicated combinations

- (iii) Contraindications for pregnant women
- (iv) Contraindicated food and drink
- (c) Dosage
  - (i) As determined by the nature of the herbs
  - (ii) As determined by the combination and the type of prescription
  - (iii) As determined by the disease situation, the constitution and age of the patient
- (d) Administration

Safety issues surrounding the use of Chinese herbs, including quality assurance and control, relevant legislation, reporting of adverse events, and the role of blood testing, are **essential** parts of a training in Chinese herbal medicine, and will be covered in detail in the module on Pharmacognosy and Dispensing.

#### *PART 2 Individual Herbs*

Considering the diversity of teaching methods, and not wishing to promote an educational regime based upon the memorisation of large quantities of information at the expense of an understanding of what was retained, the graduate needs to have certain information such as commonly used herbs at their fingertips. It is appropriate therefore for herbs to be categorised under two group headings: **essential** and **useful**.

**Essential** Students should have mastery of herbs in this group. Without using a textbook the graduate should expect to be familiar with: 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 preparation.

**Useful** Students should have an understanding of herbs in this group. The level of knowledge should be such that, without using a textbook, the student should be familiar with: the name, category, main actions and indications and differences between members of the same category. Any further information about these substances can be drawn from textbook sources.

Each educational institution should cover a minimum of 200 herbs, to be drawn from the approved list below. Each institution should define, at its discretion, 70-100 herbs as **essential** herbs to be learned in depth. These must include herbs from each category in the list.

Please note that the legal position of some of the items in the Materia Medica are affected by international agreements or UK law. These items are marked by asterisks in the following way:

\* Affected by the Convention on International Trade in Endangered Species (CITES), allowed if traded with the appropriate trade permits. If an item is banned entirely under CITES restrictions, this is indicated in the text and included for study purposes).

\*\* Non-plant materials, included here for study purposes. Under UK law, non-plant traditional medicines fall outside the remit of the licensing exemption granted to herbs by the Medicines Act 1968.

\*\*\* Restricted under SI 2130 Schedule 111, 1974, included here for study purposes

\*\*\*\* Banned for use in unlicensed medicines by Act of Parliament. Included for study purposes.

#### **Herbs that:**

##### **Resolve the Exterior (jie biao yao)**

*Warm, acrid herbs that resolve the exterior*

Gui Zhi (Ramulus Cinnamomi Cassiae)  
 Ma Huang (Herba Ephedrae)  
 Fang Feng (Radix Ledebouriellae Divaricatae)  
 Jing Jie (Herba seu Flos Schizonepetae Tenuifoliae)  
 Qiang Huo (Rhizoma et Radix Notopterygii)  
 Zi Su Ye (Folium Perillae Frutescentis)  
 Xi Xin (Herba cum Radice Asari)  
 Bai Zhi (Radix Angelicae Dahuricae)  
 Sheng Jiang (Rhizoma Zingiberis Officinalis Recens)

*Cool, acrid herbs that resolve the exterior*

Bo He (Herba Menthae Haplocalycis)  
 Sheng Ma (Rhizoma Cimicifugae)  
 Ju Hua (Flos Chrysanthemi Morifolii)  
 Chai Hu (Radix Bupleuri)  
 Ge Gen (Radix Puerariae)  
 Sang Ye (Folium Mori Albae)  
 Chan Tui (Periostracum Cicadae)\*\*  
 Niu Bang Zi (Fructus Arctii Lappae)

##### **Clear Heat (qing re yao)**

*Drain Fire (xie huo yao)*

Shi Gao (Gypsum)\*\*  
 Zhi Mu (Rhizoma Anemarrhenae Asphodeloidis)  
 Zhi Zi (Fructus Gardeniae Jasminoidis)  
 Xia Ku Cao (Spica Prunellae Vulgaris)  
 Dan Zhu Ye (Herba Lophatheri)  
 Lu Gen (Rhizoma Phragmitis Communis)  
 Tian hua fen (Radix Trichosanthis Kirilowii)

*Cool Blood (liang xue yao)*

Sheng Di Huang (Radix Rehmanniae Glutinosae)  
Mu Dan Pi (Cortex Moutan Radicis)  
Chi Shao Yao (Radix Paeoniae Rubrae)  
Xuan Shen (Radix Scrophulariae Ningpoensis)  
Di Gu Pi (Cortex Lycii Radicis)  
Zi Cao (Radix Arnebiae seu Lithospermi)  
Shui Niu Jiao (Cornu Bubali)\*\*  
Bai Wei (Radix Cynanchi Baiwei)

*Clear Heat and Dry Dampness (qing re zao shi yao)*

Huang Qin (Radix Scutellariae Baicalensis)  
Huang Bai (Cortex Phellodendri)  
Huang Lian (Rhizoma Coptidis)  
Long Dan Cao (Radix Gentianae Longdancao)  
Ku Shen (Radix Sophorae Flavescentis)

*Clear Heat and Resolve Toxin (qing re jie du yao)*

Jin Yin Hua (Flos Lonicerae Japonicae)  
Lian Qiao (Fructus Forsythiae Suspensae)  
Pu Gong Ying (Herba Taraxaci Mongolici cum Radice)  
Bai Xian Pi (Cortex Dictamni Dasycarpi Radicis)  
Tu Fu Ling (Rhizoma Smilacis Glabrae)  
Ban Lan Gen (Radix Isatidis seu Baphicacanthi)  
Bai Hua She She Cao (Herba Hedyotidis Diffusae)  
Da Qing Ye (Folium Daqingye)  
Zi Hua Di Ding (Herba cum Radice Viola  
Yedoensis)

*Clear Heat and Resolve Summerheat (qing re jie shu yao)*

Qing Hao (Herba Artemesiae Annuae)  
Bai Bian Dou (Semen Dolichoris Lablab)  
Yin chai hu (Radix Stellariae Dichotomae)

### **Precipitants (xia yao)**

*Attacking Precipitants (gong xia yao)*

Da Huang (Radix et Rhizoma Rhei)  
Mang Xiao (Mirabilitum)\*\*

*Moist Precipitants (run xia yao)*

Huo Ma Ren (Semen Cannabis Sativae)  
Yu Li Ren (Semen Pruni)

### **Transform Dampness (hua shi yao)**

Cang Zhu (Rhizoma Atractylodis)  
Huo Xiang (Herba Agastaches seu Pogostemi)  
Sha Ren (Fructus Amomi)  
Hou Po (Cortex Magnoliae Officinalis)  
Bai Dou Kou (Fructus Amomi Kravanh)  
Cao Guo (Fructus Amomi Tsao-ko)  
Pei Lan (Herba Eupatorii Fortunei)

### **Drain Dampness (li shi yao)**

Fu Ling (Sclerotium Poriae Cocos)  
Ze Xie (Rhizoma Alismatis Orientalis)  
Yi Yi Ren (Semen Coicis Lachryma-jobi)  
Mu Tong (Caulis Mutong)\*\*\*\* (All forms of Mu  
Tong banned)  
Che Qian Zi (Semen Plantaginis)

Hua Shi (Talcum)\*\*

Yin Chen Hao (Herba Artemesiae Yinchenhao)  
Bi Xie (Rhizoma Dioscoreae Hypoglaucae)  
Zhu Ling (Sclerotium Polypori Umbellati)  
Jin Qian Cao (Herba Lysimachiae)  
Di Fu Zi (Fructus Kochiae Scopariae)  
Han Fang Ji (Radix Stephaniae Tetrandae)\*\*\*\* (All  
forms of Fang Ji banned)

### **Dispel Wind and Eliminate Dampness (qu feng chu shi yao)**

Du Huo (Radix Angelicae Pubescentis)  
Qin Jiao (Radix Gentianae Qinjiao)  
Wei Ling Xian (Radix Clematidis)  
Cang Er Zi (Fructus Xanthii Sibirici)  
Mu Gua (Fructus Chaenomelis)  
Hai Feng Teng (Caulis Piperis Futokadsurae)  
Sang Zhi (Ramulus Mori Albae)  
Sang Ji Sheng (Ramulus Sangjisheng)  
Xi Xian Cao (Herba Siegesbeckiae)  
Wu Jia Pi (Cortex Acanthopanax Gracilistylis Radicis)

### **Transform Phlegm, Suppress Cough and Calm Wheezing**

*Dispel Cold and Transform Phlegm (qu han hua tan yao)*

Ban Xia (Rhizoma Pinelliae Terenatae)  
Jie Geng (Radix Platycodi Grandiflori)  
Tian Nan Xing (Rhizoma Arisaematis)  
Xuan Fu Hua (Flos Inulae)  
Bai Jie Zi (Semen Sinapis Albae)

*Clear Heat and Transform Phlegm (qing re hua tan yao)*

Qian Hu (Radix Peucedani)  
Zhe Bei Mu (Bulbus Fritillariae Thunbergii)  
Chuan Bei Mu (Bulbus Fritillariae Cirrhosae)  
Zhu Ru (Caulis Bambusae in Taeniis)  
Gua Lou (Fructus Trichosanthis)  
Gua Lou Ren (Semen Trichosanthis)  
Kun Bu (Thallus Algae)

*Suppress Cough and Calm Wheezing (zhi ke ping  
chuan yao)*

Kuan Dong Hua (Flos Tussilaginis Farfarae)  
Bai Bu (Radix Stemona)  
Su Zi (Fructus Perillae Frutescentis)  
Xing Ren (Semen Pruni Armeniacae)  
Sang Bai Pi (Cortex Mori Albae Radicis)  
Zi Wan (Radix Asteris Tatarici)  
Pi Pa Ye (Folium Eriobotryae Japonicae)

### **Regulate Qi (li qi yao)**

Chen Pi (Pericarpium Citri Reticulatae)  
Qing Pi (Pericarpium Citri Reticulatae Viride)  
Zhi Shi (Fructus Immaturus Citri Aurantii)  
Mu Xiang (Radix Saussureae Lappae)\* (All trade in  
this form of Mu Xiang banned)  
Xiang Fu (Rhizoma Cyperi Rotundi)  
Zhi Ke (Fructus Citri Aurantii)

Chuan Lian Zi (Fructus Meliae Toosendan)  
 Da Fu Pi (Pericarpium Arecae Catechu)  
 Wu Yao (Radix Lyderae Strychnifoliae)

### **Disperse Food and Guide Out Stagnation (xiao shi dao zhi yao)**

Shen Qu (Massa Fermenta)  
 Shan Zha (Fructus Crataegi)  
 Lai Fu Zi (Semen Raphani Sativi)  
 Gu Ya (Fructus Oryzae Sativae Germinatus)  
 Mai Ya (Fructus Hordei Vulgaris Germinatus)  
 Ji Nei Jin (Endothelium Corneum Gigerae Galli)\*\*

### **Invigorate Blood (huo xue yao)**

Dan Shen (Radix Salviae Miltiorrhizae)  
 Tao Ren (Semen Persicae)  
 Hong Hua (Flos Carthami Tinctorii)  
 Chuan Xiong (Radix Ligustici Chuanxiong)  
 Chuan niu xi (Radix Achyrantis Bidentae)  
 Huai Niu Xi (Radix Cyathulae Officinalis)  
 Yu Jin (Tuber Curcumae)  
 Yan Hu Suo (Rhizoma Corydalis Yanhusuo)  
 Ji Xue Teng (Radix et Caulis Jixueteng)  
 Yi Mu Cao (Herba Leonuri Heterophylli)  
 San Leng (Rhizoma Sparganii Stoloniferi)  
 Mo Yao (Myrrha)  
 Ru Xiang (Gummi Olibanum)  
 E Zhu (Rhizoma Curcumae Ezhu)  
 Ze Lan (Herba Lycopi Lucidi)

### **Stop Bleeding (zhi xue yao)**

Ai Ye (Folium Artemisiae Argyi)  
 San Qi (Radix Notoginseng)  
 Pu Huang (Pollen Typha)  
 Di Yu (Radix Sanguisorbae Officinalis)  
 Da Ji (Herba seu Radix Cirsii Japonici)  
 Xiao Ji (Herba Cephalanoplos)  
 Ou Jie (Nodus Nelumbinis Nuciferae Phizomatis)  
 Ce Bai Ye (Cacumen Biotae Orientalis)  
 Xian He Cao (Herba Agrimoniae Pilosae)  
 Bai Mao Gen (Rhizoma Imperatae Cylindrica)

### **Warm the Interior (wen li yao)**

Rou Gui (Cortex Cinnamomi Cassiae)  
 Fu Zi (Radix Lateralis Aconiti Carmichaeli Praeparata)\*\*\*  
 Gan Jiang (Rhizoma Zingiberis Officinalis)  
 Wu Zhu Yu (Fructus Evodiae Rutaecarpae)  
 Ding Xiang (Flos Caryophylli)

### **Tonify Qi (bu qi yao)**

Ren Shen (Radix Ginseng)  
 Dang Shen (Radix Codonopsis Pilosulae)  
 Bai Zhu (Rhizoma Atractylodis Macrocephalae)  
 Huang Qi (Radix Astralagi Membranaceus)  
 Shan Yao (Radix Dioscoreae Oppositae)  
 Da Zao (Fructus Zizyphi Jujubae)

Tai Zi Shen (Radix Pseudostellariae Heterophyllae)  
 Gan Cao (Radix Glycyrrhizae Uralensis)

### **Tonify Yang (bu yang yao)**

Xu Duan (Radix Dipsaci Asperi)  
 Du Zhong (Cortex Eucommiae Ulmoidis)  
 Bu Gu Zhi (Fructus Psoraleae Corylifoliae)  
 Tu Si Zi (Semen Cuscutae Chinensis)  
 Rou Cong Rong (Herba Cistanches Deserticolae)  
 Lu Rong (Cornu Cervi Parvum)\*\*  
 Yi Zhi Ren (Fructus Alpiniae Oxyphyllae)  
 Gou Ji (Rhizoma Cibotii Barometz)\*  
 Ba Ji Tian (Radix Morindae Officinalis)  
 Yin Yang Huo (Herba Epimedii)  
 Dong Chong Xia Cao (Cordyceps Sinensis)  
 Xian Mao (Rhizoma Curculiginis Orchioideis)

### **Tonify Blood (bu xue yao)**

Dang Gui (Radix Angelicae Sinensis)  
 Bai Shao Yao (Radix Paeoniae Lactiflorae)  
 He Shou Wu (Radix Polygoni Multiflori)  
 Shu Di Huang (Radix Rehmanniae Glutinosae Conquitate)  
 Long Yan Rou (Arillus Euphorbiae Longanae)  
 E Jiao (Gelatinum Corii Asini)\*\*

### **Tonify Yin (bu yin yao)**

Mai Men Dong (Tuber Ophiopogonis Japonici)  
 Tian Men Dong (Tuber Asparagi Cochinchinensis)  
 Sha Shen (Radix Adenophorae seu Glehniae)  
 Nu Zhen Zi (Fructus Ligustri Lucidi)  
 Shi Hu (Herba Dendrobii)\*  
 Bai He (Bulbus Lillii)  
 Gou Qi Zi (Fructus Lycii)  
 Gui Ban (Plastrum Testudinis)\*\* (CITES: trade allowed with appropriate trade permits)  
 Bie Jia (Carapax Amydae Sinensis)\*\*  
 Yu Zhu (Rhizoma Poligonati Odorati)  
 Han Lian Cao (Herba Ecliptae Prostratae)  
 Hei Zhi Ma (Semen Sesami Indici)  
 Huang Jing (Rhizoma Polygonati)

### **Stabilise and Bind (gu se yao)**

Wu Wei Zi (Fructus Schisandrae Chinensis)  
 Shan Zhu Yu (Fructus Corni Officinalis)  
 Lian Zi (Semen Melumbinis Nuciferae)  
 Fu Pen Zi (Fructus Rubi Chingii)  
 Ma Huang Gen (Radix Ephedrae)  
 Qian Shi (Semen Euryales Ferocis)  
 Fu Xiao Mai (Semen Tritici Aestivi)  
 Rou Dou Kou (Semen Myristicae Fragrantis)  
 Wu Mei (Fructus Pruni Mume)

### **Calm the Liver and Extinguish Wind (ping gan xi feng yao)**

Gou Teng (Ramulus cum Uncis Uncariae)  
 Tian Ma (Rhizoma Gastrodiae Elatae)\*

Bai Ji Li (Fructus Tribuli Terrestris)  
 Shi Jue Ming (Concha Haliotidis)\*\*  
 Jiang Can (Bombyx Batrycatus)\*\*  
 Di Long (Lumbricus)\*\*

### Calm the Spirit

*Nourish the Heart and Calm the Spirit (yang xin an shen yao)*

Yuan Zhi (Radix Polygalae Tenuifoliae)  
 Suan Zao Ren (Semen Zizyphi Spinosa)  
 Bai Zi Ren (Semen Biotae Orientalis)  
 He Huan Pi (Cortex Albizziae Julibrissin)  
 Ye Jiao Teng (Caulis Polygoni Multiflori)

*Settle the Spirit (zhen an yao)*

Long gu (Os Draconis)\*\*  
 Mu li (Concha Ostreae)\*\*  
 Ci shi (Magnetitum)\*\*  
 Zhen zhu mu (Concha Margaritiferiae)\*\*

### Open the Orifices (kai qiao yao)

Shi Chang Pu (Rhizoma Acori Graminei)  
 Bing Pian (Borneol)  
 An Xi Xiang (Benzoinum)

## Section C: Formulae

*PART 1 General Principles: Composing and Modifying Formulae*

1. Internal Structure of Chinese Herbal Formulae
  - (a) Principles of formula-building
  - (b) Principles of herb combination
2. Adjustment of Formulae to Fit the Individual Case
  - (a) Adding and deleting herbs
  - (b) Altering herb combinations
  - (c) Altering dose ratios
3. Categories of Formula
  - (a) Pre-modern categorisations
  - (b) Modern categorisations
4. Types of formulation
 

Decoctions, powders, pills, soft extracts, special pills, tinctures

This will be dealt with in detail in the module on 'Pharmacognosy and Dispensing'
5. Preparation and Administration
 

This will be dealt with in detail in the module on 'Pharmacognosy and Dispensing'

### PART 2 Model Formulae

The distinction between **essential** and **useful** applied in the case of individual herbs should also be applied to the study of formulae.

**Essential** These should comprise 30 to 50 formulae that are to be mastered, so that the student, without using a textbook, has knowledge of: the category. (e.g. Releases the Exterior, Invigorates Blood); ingredients and dosage; indications for dosage; contraindications; major modifications; differences in properties and usage between formulae in the same category).

**Useful** Students should have an understanding of formulae in this group, such that, without using a textbook, students will be familiar with: the category; main ingredients; indications for usage; differences in properties and usage between formulae in the same category.

Educational Institutions should cover a minimum of 100 formulae in total.

Please note asterisks against a formula indicate:

\* Contains non-plant ingredient (included for study purposes)

\*\* Contains endangered plant ingredient only available under special licence (included for study purposes)

\*\*\* Contains herb banned in unlicensed medicines under UK law (included for study purposes)

In these cases ingredients may be substituted or omitted as appropriate.

### Formulae that:

#### Resolve the Exterior (jie biao ji)

Ma Huang Tang - Ephedra Decoction  
 Gui Zhi Tang - Cinnamon Twig Decoction  
 Yin Qiao San - Honeysuckle and Forsythia Powder  
 Sang Ju Yin - Mulberry Leaf and Chrysanthemum Decoction  
 Xiao Qing Long Tang - Minor Bluegreen Dragon Decoction  
 Ren Shen Bai Du San - Ginseng Powder to Overcome Pathogenic Influences  
 Ge Gen Tang - Kudzu Decoction  
 Cang Er Zi San - Xanthium Powder  
 Chai Ge Jie Ji Tang - Bupleurum and Kudzu Decoction to Release the Muscle Layer

#### Clear Heat (qing re ji)

Bai Hu Tang - White Tiger Decoction\*  
 Ma Xing She Gan Tang - Ephedra, Apricot Kernel, Gypsum and Licorice Decoction\*

Huang Lian Jie Du Tang - Coptis Decoction to Relieve Toxicity  
 Long Dan Xie Gan Tang - Gentiana Longdancao Decoction to Drain the Liver\*\*\*  
 Qing Hao Bie Jia Tang - Artemisia Annua and Soft-shelled Turtle Decoction\*  
 Yu Nu Jian - Jade Woman Decoction\*  
 Xie Bai San - Drain the White Powder  
 Shao Yao Tang - Peony Decoction\*\*

#### **Drain Downward (xie fa ji)**

Da Cheng Qi Tang - Major Order the Qi Decoction\*  
 Xiao Cheng Qi Tang - Minor Order the Qi Decoction  
 Tiao Wei Cheng Qi Tang - Regulate the Stomach and Order the Qi Decoction\*  
 Ma Zi Ren Wan - Hemp Seed Pill

#### **Harmonise (he ji)**

Xiao Chai Hu Tang - Minor Bupleurum Decoction  
 Xiao Yao San - Rambling Powder  
 Si Ni San - Frigid Extremities Powder  
 Ban Xia Xie Xin Tang - Pinellia Decoction to Drain the Epigastrium

#### **Expel Dampness (qu shi ji)**

Wu Ling San - Five-Ingredient Powder with Poria  
 Zhu Ling Tang - Polyporus Decoction  
 Wu Pi San - Five Peels Powder  
 Ping Wei San - Calm the Stomach Powder  
 Huo Xiang Zhen Qi San - Agastache Powder to Rectify the Qi  
 Ba Zheng San - Eight-Herb Powder for Rectification  
 Er Miao San - Two-Marvel Powder  
 Fang Ji Huang Qi Tang - Stephania and Astragalus Decoction \*\*\*

#### **Warm the Interior (wen li ji)**

Li Zhong Wan - Regulate the Middle Pill  
 Zhen Wu Tang - True Warrior Decoction\*\*\*  
 Dang Gui Si Ni Tang - Dang Gui Decoction for Frigid Extremities\*\*\*  
 Wu Zhu Yu Tang - Evodia Decoction  
 Da Jian Zhong Tang - Major Construct the Middle Decoction  
 Xiao Jian Zhong Tang - Minor Construct the Middle Decoction

#### **Tonify (bu ji)**

Si Jun Zi Tang - Four-Gentlemen Decoction  
 Liu/Xiang Sha/Liu Jun Zi Tang – Six-Gentlemen Decoction et al.  
 Bu Zhong Yi Qi Tang - Tonify the Middle and Augment Qi Decoction  
 Ba Zhen Tang/Yi Mu Ba Zhen Tang - Eight-Treasure Decoction et al.  
 Shi Quan Da Bu Tang - All-Inclusive Great Tonifying Decoction

Liu Wei Di Huang Tang - Six-Ingredient Decoction with Rehmannia  
 (Zhi Bai Di Huang Tang/Qi Ju Di Huang Tang/Du Qi Wan/Mai Wei Di Huang Tang)  
 You Gui Wan - Restore the Right (Kidney) Pill\*\*\*  
 Zuo Gui Wan - Restore the Left (Kidney) Pill  
 Jin Gui Shen Qi Wan - Kidney Qi Pill from the Golden Cabinet\*\*\*  
 Er Xian Tang - Two-Immortal Decoction  
 Si Wu Tang - Four-Substance Decoction (Tao Hong Si Wu Tang/Qin Lian Si Wu Tang)  
 Zhi Gan Cao Tang - Honey-Fried Licorice Decoction  
 Gui Pi Tang - Restore the Spleen Decoction  
 Dang Gui Shao Yao San - Tangkuei and Peony Powder  
 Shao Yao Gan Cao Tang - Peony and Licorice Decoction  
 Shen Ling Bai Zhu San - Ginseng, Poria and Atractylodes Macrocephala Powder  
 Ren Shen Yang Rong Wan - Ginseng Decoction to Nourish the Nutritive Qi  
 Dang Gui Bu Xue Tang - Dang Gui Decoction to Tonify the Blood  
 Sheng Mai San - Generate the Pulse Powder  
 Yi Wei Tang - Benefit the Stomach Decoction  
 Yi Guan Jian - Linking Decoction

#### **Transform Phlegm (hua tan ji)**

Er Chen Tang - Two-Cured Decoction  
 Wen Dan Tang - Warm the Gallbladder Decoction  
 Zhi Sou San - Stop Coughing Powder  
 Ban Xia Bai Zhu Tian Ma Tang - Pinellia, Atractylodes Macrocephala, and Gastrodia Decoction\*\*  
 Bei Mu Gua Lou San - Fritillaria and Trichosanthes Fruit Powder

#### **Regulate Qi (li qi ji)**

Ban Xia Hou Po Tang - Pinellia and Magnolia Bark Decoction  
 Yue Ju Wan - Escape Restraint Pill  
 Su Zi Jiang Qi Tang - Perilla Fruit Decoction for Directing Qi Downward  
 Ding Chuan Tang - Arrest Wheezing Decoction  
 Ju Pi Zhu Ru Tang - Tangerine Peel and Bamboo Shaving Decoction

#### **Invigorate Blood (huo xue ji)**

Xue Fu Zhu Yu Tang - Drive Out Stasis in the Mansion of Blood Decoction (and variants)  
 Gui Zhi Fu Ling Wan - Cinnamon Twig and Poria Pill  
 Wen Jing Tang - Warm the Menses Decoction  
 Dan Shen Yin - Salvia Decoction  
 Tao He Cheng Qi Tang - Peach Pit Decoction to Order the Qi

**Calm the Spirit (an shen ji)**

Tian Wang Bu Xin Dan - Heavenly Emperor's Special Pill to Tonify the Heart\*\*\*  
 Suan Zao Ren Tang - Sour Jujube Decoction  
 Gan Mai Da Zao Tang - Licorice, Wheat, Jujube Decoction

**Extinguish Wind (xi feng ji)**

Tian Ma Gou Teng Yin - Gastrodia and Uncaria Decoction\*\*  
 Du Huo Ji Sheng Tang - Angelica Pubescens and Sangjisheng Decoction  
 Juan Bi Tang - Remove Painful Obstruction Decoction  
 Xiao Feng San - Eliminating Wind Powder\*  
 Di Huang Yin Zi - Rehmannia Decoction

**Disperse Food and Guide Out Stagnation (xiao shi dao zhi ji)**

Bao He Wan - Preserve Harmony Pill  
 Mu Xiang Bing Lang Wan - Aucklandia and Betel Nut Pill\* and \*\*\*

**Stabilise and Bind (gu se ji)**

Yu Ping Feng San - Jade Windscreen Powder  
 Si Shen Wan - Four-Miracle Pill  
 Gu Jing Wan - Stabilise the Menses Pill\*  
 Suo Quan Wan - Shut the Sluice Pill

**Stop Bleeding (zhi xue ji)**

Jiao Ai Tang - Ass-Hide Gelatin and Mugwort Decoction\*

**Moisten Dryness (run zao ji)**

Xing Su San - Apricot Kernel and Perilla Leaf Powder  
 Mai Men Dong Tang - Ophiopogonis Decoction

**Open the Orifices (kai qiao ji)**

Di Tan Tang - Scour Phlegm Decoction

**Expel Parasites (qu chong ji)**

Wu Mei Wan - Mume Pill

**Assessment**

As part of the process of accreditation, educational institutions should present a full course description including a statement about how each part of the curriculum is assessed.

The means of assessment should be appropriate to the nature of the learning involved. In the past too much emphasis had been placed upon assessment by conventional written examination, with the result that undue attention has been focused on memorisation, rather than the understanding and application of the underlying principles. Educational institutions are therefore encouraged to include, in addition to conventional exams, methods such as:

- (1) Case histories
  - (2) Open book exams, which go some way to reproducing the conditions of clinical practice, and allow the student to go into greater depth
  - (3) Assignments/research projects, which allow the student to go beyond what the college can teach and also promote research-mindedness
- Educational institutions are encouraged to develop and use teaching materials that will complement and enhance existing textbooks.

*Exemptions*

Educational institutions should provide a coherent policy with regard to exemptions for prior learning. Educational institutions must satisfy themselves that candidates who are exempted from parts of their curriculum have covered the required material and achieved the required learning outcomes. Automatic exemption in basic Chinese medicine theory and diagnosis should be possible only where students have satisfied the requirements laid down by the British Acupuncture Council.

**Recommended Allocation of Time**

Following the recommendations of the EHPA the total minimum course length should be 2560 hours. A minimum of one third of this should be teacher/student contact time. Within this total, allowing for a ratio of one-hour contact time to two hours directed home study, it is recommended that the hours devoted to the Specific Herbal Tradition of Chinese medicine be as follows:

- Chinese Medicine Theory and Diagnosis: 112 contact hours (8 week-ends); 336 total hours
- Chinese Herbal Medicine (Materia Medica, Formulae and Differentiation of Common Diseases) 336 contact hours (24 weekends); 1008 total hours.

**Clinical practice**

Forms a separate module in the EHPA guidelines and is in addition to the above hours. The total should be no less than 400 hours. In the case of the clinical practice module, at least half of the time should be spent on supervised clinical practice in proximity to patients (which incorporates the diagnosis and treatment of patients and planning of treatment strategies in the clinic). The remainder could consist of case discussions and supervision of students outside the immediate clinical setting, researching treatments, writing up cases and other clinically relevant activities.

## Notes on Terminology

This curriculum contains terms that have been differently translated in different English language texts on Chinese Medicine. In deciding on terminology we have sought guidance from N. Wiseman and F. Ye, *A Practical Dictionary of Chinese Medicine* (Paradigm Publications, 1998) and from a number of texts which are likely to appear on the reading list of any professional entry course on Chinese Herbal Medicine. These include: T. Kaptchuk, *Chinese Medicine* (Rider, 1983); G. Maciocia, *The Foundations of Chinese Medicine* (Churchill Livingstone, 1989); D. Bensky and A. Gamble, *Chinese Herbal Medicine: Materia Medica* (Eastland Press, 1993) and *Chinese Herbal Medicine: Formulas and Strategies* (Eastland Press, 1990).

No one usage is likely to satisfy everyone. In order to reduce the scope for ambiguity, the Pinyin versions of all Chinese terms have been added in italics, except in a very few cases where a Chinese term appears on its own without translation (e.g. Qi, Yin Yang). In addition, by way of illustration, footnotes to some of the terms have been added indicating an alternative translation.

- 1-4 Cf respectively 'generating', 'controlling', 'insulting', 'over-acting' (Maciocia)
- 5 Cf 'construction Qi' (Wiseman)
- 6 Cf 'Qi of the chest' or 'ancestral Qi' (Kaptchuk)
- 7 Cf 'mind' (Maciocia)
- 8 Cf 'curious organs' (Kaptchuk)
- 9 Cf 'meridians' (Kaptchuk)
- 10 Cf 'minor meridians' (Kaptchuk)
- 11 Xie: Wiseman gives 'evil', 'evil qi', 'disease evil', 'pathogen' as synonyms: 'pathogenic factor' is used here because of its familiarity. The terms liu yin (The Six Excesses [Wiseman]; the Six Pernicious Influences [Kaptchuk]) and liu qi (The Six Qi) are sometimes used to refer to the same external causes of disease.
- 12 Cf 'affects' (Wiseman)
- 13 Cf 'anxiety' (Wiseman)
- 14 Cf 'thought' (Wiseman)
- 15 Cf 'sorrow' (Wiseman)
- 16 Cf 'vacuity' (Wiseman)

- 17 Cf 'repletion' (Wiseman)
- 18 Cf 'qi fall' or 'center qi fall' (Wiseman)
- 19 Cf 'depression' (Wiseman)
- 20 qi ni: cf 'rebellious Qi' (Maciocia); Wiseman translates wu in the Five Phases as 'rebellion', ni as 'counterflow'--Wiseman's version has been adopted here.
- 21 shui zhong: literally 'water swelling'
- 22 Cf 'phlegm-rheum' (Wiseman)
- 23 Cf 'Reverting Yin' (Wiseman); 'Terminal Yin' (Maciocia)
- 24 Cf 'right' (Wiseman)
- 25 Cf 'tip' (Wiseman)
- 26 ba fa: the translations of the eight terms are taken from Bensky; Wiseman has, respectively, 'sweating', 'ejection', 'precipitation', 'warming', 'clearing', 'dispersing', 'supplementation'

## Indicative Reading

*Advanced Textbook on TCM and Pharmacology*. (several volumes) (Beijing New World Press, State Administration of TCM, 1995)

Bensky, D., Gamble A. *Chinese Herbal Medicine: Materia Medica*. (Eastland Press, 1993)

Bensky, D., Gamble A. *Chinese Herbal Medicine: Formulas and Strategies*. (Eastland Press, 1990)

Clavey, S. *Fluid Physiology and Pathology in Traditional Chinese Medicine*. (Churchill Livingstone, 1995)

Him-Che Yeung. *Handbook of Chinese Herbs*. (Institute of Chinese Medicine, California 1983)

Kaptchuk, T. *Chinese Medicine*. (Rider, 1983)

Maciocia, G. *The Foundations of Chinese Medicine*. (Churchill Livingstone, 1989)

Maciocia, G. *The Practice of Chinese Medicine*. (Churchill Livingstone, 1994)

MacLean, W., Lyttleton, J. *Clinical Handbook of Internal Medicine: the Treatment of Disease with Traditional Chinese Medicine*. (University of Western Sydney, Macarthur, 1998)

Wiseman, N., Ye F. *A Practical Dictionary of Chinese Medicine*. (Paradigm Publications, 1998)

Note: Chinese-language texts used in TCM universities in China.

## Appendix 3: WESTERN HERBAL MEDICINE CORE CURRICULUM

These guidelines cover the following areas:

- Aims
- Learning Outcomes
- Outline of Syllabus Contents
- Assessment

### A. *Materia Medica*

#### Aims

To ensure a sound knowledge and understanding of medicinal plants. To encourage students to take a broad and continuing interest in medicinal plants and to appreciate issues surrounding their conservation and sustainability.

#### Learning Outcomes

By the end of the course the student will:

1. be able to recognise and identify a wide range of medicinal plants, both growing and dried; have knowledge of basic botany; have an understanding of the taxonomy and morphology of medicinal plants
2. be able to classify plants according to their actions, e.g. as stimulants, astringents, etc.; relate the action of an individual herb to its indications in treatment
3. understand the pharmacological actions of medicinal plants on the body in health and disease and know which specific tissues, organs and physiological systems are affected by administration of a given medicinal plant; be aware of the influence of plant remedies on the psycho-social and spiritual aspects of a patient's being
4. understand and appreciate the relative merits of whole plant preparations, standardised extracts and isolated plant constituents for application in holistic treatment
5. know in detail the dosage range of the medicinal plants studied
6. know in detail the contraindications and incompatibilities of the medicinal plants studied
7. have developed research skills so that s/he will be able to continue to learn more about the *Materia Medica* throughout their life of

professional practice (as explained in Module 7 Core Curriculum on Practitioner Research)

8. have awareness of the role of rationality, intuition and experience in prescribing treatment
9. have awareness of the relative merits of simples and/or complex herbal prescriptions
10. be aware of the debate concerning the use of native versus foreign herbal remedies
11. be aware of conservation issues as they relate to herbal medicine. Be aware of the merits of organic and wildcrafted herbs

#### Outline of Syllabus Contents

##### 1. *Materia Medica*

*Materia medica* is the core subject in medical herbalism. This subject examines individual plant remedies and discusses the botanical, pharmacognostic, pharmacological and therapeutic aspects of each remedy, along with its indications in treatment, contraindications and incompatibilities, and posology, including dosage indications for elderly patients and children.

The plants are discussed from a traditional therapeutic aspect and modern scientific research and clinical experience is used to supplement and/or extend the understanding of the plant as a medicinal remedy. Specific indications are studied, as are herb combinations and synergy, and information sources and literature on *materia medica*.

##### 2. *Botany*

Botany is an important tool for the medical herbalist. The aim of this subject is to develop the students' skills in the use of botanical reference material, and in the field identification of plants. These skills are developed from teaching in plant taxonomy and morphology, and also the role played by taste, smell and touch in identifying plants. The course also includes an introduction to plant physiology.

##### 3. *Environmental and Conservation*

Discussion of issues surrounding the conservation and sustainability of medicinal plants. Discussion of the relative merits of global versus local herbalism. Have an understanding of the procedures used to ensure correct species identification on entry to, or in the UK.

#### Assessment

Assessment should be partly by examination and partly by project work such as the creation of a database.

## Indicative Reading

Barnes, J., Anderson, L., Phillipson, D. *Herbal Medicines* 2nd ed. (Pharmaceutical Press, 2002)

Bartram, T. *Encyclopedia of Herbal Medicine*. (Constable & Robinson, 1995)

*British Herbal Pharmacopoeia*. (three parts), (British Herbal Medicine Association, 1976)

Mills, S., Bone K. *Principles and Practice of Phytotherapy*. (Churchill Livingstone, 2000)

Priest, A., Priest, L. *Herbal Medication*. (Fowler & Co Ltd 1982)

Weiss, R. *Herbal Medicine*. (Beaconsfield Arcanum, 1988)

## B. Therapeutics

### Aims

To enable students to comprehend the clinical application of the herbal materia medica, using appropriate conventional and complementary diagnostic skills to select herbs and dietary regimes to treat a range of conditions in a holistic way.

To ensure that the student has sufficient knowledge of therapeutic skills to take individual responsibility for sensitive and competent patient care and maintain this throughout a course of treatment.

To continue to develop research skills so that the student will be equipped to continue to add to their knowledge of materia medica and therapeutics throughout a lifetime of professional practice.

To expand students' awareness of the roles of rationality and intuition in prescription and treatment.

Minimum level: 3 of an undergraduate course.

### Learning Outcomes

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

1. determine a specific treatment strategy, selecting appropriate herbal prescriptions and dietary plans for a wide range of conditions, as specified in the syllabus content of Module 3 Core Curriculum on Clinical Sciences, and having regard to the pattern of disharmony particular to the individual concerned
2. select for any particular disease or condition a range of possible herbal treatments, explaining the difference of approach in each case
3. adapt a prescription appropriately to respond to changing circumstances in the progress of an individual treatment. Know how to deal

appropriately with adverse reactions, and how to recognise and respond to a healing crisis

4. give an account of factors involved in prognosis
5. fully understand the factors involved in selecting appropriate dosages of herbs and treatments for particular individuals and conditions, including dosages for the elderly, children and infants. To have full knowledge of Schedule III herbs, and of contraindications in pregnancy.
6. recognise the limits of herbal treatment and his/her own ability and be able to refer when necessary

## Outline of Syllabus Contents

### 1. Theory and Philosophy of Health and Disease

Study of the underlying philosophies behind Western herbal practice, and highlighting awareness of the differences and the links between the orthodox and the complementary theories of health and disease. With specific reference to factors determining the evolution of a wide range of conditions, such as described in the syllabus of Module 3 Core Curriculum on Clinical Sciences.

### 2. Strategies

Application of the Materia medica: specific herbal and nutritional protocols for the range of conditions specified, and how to respond to individual needs within the basic protocols. Appropriate dosage levels for various conditions and individuals, and how and why these may be varied according to the specific needs of each case.

Treatment of multiple conditions: prioritising in selection of basic aims of treatment; understanding the importance of identifying the underlying pattern of disharmony as against treating specific symptoms.

Identifying response patterns in treatment: recognising side-effects and adverse reactions, and selecting appropriate responses to such eventualities; recognising and managing a healing crisis; assessment and management of individual progress during treatment; variation of herbal prescription according to individual response and level of treatment success; factors determining length of treatment to be undertaken.

### 3. Contingent Factors

Supporting therapies and the role they may play in successful treatment; if and when to refer, or recommend supplementary or alternative therapies; how to interact with other practitioners, including the medical profession.

## Assessment

Assessment should consist of examination as well as a written project or thesis on a specific subject of the student's choice. Examination also to include a viva as well as written examination. Full assessment in this curriculum will only be possible by linking also to Module 9 Core Curriculum on Clinical Practice.

## Appendix 4:

### TIBETAN HERBAL MEDICINE CORE CURRICULUM

The Tibetan herbal medicine core curriculum covers:

- Aims
- Learning Outcomes
- Curriculum Content
- Materia Medica
- Pharmacy and Clinical Training
- Assessment
- Allocation of Time
- Indicative Reading

#### Aims

The aim of a qualification as a Practitioner of Traditional Tibetan Medicine (TTM) is to be someone who can:

1. practise with compassion and treat all patients equally
2. maintain and establish respect and harmonious relations with fellow practitioners
3. maintain an open mind and be willing to facilitate the exchange of knowledge between different health systems
4. display an attitude of service to patients, which takes precedence over material gain
5. practise continuous effort to gain further learning and experience as aids to professional growth
6. display an appropriate theoretical knowledge and clinical competence through the study and mastery of the traditional mainstay of Tibetan medical studies, i.e. the compendium of instructions known as the *rgyud bzhi* or Fourfold Medical Treatise, taught through its major commentaries
7. display great concern for the purity and efficacy of medicines, according to traditional Tibetan

guidelines for recognising, selecting, gathering, drying, storing, purifying and processing the raw materials used to prepare the medicines and according to the regulations in force in this country and its accepted standards of good practice

8. competently use pre-prepared or personally compounded formulae of the various materia medica to suit the patient's condition, in a way which removes or minimises any possible side effects and treats the patient as a whole, rather than treating just the presenting symptoms
9. practise compassion, humility and the other noble human qualities outlined in the "Ethics and Behaviour" chapter of the *rgyud bzhi* in his or her service to others to eradicate the suffering of sentient beings, promote longevity and increase spiritual welfare

#### Learning Outcomes

Upon completion of training, the Practitioner of Traditional Tibetan Medicine (TTM) shall be able to do the following.

1. Offer diagnosis and treatment based upon the holistic approach of TTM, in which the mind and body are recognised as being interdependent.
2. Offer diagnosis based upon visual and tactile observation and questioning, as follows:

##### *Visual observation*

Based upon a general appreciation of the patient's complexion, appearance and comportment; brief examination of the eyes and ears; and a more detailed examination of the tongue and of a urine sample. Urine examination is further divided into eight sections.

- a. Advice regarding procedures to be followed the night before urine examination
- b. Time of examination
- c. Appropriate container in which to check the urine of the patient
- d. Changes of urine as it cools
- e. How to recognise a healthy person's urine
- f. How to recognise a diseased person's urine
- h. How to recognise a dying person's urine
- i. How to recognise the urine of someone under severe mental disturbance

##### *Tactile observation*

Takes the form of a general physical check

and pulse reading. Pulse reading is divided into thirteen sections, which the practitioner has to know.

- a. Procedures to be followed the night before reading
- b. Correct time of pulse reading
- c. Correct vessels for pulse reading
- d. Extent of pressure applied by the fingers of the practitioner to read the pulse
- e. How to read each specific type of pulse
- f. How to distinguish the three "constitutional" pulse types
- g. How to interpret the pulse according to the four seasons and the five elements
- h. About the presence of "extraordinary pulses"
- i. How to distinguish between the various healthy and diseased pulses
- j. How to distinguish between general and specific pulses
- k. How to detect death pulses
- l. How to detect the effect of severe mental disturbance in the pulse
- m. About the "lifespan pulses"

#### *Questioning*

Means enquiring about the case history of the patient, as well as about signs, symptoms and the evolution of the illness presenting. The practitioner shall maintain and keep in confidence all records in relation to the patient.

### 3. Offer four areas of treatment to the patient.

#### *Advice on diet*

The practitioner will advise the patient on diet according to each individual bodily constitution based on the *nyes pa gsum*<sup>1</sup>. All food and drink counselled should be based on the six primary tastes generated by the five elements and the three post-digestive effects. Advice is given to the patient on how to avoid incompatible foods and to consume food and drink in the right quantities.

#### *Advice on conduct*

The practitioner will advise the patient on the ways in which one can live more healthily and to improve life expectancy. S/he will also know the positive and negative influences exerted by being at odds or in harmony with family and society, or with one's own or the more widely

recognised moral values, and will assess how, if at all, a patient can be tactfully and skilfully counselled so as to reduce the stress and illness that past and present behaviour may be causing.

The practitioner should advise the patient on seasonal conduct and the relationship between the five internal elements and the five external elements, advising on correct behaviour according to the four seasons. The practitioner should advise on "occasional conduct" and the thirteen natural functions of the body, which should neither be over-used or suppressed.

#### *Prescription of medicines*

The practitioner has to take ten factors into consideration before prescribing medicine.

- Analysis of which of the seven bodily constituents and three eliminating functions are affected
- Geographic factors
- Seasonal factors
- Bodily constitution
- Factors relating to age
- Condition of the disease
- Location of the disease
- Metabolism of the patient
- Strength of the patient
- Eating habits of the patient

The practitioner has to identify and know the taste, potency and post-digestive effect of each individual medicine and their ingredients in order for the medicine to be correctly prescribed.

#### *Other treatments*

Other treatments, such as massage, herbal baths, application of warm herbal packs to critical points on the body etc., as outlined in the fourth section of the Fourfold Treatise (see below) and as appropriate according to the regulations on such treatments in place nationally.

### 4. Promote preventive medicine

Most diseases are seen in TTM as originating from what are known as primary causes and secondary conditions. One should avoid reinforcing secondary conditions liable to bring the *nyes pa gsum* into imbalance. The practitioner has to advise the patient with regard to appropriate and moderate use of

mind, body, speech and the five senses and encourage the patient to follow instructions on best diet and conduct.

5. *Bring into balance by either lifestyle and diet counselling or by medication the nyes pa gsum as far as possible.*

The medication should not be excessive, deficient or inappropriate with respect to the nyes pa gsum.

6. *Clearly categorise diseases into easily curable, difficult to cure, rarely curable and incurable.*
7. *Know the various signs of approaching death, according to the Fourfold Treatise categorisations of definite, indefinite, imminent etc.*
8. *Strive to care for the patient's welfare in an unbiased and open-minded way. Should her/his own skill, or TTM in general, be unable to cure the patient, the practitioner should recommend unhesitatingly recourse to another system of treatment.*

### Curriculum Content

The core curriculum laid out in this document is based upon the common ground of study in the major teaching institutions for Tibetan medicine in Dharamsala (India), Lhasa (Tibetan Autonomous Region of China) and Xining (Quighai, China).

What follows is a section-by-section description of the Fourfold Treatise, showing the main subjects studied during the four years. The Fourfold Treatise does not include training in *rtsis* (literally "calculations"), which traditionally existed as a training in its own right in Tibet and concerns a detailed study of all possible rhythms and movements in nature, including the human body. It is particularly concerned with the relation between the individual and the environment, studied through their mutual dependence and interaction, and is used, among other things, to determine the timing and suitability of treatments.

Tibet was traditionally a very religious country. The physician, who strove to lead an exemplary moral and ethical life, enjoyed a highly respected status and often gave counsel. The making and giving of medicines was treated as a sacred task, as was most of the healing art. Traditional studies included a component of spiritual training, mainly concerned with the doctor's own moral and ethical values, the treatment of the patient and the preparation of medicines. As TTM training reaches a wider world, and people of other faiths or no faith wish to study

its science, it is appropriate for a religious component to be offered as an option and not a requirement. However, the altruism, respect for others etc. which form part of the physician's ethical and moral training are an integral part of the core curriculum<sup>2</sup>.

### Overall Synopsis of the Fourfold Treatise

#### Structure

The work consists of Four Treatises, divided into 156 chapters.

4 Treatises :

	Subdivisions	Chapters
The root treatise	6 chapters	6
The explanatory treatise	11 points	31
The instruction treatise	15 sections	92
The final treatise	4 compendiums (25+2 concluding)	27
		156

#### 1. *The root treatise*

This is a very condensed outline of the whole work which, when memorised, gives all the keys and instant access to the theory developed in the other parts.

#### 2. *The explanatory treatise*

It provides the detailed explanation of the medical theory in 11 points.

#### 3. *The instruction treatise*

Comprises the bulk of the work and presents the aetiology and modes of treatment of the various diseases.

#### 4. *The final treatise*

It provides the theoretical background for the techniques of diagnosis, explains the different sorts of medicinal preparations and their processing and the various kinds of external treatments.

### Detailed Structure and Subdivisions of the Four Treatises

*THE FIRST TREATISE: 6 chapters*

Chapter 1 *gleng gzhi*

Presentation of the circumstances of this teaching

Chapter 2 *gleng slong*

Exposition : overall synopsis of the four treatises

Chapter. 3 *gzhi*

Normal physical condition viewed as the basis of illness

Chapter 4 *ngos 'dzin*

## Diagnosis and symptoms of disorders

Chapter 5 *gso thabs*

Treatment, as diet, behaviour, medication and other therapies

Chapter 6 *rtsis kyi le'u*

The tree metaphor

3 roots

9 stems

47 branches

224 leaves

*THE SECOND TREATISE: Classified into 11 points covering 31 chapters*

## Points Chapters

1. *bshad pa'i sdom* Summary general outline of the work

## OBJECT OF TREATMENT

Point 2: the body

Point 3: illness.

## TREATMENT

Point 4: lifestyle

Point 5: diet

Point 6: medicines

Point 7: external treatments

## MEANS OF TREATMENT

When in good health

Point 8: health preservation and longevity

When sick

Point 9: diagnosis

Point 10: methods and means of treatment

## THE ONE WHO TREATS

Point 11: the qualities required in a doctor

2. The Body 2-7

*chags tshul* Formation of the body (embryology)

*'dra dpe* Metaphors for the body

*gnas lugs* Nature of the body (quantitative anatomy dealing with the proportion of bodily constituents, nerves and blood vessels and other important channels in the body)

*lus kyi mtshan nyid* Characteristics (physiology)

*dbye ba* Types of physical constitutions

*'jig ltas* Signs of death

3. Illness 8-12

(Aetiology)

*nad kyi rgyu* Causes of illness 8

*nad kyi rkyen* Contributing factors of illness 9

*nad 'jugs tshul* Mode of inception of illness 10  
(Pathophysiology)

*nad kyi mtshan*

*nyid* Characteristics of illness 11

*nad kyi dbye ba* Classification of diseases 12

4. Behaviour 13-15

*rgyun spyod* Usual behaviour

*dus spyod* Seasonal behaviour

*gnas skabs spyod lam* Occasional behaviour

5. Diet 16-18

*zas tshul* Survey of foods and their nutritional value

*zas sdom pa* Dietary restrictions

*zad tshod ran pa* The right amount of food and drink to ingest

6. Medicines 19-21

*sman gyi ro* "Taste" and "post-digestive taste" 19

*sman gyi nus pa* "Potency" ("Taste-derived"potency) This chapter outlines the

theory of the six basic "tastes" and eight fundamental "potencies" which give each substance its own properties. This is the basis for compounding medicines in order to achieve the desired curative effect."

Intrinsic potency" : the *Materia Medica* <sup>3</sup> 20b

The actual Treatise gives a basic list of over 300 products with their medicinal properties, also the much larger

pharmacopoeia of TTM is also studied in famous commentaries such as *Shel gong* (Crystal Mirror) and *Shel 'phreng* (Crystal rosary)

*sman gyi sbyar thabs* The compounding of medicines (principles) 21

7. Instruments (used in external treatments) 22

*cha byad* Surgical and medical instruments

8. Health preservation 23

*mi na gnas* Remaining healthy (preventive medicine)

9. Diagnosis 24-26

*nyes pa dngos ston* Diagnosing the actual condition of the patient

*ngan gyo skyon brtag* Diagnosing by indirect

questioning: gaining the patient's confidence

*spang blang ma bzhi* Four criteria to investigate whether a disease can be treated or not

10. Treatment of illness 27-30

*gso tshul spyi* General method of treatment

*khyad par gso thabs* Specific methods of treatment

*gso thabs gnyis* Common means of treatment

*gso thabs dngos* Specific means of treatment

11. The doctor's qualities	31	<i>gso ba po sman pa</i> This outlines the professional qualities and ethical standards required of a doctor	
<i>THE THIRD TREATISE: Classified into 15 sections covering 92 chapters</i>			
NOTE : Please, consider the following English translations of diseases as PROVISIONAL. <sup>4</sup>			
<i>Request for the teaching</i>	1		
<i>Section 1 Disruption of the Three Nyes pa</i>			
<i>Rlung disorders - diagnosis and treatment</i> <sup>5</sup>	2		
<i>Mkhris pa disorders - diagnosis and treatment</i>	3		
<i>Bad kan disorders - diagnosis and treatment</i>	4		
<i>'dus nad</i> Combination of all three-diagnosis and treatment	5		
<i>Section 2 "Cold" Diseases ("Consumptive" Disorders)</i>			
<i>ma zhu ba</i> Digestive problems	6		
<i>skran</i> Tumours	7		
<i>skya rbab</i> Oedema, 1st stage	8		
<i>'or</i> Oedema, 2nd stage	9		
<i>dmu chu</i> Oedema, advanced stage	10		
<i>gchong chen</i> Chronic metabolic disorder resulting in wasting of <i>zad byed</i> bodily constituents	11		
<i>Section 3 "Hot" Diseases (Fever, Inflammations, Infectious Diseases)</i>			
<i>tsha ba spyi</i> Survey of hot disorders in general	12		
<i>gal mdo</i> Clarification of possible errors about hot and cold diseases	13		
<i>ri thang</i> "Borderline situations" ("Nyes pa" reactions <i>mtshams</i> following the treatment of a fever)	14		
<i>ma smin tsha</i>			
<i>ba</i> Immature fever	15		
<i>rgyas tshad</i> Fully developed fever	16		
<i>stongs tshad</i> Empty fever	17		
<i>gab tshad</i> Hidden or latent fever	18		
<i>rnying tshad</i> "Old" fever (chronic)	19		
<i>rnyogs tshad</i> "Turbid" fever	20		
<i>'gram tshad</i> Post-traumatic fever	21		
<i>'khrugs tshad</i> "Disturbing" fever	22		
<i>rims tshad</i> Contagious diseases	23		
<i>'brum pa</i> Pox-type diseases (smallpox etc.)	24		
<i>rgyu gzer</i> Infectious disease of intestines	25		
<i>gag lhog</i> Infectious disease of throat and of muscle tissues (could include diphtheria)	26		
<i>cham pa</i> Common cold and influenza	27		
<i>Section 4 Diseases of the Upper Part of the Body</i>			
<i>mgo nad</i> Head	28		
<i>mig nad</i> Eyes	29		
<i>rna nad</i> Ears	30		
<i>sna nad</i> Nose	31		
<i>kha nad</i> Mouth	32		
<i>lba ba</i> Goitre and throat diseases	33		
<i>Section 5 Visceral Diseases</i>			
<i>snying nad</i> Heart	34		
<i>glo nad</i> Lungs	35		
<i>mchin nad</i> Liver	36		
<i>mcher nad</i> Spleen	37		
<i>mkhal nad</i> Kidneys	38		
<i>pho ba' nad</i> Stomach	39		
<i>rgyu ma'i nad</i> Small intestine	40		
<i>long nad</i> Large intestine	41		
<i>Section 6 Sexual Diseases</i>			
<i>pho mtshan</i>			
<i>nad</i> Male genital disorders	42*		
<i>mo mtshan</i>			
<i>nad</i> Female genital disorders	43*		
* Notifiable diseases will be reported to Department of Public Health.			
<i>Section 7 Miscellaneous Diseases</i>			
<i>skad 'gags</i> Problems of voice production	44		
<i>yi ga 'chus pa</i> Loss of appetite (all forms)	45		
<i>skom dad</i> Intense chronic thirst	46		
<i>skyigs bu</i> Hiccups	47		
<i>dbugs mi de</i> Breathing difficulties (all forms, can include asthma)	48		
<i>glangs thabs</i> Sharp abdominal pains of infectious origin (includes colic)	49		
<i>srin nad</i> Infections/inflammations (micro-organisms normally present in the body become pathogenic)	50		
<i>skyugs</i> Vomiting	51		
<i>'khru nad</i> Diarrhoea	52		
<i>dri ma 'gag</i> Constipation	53		
<i>gchin 'gags</i> Urinary retention (12 different sorts of disorders: partial or total retention, reduced amount of urine, with or without pain and inflammation, etc.)	54		
<i>gchin snyi</i> Polyuria	55		
(20 sorts of disorders: excessive production of urine, with or without inflammation of urethra, possible presence of pus, blood, sperm, etc. including diabetes)			
<i>tshad 'khru</i> Infectious diarrhoea	56		
<i>dreg</i> Gout	57		
<i>grum bu</i> Rheumatic diseases (osteoarthritis)	58		
<i>chu ser nad</i> "Chu-Ser" disorders (Skin affections of various sorts due to			

serous fluid <i>dysfunction; also includes a pathology close to rheumatoid arthritis)</i>		considered patients disturbed who insisted on seeing themselves to be under demonic or other malign influence (as is the case with paranoid patients in the modern world, although it may take on a modern tinge, for example having electric shocks sent through the body).
<i>rtsa dkar nad</i> Neurological disorders	60	
<i>pags nad</i> Dermatological diseases	61	
<i>phran bu'i nad</i> Miscellaneous minor disorders	62	
<i>Section 8 Endogenous Sores/Swellings</i>		
<i>'bras nad</i> Swellings, tumours (Also various kinds of cysts and growths)	63	These perceptions of demonic influences would have been consistent with local folk understanding. Patients exhibiting such thinking were seen to be the influence of negative emotional states on the mind (i.e. to poison the mind stream).
<i>gzhang 'brum</i> Haemorrhoids	64	
<i>me dbal</i> "Fire tongues" : (Burn-like blisters, mostly on the skin but can also be internal, could include erysipelas)	65	Buddhism sees thought, emotions and biophysical aspects of the mind as inseparable. Emotions such as jealousy and rage were seen to unbalance and disturb the mind, at all levels, be this thinking, feeling or indeed in its physical manifestation. From a Buddhist perspective such emotions arise from an ego centred approach to the world. Belief in an independent ego was seen as a conceptual misunderstanding, which was seen to underlie such negative emotional states of mind. The ego and its demand for gratification were described as the "ultimate demon". Training practitioners of Tibetan Medicine, in Tibet, would have been exposed to such teachings. For example in commentary by Patrul Rinpoche, a famous meditation master of the XIX Century in Tibet:
<i>sur ya</i> "Surya" swellings Blood clots obstruct the lumen of vessels supplying the lungs, the liver, the kidneys, the stomach or the large intestine, and this causes swelling around the affected organ.	66	<i>The many spirits</i> means concepts <i>The powerful spirit</i> means belief in a self
<i>rmen bu'i nad</i> Swelling of glands	67	Again Milarepa (1052-1135), one of the founding fathers of Buddhism in Tibet:
<i>rlegs rlogs</i> Swelling of scrotum and testicles	68	<i>Take a demon as a demon and it will harm you; take a demon as your own mind and you'll be free of it</i> <sup>6</sup>
<i>rkang 'bam</i> Swelling of lower limbs	69	
<i>mstan bar rdol</i> Anal fistula (possibly)	70	<i>byungs po'i nad</i> "Elementals' influence " 77
<i>Section 9 Children's Diseases (Paediatrics)</i>		
<i>byis pa nyer</i>		Various patterns of mental disturbance accompanied by physiological manifestations and erratic behaviour, possibly referring to mood, psychotic disorders etc.
<i>spyod</i> Child care	71	
<i>byis nad</i> Children's diseases	72	<i>smyo</i> "Insanity-makers" 78
<i>byis pa'i gdon</i> Disturbances in children caused by negative influences in their environment	73	Physical signs and disturbed behaviour akin to bipolar affective disorders
<i>Section 10 Women's Diseases (Gynaecology)</i>		
<i>mo nad spyi</i> General disorders	74	<i>brjed</i> "Making one forget" 79
<i>mo nad bye brag</i> Specific disorders	75	Neurological disorder possibly akin to dementia.
<i>mo nad phal ba</i> Common disorders	76	<i>gza'</i> "Planetary influence" 80
<i>Section 11 Disorders due to "Malevolent Influences" (Neurology and Psychiatry)</i>		
This section presents a mixture of disorders: some that are mostly of a neurological nature, with or without some degree of mental illness, and some which correspond to various forms of mental illness. The person thought themselves to be under the influence of malevolent forces, as was often the case at the time (demons, elementals, etc.) Each chapter outlines specific physiological and behavioural symptoms, diagnosis and treatment.		Neurological disorders - include strokes
Every practitioner was exposed to Buddhist philosophy and psychology; this clearly demarcates the view that perception depends on the observer and there is no "objective reality". Instead the practitioner would have		

leading to hemiplegia and/or epilepsy		<i>dugs</i> 3 hot/cold applications	22
<i>klu gdon nad</i> "Naga influence"	81	<i>lums</i> 4 baths/steam baths	23
This relates mostly to the leprosy		<i>byug pa</i> 5 ointments	24
<i>Section 12 Wounds and Injuries</i>		Extra-powerful supplement to the 5 external treatments :	
<i>rma spyi</i> General	82	<i>thur dpyad</i> minor surgery	25*
<i>mgo'i rma</i> Head wounds	83	<i>mjug don + yongs gtad</i>	
<i>ske'i ma</i> Neck wounds	84	+ 2 extra chapters of conclusion and entrustment	26,27
<i>byang khog ma</i> Abdominal wounds	85		
<i>yan lag rma</i> Limb wounds	86		
<i>Section 13 Poisons</i>		* These would not be practiced in any country where the law forbids TM practitioners from undertaking such procedures or where they would be precluded by cultural constraints.	
<i>sbyar dug</i> Specially formulated poisons	87		
<i>gyur dug</i> Food poisoning	88		
<i>dngos dug</i> Natural poisons	89		
<i>Section 14 Geriatrics</i>			
<i>bcud len</i> Revitalisation treatment	90		
<i>Section 15 Virility/Fertility Treatment</i>			
<i>ro tsa</i> Virility	91		
<i>bu med btsal</i> Woman's fertility treatment	92		
<i>THE FOURTH TREATISE: known also as the 4 compendiums: pulse, urine, medicinal treatment, external treatment, 27 chapters</i>			
1. <i>Diagnosis</i>			
Through examination of pulse and urine			
<i>rtsa</i> Pulse	1		
<i>chu</i> Urine	2		
2. <i>"Calming" medicinal treatment</i>			
<i>thang</i> decoctions	3		
<i>phye ma</i> powders	4		
<i>ril bu</i> pills	5		
<i>lde gu</i> pastes	6		
<i>sman mar</i> medicinal butters	7		
<i>thal sman</i> "calcinates"	8		
<i>khanda</i> extracts	9		
<i>sman chang</i> medicinal brews	10		
<i>rin po che</i> preparations based on precious stones or substances	11		
<i>sngo sbyor</i> herbal preparations	12		
3. <i>"Cleansing" medicinal treatment</i>			
Preparation for the 5 "Works"			
<i>snum 'chos</i> Lubrication (oil therapy)	13		
The Five Works:			
<i>bshal</i> 1 purgatives	14		
<i>skugs</i> 2 emetics	15		
<i>sna sman</i> 3 cleansing via the nose	16		
<i>'jam rtsi</i> 4 gentle enema	17		
<i>ni ru ha</i> 5 forceful enema	18		
Extra-powerful supplement to the 5 "Works":			
<i>rtsa sbyong</i> "channel" cleansing	19		
4. <i>Gentle and forceful external treatments</i>			
<i>gtar</i> 1 bloodletting	20*		
<i>bsreg</i> 2 moxibustion	21*		

## Materia Medica

The traditional Tibetan Materia Medica contained certain ingredients which, at the time of writing, are not allowed under current UK law or under international convention <sup>7</sup>. This includes the use of certain toxic herbs and the use of mineral and animal ingredients. The curriculum is tailored to meet UK legal requirements and therefore covers only the herbal part of the traditional materia medica. The most common herbal components of TTM are listed (not exhaustively) below. Research is required to finalise identification of the Latin recognitions. The following are offered as current identifications.

Tibetan Transliteration	Latin Recognition
<i>A bhi kha</i>	<i>Fritillaria delavayi</i>
<i>A 'bras</i>	<i>Mangifera indica</i>
<i>A byag</i>	<i>Chrysanthemum tatsiniensis</i>
<i>A ga ru</i>	<i>Aquilaria sinensis</i>
<i>A krong</i>	<i>Thalictrum aquilegifolium</i> Loeog
<i>A krong 2</i>	<i>Arenaria Kansuensis</i> Maxim
<i>A ru ra</i>	<i>Terminalia chebula</i>
<i>A sho</i>	<i>Mirabilis himalaica</i>
<i>A wa</i>	<i>Lloydia</i>
<i>Ar nag</i>	<i>Aquilaria agallocha</i>
<i>Aug chos</i>	<i>Incarvillia compacta</i>
<i>Autpal</i>	<i>Meconopsis torquata</i>
<i>ba lu</i>	<i>Rhododendron primulaeflora</i>
<i>ba ru ra</i>	<i>Terminalia bellerica</i>
<i>ba sha ka</i>	<i>Corydalis impatiens</i>
<i>'bam po</i>	<i>Pleurospermum</i>
<i>beedurya 'dra</i>	<i>Saussurea hieraciodes</i>
<i>bo te</i>	<i>Prunus</i> sp.
<i>'bra go</i>	<i>Phoenix dactylifera</i>
<i>bra ma</i>	<i>Caragana brevifolia</i>
<i>brag lcam</i>	<i>Sedum tartarinowii</i>
<i>brag lcam 2</i>	<i>Bergenia ciliata</i>
<i>brag sgog</i>	<i>Allium sativum</i> (wild)
<i>brag skya ha bo</i>	<i>Corralodiscus kingianus</i>
<i>bre ga</i>	<i>Thlaspi arvense</i>
<i>'bri mog</i>	<i>Onosma hoolerii</i>
<i>'bri ta sa 'dzin</i>	<i>Lagotis brachystachya</i>

Tibetan Transliteration	Latin Recognition
<i>'bri ta sa 'dzin 2</i>	<i>Fragaria orientalis</i>
<i>'brug shing</i>	<i>Euonymas monbelgii</i>
<i>Btsod</i>	<i>Rubia cordifolia</i>
<i>btsong sgog</i>	<i>Allium cepa</i>
<i>'bu su hang</i>	<i>Medicago archiducis</i>
<i>bya pho tsi</i>	<i>Ceratostigma griffithii</i> C.B. Clarke
<i>bya rgod spos</i>	<i>Delphinium brunonianum</i>
<i>bya rgod spos</i>	<i>Delphinium chrysostrichum</i>
<i>bya rgod sug pa</i>	<i>Anemone trullifolia</i>
<i>bya rog nyung ma</i>	<i>Lancea tibetica</i> Hook
<i>byi bzung</i>	<i>Arctium lappa</i>
<i>byi rug</i>	<i>Elscholtzia calyocarpa</i> Diels
<i>byi shang dkar mo</i>	<i>Stellaria yunnanensis</i>
<i>byi tang ka</i>	<i>Embelia laeta</i>
<i>byis tsher</i>	<i>Xanthium sibericum</i>
<i>byi'u la phug</i>	<i>Torularia humilis</i>
<i>byi'u srad</i>	<i>Polygala sibirica</i>
<i>chu ma rtsi 1</i>	<i>Rheum pumilum</i> Maxim
<i>chu ma rtsi 2</i>	<i>Polygonum hookeiri</i> Moissn.
<i>chu rtsa</i>	<i>Rheum spiciforme</i> Royle
<i>chu rug</i>	<i>Cardamine macraphylla</i> Willd.
<i>chu sho</i>	<i>Acalypha australis</i>
<i>da lis</i>	<i>Rhododendrom anthopodon</i>
<i>'dam bu ka ra</i>	<i>Catabrosa aquatica</i>

Tibetan Transliteration	Latin Recognition
<i>dar shing</i>	Lepidium apetalum -wood
<i>dar ya kan</i>	Lepidium apetalum
<i>dbyi mong</i>	Clematis rhederianum
<i>de ba</i>	Corydalis melanochlora
<i>dgu thub/rgu thub</i>	Peucedanum praeurptorum Dunn.
<i>dngul sha ma</i>	No currently accepted Latin recognition
<i>dngul tig</i>	Cerastium arvense
<i>dong ga</i>	Cassia fistula
<i>dpa' bo chen po</i>	Panax ginseng C A May
<i>dpa' bo dkar po</i>	Phytolacca acinosa esculenta
<i>dpa' rgod</i>	Curcuma zedoaria
<i>dpa' ser</i>	Phytolacca acinosa Roxb.
<i>drag spos</i>	Lepisorus soulieanus
<i>'dre sha ma</i>	Lycium chinense
<i>dug nyung</i>	Chamaeneriom angustifolium
<i>dug srad</i>	Astralagus strictus
<i>dur ba</i>	Cynodon dactylon
<i>dur byid</i>	Euphorbia fischeriana
<i>dva ba</i>	Arisaema sp.
<i>dza ti</i>	Myristica ficafragrans
<i>ga bra</i>	Rubus subomatus and other Rubus
<i>ga bur</i>	tiger camphor=blumea balsamifera and crystal camphor=cinnamomum camphorum
<i>ga bur tis lo</i>	No currently accepted Latin recognition
<i>ga dur</i>	Bergenia purpurascens (Hook f et Thoms)
<i>gandha bhadra</i>	Cnaphalium affine
<i>gang ga chung</i>	Gentiana urnula
<i>ge sar gsum</i>	Bombas malabaricum: 1. stamen 2. calyx 3. corolla
<i>gla ba srad ma</i>	Hedysarum

Tibetan Transliteration	Latin Recognition
<i>gla sgang</i>	Cyperus scariosus
<i>glang ma</i>	Salix thompsoni
<i>glang sna</i>	Pedicularis longiflora
<i>gnyan 'dul ba</i>	No currently accepted Latin recognition
<i>gnyan thub pa</i>	No currently accepted Latin recognition
<i>go bye</i>	Semiecarpus anacardius L.
<i>go snyod</i>	Carum carvi
<i>gres ma</i>	Iris nepalensis (anthers)
<i>gro ma</i>	Potentilla fulgens
<i>gser me</i>	Herpetospermum pendiculosum
<i>gser phud</i>	Luffa cylindrica
<i>gser tig</i>	Saxifraga montana
<i>gu gul</i>	Commiphora mukul
<i>gur gum</i>	Crocus sativus
<i>gur tig</i>	No currently accepted Latin recognition
<i>gya' kyi ma</i>	Chrysopenium carnosum Hook
<i>gyar mo thang</i>	Primula fasciculata
<i>gyer ma</i>	Scrophularia dentata
<i>gyer shing pa</i>	Schrophularia dentata
<i>gza' dug</i>	Saussurea obvallata
<i>gze ma</i>	Tribulus terrestris
<i>hong len</i>	Lagetus yunnanensis
<i>ja shing</i>	No currently accepted Latin recognition
<i>'jam 'bras</i>	Caesalpina crista L.
<i>'jib chen</i>	Dracocephalum heterophyllum Benth.
<i>'jib chen 2</i>	Salvia Przewalskii Maxim.
<i>ka bed</i>	Curcurbita pepo
<i>ka ko la</i>	Amomum tsao-ko
<i>ka randza</i>	Caesalpinia crst L.
<i>kanda ka ri</i>	Rubus niveus Thumb.
<i>kham bu</i>	Prunus sp.

Tibetan Transliteration	Latin Recognition
'khan pa	Artemisi sieversiana
khrog chung ba	Lepidium apetalum Willd.
khu byug pa	Cypripedium tibeticum
khur mong	Taraxacum tibeticum
khyi shing	No currently accepted Latin recognition
khyung sder dkar po	Uncaria scandens (Smith) Hutch
khyung sder smug po	Saussurea stella Manim
klung sho	Rumex nepalensis
kon pa gab skyes	Saussurea bodiueri
ku sha	Poa sp.
ku shu	Malus sp.
kyi lce dkar nag	Gentiana straminea Marin (light form) and G. crassicaulis Duthie ex Burkill (dark form)
la la phud	Foeniculum vulgare
lca ba	Angelica sinensis
lcags kyu	Corydalis sp.
lcags tig	Gentianopsis grandis
lcam pa	Malva verticillata
lcang ma	Salix sp.
lcum rtsa	Rheum officinale Baill.
ldum nag	No currently accepted Latin recognition
le brgen	Targetes erecta
li shi	Eugenica aromatica
lug chung	Heteropapus crenatifolius
lug mig	Aster himalyicus
lug mur	Phlomis younghusbandii
lug ngal	Corydalis adunca
lug sho	Oxyria dygina
lung tang	Sapindus mukorsii
ma gal	Populus daviana
ma nu	Inula racemosa Hook
ma ru rtse	Butea monosperma
mchin pa zho sha	Entada scandens

Tibetan Transliteration	Latin Recognition
mdzo mo shing	Caragana tibetica
me tog ser chen	Ixeris sp.
mkhal zho	Canavalia Gladiata
mon cha ra	Quercus (acorns)
mtshe ldum	Ephedra equisetina
myong tsi spras	Coptis teetoides
na le sham	Piper nigrum
na rams	Triglochia maritimum
nad ma	Cynoglossum wallichii
nags ma' thang chu	No currently accepted Latin recognition
nim pa	Azadirachta indica
nye shing	Asparagus filicinus
'o se	Pyrus pashia
'od ldan	Saxifraga egregia
'ol mo se	Sinopodophyllum hexandrum
'om bu	Myricaria garmanica
pa to la	Bletilla striata
pad rtsa	Nelumbo nucifera Gaertn
par pa ta	Hypocoum leptocarpum
phur mong	Artemisia nestita
pi pi ling	Piper longum
pri yang ku	Dracocephalum tanguticum
pu shel	Dendrobium nobile
pushkar mu la	Inula racemosa
ra mnye	Polygonatum cyrrhifolia
ram bu	Polygonum viviparum
re lcag	Stellera chamaejasmae
re ral	Dryanaria sinica
re skon	Corydalis hendersonii
rgu drus	Corydalis dasypetra
rgun 'brum	Vitis vinifera
rgya men	Papaver sp.
rgya sgog	Alium sativum (lower altitude)

Tibetan Transliteration	Latin Recognition
<i>rgya sho</i>	Rumex crispus L.
<i>rgya shug 'bras bu</i>	Juniperus formosana Hayata
<i>rgya skyegs</i>	Lacifer lacca Kerr
<i>rgya spos</i>	Delphinium chysotrichum
<i>ri sgog</i>	Allium atrosanguinum
<i>ri sho</i>	Ligularia vigaurea
<i>rta lpags</i>	Lamiophlomis rotata
<i>rta rmig</i>	Viola biflora
<i>rtsa mkhris</i>	Saussurea graminea
<i>Rtsad</i>	Pleurospermum sp.
<i>ru rta</i>	Vladmiri souliei
<i>rug sgog</i>	Allium prattii
<i>se 'bru</i>	Punica granatum (seeds only)
<i>se rgod</i>	Rosa sertata
<i>se yab</i>	Chaenomeles speciosa
<i>seng ge 'jigs med</i>	Silene sp.
<i>seng ldeng</i>	Rhamnella gilgitica
<i>sga chung</i>	No currently accepted Latin recognition
<i>sga sho</i>	Cremanthodium sp.
<i>sga skya</i>	Zingiber officinalis Rose
<i>sga tig</i>	Androsace aizoon Duly var. coccinea Franch.
<i>sga tsha</i>	No currently accepted Latin recognition
<i>sgang thog pa</i>	Sisymbrium heteromallum
<i>sgog skya</i>	Alium sativum
<i>sgron shing</i>	Pinus tabulaeformis, but also P. massoniana, P. yunnanensis, P. densata, P. griffithii, P. smithiana, P. armandi
<i>sha la yu ring</i>	Cremanthodium sp.
<i>Shang dril</i>	Primula sikkimensis
<i>shang len smug po</i>	Eryophyton wallachii

Tibetan Transliteration	Latin Recognition
<i>shang tsher</i>	Orobanche alsatica
<i>shel ta</i>	Pinus tabulaeformis (resin)
<i>Shing kun</i>	Ferula asafoetida
<i>Shing mngar</i>	Glycerrhiza uralensis
<i>Shing tsha</i>	Cinnamomum cassia
<i>sho mang</i>	Rumex nepalensis
<i>shu dag</i>	Acorus calamus
<i>shu mo za</i>	Trigonella foenum graecum
<i>shu ti</i>	Mentha arvensis
<i>shug tsher</i>	Juniperus formosana
<i>ske tshe</i>	Sinapsis sp.
<i>skyer ba</i>	Berberis wood
<i>skyer me</i>	Berberis jamesiana (flower)
<i>skyi 'brum</i>	Sophora Davidii
<i>skyu ru ra</i>	Phyllanthus emblica
<i>sle tres</i>	Tinospora sinensis
<i>Smag</i>	Metroxylum sago
<i>sman sga</i>	Alpinia officinalis
<i>smug chung 'den yon</i>	Meconopsis henricii
<i>smug cu gang</i>	Schizostachyum chinense
<i>sne'u 1</i>	Chenopodium album
<i>sne'u 2</i>	Amaranthus caudatus
<i>sngon bu</i>	Cyananthus sherifii
<i>snya lo</i>	Polygonum polystachium
<i>snyi ba</i>	Codonopsis convulflacae
<i>snying zho sha</i>	Choerospondia axillaris (Roxb.) Burtett Hill
<i>so cha</i>	Randia dumetorum
<i>so ra</i>	Abelmoschu moschatus
<i>sog ka</i>	Capsella bursa pastoris
<i>spa 'brum</i>	No currently accepted Latin recognition
<i>spa yag</i>	Lancia tibetica

Tibetan Transliteration	Latin Recognition
<i>Spang rgyan dkar</i>	<i>Gentiana szechenyii</i>
<i>Spang rgyan dkar 2</i>	<i>Gentiana algida</i>
<i>Spang rgyan nag po</i>	<i>Gentiana veitchiorum</i>
<i>Spang rgyan sngon po</i>	<i>Gentiana stipitata</i>
<i>Spang rtsi</i>	<i>Pterocephalus hookerii</i>
<i>spen dkar</i>	<i>Potentilla glabra</i>
<i>Spor</i>	<i>Sedum sp.</i>
<i>spra thog</i>	<i>Leontopodium franchetii</i>
<i>spru ma</i>	<i>Heracleum wallachii</i>
<i>Spyang dug pa</i>	<i>Cirsium souliei</i>
<i>Spyang tsher</i>	<i>Morina kokonorika Hao</i>
<i>sra 'bras</i>	<i>Syzgium cumini</i>
<i>srad ma rigs</i>	<i>Astralagus sp.</i>
<i>srin shing</i>	<i>Daphne tangutica</i>
<i>sro lo</i>	<i>Pegaeophyton scapiflorum</i>
<i>srog shing</i>	No currently accepted Latin recognition
<i>srub ka</i>	<i>Anemone rivularis</i>
<i>stabs seng</i>	<i>Fraximus saureolans</i>
<i>stag ma' me thog</i>	<i>Rhododendron arboreum</i>
<i>stag sha</i>	<i>Oxytropis chiliophylla</i>
<i>stang ri zil ba</i>	No currently accepted Latin recognition
<i>star bu</i>	<i>Hippophae rhamnoides</i>
<i>star ga</i>	<i>Juglans regia</i>
<i>su mi</i>	<i>Corydalis yanhusuo</i>
<i>sug pa</i>	<i>Solms-Laubachia earycarpia</i>
<i>sug smel</i>	<i>Elettaria cardamomum</i>
<i>tang ku</i>	<i>Ledabouriella seseloides</i>
<i>tang ku 2</i>	<i>Sinolimprichtia alquina</i>
<i>tha ram</i>	<i>Plantago depressa</i>
<i>thal rdor</i>	<i>Cassia tora</i>
<i>thang khrag</i>	<i>Abies spectabilis?</i>
<i>thang phrom</i>	<i>Przewalskia tangutica Maxim</i>

Tibetan Transliteration	Latin Recognition
<i>ti mu sa</i>	No currently accepted Latin recognition
<i>tig ta</i>	<i>Swerta chirayita</i>
<i>til</i>	<i>Sesamum indicum</i>
<i>tsam pa ka</i>	<i>Oroxylum indicum</i>
<i>tsan dan</i>	<i>Santalum album</i>
<i>tsar bong</i>	<i>Artemisia desertorum</i>
<i>tsher sngon</i>	<i>Meconopsis horridula</i>
<i>tsi tra ka</i>	<i>Capsicum frutescens</i>
<i>'u su</i>	<i>Coriandrum sativum</i>
<i>yo 'bog</i>	<i>Ulmus</i>
<i>yog mo</i>	<i>Rabdosia rubescens</i>
<i>yu gu shing</i>	<i>Senecio soliagineous</i>
<i>yu mo 'de'u 'byin</i>	<i>Paraquilegia microphyta</i>
<i>yung ba</i>	<i>Curcuma longa</i>
<i>zangs rtsi dkar</i>	<i>Galium aparin</i>
<i>zangs rtsi nag</i>	<i>Artemisia hedinii</i>
<i>zangs tig</i>	<i>Swertai mussofi</i>
<i>zhim thig le 1</i>	<i>Lagopsis supina [Steph]</i>
<i>zhim thig le 2</i>	<i>Phlomis betonicoides Diols</i>
<i>zhim thig le 3</i>	<i>Salvia roborowskii</i>
<i>zhim thig le 4</i>	<i>Nepeta coerusens</i>
<i>zhim thig le 5</i>	<i>Stachys. sp</i>
<i>zhim thig le 6</i>	<i>Galeopsis bifida Boenn.</i>
<i>zhim thig le 7</i>	<i>Stachys kouyangensis (Vaniot)</i>
<i>zhim thig le 8</i>	<i>Lamium amphexicaule</i>
<i>zhim thig le 9</i>	<i>Salvia wardii</i>
<i>zhu mkhan</i>	<i>Skimia multinerva</i>
<i>zin tig</i>	<i>Ajuga lupulina</i>
<i>zir dkar</i>	<i>Cuminum cymnum</i>
<i>zir nag</i>	<i>Nigella glandulifera</i>
<i>zla gor zho sha</i>	<i>Entada phaseoloides</i>
<i>zva' 'drum</i>	<i>Urtica triangularis</i>
<i>zva phyi A yas</i>	<i>Urtica tibetica</i>

## Pharmacy and Clinical Training

Pharmacy and clinical training are covered in separate modules in the EHPA core curriculum and will be provided in those contexts. Pharmacy training will prepare the student to recognise the various materia medica; understand the different qualities of plants of the same species growing in different environments; know when Materia medica are collected according to their destined purpose, how the materia medica are collected in order to best preserve their properties, how they are transported and stored; and, understand the proper processing and preparation of the medicinal compounds according to the established rules and formulae. Traditional Tibetan Medical practitioners and manufacturers are aware of good manufacturing practice and are moving swiftly to make GMP the standard for all herbal remedies used. They are similarly aware of the need to have Government certified GMP(CGMP), in manufacturing and importing businesses handling and manufacturing such remedies.

Traditionally, TTM trainees would be immersed in a clinical environment throughout their training. In order to emulate this as far as possible, students are to be encouraged to use every opportunity to observe medical practice from the start.

## Assessment

### *Study*

The principal means of assessment should be by written and oral examination. Educational institutions should endeavour to formulate these exams so as to prioritise understanding of principles, rather than simple memorisation. Nonetheless, it has been traditional to learn certain parts of the main *rgyud bzhi* text by heart, as the knowledge contained should be at the practitioner's fingertips at all times, being the very essence of the theory. In view of this, institutions should carefully consider the weighting to be given to this aspect.

### *Materia Medica Recognition and Pharmacy Training*

This will be primarily subject to continued assessment during field trips and laboratory visits, with spot checks on field trips leading to points being subtracted from an overall total for wrong answers given. Written and oral examination on materia medica forms part of the general examination on study (above).

### *Clinical Practice*

Competence will be judged by continuous assessment by supervising physicians during clinical training. This will require the supervising physicians to maintain a record of diagnoses offered and treatment suggested by the student during clinical training. Not all cases need be recorded but should cases be selected, that selection must be made before the student is asked to diagnose and not in retrospect. At least twenty per cent of the student's cases should be followed for assessment. Clinical examination will form part of the end of year and final examinations. This aspect of the assessment will be a critical factor determining the candidate's suitability to proceed to the next year or to qualify.

### *Attendance*

Failure to attend more than eighty-five per cent of classes will result in that term's study not being credited. Although this is the general rule, exemption may be made for sickness or other reasons, provided that the tutorial staff are satisfied that the missed ground has been adequately covered by the student.

### *Exemptions*

Educational institutions should provide a coherent policy with regard to exemptions for prior learning. They must satisfy themselves that candidates who are exempted from parts of their curriculum have covered the required material and achieved required learning outcomes. After consultation with the world's major TTM teaching institutions clear guidelines on this issue will be set out by the UK governing body on TTM. The governing body will have the power to annul any granted exemption it deems unjustified.

## Recommended Allocation of Time

Following the recommendations for the common core curriculum presented elsewhere in this report, it is proposed that the total minimum course length should be 2560 hours, of which a minimum of one third should be teacher/student contact time. Within this total, it is proposed that a minimum of 1150 hours be devoted to Tibetan Traditional Medicine (traditional physiology, pathology, diagnostic methods and study of the materia medica). In addition, a minimum of 450 hours of clinical practice is proposed.

## Indicative Reading

Donden, Dr Y. *Health Through Balance, an Introduction to Tibetan Medicine* (Ithaca NY: Snow Lion Publications, 1986)

Finck, Dr E. *Studies in Tibetan Medicine* (Ithaca NY: Snow Lion Publications, 1988)

Meyer, Prof. F. *Gso-ba rig-pa, le système médical tibétain* (Paris: CNRS, 1981)

Rinpoche, R., Kunzang, J. *Tibetan Medicine*. (Berkeley and Los Angeles: University of California Press, 1973)

Tsarong, Dr T. J. *Fundamentals of Tibetan Medicine, according to therGyud bzhi*. (Dharamsala: Tibetan Medical Centre)

Van Alphen, Aris. *Oriental Medicine, Chapters on Tibetan Medicine*. (London: Serindia Publications, 1995)

Clifford, T. *The Diamond Healing: Tibetan Medicine and Psychiatry*. (Motilal Banarsidass, 2003)

## Footnotes to Appendix 4, Tibetan Herbal Medicine Core curriculum

1. This term refers to one of the fundamental principles of TTM, a field of study that is both vast and subtle. As there is nothing resembling this in modern allopathic medicine, it is impossible to find an adequate English translation and the westernised transcription of the Tibetan has been given here. A very approximate translation could give "agents" when they are in their healthy, unaltered state and pathologia when they have altered. (see OED).
2. Eminent authorities, such as HH the Dalai Lama and Prof Khenpo Troru Tsenam in Lhasa, have insisted that TTM stands perfectly in its own right as a medical system without the Buddhist element and that the prayerful, religious component is an "added value" but not a necessity. Therefore making these an option rather than a requirement seems to pose no problem to the main holders of the traditions. The time devoted to these is not included in the study hours cited above.
3. See list of principal herbs (not exhaustive) used in Materia Medica section below
4. Much long-term research is required to ascertain the exact nature of each illness categorised in the Tibetan medical system in

order to find equivalences in the Western medical classification wherever possible, and to establish the right terminology. This work is presently underway. At this early stage, tentative equivalents are sometimes given in brackets as indications, without certainty.

5. (See the Note on Principles of TTM and terminology). This section shows disorders caused by the disruption of each one of the three Nyes Pa . These can be viewed as key pathologies since all illnesses are due to a disturbance of the basic balance between the three agents which make up the body and ensure the functioning of all body systems.
  - \* Words of My Perfect Teacher by Patrul Rinpoche translated by Padmakara Translation Committee Harper Collins 1994
6. Words of My Perfect Teacher by Patrul Rinpoche translated by Padmakara Translation Committee, Harper Collins, 1994
7. Affected by the Convention on International Trade in Endangered Species, allowed if traded with the appropriate trade permits OR non-plant materials as, under UK law, non-plant traditional medicines fall outside the remit of the licensing exemption granted to herbs by the 1968 Medicines Act OR restricted under SI 2130 Schedule 111, 1974 OR banned for use in unlicensed medicines by Act of Parliament.

# ANNEX II: ACCREDITATION HANDBOOK

## Contents

Background to the Herbal Medicine Regulatory Working Group
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Acknowledgements

## Background to the Herbal Medicine Regulatory Working Group

The launch of the Herbal Medicine Regulatory Working Group in January 2002 was sponsored by the Department of Health. Key objectives include: to support and promote moves towards unification within a federal structure of the herbal practitioner profession and to recommend the form that herbal medicine regulation should take for the statutory profession.

The Herbal Medicine Regulatory Working Group recognises existing policies and sub-committees of the European Herbal Practitioners Association concerned with regulatory issues, and will liaise closely with the Department of Health, European Herbal Practitioners Association and The Prince of Wales's Foundation for Integrated Health.

The Education Committee and the Accreditation Board, originally set up under the umbrella of the European Herbal Practitioners Association, will change in their form once the regulatory processes anticipated by the work of the Herbal Medicines Regulatory Working Group are enacted in law. It is anticipated that the Education Committee and the Accreditation Board will become part of the General Herbal Council or CAM Council.

## Aims of the Accreditation Board

To define and maintain standards of education which ensure the good practice of herbal medicine through the accreditation of individual programmes of study within approved institutions.

To encourage institutions to respond to developments in healthcare practice and research.

In collaboration with institutions, to recognise and develop good quality education in herbal medicine in order to justify public confidence in the validity of qualifications awarded.

To actively promote the development and implementation of equal opportunity policies that support the diverse ethnic and cultural philosophies of herbal medicine.

## Constitution of the Accreditation Board

Current Board membership is divided between practitioners of herbal medicine, educationalists and other professionals who represent the wider

interests of the community. In addition, each professional body will be responsible for putting forward a pool of specialists in the curriculum of their tradition who will form part of the accreditation process.

1 x Independent Chairperson, 1 x Accreditation Officer plus: practitioners represented by NIMH x 1, RCHM x 1, other professional bodies x 4 (by rotation), accredited schools/courses in herbal medicine x 2. Wider community represented by senior professionals drawn from western medicine x 1, education x 2, general management x 1, healthcare/complementary therapy x 1.

The Board constitution will be kept under review, and as organisations change so too may Board membership. Similarly, as part of the wider community, consideration needs to be given to ways and means of ensuring appropriate patient representation.

## Purposes of the Accreditation Board and Accreditation Process

To accredit programmes within approved institutions, which lead to qualified practitioner status (and in the future, to mandatory registration). Courses will not be accredited if franchised to other educational institutions.

To determine and put in place robust systems for the accreditation of programmes.

To receive and scrutinise documentation on the organisation, content, assessment and evaluation of programmes leading to qualifications in herbal medicine.

To determine the suitability of institutions and to visit those institutions in order to assess the availability of resources to support qualifying programmes and the appropriateness of the student learning environment.

To protect the public by promoting educational procedures that ensure safe, effective standards of care.

To ensure that courses meet the requirements of the Core Curriculum, provide a satisfactory standard of education and meet the needs of users of the service.

To maintain standards of entry to the profession and ensure competence to practise as an independent practitioner.

To monitor and consider proposed modifications to accredited programmes.

To review accredited programmes on an annual basis and reaccredit programmes at the time agreed when initially accredited.

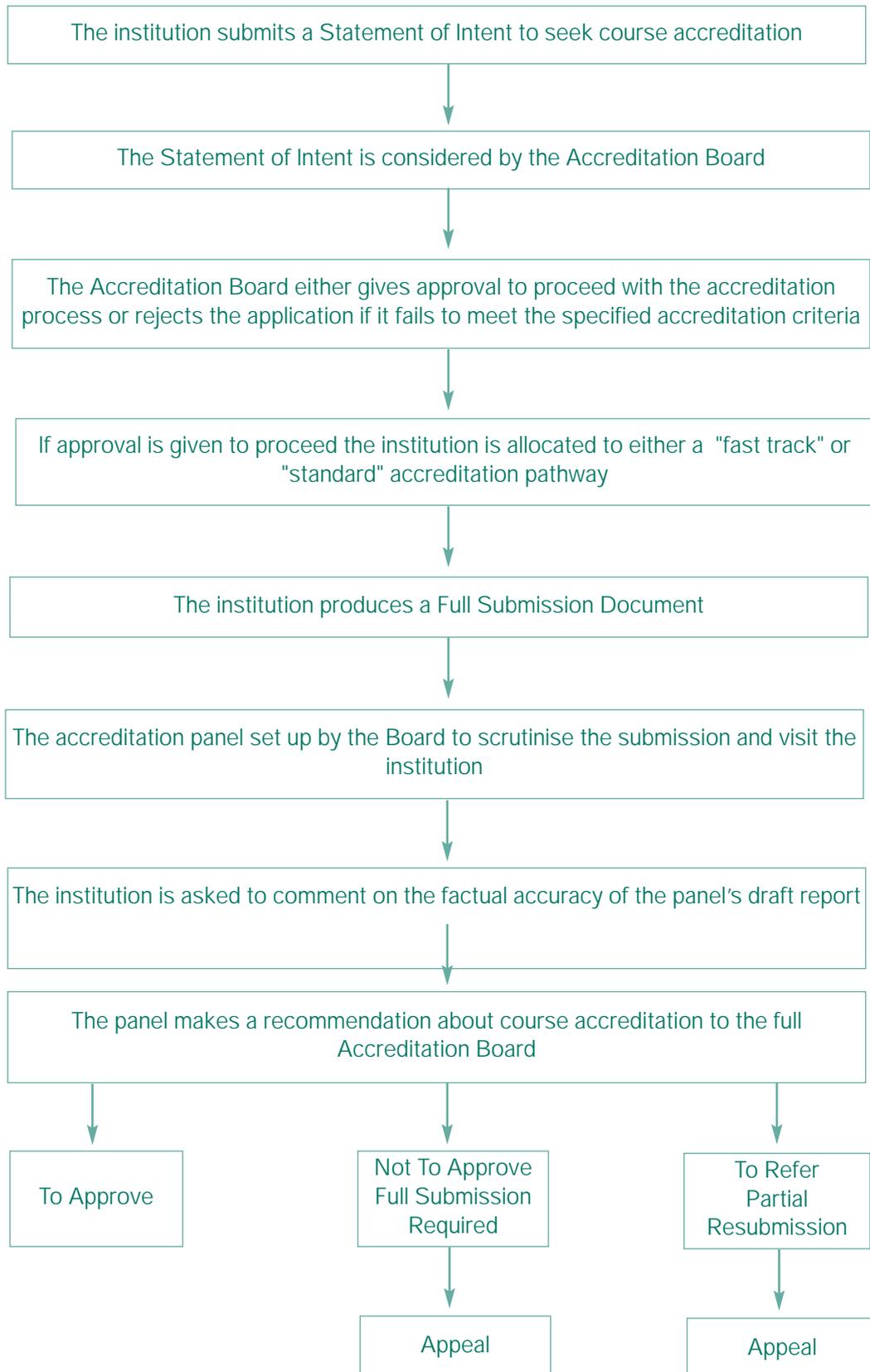
To inform any future regulatory body or Education Committee of any issues which impact upon professional development and education.

To provide advice to institutions planning qualifying programmes in herbal medicine.

To engage with all those involved in professional education, sharing good practice and promoting professional development within existing traditions.

To ensure representation from the broadest range of herbal traditions by rotating membership of the Accreditation Board.

## Overview of the Accreditation Process



## General Guidance

### Institutional Approval

Any higher education institution, including universities and independent colleges wishing to obtain approval to conduct educational programmes leading to professional/academic qualifications, is required to submit evidence of its capacity and capability to meet the requirements of the Board.

Institutions in the independent sector may choose to apply for course accreditation or may wish to participate with an approved higher education institution. In the latter instance they will need to establish formal links with the chosen higher education institution and become familiar with their policies and procedures.

### A Developmental Approach

The Accreditation Board welcomes the opportunity to work with staff of institutions during the process of self-review and the development of the programme and are available to offer guidance at all stages of the accreditation or conjoint validation process. However, please note that the primary responsibility of the Accreditation Officer is to assist the work of the Board and members of the Board and/or Visiting Panel, and they are unable to act as consultants to the applicant institution. Institutions requiring specialised advice on developmental matters may wish to seek advice from skilled independent educationalists.

### Approval Pathways

#### Pathway One

Designed for institutions that have not yet undergone any external peer review or evaluation. Prior to the formal full submission of documentation both the Accreditation Officer and a mentor institution will offer support in the planning and development of the submission. It is anticipated that this could take a period of up to two years and will include visits to the institution by members of the Board.

Institutions offering EHPA accredited courses are encouraged to mentor another institution embarking upon Pathway One if asked to do so.

#### Pathway Two

Designed for institutions that have already undergone a quality audit by an external body. It is anticipated that institutions, which already have undergone course accreditation, will have that accreditation recognised for a specified period of time after which EHPA procedures will be followed. Documentary evidence of external scrutiny will

need to be provided plus any additional information specified by the Board, in order to obtain EHPA recognition.

The Accreditation Board will decide, for each institution, where in the process they are deemed to fit, i.e. Pathway One or Two, and the documentation which must be provided.

### Working in Partnership

The EHPA respects the right of universities to validate and review their programmes, and in an effort to avoid duplication and overload, advocates a process of conjoint validation and accreditation, working in partnership with universities.

Integration of theory and clinical practice is an important component of a programme, which confers practitioner qualifications. Conjoint accreditation and validation between universities and the EHPA promotes such integration. In order for this approach to succeed it is important that EHPA Accreditation Board representatives at conjoint events are able to consider and comment upon all aspects of the programme, both clinical and theoretical, and for clinical education to be considered as well as the students' university experience.

It is likely that the Accreditation Board will appoint one practitioner and one educationalist from its list of approved panel members, to attend joint events with universities. (The Accreditation Officer of the Board will also attend as an observer/adviser). Potential panel members will be asked if they have any pecuniary or non-pecuniary interest to declare in the institution to be visited. As nominated representatives of the EHPA they will have delegated authority to consider the proposal and make recommendations to the full Accreditation Board. Authority to accredit courses rests with the full Accreditation Board.

### Organisation of Accreditation Events

There are two kinds of events and processes differ slightly. If a **conjoint event**, that is when professional accreditation and university validation are being carried out simultaneously, it is expected that the host university will appoint the chairperson and provide a written record of the event and associated outcomes. In the case of an independent college seeking **professional accreditation only**, the Accreditation Board will organise the event/visit, and the panel will consist of three or four members, one chairperson, and three others who are either practitioners or educationalists. The visiting panel will produce the report for independent colleges.

The Accreditation Officer of the Board will liaise with a named person of the institution during the organisation and planning of the event.

It is anticipated that the date of the event will be subject to early negotiation so that a mutually convenient date can be agreed. A minimum of twelve weeks notice will be required and only in exceptional circumstances will it be possible to agree to accreditation events during the months of July and August. Three copies of the Full Submission Document and the appropriate fee should be submitted to the Accreditation Officer of the Board at least six weeks before the event.

The institution concerned will meet specified expenses incurred by EHPA representatives, either attending accreditation events or making visits to institutions/clinical areas. This is in addition to the fees specified elsewhere.

The Accreditation Board does not intend to approve individual external examiners for programmes in herbal medicine. However particular attention will be paid to the way in which institutions select, induct and use external examiners as part of their quality assurance system and the role of the external examiner in annual monitoring/quality enhancement.

## Statement of Intent to Apply for Course Accreditation

All institutions seeking course accreditation begin by completing the Statement of Intent. The earlier this is submitted the better, for the longer the lead-in time the better the joint planning and collaborative working will be. All institutions, including those in their early and formative stages of development, are encouraged to submit a Statement of Intent, and to receive the ongoing consultation, evaluation, and guidance from the Board which is provided to applicant institutions through the services of the Board's Accreditation Officer. This may include a one-day site visit, at the institution's invitation and expense, before completing the Full Submission Document.

The information provided in the Statement of Intent will be used to determine whether the institution can be approved to proceed to the next stage of the accreditation process, and if so, which Accreditation Pathway is appropriate. It is the institution's responsibility to obtain the most recent Accreditation Handbook from the Board's office.

When preparing the Statement, it is important to

ensure that, having carried out a self-review, evidence is provided which **demonstrates the ability of the institution to meet Accreditation Criteria 1.1, 2, 3, 4 and 11.** (See Appendix One).

There is not a required format for the presentation of the Statement of Intent but institutions are asked to ensure that the following information is also provided:

Name of organisation  
Main address  
Other addresses  
Tel/Fax/ E Mail  
Details of whether an independent or university institution  
Name of lead person and telephone number

1. Minimum and maximum student numbers per intake, numbers of intakes per annum and entry qualifications
2. An indication of the established or potential market for the programme
3. Confirmation that there will be sufficient staff appropriately qualified to support the programme
4. Confirmation that sufficient and appropriate physical resources will be allocated for the development and implementation of the programme
5. Intended timescale for development and process of approval
6. Whether another body accredits the course and date of next re-accreditation
7. Whether a university validates the course and date of next revalidation
8. A summary of the aims, process and intended outcomes of the educational programme, briefly outlining how learning outcomes will be achieved
9. Whether it is intended to utilise distance learning and if so, to what extent
10. A description of the proposed organisation of clinical education
11. An outline assessment strategy for both theory and practice
12. Confirmation that the proposal will comply with the core curriculum
13. Names of course leader and module/unit leaders (if the course is already running)

Board officers will be happy to offer guidance and advice if institutions are unsure of any aspect.

### The Review of the Statement of Intent

The Accreditation Board reviews the Statement of Intent. It may, at this time, seek additional information from the institution to support or clarify the application. The Accreditation Officer and at least one member from the Accreditation Board will review the application in detail and the Accreditation Officer will produce a report for consideration at the next Board meeting. The Board may decide to ask representative(s) to visit the institution, following which a report is submitted to the next meeting of the Accreditation Board. The report is considered and a decision made as to whether or not the institution should proceed to course accreditation. The Board may recommend that the institution be given further time within which to resubmit its documentation and may offer the institution advice about where to seek help. The Accreditation Board will also determine the fee for resubmission up to a maximum of £200.

Once the Board has considered the Statement of Intent and has agreed to proceed with the accreditation process by allocating the institution to one of two pathways the institution may, if it wishes, indicate in its printed literature that accreditation is being sought. However, achievement of accreditation cannot be guaranteed and care needs to be taken with wording in order not to inadvertently mislead potential applicants. An institution may withdraw their Statement of Intent at any time before a final decision whether or not to proceed is made by the Board.

### Achieving Accreditation

An institution is required to prepare a Full Submission Document in order to demonstrate how it will successfully deliver the Core Curriculum and can meet each of the criteria for accreditation. Once the Accreditation Board has considered the submission, a visit to the institution will be organised. The visiting panel will normally consist of three or four members: one/two educationalists, one/two practitioners and one chairperson who will be a member of the Accreditation Board. The Board's Accreditation Officer will accompany the panel and provide administrative support to EHPA panel members.

Whilst encouraging flexibility in the way institutions operate, the Accreditation Board expects each institution, through a process of self review, to demonstrate how it is accomplishing its educational intentions and delivery of the Core Curriculum, whilst meeting the Board's criteria for accreditation.

### Requirements for the Full Submission Document

There is no predetermined format for the Full Submission Document other than the first two sections entitled "The Candidate Organisation" and "Course Outline".

#### The Candidate Organisation

Name  
Main address  
Other addresses  
Date organisation established  
Status: Independent/University based  
Details of associated organisations  
Shared facilities

#### Course Outline

Course title  
Please specify Final and Intermediate Awards  
Credit requirements (if a conjoint award with a university)  
Mode of delivery: Full Time/Part Time/Sandwich/Distance Learning \*\*  
Month and year of first intake  
Total annual student intake  
Number of intakes per annum  
Number of students per intake

The remainder of the Full Submission Document must clearly demonstrate how the remaining accreditation criteria of the Board (see Appendix One) will be met.

Appendix Two lists information which, if not included within sections relating to the accreditation criteria, should also be provided as part of the submission.

Within Appendix Two please note those items identified with \*\* which will require particular attention if delivery by distance learning is anticipated.

### Institutional Visit

The Accreditation Panel will arrange to visit the institution and related clinical/off campus areas as part of the process of accreditation. The pro-forma indicates the focus of the visit, the outcome of which will contribute towards the final decision regarding whether or not to accredit the course.

#### Institutional Visit Pro-forma: To be completed by the Accreditation Panel

##### General Details

Name of organisation  
Address  
Tel/Fax/E Mail

Host name and position  
 Dates/time of visit  
 Name of Chairperson of Institutional Visiting Team  
 Names of additional Accreditation Board representatives  
 Name of observer from host organisation

#### Details of Facilities of Institution

Comments/Grading (1=Poor 5= Excellent)  
 Reception area  
 Classrooms  
 Seminar/tutorial rooms  
 Laboratories  
 Practical rooms  
 Student facilities  
 Library  
 IT resources  
 Pharmacy  
 Herb garden  
 Clinic  
 Additional comments/appraisal of facilities

#### Details of Staff Met

Name(s)  
 Position(s)

#### Possible topics for discussion during meeting

- Management of programme
- Organisation of course
- Are minimum theoretical and clinical hours met?
- Content of module:
  - Is coverage adequate?
  - Is depth/breadth appropriate?
- Teaching and learning methods to be used - theory
- How issues around the Code of Ethics will be addressed
- Extra tuition/tutorials available
- Teaching and learning methods to be used - clinical
- Are learning outcomes achieved in each module?
- Assessment strategy - theory
- Assessment strategy - practice
- Student evaluation of course and evidence of action taken
- Any issues arising from appraisal of organisations' documents
- Pass rate for theory and practice
- Student numbers and drop out rate (year by year)
- Plans for expansion
- Plans for improvement
- Staff appraisal and continuing professional development
- Are teaching staff involved in decision-making and curriculum development?
- Is debate encouraged in the institution?

- Are students fully prepared for independent practice
- financial management
- preparation of medical reports
- to liaise with other health providers, especially GPs?

\*\* Distance learning - additional topics if appropriate

#### Review course/student records

*Please note that patient/student confidentiality should be maintained at all times*

#### Meeting with students (for distance learning students' topics\*\* are especially important)

Discuss: Course organisation  
 Student academic support and guidance\*\*  
 Facilities, including library/IT  
 Teaching and learning methods\*\*  
 Clinical facilities, practice and supervision\*\*  
 Assessment strategies/feedback to students\*\*  
 Mechanisms for student representation\*\*  
 Course evaluation and monitoring

## Institutional Summary

#### To be used by the Accreditation Panel When Determining the Final Outcome

Key Questions to be included:

- Are the minimum theoretical requirements of the core curriculum met?
- Are the stated theoretical learning outcomes appropriate and achievable?
- Are the minimum practical requirements of the core curriculum met?
- Are the stated clinical learning outcomes appropriate and achievable?
- Is the stated academic level of each module appropriate and achievable?
- On completion of the course are students safe and competent to practise as independent practitioners?
- Are the resources of the institution adequate for the needs of the course?
- Have the EHPA Accreditation Criteria been met?

The Institutional Summary also needs to cover the following areas:

- What strengths and elements of good practice have been identified?
- What areas require further development?
- What advice will be/was given to the organisation?

## Recommendation to Accreditation Board

### The suggested options are as follows.

- Unconditional approval for a period of **up to** five years (it may be less), with or without recommendations, or
- Approval for a period of **up to** five years with conditions to be met, or
- Referred: partial resubmission necessary within agreed timescale, or
- Not approved: full resubmission required

NB Five years is the maximum period of approval. Panels may determine that a shorter period is appropriate.

Institutions may appeal to the Chair of the Accreditation Board against the decision no later than ten working days after receipt of the final panel report.

The Board reserves the right to require institutions to amend accredited and recognised courses if changes are made to the curriculum by the EHPA which, if not implemented within the period of accreditation, would significantly disadvantage students and/or have an adverse effect on client safety.

Signed for Institutional Visiting Panel

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## Appeal Procedure

Before submitting their final report to the Accreditation Board, the Accreditation Panel will provide a draft copy for the institution so that staff may correct any factual errors.

The Chair of the panel, in conjunction with panel members may amend the draft report in light of factual evidence provided by the institution. Once amended the final report will be forwarded to the institution and the Accreditation Board.

An institution which considers that the final report features any of the following may appeal against the decision of the Accreditation Board:

1. errors of fact which have unduly influenced the outcome; or
2. who consider that the panel failed to adhere to agreed procedures and processes which unduly influenced the outcome; or
3. who consider that substantial evidence on the record has not been taken into account which

unduly influenced the outcome.

A written appeal should be submitted by the Principal/Dean of the institution to the Chair of the Accreditation Board within twenty working days of receipt of the final agreed report and should clearly state the grounds for the appeal. When considering the appeal, account will only be taken of information available to the Board at the time of the original decision, and it is for the institution to establish that one of the above three criteria applied when the Board reached its decision.

An appeal panel shall be set up by the Chair of the Education Committee and will consist of two other members in addition to the Chair. The first will be drawn from the Board's list of educationalists approved to carry out accreditation visits and the second will be one of the lay members of the Regulatory Working Group.

The Board will provide the appeal panel with a complete record of the Accreditation Panel and Board proceedings when reaching their original decisions, and the institution's request to appeal.

The panel will consider the appeal, and may, at their discretion, include a meeting with representatives of the institution and/or the Board.

The appeal panel will produce a written report within twenty working days of beginning deliberations or as soon as possible thereafter, and will include the decision and reasons for that decision. If the appeal panel does not support the decision of the Accreditation Board it will refer the decision back to the Board for further action in accordance with the findings of the appeal panel. The Board will meet within 20 working days and will notify the Principal/Dean of the new decision as soon as possible thereafter. Under no circumstances shall the appeal panel grant, deny or revoke accreditation.

All expenses incurred as a consequence of the appeal, including any meeting costs, will be met in full by the institution concerned. Where the appeal is upheld in accordance with the criteria for appeal above, the Board will bear its own expenses, including those of the appeal panel.

## Annual Review

It is expected that institutions will have in place quality monitoring procedures that will include an annual review of the programme for the duration of the period of accreditation. This should take the form of a critical self review of the operation of the

programme and should document the following:

- changes to personnel and roles
- changes made to the course during the year
- an analysis of student enrolment and retention
- external examiner reports and a response to any issues raised
- student and staff evaluation of the programme and action to be taken in response to evaluation
- analysis of assessment/examination results
- student evaluation of clinical education with additional comments from clinical staff
- an action plan, showing how issues identified are to be addressed and any planned changes to the course.

In addition, the opportunity should be taken, at the time of the first annual review, to comment upon progress made with the implementation of recommendations or conditions set at the time of the accreditation event.

Independent colleges, in addition to the requirements specified above, should also include in their review document any changes to the structure of the institution; the financial accounts for the year being reported on and commentary on the financial results. Details provided must be based upon the most recent Annual (Company) Report and have been agreed by the governing or advisory board for the institution.

A copy of the annual review document and the annual review fee should be forwarded to the Accreditation Officer by the end of October each year. The Board will revisit institutions once during the period of accreditation if the institution has not undergone a visit from another external quality agency during the period.

The Accreditation Officer and members of the Accreditation Board will produce a report for submission to the Accreditation Board and copy it to the institution.

## Modifications to Programmes During the Period of Accreditation

Curricula will inevitably undergo development in response to informed debate, quality assurance processes and the external environment. However, the Board must give approval in advance of significant changes being made to an accredited programme. The need for change will normally be

identified as part of the annual monitoring process. Institutions are strongly advised to seek preliminary advice from the Board before embarking upon significant change. Significant changes are any which might impact deleteriously upon the quality of the students' learning experience, or the satisfactory achievement of agreed learning outcomes at the appropriate level or fitness to practise. All other changes must be described and explained in the annual review.

Incremental change increases the risk of curriculum drift, therefore the Board, when considering the proposed changes, reserves the right to decline the request and/or require a formal review.

## Re-accreditation

At the end of the agreed period of accreditation it will be necessary to have the programme formally re-accredited. Re-accreditation is as substantial in scope as the original accreditation and will incorporate a Full Submission Document and Accreditation Panel visit.

Institutions will normally notify the Accreditation Board of their intention to seek re-accreditation as part of their annual review, at least twelve months in advance of the expiry of the current accreditation period. If, as can reasonably be expected, the annual reviews have been conducted thoroughly, there should not be a need for the institution to resubmit a full Statement of Intent and the content of the Statement of Intent will be agreed in advance with the institution.

Earlier complete or partial re-accreditation may be required at any time for good reason. Institutions offering accredited courses must notify the Board within thirty days of changes in ownership, management, contractual affiliations with other institutions, and of any issues which could substantially affect the institution's policies, staff, curricula, reputation, legal or financial status.

## Withdrawal of Accredited Status

The Board will normally withdraw accreditation if:

1. specific conditions set at the time of accreditation by the Board, have not been met within the time limit set, or without good reason acceptable to the Board
2. the Board concludes that the institution has engaged in illegal conduct, or is deliberately misrepresenting itself, or presenting false

information to its staff, students, the public or the Board

3. the institution fails to provide all pertinent information and materials requested by the Board
4. the institution does not submit its Annual Review documentation within the time limit set by the Board
5. the institution fails to seek and obtain the Board's approval prior to implementing substantial changes to the programme
6. the institution fails to pay any fees due to the Board, within the time limit set by the Board
7. the institution ceases to offer the accredited course
8. the institution adds unrelated courses to its portfolio which the Board considers will have a deleterious effect on the accredited programme.

An institution may withdraw its course from accreditation by giving due notice to the Board. Such notice should be sufficient not to disadvantage those students already enrolled and should enable them to complete the accredited course. Any subsequent reinstatement is entirely at the discretion of the Board.

If withdrawal of accreditation occurs for whatever reason, the institution must delete all reference to accreditation from prospectuses, advertising and other printed promotional material within a time limit set by the Board.

Accreditation does not automatically transfer with changes of ownership or type of control, and full and complete information shall be submitted to the Board within thirty days for such action as it may decide to take.

## Appendix 1: ACCREDITATION CRITERIA

### Institutional policy, organisation and management.

#### 1. Policy

The institution shall have an overall policy or mission statement which indicates the institution's overall intentions/aims.

1.1 *Relationship.* This statement should link with the institution's education policy statement and should be known, and subscribed to, by its governors, staff and students.

Guideline: the statement of policy should provide

direction for the institution. The statement should incorporate the purpose for which the institution was founded and relate to other policies of the institution.

1.2 *Policies.* The institution must provide clear statements of policy in respect of those matters, which support the fair and efficient delivery of the course.

Guideline: written statements should be included about: the assessment and examination procedures; the equal opportunities policies; recruitment policies; pastoral and tutorial support for students; policies for keeping the course under review and development; and procedures for quality assurance.

1.3 *Review.* Statements of institutional policy must be reviewed periodically and revised when necessary.

Guideline: the re-examination of policy should determine whether they are still relevant, whether they are being fulfilled, and whether the statements are understood adequately by all those involved. This review process should include comments from representatives of the student body, teaching staff, administration, practitioners and the governing board.

#### 2. Legal Organisation

The institution shall be legally constituted and shall be in compliance with all applicable statutory regulations.

#### 3. Institutional Management

The institution shall have a governing body or advisory board, which includes representation reflecting the public interest.

3.1 *Representation.* The board, whose duties and responsibilities must be clearly defined, must exercise ultimate and general control over affairs of the institution. The Board should be appropriate to the legal structure and the submission document should indicate how it operates.

Guideline: board members should be responsible for directing the accomplishment of the purposes for which the institution was founded. They should be responsible for establishing broad policy and long-range planning, appointing the Principal and/or Dean, developing financial resources, and playing a major role in the development of external relations.

Guideline: board membership should provide representation of public interest.

3.2 *Control.* A clear separation should be made between those having a direct financial interest,

and those responsible for the academic policies of the institution.

Guideline: there should be a clearly set out relationship between those with overall control and those responsible for implementing the academic policies of the institution.

3.3 *Meetings*. Board meetings must be held at regularly stated times. Agendas of meetings must be prepared and accurate minutes of the meetings kept and filed.

#### 4. Administration

The institution shall have a Director, Principal or Dean whose full-time or major responsibility is to the institution, and an administrative staff of a size and organisational structure which is appropriate to the size and purpose of the institution.

4.1 *Institutional Administration*. The Director, Principal or Dean shall be responsible to the governing board for the entire operation of an institution. S/he shall be directly responsible for the administration of the policies and procedures determined by the governing board.

4.2 *Academic Administration*. Institutions must have clearly defined the academic responsibility for facilitating curriculum development and assessment of courses and vested this in a committee or board (e.g. an Academic Board), chaired by an appropriate senior person.

#### 5. Records

The institution shall have appropriate record-keeping systems.

5.1 *Permanent Records*. The institution shall maintain, and safeguard, accurate academic and other records which document the attainment of the institution's requirements, while observing the requirements of the Data Protection Act and other relevant legislation.

5.2 *Data*. The institution must maintain data which will facilitate the compilation of the following records and statistics: student profiles, showing the number of students enrolled, graduated and readmitted; admissions data showing the number of applications received and accepted; the ages, and the educational and ethnic backgrounds of the student body; assessment and examination papers and student results and external examiner reports.

5.3 *Clinical Records*. The institution must maintain accurate, secure, and complete clinical records of patients currently being treated by students.

#### 6. Equal Opportunities Policy

The institution shall have adopted a comprehensive policy demonstrating commitment to equal opportunities.

6.1 The policy should underpin all the institution's activities.

Guideline: the institution should document details of the application of its Equal Opportunities Policy in its dealings with students, employees and patients, for example in a Code of Practice.

6.2 All institutional procedures, documents and publications must, where appropriate, indicate an awareness of, and a commitment to, equal opportunities.

Guideline: the institution's prospectus, or other official publication, as well as published staff recruitment material, should state, explicitly, a commitment to equal opportunities.

#### 7. Staffing

The institution shall have staff adequate for institutional management, the educational courses and clinical teaching offered.

7.1 *Number*. The institution shall maintain sufficient numbers of teaching staff to perform the responsibilities assigned to them.

7.2 *Background and Experience*. The general education, the professional education, the teaching experience and the practical professional experience shall be appropriate to the subject taught. Every staff member shall provide evidence of satisfactory experience and provide continuing evidence of awareness of developments in his or her field.

7.3 *Professional Development*. Staff members should be provided with appropriate opportunities for professional growth and development, and adequate preparation time.

Guideline: provisions for professional development should be reviewed periodically.

Guideline: staff contracts should specify responsibilities clearly.

Guideline: evaluation of staff performance should be carried out periodically.

7.4 *Policy and Procedures*. The recruitment, appointment, promotion and retention of appropriately qualified staff members must be outlined in institutional policies and/or procedures.

7.5 *Communication*. Provision shall be made for regular and open communication among members

of staff, and between the staff and administrative officers of the institution.

Guideline: the staff shall collectively consider educational policies and issues. Minutes of meetings or outcomes of alternative methods of communication shall be kept in a permanent file within the institution.

## 8. Students' Rights and Responsibilities

The institution shall develop a statement of the rights, privileges and responsibilities of students and of disciplinary proceedings for failing to meet those responsibilities. This statement shall be made available to students through the prospectus, student handbook, or other appropriate means.

8.1 *Opportunity to Be Heard.* Some provision shall be made for obtaining students' views and for their participation in institutional decision-making.

8.2 *Grievances.* The institution must have fair and efficient procedures for receiving, reviewing and responding to grievances expressed by students.

## 9. Learning Resources

The institution must provide learning resources and equipment adequate for the educational courses offered, or must have made specific long-term written arrangements for reasonable access by students to alternative resources.

9.1 *Resources and Access.* The institution must have its own library or collection of learning resources for students, or must have executed long-term written contracts providing for the use of other specific library resources, with adequate and reasonable accessibility.

Guideline: the library's materials, services, and related equipment should facilitate and improve learning, and support the educational programme.

Guideline: the library should be available to students and staff, and it should contribute to the achievement of the objectives of the institution.

## 10. Institutional Resources

The institution must provide facilities which are safe, accessible, functional, appropriately maintained and sufficient to house, and to provide for, effective functioning of the course, and to accommodate the staff and the student body. It shall ensure access to clinical and practical resources adequate for the educational courses offered, or, in lieu of a clinic, shall have made specific long-term written arrangements for

reasonable access by students to such resources. The written agreement should clearly specify responsibility for quality assurance arrangements of the student experience.

10.1 *Classroom Size and Equipment.* The institution shall provide clinic and classroom space, properly equipped and appropriate to its curriculum and size.

10.2 *Health and Safety.* Facilities shall meet all applicable legislation including fire and health and safety standards.

10.3 *Staff Facilities.* Adequate facilities and appropriate media and learning equipment shall be available for the support of administrative and other staff, as well as for students.

10.4 *Quality Assurance.* The institution must be directly responsible for all off-campus clinical and other educational activities, regardless of whether the activity has been arranged in agreement with other organisations or individuals, or not.

Guideline: if components of the course are conducted at sites geographically separate from the main campus, Quality Assurance (QA) systems in place should demonstrate that clinical and educational components/services are of equivalent quality.

Guideline: details of the Memorandum of Agreement for off-campus provision should be made available.

## 11. Finance

The institution shall have an adequate financial base for existing course commitments, must demonstrate adequate financial planning and must have an appropriate financial management system.

11.1 *Resources.* The institution shall be financially stable, with resources sufficient to carry out its objectives, support adequately its courses and activities, and ensure, as a minimum, that all enrolled students will be able to complete the course.

Guideline: in the case of an institution which is a sole-proprietor, separate accounts for the course are required.

Guideline: the institution should have the financial capacity to respond to financial emergencies and unforeseen occurrences.

Guideline: if an accumulated deficit has been recorded, a realistic plan to eliminate such deficit should be presented clearly, understood, and

approved by the governing board.

Guideline: The institution should demonstrate that, if it were to cease functioning as an educational establishment, it could meet its obligation to provide appropriate refunds to students.

11.2 *Control*. The institution shall have control of its financial resources and budgetary process and be free from undue influence or pressure from external funding sources or agencies.

11.3 *Budgetary Process*. The process by which the institution's budget is established, and resources allocated, must be defined clearly and implemented consistently. The institution shall be able to project its income and expenditure for a three-year period.

11.4 *Expenditure*. The income of the institution shall be expended to provide adequately for: instruction; administration; learning resources; student services and activities; staff development; course development; maintenance; equipment; supplies; and other specific functions which are consistent with the goals of the course.

11.5 *Management*. The financial management system shall be set up to allow for a reviewed audit, each year, by an independent registered auditor.

11.6 *Insurance*. Adequate and proper insurance shall be in place, including cover for employer's liability, third party liability, buildings and contents, loss of business income, and professional indemnity insurance relating to the carrying out of treatment by students.

11.7 *Refund Policy*. The institution must state clearly, and follow uniformly, a fair and equitable refund policy in respect of tuition paid for by students but not taken up.

## 12. Publications

The institution must publish and make available to students and to the general public, official publications which honestly and accurately set forth the following information.

- Educational aims and intentions
- Entrance requirements and procedures
- Rules and regulations for conduct and attendance
- Opportunities and requirements for financial aid (if applicable)
- Procedures for discipline and/or dismissal (for academic and other reasons)
- Grievance procedures for students
- Fees and equitable refund policies

- Course completion requirements
- Members of the governing/advisory boards
- The outline syllabus, academic calendar, and course schedule
- The institution's admissions (and credit transfer if appropriate) policies
- An accurate description of each component of the course of study and how it is to be assessed
- A description of learning and other physical resources
- Details of the qualification(s) to be awarded upon successful completion of the course
- Any legal requirements for practice which may be applicable
- Reference to the institution's policy on equal opportunities

12.1 *Honesty and Accuracy*. Publicity, advertising, and other literature shall represent the institution's educational opportunities to students and the public, in language which is accurate, honest, clear, and unambiguous. Publicity and advertising should not misrepresent employment, career, or registration prospects.

12.2 *Disclosure*. Courses, services, and personnel not available during the academic year must be identified clearly.

12.3 *Status with the EHPA*. The institution shall report, accurately, to the public, its status and relationship with the EHPA, using words and phrases acceptable to the Board.

## 13. Educational Policy

The institution shall have a formally adopted educational policy on the preparation of herbal medicine professionals as independent and accountable healthcare practitioners.

13.1 *Content*. The statement of policy must demonstrate how the course meets the standards for entry to the profession set by the EHPA.

Guideline: the institution should set out its own definition of a competent practitioner within the framework of general competence requirements of the EHPA.

Guideline: the statement of policy should guide the educational processes and the adoption of priorities in allocation of resources.

13.4 *Review*. Statements of educational policy must be reviewed periodically and revised when necessary.

Guideline: the re-examination of policy should determine whether courses are relevant to stated

objectives, and whether the objectives are being met. This review process should include comments from representatives of the student body, teaching staff, administration, practitioners and the governing board.

#### 14. Educational Programme Admissions

The institution shall have adopted a statement explaining the prerequisites for entry, including ways in which mature students with prior learning or experience will be awarded credit.

14.1 *Criteria.* The admissions policy should make clear its criteria for accepting, or not accepting, various entry prerequisites.

14.2 *Prerequisites.* If courses substituting as prerequisites for entry are also offered by the institution seeking accreditation, these must be identified as "stand alone" courses, distinct from the professional herbal medicine course. The institution must demonstrate that appropriate resources are available to sustain these courses without adversely affecting the herbal medicine course.

#### 15. Programme of Study

The course shall satisfy minimum requirements of the core curriculum in respect of levels, hours, professional clinical competence, achievement of learning outcomes and other standards of education established by the EHPA designed to provide students with the information necessary to practise independently.

15.1 *Core Curriculum.* The course enables achievement of the learning outcomes within the stated hours. The hours are a minimum requirement and may be exceeded.

15.2 *Completion Certificate.* To each person successfully completing the professional course, the institution shall award a certificate, diploma, or degree following general practice in education and relevant legislation.

15.3 *Relationship to Purpose.* A herbal medicine institution shall offer a course of study which is consistent with, and clearly related to, its statement of educational policy.

15.4 *Teaching and Learning.* The course must demonstrate that it achieves the levels in the core curriculum by utilising a variety of appropriate adult teaching and learning strategies.

Guideline: the course should be sufficiently rigorous in breadth and depth and appropriate to the education and training of independent practitioners.

15.5 *Teaching.* The teaching of students shall be the institution's main priority, enabling students to prepare for safe, independent, professional practice, by gaining knowledge and skills as outlined in the core curriculum published by the EHPA.

15.6 *Code of Practice.* Before entering the clinical section of the course, students should be both conversant with the EHPA Code of Practice and the relevant professional body codes of practice and ethics.

15.7 *Clinical Teaching.* The institution shall organise and provide a clinical programme of sufficient size, variety, and quality to fulfill its educational purposes. Clinical teaching and practice shall consist of formal tuition and practical clinical training, and shall include supervised care of patients that allows the student to take increasing levels of responsibility for patient care.

Guideline: when a large proportion of the students' clinical experience is gained at off-campus premises, there should be written agreements covering the use of those premises, specifying how the institution's objectives, course requirements, and standards of clinical training are to be carried out.

Guideline: the institution should assure each student of the opportunity to observe, participate in and, under supervision take responsibility for, the care of patients. Supervision should be sufficient to ensure the safe and competent care of patients.

Guideline: clinical teaching hours should be clearly recorded so that time spent during formal tuition, observation only and actual practise under supervision is differentiated.

15.8 *Professional Competencies.* The syllabus shall lead to minimum professional competencies to be attained through clinical experience included in the core curriculum published by the European Herbal Practitioners Association.

15.9 *Pastoral Care.* There should be a clear policy on pastoral and tutorial support for students.

#### 16. Assessment

The assessment of students' achievement shall be applied systematically throughout the course. A variety of measures shall be employed to ensure the acquisition of knowledge, skills, attitudes and behaviour commensurate with each stage of the course leading ultimately to the performance expected of a qualified, independent practitioner.

16.1 *Assessment Calendar*. The institution shall have developed an appropriate set of assessment stages throughout the course which should be presented in diagrammatic terms. Details should be offered to demonstrate and provide evidence of, an assessment system which can keep each student, and the institution, informed about their educational progress. This should enable a clear decision to be reached at the end of the course in respect of each student, about the awarding of a professional qualification to practise.

Guideline: a range of suitable assessment strategies and clinical evaluation should be used to document the acquisition of knowledge, skills, and attitudes.

Guideline: each module and each level of clinical teaching should have clear intentions linked to a clear means of assessing whether achievement is attained.

Guideline: the institution should have an effective and efficient system to monitor students as they progress through clinical learning. Students who have difficulties should be identified early, and such weaknesses should be documented and communicated to the student and other relevant persons. Suspension, dismissal, or the assignment of remedial work, if necessary, should be determined in a just and timely manner.

Guideline: the variety of assessment outcomes obtained during the clinical learning of all students should be recorded adequately, be transparent and equitable.

16.2 *External Examiners*. The institution shall have appointed at least one external examiner who will ensure the following in respect of the course:

1. students' overall standards of achievement in both the academic and practical components of that course are commensurate with, and judged in line with, standards normally applying in other equivalent educational institutions
2. assessment methods and intentions support the learning of the profession's core curriculum
3. all assessments are conducted fairly and without prejudice

Guideline: the examiner(s) should be demonstrably knowledgeable about the standards and requirements of the profession and capable of overseeing the institution's assessment procedures and results.

Guideline: the procedures for appointing such examiners should be clearly set down.

Guideline: the roles and responsibilities of such examiners should be clearly set down in an examinations policy.

Guideline: examiners should write annual reports that identify the institution's strengths and weaknesses in respect of assessment. These should be included as part of course documentation and quality assurance procedures which are presented to the Board.

## 17. Evaluation

A summary of course evaluation systems and quality assurance procedures should be provided. The institution shall evaluate the effectiveness of its education, and the accomplishment of its stated intentions, by measuring and documenting the achievement of a sufficient number of students and graduates, in verifiable and internally consistent ways.

17.1 The institution should have procedures in place for carrying out annual evaluations of its structures and delivery of the curriculum.

17.2 Such policies and procedures should have demonstrable impact upon the development of the course.

Guideline: students' evaluation of courses and the teaching faculty should be one of many perspectives considered in determining whether the institution is meeting its objectives.

Guideline: retention rates, drop-out rates, completion rates, and the average length of time students take to complete the course should be calculated, maintained, and used in helping to measure the outcomes of the course.

Guideline: there must be ways of ensuring that policy and procedures regarding academic progress and grading are fair, consistent, published and made available to students.

## Appendix 2:

### INFORMATION TO BE INCLUDED IN A FULL SUBMISSION DOCUMENT

Information about all on and off-campus activities must be included in the submission and where off-campus sites are used to provide part of a course, details are needed of each separate site and clinic, some or all of which may be included in the panel visit.

#### Distance Learning

Institutions who intend to utilise distance learning for part of the course will need to demonstrate how the

student experience, although different, results in achievement of learning outcomes and a satisfactory educational experience that is of a comparable standard to that of a more conventional course. Items marked \*\* will warrant detailed explanation.

In addition, please explain how distance learning materials are developed, evaluated and approved prior to implementation.

**University Only**

Quality Assurance Agency (QAA) report summaries - subject and institution to be provided.

If conjoint validation and accreditation is being sought a separate document is not required, however please ensure that the accreditation criteria are clearly identified with an index and cross-references to the body of the text.

If only accreditation is being sought forward a copy of the separate validation document and only provide additional information as necessary.

**Information likely to be included in order to demonstrate that criteria can be met**

**Staffing Resources**

*Head of Institution:*

Title		
Name		
Qualifications	Academic Professional	
Teaching Role	No Yes	Details

*Course Leader/Director*

Name		
Qualifications	Academic Professional	
Publications		
Teaching Role	No Yes	Details

*Lecturer/s*

Name  
Qualifications  
Publications  
Hours of Working: F/T, P/T(+hours)/visiting (V)

*Clinical Teaching Staff*

Name  
Qualifications  
Post held  
Have any staff been approved as clinical instructors by professional bodies, e.g. NIMH?

*Other Staff*

Number of administration

	Full time	Part time (+ hours)
Number of qualified librarians	Full time	Part time (+ hours)
Number of unqualified library staff	Full time	Part time (+ hours)
Other (please specify number and role)	Full time	Part time (+hours)

*Arrangements to cover staff sickness and/or absence*

**Other Resources**

*Teaching Facilities: \*\**

Classrooms (Size/number)  
Seminar rooms (Size/number)  
Practical rooms  
Other

*Student Facilities and Services: \*\**

Canteen  
Cloakroom  
Common room  
Other services (please describe)

**Learning Resources\*\* If alternative arrangements exist, please describe**

*Library*

Size  
Book stock and number of journals  
-Specific to herbal medicine  
-Relating to medicine  
-Relating to complementary therapies  
-Supporting other Core Curriculum modules  
Opening days/hours

*IT Facilities*

Number of PCs/printers accessible to staff  
Number of PCs/printers accessible to students  
Availability of technical support  
CD-ROM systems  
Access to on-line databases

*Photocopying Facilities*

Please indicate the hours of availability of IT/Photocopying facilities.

The Board recognises that in a university setting many facilities are shared between students on a variety of courses. Please indicate the number of students sharing the available facilities with students of Herbal Medicine.

*Laboratory Facilities*

Number/Size  
Equipment available

Any other information e.g. reciprocal arrangements with other institutions

*Herbal Pharmacy*

Please describe

*Medicinal Herb Garden*

Please describe

*Clinical Resources*

Please describe

*Additional facilities / resources\*\* (please describe)*

Liaison with local GP's and hospitals

Research facilities

Other

**Student Support Systems\*\***

Details of academic support

Details of clinical support

Other

**The Herbal Medicine Course**

Title of course

Entrance requirements and selection procedure

Mechanisms for Accreditation of Prior Experiential

Learning (APEL) or Accreditation of Prior

Certificated Learning (APCL)

Title of award given on successful completion

Duration of course:

*Full Time* Number of years

Number of taught weeks per year

Hours of study per week

*Part Time* Number of years

Number of taught weeks per year

Hours of study per week

*Distance Learning\*\** Describe how course requirements are met

Course promotion and advertising literature (please submit)

Course/curriculum document incorporating course structure; compulsory and elective features; evidence of coherence and logical progression

Programme management arrangements\*\*

Range and provision of clinical placements

Total clinical hours and supervision arrangements

Learning outcomes and associated assessment strategies for all units/modules. e.g. for

knowledge

practical skills

attitudes

Teaching and learning strategies\*\*

Assessment regulations and documents (for theory and clinical practice)

Examination Board membership and terms of reference

Quality Systems\*\*

Quality assurance procedures

Selection, appointment and induction of External Examiners

External Examiner reports for the previous 3 years (if course already running)

Student involvement in course evaluation and review

Mechanisms for student representation

Any additional information which confirms that the course is/will be offered at a satisfactory standard

How the course is underpinned by staff development and research

Institutional policies, which underpin the course, e.g.: complaints; grievance; appeals; equal opportunities

Has the course received professional body accreditation (e.g. NIMH)?

If yes: Date of accreditation  
Duration of accreditation  
Name of professional body

Has the course received university validation?

If yes: Name of university  
Qualification awarded  
Date of validation event  
Date of next formal review  
Date of revalidation (if applicable)

If not already included as part of the submission, institutions are asked to append the following documents.

1. The institution's charter or articles of incorporation.
2. Proof that the institution is in compliance with all relevant local and statutory planning requirements.
3. The Constitution and Terms of Reference of its governing or advisory board.
4. A copy of the institution's organisational chart.
5. Confirmation that the accounting system has been set up or is being set up, in such a way that a complete certified financial statement (including a balance sheet and statements of income and expenditure, profit and loss, and change in financial position) will be able available by the time the first annual monitoring report is submitted.
6. A copy of the diploma, certificate or degree to be issued at the completion of the course.
7. A copy of any lease, licence or other legal document setting out the terms under which the premises are used.

## Appendix 3: EQUAL OPPORTUNITIES GUIDELINES

### Aim

To provide guidance for institutions in order to help prevent direct or indirect discrimination against any potential or actual student of herbal medicine.

### Definitions

Direct discrimination is treating a person less favourably than others who are in the same or similar circumstances.

Indirect discrimination is applying, in any circumstances, a requirement or condition, which although applied equally to all persons, is such that a considerably smaller proportion of people can comply with it, and it cannot be shown that the requirement or condition is justifiable.

### Notes of Guidance

- Practitioners of herbal medicine work within the community, therefore potential applicants should be encouraged from a wide variety of backgrounds so that the profession is broadly representative of the community it serves. Career information should be presented to as diverse an audience as possible.
- All actual and potential students of herbal medicine are entitled to equality of opportunity and all those involved in herbal medicine education shall consciously promote this.
- The prime consideration of admission tutors, when considering applicants, must be whether they are capable of successfully completing the programme and functioning as an independent practitioner of herbal medicine.
- Programmes are intended as preparation for subsequent clinical practice but there should be no upper age limit to entry for herbal medicine education.
- There should be no infringement of the individual's cultural practices or beliefs unless vital to the study of herbal medicine.
- The accessibility of buildings and facilities should be considered for students with disabilities. To enable support to be given to students with different needs, staff should encourage students to make them aware of any disability present at the start of the programme, or any that is recognised subsequently.
- Students should be made aware of the equal opportunities policy in operation and should be encouraged to voice any concerns they may have.
- Students should be made aware that they have a responsibility not to treat other students or staff in a discriminatory way.

## Appendix 4: EXTERNAL EXAMINER GUIDELINES

External examiners are an important part of ensuring that academic standards and professional competence to practise are maintained. These guidelines are intended to assist all institutions offering herbal medicine programmes that lead to qualified practitioner status. However it is recognised that universities, in particular, will already have their own established policies and procedures in places.

### Recruitment and Selection

External examiners should have professional and academic qualifications and experience commensurate with the course being examined. At least one should be engaged in the educational preparation of students of herbal medicine. Once systems are in place to create one professional register of practitioners, it will be necessary for at least one external examiner of the herbal medicine course to have their name on the register of the (yet to be established) General Herbal Council or shared CAM Council or interim body.

Initially, it is recognised that there may be a shortage of appropriately qualified and experienced external examiners. The EHPA accept that under such circumstances, more than one institution, may through necessity, appoint the same examiners. Institutions may like to consider appointing assistant examiners who will work alongside experienced external examiners for a predetermined period providing them with the experience to be appointed in their own right at a later date.

External examiners should:

- not have been on the staff of the institution responsible for the course within the previous three years
- not be closely associated with a member of staff or a governor of the institution responsible for the course
- normally be appointed for a period of four years

4. not be selected from an institution where a member of the inviting institution staff is serving as an external examiner
5. receive full briefing on their role, full documentation of the accredited course, conduct of assessments and examinations, appeals procedure, and remuneration of fees and expenses.

### Responsibilities

The maintenance of academic and professional standards.

To ensure that assessment/examination strategies and regulations are interpreted and applied in such a way that students are treated fairly and consistently.

To ensure that the qualification is of an appropriate standard for fitness to practise.

To advise institutions whether their standards are comparable to other institutions' qualifying programmes.

To ensure that students have reached the required standard of competence, and that no qualification is awarded unless the candidate has successfully completed the clinical education requirements and the clinical examinations and assessment.

To attend the Examination Board, sign the official pass list and approve the grade of award recommended for each candidate.

To provide for the institution an annual written report on the overall standard of the course.

To contribute to the quality enhancement process in an advisory capacity.

### Additional Guidance

The course team and examiner should agree timetables for marking and moderation of students' work which ensure that i) there is sufficient time for the external examiner to consider scripts and respond to the institution by the required date, and ii) there is sufficient time prior to the meeting of the Examination Board for adequate marking and moderation to take place.

After the course team has set examination papers it is expected that the external examiner will be asked to comment and approve them prior to their use.

It is not the role of the external examiner to act as a first or second marker. Internal markers should agree marks: it is the role of the external examiner to satisfy themselves that marking procedures are efficient and robust.

External examiners should be able, if they so wish, to see any/all assessed or examined work. However it is usual for examiners to agree with the course team how they wish to sample students' work, when and in what quantity.

External examiners should complete their annual report as soon as possible after the Examination Board meeting, and in any case, no later than the date predetermined by the institution as part of its examination and assessment policy.

Institutions should acknowledge receipt of the report and inform the external examiner what action is being taken in light of any recommendations contained within the report.

The institution is responsible for agreeing a fee with the external examiner.

## Appendix 5:

### QUALITY ASSURANCE AGENCY (QAA) BENCHMARKING ACADEMIC STANDARDS FOR COMPLEMENTARY MEDICINE

The following paragraphs are extracted from a consultation document issued by the QAA. It is anticipated that benchmarked standards for complementary medicine will be agreed in the near future. Therefore they are included here in draft form for information only, as they only apply to higher education institutions at Levels One to Three at the present time.

Benchmark information was seen as essential to ensure public and employer confidence that higher education awards, especially at first-degree level, were recognised nationally and widely understood.

By describing the nature and standards of honours degrees, the statements provide the academic community with a means of defining what can be expected of a graduate in a particular subject area.

As award holders are able to register with the relevant professional or statutory body in order to practise professionally, the statements are intended to benchmark both academic and practitioner standards.

Benchmarking standards can provide information to meet the following purposes.

1. To inform the public at large about the nature of higher education awards.

2. To guide intending students, employers and others about the range of provision in particular subject/discipline areas and the standards that might be expected of graduates in those areas.
3. To provide institutions with a framework for developing and specifying the intended learning outcomes of programmes.
4. To assist external reviewers with a point of reference, amongst others, for making judgments about the appropriateness of standards.
5. To assist reviewers in determining whether learning outcomes of individual programmes are appropriate in the review of standards under academic review.

Specific elements of knowledge, understanding and skills to be covered are described under the following headings.

- Concepts, principles and philosophy central to practice
- Clinical education and clinical skills
- Health sciences
- Background and transferable skills
- Professional contexts
- Professional evaluation and research
- Reflective practice
- Personal and professional skills
- Professional relationships
- Professional autonomy and accountability

Examples of standards to be achieved.

- The ability to select and interpret research related and other data for quality assurance purposes
- Demonstrate proficiency in clinical investigation and management
- Demonstrate independent thinking and self-directed learning
- Demonstrate an understanding of the therapeutic relationship and the boundaries of the professional role
- Understand the legal and ethical issues of professional practice
- Be accountable and uphold the principles and practice of clinical governance
- Formulate, justify and apply treatment and management plans, generating coherent differential diagnoses and evaluating outcomes

Once QAA produces the definitive document the EHPA will circulate it to those institutions that do not have access to their own copy. When the Core Curriculum is reviewed, the standards such as those

above will need to be taken into consideration.

## Appendix 6:

### INDICATIVE COSTS FOR ALL INSTITUTIONS

Initial fee submitted with Statement of Intent	£300 non-refundable
Review of Statement of Intent	£600 (minus £300 above)
Review of Full Submission Documentation for accreditation or re-accreditation	£600
Panel visit to institution	£1200 per visit
Annual Review	£600
Amendments to accredited programmes	£ negotiable, depending on scale of changes.

The fee for reviewing documentation includes payment to panel members, travelling expenses, associated clerical and administrative salary costs and overheads and the provision of additional guidance and advice if required.

The panel visit fee includes payment to members of the panel, associated clerical and administrative salary costs and the provision of a post visit report. It is anticipated that each one day visit will require panel members to commit at least one additional day for preparation and one day after the visit to write, collate and agree the visit report.

Travelling expenses are excluded as these will be identified on an individual institution basis in advance.

Fees will be reviewed on an annual basis.

## Acknowledgments

The Accreditation Board of the EHPA gratefully acknowledges earlier work done by the National Institute of Medical Herbalists, the British Acupuncture Accreditation Board, The Chartered Society of Physiotherapy, the Physiotherapists' Board at the Council for Professions Supplementary to Medicine and the English National Board for Nursing, Midwifery and Health Visiting.

# ANNEX III: CODE OF ETHICS: CODE OF CONDUCT AND DISCIPLINARY PROCEDURES

## Definition of terms used throughout this document

**The Practitioner:** the person registered as a qualified herbal practitioner.

**The Council:** the registering body for herbal practitioners.

**The Patient:** the person requesting treatment or the person being treated in the case where a third party has legal responsibility for the patient.

**The Practice:** the business and/or the place of business of the practitioner.

**Colleagues:** fellow herbal practitioners and students training at establishments accredited by the Council and fellow health professionals of other disciplines.

**Unacceptable Professional Conduct:** dishonourable or ethical misconduct which falls short of the standard required of a registered herbal practitioner.

**Official Complaint:** a written complaint regarding a practitioner addressed to the Council.

**Professional Association:** a professional herbal association which is affiliated to the Council.

## Abbreviations

PCC Professional Conduct Committee

PCO Professional Conduct Officer

PESC Professional Ethics Sub-Committee

PEAC Professional Ethics Appeal Committee

## Code of conduct

### 1. Compliance with Code of Conduct

Practitioners shall at all times comply with the Code of Conduct.

The principle of the code is to encourage honesty and responsibility in the practice of herbal

medicine. The Code of Conduct will be used when considering any complaint made against a practitioner. Practitioners failing to meet the requirements outlined below may be subject to disciplinary measures on the grounds of unacceptable professional conduct.

Practitioners are expected to seek advice from the Professional Conduct Officer or elsewhere if uncertain as to how to behave in any clinical or other situation.

Practitioners are reminded that this Code of Conduct represents minimally accepted standards of legal and ethical conduct in the United Kingdom at the present time. The primary reason for adhering to them is to ensure the well being of the patient, the public, of colleagues and of the profession.

The practitioner must be familiar with all laws or regulations relevant to the practice of herbal medicine in the locality in which they practise. The practitioner must obey the provisions of all current health and safety legislation, employment legislation, medical and pharmaceutical legislation. The practitioner should make her/himself aware of the relevant provisions of the Medicines Act 1968 and any subsequent medicines legislation.

Furthermore it is the responsibility of the practitioner to ensure that s/he becomes aware of any legal changes that may affect her/his practice.

The practitioner must be covered by professional and public liability insurance.

## 2. Relationship with Patients

### 2.1 Obligations to Patients

The relationship between the practitioner and the patient is a professional relationship and is based on trust. The practitioner must at all times exercise her/his moral judgement with regard to this relationship. In particular, the practitioner should listen to and respect the views of the patient and ensure that the practitioner's own beliefs do not adversely affect the therapeutic relationship. Where necessary, the practitioner should refer patients promptly to another competent health professional.

Practitioners must act with consideration when considering fees and justification for treatment.

It is unacceptable to solicit a patient by any means other than when treatment is specifically requested, but it is acceptable to advertise within the guidelines set out here.

Practitioners who have reason to believe that patients may be at risk due to their own ill health,

whether mental or physical, have an obligation to seek and to follow professional advice. Failure to act with regard to the interests of patients in this case may be regarded as unacceptable professional conduct.

Practitioners should not use their professional position as a means of pursuing an improper personal relationship with a patient or a relative/personal companion of a patient.

Where it appears that a patient is becoming involved in an improper personal relationship with the practitioner, it is the duty of the practitioner not to encourage the patient and to seek advice from another professional or from the Professional Conduct Officer.

Practitioners who find that they are becoming involved in a sexual or non-professional relationship with a patient should end the professional relationship and arrange alternative care for the patient.

## **2.2 Examination and Treatment of Patients: Informed Consent**

It is the practitioner's duty to explain the procedures applied in treatment, and to obtain informed consent for any treatment administered. Practitioners should inform patients about any matters relating to their condition, treatment or prognosis in a way that can be understood. The practitioner must recognise the right of the patient to refuse treatment and to refuse to follow advice.

Any physical examination requires the patient's consent, or the consent of the person legally responsible for the interests of the patient. Examination of any intimate area requires the presence of a third party unless explicitly agreed to by the patient.

A person from whom informed consent for examination or treatment is sought must possess the necessary intellectual and legal capacity to give consent. It is necessary to write on the patient record that informed consent was obtained. A person has the intellectual capacity if able to understand in simple language, what the examination or treatment is, its purpose and why it is being proposed, its principal benefits, risks and alternatives, and is able to retain the information for long enough to make an effective decision and make a free choice.

## **2.3 Treatment of Minors and Patients with Learning Disabilities**

In the case of minors or patients with learning disabilities, the informed consent of the

parent/guardian or the person legally responsible for the patient is necessary.

In the case of patients under the age of 16, practitioners are advised not to institute any examination or treatment unless they are satisfied that the patient's parent or other legal guardian has given informed consent.

Examination of a child under the age of 16 requires the presence of a third party.

In the case of patients aged over 16 but under 18, consent may be given by the patient, if able to make an informed decision, or by the patient's parent or guardian.

In the case of patients aged under 18, where there is or may be a conflict between the patient and a parent or guardian, or between parents, the practitioner is advised to seek the advice of the Professional Conduct Officer before undertaking any treatment or advice.

The practitioner is required to act responsibly when there is evidence of a child being at risk of sexual abuse or of other harm, and to contact the Child Protection Officer at the local social services department so that action may be considered under the Children Act (1989).

## **3. Competence**

Practitioners are responsible for undertaking continuing professional development.

Where offering another therapy apart from herbal medicine, practitioners must ensure that their training is adequate, that they remain aware of changes in that therapy, and that, where possible, they remain registered with the relevant professional association.

Where possible, the practitioner must ensure that s/he is aware of current practice in other health professions.

The practitioner must remain aware of current information relevant to the medical care that s/he gives and to the prescription of herbal medicines. It is the practitioner's duty to read and retain relevant documents received from the Council or affiliated professional associations and take note of the advice of the Medicines and Healthcare Products Regulatory Agency (MHRA), his/her professional association or the Traditional Medicines Evaluation Committee (TMEC) of the EHPA regarding the quality and safety of herbal medicines.

It is illegal for anyone not registered as a medical practitioner to attempt to procure an abortion. A

practitioner must not knowingly administer an abortifacient or emmenagogue herb for the purposes of procuring an abortion, nor use instruments for the purpose of procuring an abortion, nor assist in any illegal operation.

The practitioner must be aware of those diseases that are notifiable and take appropriate action in such cases.

## 4. Practice Management

### 4.1 Due Diligence in the Management of the Practice

Practitioners must take care to see that their practices are managed with due diligence. In particular, delegation of any professional duty, including preparation of medicines, should be made only in favour of those qualified to accept them. Where the practitioner has employed people, (paid or unpaid, e.g. receptionist, dispenser) to carry out a function in the practice, it is the practitioner's duty to ensure that they are suitably trained in their function, and are aware of the relevant parts of the Code of Conduct that relate to their activity within the practice. The practitioner is responsible for mistakes in dispensing and should ensure that dispensers are competent.

The practitioner is responsible for the actions of assistants, including students or colleagues who are not registered with the Council. Practitioners must ensure that patients are not misled, directly, indirectly or by default, so as to believe that any person giving treatment as an assistant is registered with the Council when they are not.

It is the practitioner's duty to ensure that adequate arrangements are made for patients to receive treatment if, or when, the practitioner is away from their practice for any length of time and to make patients aware of these arrangements. It is the practitioner's duty to provide adequate means of contacting the practitioner out of clinic hours.

The safe and effective disposal of disposable surgical appliances and examination equipment must be carried out as advised by the Council Quality and Safety Committee. The Environment Protection Act specifies that it is the duty of all persons involved in producing clinical waste to dispose of it safely and effectively.

It is the practitioner's duty to inform the patient of the Council's complaint and disciplinary procedures, if requested to do so by the patient or the person legally responsible for the patient's interests.

Practitioners must provide a practice complaints procedure and advise the patient who to contact in the first instance.

### 4.2 Patient Records

Patient records belong to, and thus are the responsibility of, the practitioner.

Patient records must on no account be transferred to a new practitioner without the authorisation of the patient.

Patient records should be retained in safe custody, by the practitioner to whom they belong, for a minimum of seven years from the date of the last appointment. Where the practitioner retires or otherwise ceases practice at any practice address, appropriate arrangements must be made for the safe custody of, and access of patients to, the records.

Where herbal practitioners work together, in any capacity, in the same practice or premises, they are advised to enter into a specific agreement as to the ownership and thus, responsibility for the records of patients.

Where practitioners practise at a clinic owned by a third party, the ownership of and responsibility for the patient records should be made clear in the contract between the parties.

If so requested by a patient in writing, a practitioner shall make available without delay copies of any patient records.

Where the patient wishes to transfer to another practitioner, a request for the transfer of patient records should be dealt with promptly.

Practitioners who retire or who sell practices are advised to follow good practice on sale of practices. In particular, they must ensure the continuity of patient care by making clear arrangements for the patient notes to be available to the patient if they wish to transfer to another practitioner or, with the consent of the patient, to the new practitioner. Patients should be informed of the intentions of the practitioner.

### 4.3 Confidentiality

The protection of confidentiality is a legitimate expectation of patients and failure to observe confidentiality may be regarded as unacceptable professional conduct.

The practitioner must abide by the law of the country including that relating to electronic recording of patient information including the Data Protection Act (1984).

Practitioners have an implicit duty to keep all information concerning, and views formed about, patients entirely confidential. Practice personnel must maintain the same level of confidence. This duty applies also to disclosure of information about a patient to a member of the patient's family, other than parent, guardian or the person legally responsible for the patient's interests.

A practitioner may disclose information relating to a patient if:

- disclosure is required by statute or law.
- the practitioner believes it to be in the patient's interest to disclose information to another health professional.
- the practitioner believes it to be essential for the sake of the person's health to disclose information to someone other than a health professional.
- the advice of the Professional Conduct Officer is that disclosure should be made in the public interest.

In each of the cases above the practitioner shall:

- inform the patient, before disclosure takes place, of the extent of the information to be disclosed, the reason for the disclosure and, where possible, the likely consequences.
- disclose only such information as is relevant, and ensure that the information is held in an appropriate manner by the person to whom it is disclosed.
- record in writing both the information disclosed and the reasons for disclosure.
- be prepared to justify the decision.

#### 4.4 Court Proceedings

Patient records do not enjoy legal protection; police can apply to a court for an order for access, and the Court may insist on disclosure.

If requested to provide a copy of patient records or to give evidence in court, the practitioner should immediately refer the matter to the Professional Conduct Officer for advice. In a court of law, the practitioner may request the court's exemption, for not wishing to divulge information between patient and practitioner on the grounds of professional confidentiality. If the court overrules this contention and requires disclosure, the practitioner should be aware that further refusal may place the practitioner in contempt of court.

Please note: In cases where the practitioner withholds information against a court's decision,

the court may construe the action to be an attempt to obstruct the course of justice. In cases where sensitive information is given to a practitioner, especially regarding activities of a possibly criminal nature, practitioners are strongly advised to take legal advice and to consult the Professional Conduct Officer.

#### 4.5 Research

When taking part in clinical trials, clinical audit, case history reporting, qualitative research or any other method of research, practitioners must ensure that:

- where appropriate, they adhere to a research protocol, which has been approved by the appropriate ethics committee, e.g. Traditional Medicines Evaluation Committee (TMEC) and that adequate records are maintained and the true findings published.
- informed consent is obtained from any patient involved.
- confidentiality of the patient is maintained.
- current professional guidance is sought.

### 5. Relationship with Colleagues

#### 5.1 Honourable Conduct

Practitioners must at all times conduct themselves in an honourable manner in their relations with fellow practitioners and other healthcare professionals.

Practitioners should be respectful of the treatment philosophy of other professional associations.

Practitioners must not speak publicly in a derogatory manner with reference to colleagues. Criticism of fellow practitioners and other healthcare professionals should be communicated in a discreet and professional manner through the appropriate channels. Critical views concerning a fellow practitioner's competence and/or behaviour should be brought to the attention of the Professional Conduct Committee through the PCO, where possible with necessary evidence and the consent of any patients concerned for information disclosure.

Action taken by a practitioner to persuade the patient of another practitioner to patronise her/him is in all circumstances considered unethical. It is advisable that practitioners should apply a clear and proper procedure when exchanging or referring patients or dealing with the patients of other practitioners.

Where a practitioner wishes to pursue a complaint against another practitioner, the principles and

procedures of the Council complaints and disciplinary procedure apply.

## 5.2 Communication with Other Healthcare Professionals

Herbal practitioners must always be aware of the necessity to communicate with the relevant healthcare professional, directly or indirectly, when the expertise of such a professional fits more properly the needs of a particular patient.

Subjects of communication may include a request that a particular medical investigation be conducted. This could be concerned with any of the following.

- Request to refer to other medical practitioners/services (e.g. consultant, speech therapist, counsellor, physiotherapist).
- Alert the prescribing practitioner to a possible adverse drug reaction; to discuss the possibility of a patient withdrawing from a conventional drug onto a herbal medication.
- Query the appropriateness of a specific investigative procedure, medication, treatment plan, or diagnosis.
- Alert the patient's doctor to a possible undiagnosed condition or other problem (e.g. suspected abuse).
- Inform of a herbal medicine being prescribed and to list its contents, actions and potential adverse drug interactions; to alert the patients doctor to a possible case of a notifiable disease.
- Request further details of the patient's case e.g. test results, prescribing details, treatment plan, diagnosis, prognosis.
- Ask for a professional opinion or to seek guidance and advice; to give feedback on a particular intervention; to give evaluation, criticism and praise.

When dialogue with another healthcare professional is deemed desirable the reasons for this should be explained to the patient. The patient should then have an opportunity to discuss these reasons. The patient's consent should be sought before contacting the other healthcare professional and their written and signed consent should be attached to the letter. A copy of all written communications should be kept on file and made available to the patient on request. There are circumstances when it may be appropriate to contact another healthcare professional without the patient's consent (e.g. in cases of threatened

suicide) or indeed their knowledge (e.g. when abuse is suspected).

A number of avenues of communication are open. These include letter, telephone, fax, email, and discussion in person. The professional letter however still remains the major medium for formal correspondence. Herbal practitioners are advised that all potentially important medico-legal issues should be documented in letter form and that copies of all originals should be kept on file. There may be times when a matter is of such urgency that a letter sent by post is an unsuitable first choice of communication. If a fax or email is sent instead, a copy of this should be kept on file. It may also be necessary to speak directly with a fellow healthcare professional, making email or fax an unfeasible alternative to a posted letter. In such cases a written account of the conversation should be made and saved. Such records will normally be appended to the patient's notes and/or in a file dedicated to professional case correspondence.

## 6. Relations with the Public

### 6.1 Honourable Conduct

Practitioners shall at all times conduct themselves in an honourable manner in their relations with the public.

Communication with the public may include advertising, contact through the media (newspapers and other publications, television, radio, world wide web), talks to public groups, discussions with enquirers. In all instances practitioners are required to conduct themselves in a manner congruent with the Code of Ethics. Practitioners must therefore avoid giving misleading claims to cure disease or in any way imply abilities beyond their competence.

### 6.2 Advertising

The promotion of a practitioner's practice should be in compliance with both legal requirements and with the British Code of Advertising Practice.

Advertising and promotion must not be false or fraudulent. It is not permitted for the practitioner, in any form, to claim a cure for illness.

In cases where there are no legal guidelines regarding this issue, advertising and promotions should be in accordance with the Code of Conduct and also in line with that of other healthcare professionals.

Advertising and promotion, both in form and content, on paper, websites or in any other presentation, shall

be appropriate to the interests of patients and to the standing of the profession. Advertising shall not denigrate colleagues or other professions.

### 6.3 Teaching

The practitioner must not teach or instruct in the practice of herbal medicine on any course, which is incorrectly presented as being accredited by the recognised accreditation authority.

## 7. Infringement of the Code

Infringement of this Code of Conduct may render practitioners liable to disciplinary action with subsequent loss of the privileges and benefits of registration.

A complaint can only be upheld when it is shown to be in breach of the Code of Conduct. However, it is the principle of ethical professional conduct which informs discussion of allegations made against practitioners. Practitioners must therefore always be prepared to explain and justify their actions and decisions. The interpretation of "unacceptable professional conduct" provided in the Code of Conduct cannot be exhaustive and is intended as guidance only.

The Professional Ethics Appeal Committee and Council (PEAC) are obliged to accept the findings of a court of law and are not able to re-open the investigation of facts which led to a conviction. The PEAC will consider only the seriousness of the conviction and any surrounding circumstances in mitigation. Practitioners should therefore treat with caution any encouragement to plead guilty to an offence and should take appropriate legal advice.

Where revalidation has been refused due to a relevant criminal offence (as defined by the PCC), due to ill-health or due to failure to fulfil the requirements of the revalidation committee, then the disciplinary procedure will be invoked by a complaint from the Board of the Council to the PCC.

## Complaints and disciplinary procedures

The following procedures will be used to investigate all allegations made against practitioners.

### 8. Complaints Procedure

#### 8.1 The Professional Conduct Committee

The Council will set up a permanent Professional Conduct Committee (PCC) which will have an effective role in promoting high standards of

professional conduct. It will continue to review practice within herbal medicine in the light of current good practice in health professions and the wider society.

The PCC will:

- be responsible for the effective implementation of the Code of Conduct, Complaints Procedure and Disciplinary Procedure.
- ensure that a system for monitoring and audit of procedures is in place and maintained.
- ensure procedures such that the strictest confidentiality is maintained at all parts of the procedure.
- ensure that the time taken to make decisions is reasonable.
- ensure that written or oral evidence is provided by any other relevant Council Committee such as or by any committee of a member professional body.

#### 8.2 Membership of PCC

The Chair will be the Member of the Council responsible for ethics and professional conduct. There should be seven Members. At least two should be non-practitioners and the composition of the Committee will include legal representation, elected representatives of the profession and appointed or elected laypersons. The appointment procedure will be transparent, fixed term, with formal declaration of interests.

#### 8.3 Professional Conduct Officer

The PCC will appoint a Professional Conduct Officer (PCO) who will be responsible to the PCC for implementation of the Complaints Procedure and Disciplinary Procedure. The PCO will be responsible for ensuring the progress of cases.

The PCO will be responsible for advising practitioners concerning the Code of Ethics and Code of Conduct, and complaints procedures.

#### 8.4 Verbal Complaints

Where a verbal complaint is received by any officer of the Council, this should be passed on immediately to the Professional Conduct Officer (PCO). The name, address and telephone number of the complainant should be noted. The PCO should call the complainant within 48 hours.

The PCO may:

- record the complaint on an action log and contact the practitioner verbally in an effort to

resolve the complaint. A system where some complaints can be dealt with informally and verbally can be supportive to all parties.

- request that the complaint be submitted in writing and send a pack including a summary of the Council complaints procedure and, where necessary, code of conduct, a form on which to give a statement and a form giving permission for an investigation.
- where the patient insists on remaining anonymous, enquire whether the complainant would like to speak to a mediator appointed by the Council.
- where the practitioner is not on the register of the Council, advise the complainant how to pursue the matter directly with the practitioner.

### 8.5 Written Complaints

Where a written complaint is received by any officer of the Council, it must be passed on immediately to the PCO and a reply sent within four days.

The PCO may:

- record the complaint on an action log and contact the patient and the practitioner by telephone in an effort to resolve the complaint.
- request further details and send a pack including a summary of the Council complaints procedure and where necessary, code of conduct, a form on which to give a statement and a form giving permission for an investigation.
- refer the complaint directly to the Professional Conduct Committee to refer to the Disciplinary Procedure.

The Professional Conduct Officer will need to be able to refer immediately to specialised legal advice where it appears that the complaint may have to be passed straight to the Disciplinary Procedure.

### 8.6 Progress of Complaints

The PCO, with reference to the Council Code of Conduct and related Council documents, will be able to resolve some complaints. The PCO must submit a report to the PCC of all complaints dealt with during the preceding period. The PCC will review the decisions and recommendations of the PCO.

When the complaint is resolved, whether verbally or by correspondence, the action log and any relevant documents must be kept on file for seven years. (Guidelines to be prepared for this procedure.)

### 8.7 Referral to PCC

Where the PCO refers the complaint to the PCC, the complainant must be kept informed of progress and informed of the next meeting date of the PCC.

The Professional Conduct Committee reviews all written complaints and has the authority to:

- dismiss the complaint.
- investigate whether the health of the practitioner is such that there is a risk to patients.
- complete the complaints procedure and, for example, reprimand the practitioner or advise the practitioner to take further training or advice.
- refer any complaint to be dealt with according to the Disciplinary Procedure.
- advise the Council to make an interim order suspending registration for a specified period, while the Disciplinary Procedure is completed. Criteria for such decisions will be prepared based on the General Medical Council interim orders committee referral criteria.
- advise that, where any practitioner against whom a complaint has been made which is under investigation, tenders her/his resignation or allows her/his registration to lapse by not renewing their subscription, the resignation will be received and placed on file but not accepted until the Complaints and Disciplinary Procedure is completed.

It is the duty of the PCO, acting on behalf of the PCC, to ensure that the practitioner complies with any advice. Non-compliance with advice may result in a further allegation of unacceptable professional conduct.

## 9. Disciplinary Procedure

Where the Professional Conduct Committee wishes to investigate an allegation of unacceptable professional conduct it will, within seven days, appoint a Professional Ethics Sub-Committee (PESC).

### 9.1 Composition of the Professional Ethics Sub-Committee

The PESC consists of not less than three and not more than five persons appointed by the Professional Conduct Committee. It should include a minimum of three herbal practitioners who provide a reasonably balanced representation of the Membership and preferably include a representative of the traditional system practised by the Practitioner concerned. If, after the first

hearing, the membership of the PESC shall fall below five, for any reason whatsoever, the remaining members of the PESC, who sat at the first hearing shall be deemed to be a properly constituted PESC for further or adjourned hearings, provided that their number does not fall below three. No more than one member of the PESC should be a member of the PCC, the Council or the Board of any of its associated professional bodies.

Any person about whose conduct a complaint has been made; who has lodged a complaint against a practitioner; is likely to be called upon to give evidence in relation to any such complaint; or, who is directly interested in its outcome shall not be eligible to sit on the PESC at which any such complaint is considered.

### 9.2 Notice to Practitioner

The PCC shall, within seven days of the decision to refer the complaint to the disciplinary procedure, serve on the practitioner concerned written notice of the allegation made against him including:

- full details of the complaint made against him/her.
- the date, time and place of the first hearing of the PESC which shall be not less than fifteen days after the date of service of the notice.
- notification of his/her right to submit a full written statement of evidence on his/her own behalf.
- a written request to submit oral evidence on his/her own behalf if s/he wishes to do so.
- notification that such statement and/or request must be served on the PESC not more than twelve days after service on the practitioner concerned of the notice specified in this clause.
- notification of the practitioner's right to seek legal representation.

### 9.3 Postponement of Hearing and Request for Further Evidence

The practitioner concerned may, not less than seven days before the date for the hearing notified to her/him (but not an adjourned or postponed hearing), serve on the PESC a request for further time in which to prepare her/his case. The PESC shall, on receipt of such a request, adjourn or postpone the hearing for a period of at least fifteen days from the date of the request for further time.

The PESC may call for any further evidence it requires to be submitted before the first or subsequent hearings (or any adjournment or postponement), provided that it serves on the practitioner concerned a written notice. This must include reasonably full details of the further evidence required and notify her/him of the right to submit a written:

- reply to such further evidence.
- request to give oral evidence in reply to such further evidence.

Such reply and/or request is to be served on the PESC not more than fourteen days after service on the practitioner concerned of such notice of further evidence. If there are less than fourteen clear days between the service of a notice requesting further evidence and the date (or adjourned or postponed date) of the first or subsequent hearing, the PESC shall postpone or adjourn such hearing and give notice thereof at the same time as it serves the notice of further evidence specified in this section.

### 9.4 Conduct of the Enquiry

The decision whether to accept oral evidence at the first hearing shall be at the absolute discretion of the PESC who shall, before the date of the first hearing (or any adjourned or postponed date) serve on the practitioner notice of such decision.

If the practitioner concerned shall fail to serve a statement and/or reply and/or notice in accordance with 9.2 or 9.3, the PESC may, after expiry of the time for service permitted by such clause, proceed to the first hearing without considering any written evidence which would have been included in such statement and/or reply and/or notice and in the absence of the practitioner concerned.

The PESC may adjourn or postpone (more than once, if necessary) any hearing for such period as it thinks fit. This is provided that at least fifteen days before the new date fixed for such hearing, it serves written notice of the new date, time and place for such hearing on the practitioner concerned.

### 9.5 Decision of Professional Ethics Sub-Committee

The PESC shall, at the time and place and on the date notified for the first hearing, or of any duly notified postponement or adjournment thereof, meet to decide whether a case of unacceptable professional conduct has been made out against

the practitioner concerned.

If it finds that a case has not been made out against the practitioner concerned, the PESC shall dismiss the case.

If it finds that a case has been made out, then it shall hear the matter and, if it finds the case proved, it may advise the Professional Conduct Committee to:

- admonish the practitioner.
- admonish and fine the practitioner concerned a sum not exceeding £2,000 requiring him/her to pay such sum within twenty eight days.
- make the practitioner subject to a conditions of practice order for up to three years, or a suspension order for up to one year and refer the case to the Professional Ethics Appeal Committee.

#### **9.6 Decision of Professional Conduct Committee**

The Professional Conduct Committee shall, not more than twenty-eight days after receiving the report from the PESC, submit a written report to the Council, and serve written notice on the practitioner concerned, of the decision of the PCC and of her/his right to appeal to the Professional Ethics Appeal Committee and details of the appeal procedure.

#### **9.7 Appeal by Practitioner**

If the practitioner concerned intends to appeal to the PCC against either the finding of the PESC or the penalty imposed or a fine imposed, s/he shall appeal not more than twenty eight days after service on her/him of written notice of the decision of the PESC and PCC. If the practitioner concerned fails to serve such notice within such time, her/his right to appeal shall be lost.

If the PCC shall have received notice of appeal in accordance with Point 9.7 and 9.8 it shall, within fourteen days, notify the practitioner of the date that the appeal procedure will begin.

#### **9.8 Service of Notices**

Notices to be served in connection with any procedure relating to unacceptable professional conduct shall be served in accordance with the following procedure.

- A notice may be served by the Council, PCC, PESC or PEAC upon any practitioner either in person or by letter, sending it by first class recorded delivery post addressed to the

practitioner at his/her last registered address.

- A notice so sent through the post shall be deemed to have been served two days following that on which the letter containing the same was posted.
- Any notice, requisition or other document which is to be served on the PCC, Council or any officer thereof may be served by sending it by first class postal delivery to the registered office.

#### **9.9 Professional Ethics Appeal Committee**

The Appeal will be heard by the Professional Ethics Appeal Committee. The PEAC shall have vested in it all the powers and discretions conferred upon the Council by the Memorandum of Association or by these clauses so far as they relate to any disciplinary action to be taken against a practitioner or the reason therefore.

#### **9.10 Composition of Professional Ethics Appeal Committee**

The PEAC shall consist of six to seven persons, including at least two lay members, who will be assisted by a Legal Assessor who shall be a barrister or solicitor. The PEAC is appointed by the Council, with the advice from the PCC, using appropriate procedures. If sufficient members of the PEAC are not available or eligible to form a quorum, sufficient additional persons may be appointed by the Council as members of the PEAC to constitute a quorum.

A minimum of four members of the PEAC must be herbal practitioners preferably including a representative of the traditional system practised by the practitioner concerned. No more than two members of the PESC should be members of the PCC, the Council or of the Board of any of its associated professional bodies.

#### **9.11 Notice to Practitioner**

The PEAC shall serve on the practitioner concerned written notice informing him/her of the hearing, which shall be not less than fifteen days after the date of service of such notice. The practitioner concerned will also be notified of her/his right to submit notice of his/her intention to be heard in person or through his/her counsel, solicitor or lay representative.

Such notice or statement to be served on the PEAC not more than fourteen days after service on the practitioner concerned of the notice specified in this clause.

The practitioner concerned may, not less than seven days before the date for the hearing (but not an adjourned or postponed hearing) notified to him/her, serve on the PEAC a request for further time in which to prepare his/her case. The PEAC shall, on receipt of such a request, adjourn or postpone the hearing for a period of at least fifteen days from the date of the request for further time.

### 9.12 Decision of Professional Ethics Appeal Committee

The PEAC shall at the time and place and on the date notified for the hearing or any duly notified postponement or adjournment thereof, meet to determine the case. In considering the case, a conviction of any offence or any finding of fact by a court or competent jurisdiction or of any other relevant professional tribunal shall be binding on the PEAC. After hearing all the evidence presented for and against the practitioner concerned, the PEAC shall determine whether s/he has been guilty of unacceptable professional conduct.

If it finds that s/he has not been guilty of unacceptable professional conduct, the PEAC shall dismiss the case.

If it finds that the practitioner has been guilty of unacceptable professional conduct it shall:

- admonish the practitioner.
- admonish and fine the practitioner concerned a sum not exceeding £1000, requiring her/him to pay such sum within twenty-eight days.
- make the practitioner subject to a conditions of practice order for up to three years or suspension order for one year.
- remove the name of the practitioner from the Register.

The PEAC shall, not more than fourteen days after the final hearing, serve written notice on the practitioner concerned of its decision, which will be final and binding on all parties and shall submit a written report to the Council.

The final decision to remove the name of the practitioner from the Register must be ratified at a meeting of the Council.

### 9.13 Fines

No practitioner who has been fined shall, so long as his/her fine remains unpaid, be entitled to attend or take part in the meetings of her/his Professional Association nor shall s/he be entitled to vote. If any practitioner on whom a fine has

been imposed in accordance with points 9.5 or 9.12 shall fail to pay such fine in full within the period required for payment thereof, the Council may resolve that name be removed from the Register forthwith and, if it thinks fit, the Council may prescribe a period of time during which no application for reinstatement of the practitioner concerned shall be considered.

### 9.14 Reinstatement onto Register

A person who has been removed from the Register, or whose membership has been terminated, may apply for re-admission to the Register. This is provided that such application is made after any period which has been prescribed in accordance with such clauses and subject to the provisions of Council Articles (reinstatement following termination of membership or expulsion from the Register).

### 9.15 Variation in rules

The Council, having been advised by the PCC, shall have power to make or vary rules for any matters or procedures relating to unacceptable professional conduct which are not covered by these clauses.

## 10. Recommended Appendices

Appendix 1	List of Legislation
Appendix 2	Guidance to Children Act 1989
Appendix 3	Notifiable Diseases
Appendix 4	Access to Health Records 1990
Appendix 5	Advertising
Appendix 6	Data Protection Act 1984
Appendix 7	Remit of Health Committee and Remit for Investigation

## ANNEX IV: CORE SCHEME FOR CONTINUING PROFESSIONAL DEVELOPMENT

### 1. Mandatory Scheme

There is a growing emphasis on the importance of lifelong learning as a condition of self-regulation by the professions and by health professionals in particular. This is reflected in the Department of Health consultative document *Supporting Doctors, Protecting Patients*

([www.doh.gov.uk/cmconsult.htm](http://www.doh.gov.uk/cmconsult.htm)), which emphasises that regulatory bodies must concern themselves with the competence and conduct of practitioners at all stages of their careers. It proposes that in future all registered doctors will be periodically required to demonstrate that they are up to date and fit to practise in their chosen field. The aim is to move away from a reactive model which attempts to assure fitness by dealing with exceptions, and instead to provide a positive reaffirmation of continuing fitness to practise.

Continuing Professional Development (CPD) is a central part of this process. Mandatory CPD is built into the Osteopaths and Chiropractors Acts, and it is appropriate for the herbal profession to demonstrate a similar serious intent. The implication of the adoption of a mandatory scheme is that unless members fulfil the requirements of CPD they incur some penalty, including as a last resort loss of membership of the professional body. It will be up to the proposed statutory herbal body to establish the rules in detail.

In order to allow time for consultation with the membership, to provide a supportive environment in relation to the culture of continuing learning, and to evaluate the initial results of the present scheme, it is proposed that the scheme become mandatory after a preparatory period. This period is to be decided by the statutory body. It is also proposed that the scheme be reviewed three years after implementation.

### 2. Criteria

The research evidence shows that attendance at formal courses is only one part of the continued learning of practitioners. Practitioners also learn in important ways from the problems that face them in relation to their own practice, and from other practitioners who may be more senior to them or at the same level of experience. This latter may be called the 'community of practice', which poses a particular challenge to herbalists (and other practitioners in the field of complementary and alternative medicine), who are likely to suffer from isolation. A practitioner also learns from teaching or supervision (which involves reflecting on and synthesising knowledge), and of course from research activities and publication. Contribution to the work of professional and accreditation bodies is a form of participation in the community of practice in a wider sense, and so also deserves to be included within the CPD context. Hence it is important that a wide variety of activities qualify as criteria of professional development.

In common with many other professions the proposed scheme is based on the accumulation of credits. However, since there is the risk that this form of assessment highlights what is measurable at the expense of what is really useful, we make provision for members to include 'any other activity' that they might wish to be considered. This means that the scheme in principle allows members themselves to define what is most important for their practice, to set goals and to relate their CPD activities to this context. Such a provision is in line with the Department of Health Review of Continuing Professional Development in General Practice

([www.open.gov.uk/doh/cmoh/cmoh.htm](http://www.open.gov.uk/doh/cmoh/cmoh.htm)) which stresses that forms of learning which have in the past not been credit-bearing, should be recognised and valued. These might include, for example, reading, informal discussion with colleagues and participation in email groups. An additional benefit of such flexibility is that it broadens opportunities for practitioners who might find it difficult to take advantage of formal CPD events, whether for reasons of cost, distance or because of the cultural context (for example, practitioners from ethnic minorities, though perfectly competent in English, might not be attracted to events that take place within a majority-culture setting).

We propose that members must obtain at least eight credits a year. The credits may be gained from the following activities, which need not

necessarily be directly concerned with herbal medicine, but which must constitute a further development of areas of study covered in the core curriculum.

- a. Attending a seminar/conference: one day = 4 credits
- b. Attending peer support groups: one meeting = 2 credits
- c. Supervision with a more senior practitioner, which could be on a one-to-one or group basis = 2 credits per session, with a minimum of two hours per session
- d. Undertaking supervision of new practitioners = 2 credits per session, with a minimum of two hours per session. It is recommended that supervisors undertake training in supervision, and they will be advised of relevant courses
- e. Teaching at an accredited college or seminar: one day = 4 credits
- f. Study trip to a hospital or clinic, minimum of one week = 8 credits
- g. Article published in a professional journal: one article = 8 credits
- h. Attendance at an MSc, MPhil or PhD course = 8 credits per year
- i. Authorship of an academic or professionally-oriented book = 8 credits per year (with report on progress after each year) up to a maximum of 24 credits over three years
- j. Contribution to the work of a relevant professional body (committee work, project groups, accreditation board) = maximum of 4 credits over a one-year period
- k. Any other activity that a member might wish to be considered (in this case the CPD committee will be able to advise on which activities can count as CPD)

The credits suggested here are eminently achievable, and are made more so by the emphasis attached to item (k). The aim is not to set up hurdles for their own sake but to facilitate and encourage a culture of continuous professional development.

### 3. New Practitioner Scheme

A new practitioner scheme will be implemented. For the first two years of membership, newly graduated members will be required:

- a. To participate in clinical supervision sessions: six hours in the first year, four hours in the second year
- b. To attend two postgraduate seminars per year
- c. To present a completion portfolio which records hours of supervision and seminars attended

Thereafter, the requirement to obtain eight credits per year would come into effect.

### 4. Extenuating Circumstances

A policy on extenuating circumstances, relating for example to chronic illness, maternity leave or absence abroad will need to be defined by a CPD committee of the statutory herbal body. In such circumstances it might be decided to allow for the accumulation of credits over a longer period, for example, two years rather than one year. If such a policy were adopted and the practitioner were unable after two years to provide evidence that the requirements had been met, a policy on temporary suspension from the register (with clear conditions for re-entry) would need to be established.

### 5. Administration of the scheme

A committee of the statutory herbal body will administer the scheme. Administration will include approving courses for CPD status. Courses run by accredited colleges, and by colleges which have been accepted as candidates for accreditation, will be given automatic approval; other courses will need to be sanctioned by a CPD committee.

### 6. Appeals Procedure

The process of assessment will need to be transparent, with a clear and independent disputes procedure in the event that a practitioner challenges a decision of the CPD committee.

## ANNEX V: GRANDPARENTING

### Introduction

A grandparenting scheme is intended to ensure that the following practitioners are given a vehicle through which they can attain statutory regulation and inclusion on the Register of Herbalists administered by the Herbal Council or CAM Council.

1. Herbalists in practice prior to the introduction of statutory regulation.
2. Herbalists who trained through a professional association which was not party to the development of statutory regulation.
3. Herbalists who do not belong to any professional association.
4. Herbalists who trained overseas and who wish to practise in the UK.

It is recognised that herbalists currently in practice have a wide range of training, skills and experience. These proposals for grandparenting acknowledge this diversity and seek to be as inclusive as possible whilst ensuring a standard of practice that is commensurate with the requirements of public safety.

The scheme should be affordable as well as simple to understand and achieve, practical to administer and transparent in accountability and evaluation. It should be an enabling process for the applicant, so that in the event of any questions arising during the assessment, the applicant will be given full guidance in respect of the measures deemed necessary for successful entry to the Register.

### Stage One: For All Applicants

Applicants seeking inclusion on the Register of Herbalists may be accepted on the basis of a Professional Portfolio providing written evidence of competence to practise, the details of which are set out below.

The Professional Portfolio should include the following data.

- A written application.
- Proof of the criterion the 'three out of five year rule', i.e. lawfully, safely and effectively practised for at least three out of the five years prior to the opening of the Register. The

Register will have the power to modify this requirement in the case of new graduates or practitioners who have taken a career break for children or other reasons.

- Where applicable proof of attainment of CPD credits for the past year as specified in the CPD policy.
- A character reference from a person (unrelated to the applicant) of good standing in the community who has known the applicant for at least four years. Where applicable this person may reside abroad.
- A health reference from a medical practitioner or recognised health professional certifying that the applicant enjoys reasonable physical and mental health. (Recognised healthcare professional could include a member of the Register of Herbalists).
- Professional references from a member of a recognised health profession (MD or Member of Register of Herbalists).
- Details and evidence of training undertaken by the applicant. The applicant should provide original copies of certificates/diplomas of herbal qualification from the college/university concerned. In cases where such certificates/diplomas are unavailable, the applicant should provide an original and certified letter from the relevant college/university that confirms the period of training of the applicant and the qualification obtained. In addition, the applicant may be required to provide a transcript of their academic record or details of the curriculum studied. Any documents not in English should be accompanied by an original translation from a recognised translator (not a colleague or a friend). Where the academic institution studied at is no longer in existence, or where entry into the profession was through another route, and the applicant is a member of a recognised professional body evidence of CPD will be considered a major part of the entry criteria.
- Proof of time spent in safe and competent current practice. To determine these criteria, the applicant should provide evidence of membership of any professional herbal register and maintained professional indemnity insurance in respect of herbal practice or details of any other circumstances in which the applicant has worked as a herbal practitioner detailing the nature and extent of this practice.

- Copies of any leaflets or information that they use, and copies of any adverts/yellow pages entries used.
- Details of any professional misconduct ruling or claim for malpractice either currently in train or previously upheld against the applicant.
- In the case of a practitioner without an EU passport, provide evidence sufficient to show that the applicant has a satisfactory command of English. If the applicant is unable to speak English, evidence that all consultations are carried out in the presence of a qualified interpreter. The applicant would be given a period of time (e.g. two years) to achieve language competence.
- Details of any other health professional qualifications.
- The appropriate fee. The applicant will be expected to make an Enhanced Disclosure Application to the Criminal Records Bureau.

It is envisaged that the following categories of practitioner would be accepted onto the register on submission of the professional portfolio meeting the above criteria.

1. Graduates of fully accredited degree courses in Herbal Medicine both in the UK and abroad.
2. Practitioners who completed training courses that were approved by professional associations affiliated to the Herbal Council or CAM Council, before the introduction of accreditation of courses.

## Stage Two: Where the Professional Portfolio is Incomplete

Where the Register deems necessary, an applicant may be called for an interview in person and may be required to take a Test of Competence to ensure fitness to practice.

The Inspection Panel, after looking at the information provided in a professional portfolio, may subsequently require the applicant to pass a Test of Competence described below, or such part of it as the Registrar considers appropriate after consulting the Education and Training Committee.

It is envisaged that the Education and Training Committee would determine the required criteria for each element of the Test of Competence. These would be:

- Written Case Histories
- Interview

- Practical Clinical Examination

The prescribed Test of Competence may be a written and/or oral test conducted and assessed by a panel of three practitioners appointed by the Registrar. At least two of the practitioners on the panel should be trained in the specific herbal tradition practised by the applicant. The applicant will be required to:

- Present five case histories demonstrating an understanding of the system of herbal medicine s/he is practising and clearly explaining the diagnosis and treatments appropriate to each of the case histories presented. The applicant may be further questioned by the panel about these case histories as well as about other cases outside the scope of the case histories presented.
- Demonstrate an understanding of orthodox medicine and the interactions between herbal medicines and pharmaceutical drugs. Understand adverse events in herbal medicine.
- Show an understanding of the UK and EU medicines legislation insofar as it pertains to herbal medicine and the legal position of herbalists.
- Show understanding and acceptance of the Code of Ethics as laid down by the Herbal Council or CAM Council.

The prescribed Test of Competence may in addition, if the Registrar and Panel so require, include a practical clinical examination of a patient, provided by the panel in order to further evaluate the applicant's clinical skills.

The prescribed Test of Competence shall be conducted by examiners appointed by the Herbal Council or CAM Council who have not less than five years of experience in herbal practice and have successfully completed a course of training in the methods of assessing an applicant undergoing the Test of Competence.

## Required Undertaking

Following a Test of Competence, the Registrar, after consultation with the Education and Training Committee, may specify additional training and experience to be gained by the applicant to enable the applicant to be able to meet the required standard of proficiency. At least one of the practitioners on the panel should be trained in the specific herbal tradition practised by the applicant.

In the event of additional training being necessary, the applicant will be given a reasonable timeframe in which to complete the requirements. S/he will receive supervision during this period, enabling her/him to practise within a safe and supportive framework, providing that the panel receives an undertaking of intention to complete.

Applications under the transitional arrangements can only be made during the two-year transition period, which begins on the date that the Council Register is opened by Privy Council. There is no legal discretion to extend the transitional period.

Applicants who fail will be allowed to reapply within a given timeframe.

An appeal process will need to be set in place. Careful consideration needs to be given to how this will be administered.

## ANNEX VI: PROPOSED CORE CURRICULUM FOR AYURVEDIC MEDICINE IN UK

**Prepared by Department of Indian Systems of  
Medicine and Homeopathy**

**Ministry of Health and Family Welfare**

**Government of India, New Delhi**

The curriculum is prepared assuming that the students will also be taught the basic subjects of modern western medicine such as Anatomy, Physiology, Preventative and Social Medicine, Forensic Medicine and Toxicology. The Curriculum covering Ayurvedic medicine will contain the following subjects.

1. Fundamentals of Ayurved.
2. Dravya-guna Vigyan (materia medica and Pharmacodynamics of medicinal plants and minerals).
3. Rasashastra-Bhaishajya – Kalpana (Ayurvedic pharmaceutical procedures).
4. Nidan Panchak and Samprapti Vigyan (Five Diagnostic Modalities and Aetio-Pathogenesis)
5. Kaya-Chikitsa (internal medicine).
6. Shalya-shalakya (Ayurvedic General Surgery, E.N.T. and Ophthalmology).
7. Streeroga-Prasuti tantra and Kaumar-bhritya tantra (Ayurvedic Gynaecology, Obstetrics and Paediatrics).

### 1. Fundamentals of Ayurved

The subject deals with the fundamental principles of Ayurved and covers the science of Dosha – the Humors, Dhatu – the Body Tissues, Malas – the Excretory Products along with the anatomical concepts of Ayurved.

#### Theory Curriculum

Number of Lectures: 150

Content.

1. Definition, scope and introduction of *Ayurved*, Evolution of Universe.
2. Concept of *Purusha* – the subject of medicine and Prakriti, the primordial substance.

3. Theory of *Panchmahabhootas* (Five Basic Materialistic Elements) and its relation to the human body. Organic and physiological division of the human body.
4. Concept of *Dosha, Dhātu, Mala* and their relation to the human body.
5. Three *Doshas* – the three Humors.
6. Seven *Dhatus* – the seven Body Tissues.
7. Three *Malas* – the three Excretory Products.
8. *Prakriti* and *Sara* – physical and psychological constitution and differential tissue quality.
9. *Agni* – the biofire and process of digestion and metabolism.
10. *Srotas* and their functions. The channels of circulation.
11. *Upadhatus, Sira, Dhamani, Snayu, Kandara, Kala*, etc.
12. *Ojus*.
13. Sensory and motor organs.
14. Concept of *Manas*, i.e. Mind.
15. *Marma* – the vital points of the body.
16. Concept of fertilization and embryo foetal development.

### Practical Curriculum

Number of Practicals: 100

Content.

1. Examination of an individual for determination of *Prakriti*. The physical and psychological constitution.
2. Examination of an individual for determination of *Sara*. The differential tissue quality.
3. Examination of an individual for *Srotas*. The body channels.
4. Examination of urine, stool and blood.
5. Location of *Marma*. The vital points.

## 2. Dravya-guna Vigyan: Materia Medica and Pharmacodynamics of Medicinal Plants and Minerals

The subject basically deals with the general principles of materia medica and pharmacodynamics in Ayurved and the physicochemical and medicinal properties of raw materials and drugs used in Ayurvedic Medicines

e.g. medicinal plants, medicinal minerals, substances of animal origin, marine products, etc.

### Theory Curriculum

Number of Lectures: 150

Content.

1. Concepts and principles of *Dravya-guna vigyan*.
2. Five basic materialistic (Panch-bhoutik) composition of *Dravya*.
3. Classification of *Dravya*. (Types of Matter). Classification of *Ahar dravya*.
4. Food articles. Definition of comparison of Food and Drug.
5. Concept of *Guna* – (Properties of Substances) *Atma-guna, Vaisheshik guna and Samanya guna* (*Gurvadi and Paradi*).
6. *Rasa* – its properties, actions and therapeutic effects.
7. *Veerya*, the active principle, *Vipak*, the end product of metabolism and *Prabhav*, a specific action.
8. *Karma* – the pharmacological action.
9. Study of medicinal plants – 200.
10. Poisonous medicinal plants.
11. Technical terminology in relation to standard drug formulations.
12. Introduction, physicochemical, therapeutic properties, therapeutic uses of *Rasa*, mercury and its compounds, minerals, metals, sub-metals, *Ratna*, the precious stones useful in medicine. (Note: the study of mercury is for historical reasons only. Mercury is a poisonous substance.).
13. Principles of administration of drugs and dose schedules. Concept of *Anupan* and *Sahapan*.
14. Study of 200 important single and multi-ingredient medicinal formulations.

### Practical Curriculum

Number of Practicals: 50

Content.

1. Identification of morphological study of 200 medicinal plants.
2. Identification and study of organoleptic characters, physicochemical properties of all the mercury, compounds of mercury, metals, sub-metals, minerals, marine products and

animal products useful in medicinal preparations. (Note: the study of mercury is for historical reasons only. Mercury is a poisonous substance.).

3. Preparation of herbarium. 100 medicinal plants.

### 3. Rasashastra-Bhaishajya – Kalpana: Ayurvedic Pharmaceutical Procedures

The subject deals with the pharmaceutical procedures used in preparation of Ayurvedic medicines

#### Theory Curriculum

Number of Lectures: 150

Content.

1. Technical terminology used for drug processing and pharmaceutical procedures.
2. Equipment and instruments used in pharmaceutical procedures and drug processing.
3. Five basic drug delivery systems for preparations of medicinal plants, i.e. *Panchavidha Kashaya kalpana*.
4. Methods of preparation of various drug delivery systems.
5. Medicated oils and ghee.
6. Fermentation and fermented medicinal preparation. (*Sandhan Kalpana*).
7. Ophthalmic and nasal drug delivery systems.
8. External applications.
9. Concept of *Basti*, the enemata and method of preparation.
10. Methods of preparation of food preparations (*Kritanna kalpana*).
11. Concept of purification procedures of medicinal substances. Concept of pharmaceutical processing (*Sanskar*).
12. Pharmaceutical procedures used in preparation of mineral medicinal formulations.
13. Pharmaceutical processing of mercury. (Note: the study of mercury is for historical reasons only. Mercury is a poisonous substance.).
14. Pharmaceutical procedures of mercurial medicinal formulations. (Note: the study of mercury is for historical reasons only. Mercury is a poisonous substance.).

15. Pharmaceutical processing minerals.
16. Pharmaceutical processing of metals and sub-metals.
17. Pharmaceutical procedures of medicinal formulations of *Ratna*, the precious stones and marine products.
18. Processing of poisonous medicinal plants.
19. Pharmaceutical processing of 100 important classical formulations.

#### Practical Curriculum

Number of Practicals: 100

Content.

1. Preparation of *Panchavidha Kashayas*.
2. Preparation of various drug delivery systems.
3. Preparation of medicinal oils and ghee.
4. Preparation of external applications.
5. Preparation of dietary preparations.
6. Preparation of fermented medicinal preparations.
7. Pharmaceutical processing of mercury and preparation of mercurial medicinal formulations. (Note: the study of mercury is for historical reasons only. Mercury is a poisonous substance.).
8. Pharmaceutical processing of minerals.
9. Pharmaceutical processing of metals and sub-metals.
10. Pharmaceutical processing of marine products.
11. Pharmaceutical processing of *Ratna*, the precious stones.
12. Processing of poisonous medicinal plants. Preparation of 50 classical formulations.

### 4. Nidan Panchak and Samprapti Vigyan: The Five Diagnostic Modalities and Aetio-Pathogenesis

The subject deals with general as well as specific aetio-pathogenesis of the disease process.

#### Theory Curriculum

Number of Lectures: 150

Content.

Part a.

1. Concept of *Nidan panchak* – the five diagnostic modalities of a disease.

2. Concept of *Chaya* – the accumulation and *Prakop* – the spread of the *Doshas* – the humors.
3. Aggravated and depleted states of *Dosha*, *Dhatu* and *Malas*.
4. *Shadkriya kala* – Stages of the manifestation of disease where the disease process can be intercepted.
5. *Srotodushti* and related diseases.
6. Interrelationship of disease and *Doshas* – cause and effect relationship.
7. Definition of disease - classification of diseases.
8. Clinical methods of examination *Rogi-roga* pariksha.
9. General and specific methods of diagnosis.
10. *Samprapti vigyan* including concept of *Dosha-dooshya Sammorchana*.
11. Role of *Agni* – the biofire in pathogenesis. Concept of compatible and incompatible food and drug combinations.
12. Concept of *Aam* – the Pathogenic Metabolites. The concept of *Saam* and *Niraam* stages of disease.
13. Five diagnostic modalities *Panch Nidan - Hetu*, the causative factors, *Poorvaroop*, the prodromal symptoms, *Roop*, the clinical manifestations, *Upashaya*, the palliative factors, *Anupashaya*, the provocative factors and *Samprapti*, the pathogenesis.
14. Concept of *Aavaran* and *Ashayapakarsha*.
15. *Upadrava* and *Arishta*. *Sequalae*, complications and prognostic features of the disease.
16. *Janapadodhwansa* the epidemiology.
17. *Oupasargik roga*, the infectious disease.

Part b.

Study of Etiopathology, clinical manifestations, diagnosis, complications and prognosis of the following diseases.

1. Diseases related to various *Srotas*.
2. *Jwara* (pyrexia).
3. *Pandu roga* (anaemia), *Udar roga* (ascites).
4. *Prameha* (diabetes).
5. *Vata vyadhi* (neurological disorders).
6. *Agnimandya*, *Ajeerna*, etc. (diseases related to the digestive system).
7. *Yakrit roga* (liver diseases).
8. *Medoroga* (obesity).
9. *Manas roga* (mental disorders).
10. *Kushtha roga* (skin diseases).
11. *Guda roga*, (ano-rectal diseases).

### Practical Curriculum

Number of Practicals: 50

Content.

1. Methods of examination of a patient. *Ashtavidha*, *dashavidha* pariksha.
2. Method of examination of *Srotas*, the channels of circulation.
3. Examination of urine, stools, sputum, blood, etc.

### 5. Kaya Chikitsa: Internal Medicine

The subject deals with general Ayurvedic medicine i.e. the general basic principles of management of disease, understanding of the specific pathogenesis and management of specific diseases.

#### Theory Curriculum

Number of Lectures: 200

Content.

1. General preventive aspect of disease. Definition of health, daily routine i.e. *Dincharya*, the Seasonal Regimens, i.e. *Ritucharya*. Principles of healthy lifestyle, personal and social hygiene.
2. Three pillars of life (*Trayopastambh*) *Sadvritta* the Code of Social Conduct.
3. Dietary habits and way of life (*Aahar and Vihar*).
4. Suppressible and non-suppressible urges.
5. Principles of beneficial and harmful behavioural practices (*Pathya and Apathya*).
6. Introduction to *Kaya-chikitsa* and basic principles of management of disease. Concept of *Trividh chikitsa* (*Daiva vyapashraya*, *Yukti vyapashraya* and *Satvavajaya*).
7. *Kriya-kala*, the stages of intervention of disease process.
8. Management of conditions resulting from abnormal states of *Dosha*, *Dhatu* and *Mala*.
9. Principles of management of *Dosha* specific conditions.

10. Concept of *Saam and Niraam* states of diseases and their management.
11. Concept of *Aavaran* and its management.
12. *Ashayapakarsha* and diseases related to distortion of *Dhatu* and its management.
13. *Shadvidha and Dwividha Upakrama*. Six and two modalities of treatment. Biopurificatory and palliative procedures (*Shodhan* and *Shaman*). Principles of dietary management of disease. Importance of avoidance of disease causative factors (*Nidan-parivarjan*).
14. Classification of diseases.
15. Management of *Jwara*, (pyrexia).
16. Management of disease related to *Srotas*.
17. *Yakrit roga* (liver diseases).
18. *Pandu roga* (anaemia), *Udar roga* (ascites).
19. *Prameha* (diabetes) *Medo roga* (obesity).
20. *Agnimandya*, *Ajeerna* (diseases related to digestive system).
21. Management of skin diseases.
22. Nutritional disorders.
23. Sexually transmitted diseases.
24. *Vata Vyadhi* - neurological and musculo skeletal diseases.
25. *Kushtha roga*.
26. *Kshudra roga* (skin diseases).
27. *Manas roga* (mental disorders).
28. *Jara vyadhi* (geriatrics).
29. *Panchakarma* – the five Bio-Purification Procedures. *Poorva* and *Pashchat karma* and dietary regimens after purification therapy.
30. *Rasayana* and *Vaajikaran* (rejuvenation and aphrodisiacs). Eight Yogic Practices, the Ashtang Yoga and their application in the management of somatic and psychosomatic and psychological disorders. Stress Management – Ayurvedic and Yogic Practices.

### Clinical Training

Number of Training Days: 100

## 6. Shalya-Shalakyā: Ayurvedic General Surgery, ENT and Ophthalmology

The subject deals with the concept, principle and practises including surgical management of diseases involving minor surgical procedures and certain specialised therapies practiced in general as well as in ENT and Ophthalmic diseases.

### Theory Curriculum

Number of Lectures: 100

Content.

Part a.

1. *Susruta's* contribution to surgery. *Ashtavidha Shalya karma*, the eight basic surgical procedures. *Shashti upakram*, the sixty procedures.

Surgical Management of following conditions:

2. *Vrinashotha* (inflammatory condition).
3. *Vidradhi* (abscess).
4. *Vrina* (ulcer and wound).
5. *Raktasraava* (haemorrhage).
6. *Arbud* (tumor).
7. Diseases related to *Sira*, *Dhamani* (vascular diseases) and skin diseases.
8. Disease related to *Mansdhatu* and *Snayu* (musculo-skeletal disorders).
9. Management of fracture, dislocation and joint diseases. *Manya vikar*.
10. Ano-Rectal diseases – *Bhagandar* (anal fistula), *Arsha* (haemorrhoids), *Parikartika* (fissure) etc.
11. *Mootrakricchra* (urinary disorders).
12. Disease related to *Yakrit* (liver), *Pittashaya* (gallbladder), *Pliha* (spleen) and other vital organs.
13. *Aantra vridhhi* (hernia), *Vrishan vridhhi* (Hydrocele), *Niruddha prakash* (phymosis, para phymosis), *Guda bhrinsha* (rectal prolapse).
14. Para surgical procedures - *Ksharsutra*, *Agni*, *Jalauka* etc.

Part b.

1. Diseases of the eye and their management.
2. Diseases related to the head e.g. *Suryavarta*, *Ardhavabhedak*, *Anantwat* etc. and their management.

3. Diseases of the ear and their management.
4. Diseases of the nose and their management.
5. Diseases of the throat and oral cavity and their management.
6. Dental diseases and their management.
7. Ophthalmic drug dosage forms.

### Clinical Training

Number of training days: 50

## 7. Streeroga Prasuti tantra and Kaumar-bhritya: Ayurvedic Gynaecology, Obstetrics and Paediatrics

The subject deals with Obstetrics, Gynaecology and Paediatrics described in Ayurved.

### Theory Curriculum

Number of Lectures: 100

Content.

1. Anatomy and physiology of female reproductive system.
2. *Rajovigyan*, the physiology of menstruation.
3. Fertilization and embryo foetal development.
4. Concept of female health in *Ayurved*. Lifestyle during pregnancy and lactation period.
5. Physiology of pregnancy.
6. Pregnancy related disorders and their management.
7. Normal labour and its management.
8. Labour related problems and their management.
9. Purperium and diseases related to purperium and their management.
10. Menstrual disorders, infertility, *Yonivyapad*, prolapse of uterus, fibroid, leucorrhoea and other gynaecological disorders.
11. Diseases of the breast and their management.
12. Problems of menopause and their management.
13. Paediatrics in *Ayurved*. Concept of child health, (*Balak paricharya*). Division of childhood. Principles of food and drug administration in children.

14. Principles of management of paediatric diseases.
15. Introduction and management of paediatric diseases described in *Ayurved* like Griha badha, Fakka, nutritional disorders. Concept of nutrition in paediatrics in *Ayurved*.

### Clinical Training

Number of Training Days: 50

Summary of Subject, Theory and Practical

1. Fundamentals of Ayurved	150	100
2. Nidan Panchak and Samprapti Vigyan	150	50
3. Dravya-guna Vigyan	150	50
4. Rasa-shastra , Bhaishajya – Kalpana	150	100
5. Kaya-Chikitsa	200	100
6. Shalya-shalakya	100	50
7. Streeroga-Prasuti-tantra and Kaumar-bhritya tantra	100	50
<b>Total</b>	<b>1000</b>	<b>500</b>

Each theory lecture will be of 50 minutes duration while the practical will be of 100 minutes duration. Thus the total syllabus will have to be covered in 1666 hours.

This curriculum should be substantially supplemented by teaching of modern medicine.

Theory – 833 hours

Practical – 833 hours

### Note

1. This curriculum and the number of theory, lectures and practical are designed to equip a person to practice Ayurveda.
2. A course curriculum comprising less than 1666 hours would not be supported as this would not provide sufficient training for the practice of Ayurveda.
3. Bibliography, textbook and reference books, research papers, etc would be provided.

A REPORT FROM THE HERBAL MEDICINE REGULATORY  
WORKING GROUP:

# REFORM OF SECTION 12(1) OF THE MEDICINES ACT 1968

## Explanatory Notes

This document is the result of deliberations over the past eighteen months by the Herbal Medicine Regulatory Working Group (HMRWG) which has been charged by the Government with the task of making proposals for public discussion for the reform and updating of Section 12(1) of the Medicines Act 1968.

In order to help understand this document, much of which is necessarily technical, this section summarises UK medicines law as it currently affects the sale and supply of herbal medicines. It also outlines the main reasons for reform of Section 12(1) of the Medicines Act 1968 in a way that assumes no prior knowledge.

At present, the majority of herbal medicines on the UK market are sold and supplied as unlicensed herbal remedies under a legal provision dating back to 1968. The main European medicines legislation (Directive 2001/83/EC) requires that medicines placed on the market must have a licence (known as a marketing authorisation). This is based on showing that the product meets standards of safety, quality and efficacy. However, for some herbal medicines it can be difficult to show efficacy to the standard required to get a marketing authorisation. This is mainly because plants are chemically very complex and variable and the active constituents are not always known. For this reason, there are a relatively limited number of licensed herbal medicines on the UK market.

Under the terms of the Medicines Act 1968, herbal remedies in the UK are exempt from the requirement to obtain a medicines licence under certain conditions. Either the herbal remedy must be made up on the premises from which they are supplied and be prescribed after a one-to-one consultation (Section 12(1)) or, if it is an over-the-counter (pre-prepared) remedy, then it must not make any written therapeutic claims (Section 12(2)). In both cases the remedy must comprise only plant materials.

For a long time this aspect of medicines law, which left herbal medicine essentially unregulated in terms of quality and safety, appeared adequate. But in recent years, along with a rapid expansion of the herbal sector, questions have arisen about the quality and safety of some herbal products. These questions have been variously associated with:

- a. adverse effects resulting from the inherent toxicity of certain herbal ingredients (natural does not always mean safe);
- b. misidentification or substitution of one plant species for another, in some cases leading to the substitution of a safe with a toxic species;
- c. adulteration of herbal medicines with prescription-only drugs or heavy metals;
- d. microbial or fungal contamination of herbal remedies;
- e. discovery of possible herb-drug interactions which may interfere with or confuse the results of treatment;
- f. insufficient information provided to the consumer concerning the safe use of a herbal medicine.

For all these reasons, measures to reform the Medicines Act 1968 herbal provisions are now underway. UK law relating to the sale and supply of over-the-counter (OTC) herbal remedies (Section 12(2)) is set to be replaced by a proposed European Directive, the Traditional Herbal Medicinal Products Directive, which is to establish a registration scheme for authorising manufactured OTC traditional herbal medicines. Under the terms of this proposed Directive, manufacturers will have to demonstrate safety and quality (guided by European Good Manufacturing Practice - GMP), but not efficacy. Safety will be ensured by requiring the evidence of at least thirty years of safe use. The Directive is currently under negotiation in Europe where it has found considerable support from Member States and may be agreed as soon as 2004. If the legislation is agreed there is likely to be a lead in time of several years while the proposals are fully implemented. This will allow manufacturers and suppliers time to make the necessary adjustments.

As already explained, Section 12(1) provides an exemption from licensing requirements for remedies made up by herbalists after a personal consultation. Because these Section 12(1) remedies are not industrially produced, control of their supply remains under UK not EU legislation. Consequently Section 12(1) will remain in force when the Traditional Herbal Medicinal Products Directive becomes law. This means that in the UK, herbal medicines that are made up on the premises and sold after a one-to-one consultation will continue to be exempt from licensing requirements under this Section 12(1) provision. But how can the quality and safety of medicines used under this arrangement be assured? This is the general question which this HMRWG report addresses. The fundamental objective of proposals made in this report are to protect consumer choice, whilst ensuring that the public has access to safe, good quality herbal medicines and that those supplying these remedies are subject to scrutiny and accountability.

## 1. Introduction

1.1 Ministers have invited the Herbal Medicine Regulatory Working Group (HMRWG) to advise them on the reform of Section 12(1) of the Medicines Act 1968. This paper discusses possible areas of reform.

1.2 The HMRWG has explored the ideas set out in this paper with a range of interested parties. However, this is a complex area of regulation and the HMRWG considers it particularly important that there are further detailed discussions with interested parties if the proposals are pursued further.

1.3 The membership of the HMRWG is set out in Section D on page 10. The Medicines and Healthcare products Regulatory Agency (MHRA) (formerly Medicines Control Agency), is not a member but has been invited to attend by the HMRWG in order to provide input on the current legal position and on the feasibility of various avenues of reform which the HMRWG is considering.

## 2. Why reform?

### a. Meeting ministers' objectives

2.1 Ministers' stated objective for herbal remedies is that the public should have continuing access to a wide range of safe herbal remedies of acceptable quality with appropriate information about the use of the product. Reform of herbal medicines legislation is in line with recommendations made by the House of Lords' Select Committee on Science and Technology. Its report on Complementary and Alternative Medicines (November 2000), compiled after taking evidence from a wide range of sources, was clear on the public health case for regulation of herbal remedies stating:

*"We are concerned about the safety implications of an unregulated herbal sector and we urge that all legislative avenues be explored to ensure better control of this unregulated sector in the interests of the public health."*

Part of this objective is being addressed through work on the proposed Directive on Traditional Herbal Medicinal Products which the HMRWG understands would wholly or largely replace Section 12(2) as the route by which OTC herbal remedies without a marketing authorisation reach the market. Section 12(1) is an alternative route by which the public has access to herbal remedies and the Government's stated objective seems no less relevant in this area.

2.2 In its response to the House of Lords Report on Complementary and Alternative Medicine the Government indicated that it would be reviewing the Section 12(1) arrangements.

### b. Defects in current legislation

2.3 There are some obvious flaws in various parts of the current legislation relating to Section 12(1), some of which are outlined in Section 3. It is clearly important to have a legal framework that provides freedom of choice to those wishing to use herbal medicines whilst ensuring their safety. This evidently requires the overhaul of inadequate and outdated legislation.

### c. Statutory regulation

2.4 The proposed statutory regulation of the herbal profession would in any case suggest the need for a review of the medicines legislation relating to Section 12(1). Statutory regulation may offer opportunities to resolve some of the problems with the existing framework.

## 3. Legal Provisions

### 3.1 Section 12(1) of the Medicines Act 1968

This permits anyone in the course of a business to make up and supply an unlicensed herbal remedy where they do so after being requested by an individual, and in that individual's presence, to exercise judgement as to the treatment required. The remedy must be manufactured or assembled on the premises occupied by the person carrying out the consultation. There is no restriction as to the processes to which the remedy may be subject.

#### Comment on Section 12(1)

- There is currently no further definition in law as to who carries out the consultation, e.g. whether any particular skills or experience are required. In principle, therefore, anyone can carry out this operation.
- Section 12(1) provides an exemption from certain requirements of the Medicines Act 1968. We understand from the MHRA that the legal position is that Section 12(1) does not, and cannot, provide an exemption from Directive 2001/83/EC if a product would fall within the terms of that Directive (see paragraph 3.4 below).

### 3.2 SI 1971/1450 The Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971

This Order permits a third party to manufacture (non-industrially produced) unlicensed herbal remedies for use in one-to-one consultations. The third party must hold a Manufacturer's (Specials) Licence. The product is made to the **manufacturer's specification**. There is no specific restriction as to the processes to which the herbs may be subjected. The remedies cannot be advertised to the public and no advertisement by means of any catalogue, price list or circular letter can be issued by, or at the request of, the person selling or supplying the product by retail, or selling it by way of wholesale dealing, or the person who manufactures or assembles; and the sale or supply is in response to a bona fide unsolicited order.

#### Comment on SI 1971/1450

- We understand from the MHRA that the provisions of this law as outlined above have for some years not been applied fully in practice. The MHRA indicates that one of the reasons for this is that, in the interests of consumer choice, the Agency has applied a relatively broad interpretation in relation to that part of the Section 12(2) exemption which applies a restriction as to process. *(Under Section 12(2) there is no requirement for a one-to-one consultation, hence the use of Section 12(2) as the main route for supplying OTC herbal remedies, but the herbs must only be subject to the simple processes of drying, crushing or comminuting, i.e. powdering.)* A manufacturer therefore, selling a remedy to a herbalist for use in one-to-one consultations might see this as falling within Section 12(2) and not required to meet the terms of SI 1971/1450, even where the herbal remedy had been processed in a way which arguably fell outside the simple processes.
- Note that there is currently no specific provision for a herbalist to ask a third party to make up an unlicensed herbal remedy to the **herbalist's specification** – although some of these remedies can no doubt be legally supplied under Section 12(2). There may be a question as to whether it would be reasonable to regard some of the typical remedies made up to the manufacturer's specification for use by herbalists as non-industrially produced.

### 3.3 SI 1977/2130 The Medicines (Retail Sale and Supply of Herbal Remedies) Order 1977

This Order restricts the use in unlicensed herbal remedies of certain of the more potent herbal ingredients. The herbal ingredients listed in Part I of the Schedule are pharmacy only. Those listed in Parts II and III are permitted, subject to specific restrictions on strength and dosage, to be used following one-to-one consultation. Outside these parameters Part II and III substances become pharmacy only.

#### Comment on SI 1977/2130

- Herbal substances are listed in Parts II and III because of their potency. This would appear to imply the need for the person carrying out the consultation and using a remedy containing such ingredients to have suitable expertise. This highlights the anomaly that there is no legal requirement for the person supplying remedies in this situation to meet any particular criteria.
- The more potent of the herbal substances listed are pharmacy only. There is an issue of whether this is the most appropriate form of control for such substances. For example, there is a question of whether herbs that are potent but useable in trained professional hands are best defined as pharmacy only, instead of prescription only medicines (POM) or for use by a registered herbalist, or a combination of two or indeed all three options.
- The Order as a whole is drafted in a way that is highly complex and difficult to understand.

### 3.4 European Directive 2001/83/EC

This is the main European legislation providing the underpinning legislative framework and contains provisions such as the requirement for medicines placed on the market to have a marketing authorisation. It consolidated a number of existing Directives, including 65/65/EEC. A key provision is Article 2 *"The provisions of this Directive shall apply to industrially produced medicinal products for human use intended to be placed on the market in Member States."*

#### Comment on 2001/83/EC (Art 2)

- The current basis for Section 12(1) (as indeed for the Section 12(2) exemption) is that herbal remedies supplied in these circumstances are regarded as not industrially produced and hence are not covered by the various requirements of 2001/83/EC, not least the provisions requiring a marketing authorisation.

- Where a herbal remedy is made up by the Section 12(1) operator from unprocessed herbs the MHRA takes the view that for practical purposes it would appear legally safe normally to regard this as fitting the criterion of "non industrially produced". The position in other circumstances, that is where the herbalist is not simply using unprocessed herbs to make remedies, is more complex and open to argument. The question of what would be regarded as "industrially produced" has never been tested in law.

### 3.5 The proposed Directive on Traditional Herbal Medicinal Products

This proposed Directive provides a simplified registration procedure for certain traditional herbal medicinal products which would otherwise require a marketing authorisation.

#### Comment on proposed Directive on Traditional Herbal Medicinal Products

- The HMRWG understands that the Government's current intention is that a scheme under the Directive should wholly or largely replace the Section 12(2) exemption. Since the Directive would apply to products that were industrially produced, this would entail adjusting the previous stance on the issue of industrial production.

## 4. Public health risk from Section 12(1)

4.1 Public health risk associated with remedies supplied under Section 12(1) can potentially arise in a number of different ways, including:

- lack of professional competence of the person carrying out the consultation under Section 12(1) leading to incorrect diagnosis and supply of a remedy which does not meet the needs of the patient;
- supply of a remedy that is harmful to the patient through inherent toxicity of the intended ingredients;
- supply of a remedy that is harmful to the patient as a result of poor quality or adulteration. In particular where the remedy is adulterated with undeclared POMs (e.g. corticosteroids or glibenclamide), contains heavy metals (intentionally included in manufacture or through contamination) or where a herbal ingredient has been misidentified (for example *Aristolochia* instead of *Stephania*);

- lack of effective means to identify and communicate with all Section 12(1) operators where safety issues arise.

4.2 The problem at c. is essentially an issue of compliance rather than legal use of Section 12(1) but the existence of the problem illustrates the shortfall in systematic quality controls in parts of the sector. The MHRA notes that it has had several successful prosecutions in this area and information about this is on the MHRA website ([www.mhra.gov.uk](http://www.mhra.gov.uk)). In one recent case the fines totalled £30,000. A further illustration of safety concerns associated with herbal practice is contained in the Journal of the Royal Society for the Promotion of Health, December 2002. There clinicians report on cases of women hospitalised after having been prescribed Chinese herbal slimming remedies found to contain the drug Fenfluramine, which is linked to primary pulmonary hypertension and valvular heart disease. The prevalence of confusion of the potentially nephrotoxic ingredient *Aristolochia* with certain other ingredients used in TCM, as a result of similar appearance or similar nomenclature, led to a prohibition not only of *Aristolochia* but of other ingredients not believed to be inherently harmful. A range of safety issues relating to herbal remedies is covered in greater depth in the MHRA's report on the Safety of Herbal Medicinal Products.

## 5. How could statutory regulation address public health risk?

5.1 The statutory regulation of herbalists has the potential to improve public health protection, for those Section 12(1) operators who come within regulation, in relation to all four of the issues identified previously. These are as follows.

- Herbalists on the register will have met various requirements relating to training and/or experience, and continuing professional development and can be subject to remedial action or discipline by their professional body if they are found to fall short of the standards required.
- The herbalist's professional body can liaise with the MHRA about any new herbal safety issues that arise.
- The herbalist's professional body can set out for its members a code of practice relating to the making up and use of Section 12(1) remedies. For example, as to purchasing ingredients from reputable suppliers,

and can take proportionate disciplinary action up to and including striking off the Register for non-compliance. This would mirror the situation with the pharmacists' code of practice.

- d. A clearly identified body of herbalists will facilitate communication on safety issues.

## 6. Possible reform of the basis on which professional herbalists operate in their use of herbal remedies

6.1 Section 12(2) products have always been more visible than Section 12(1) as the former are widely advertised and available for over-the-counter sale. This, combined with the scale of production of some Section 12(2) remedies, has meant that concerns about the soundness of the legal basis of the UK herbal exemptions have tended to focus on Section 12(2) rather than Section 12(1). Nonetheless, the existence of the proposed Directive on Traditional Herbal Medicinal Products may at some point serve to throw the spotlight on whether all the activities currently seen as being accommodated under Section 12(1) can reasonably be regarded as meeting the criteria of "non industrially produced".

6.2 This concern, combined with opportunities opened up by the statutory registration of herbalists, offers the possibility of updating and clarifying the basis on which herbalists operate.

6.3 A possible revised framework for regulation of herbal remedies used by professional herbalists on the proposed statutory Register might be as follows.

### Possible framework for regulation of remedies used by registered herbalists

- **Company places industrially produced herbal remedies on the market and sells them to herbalists**, whether this route of supply is, for example, for reasons of targeting of marketing, or due to the product requiring professionally supervised use. Such remedies would seem to be subject to Directive 2001/83/EC and would therefore legally require the company placing the products on the market to have marketing authorisation(s) or traditional use registration(s). In such cases, the MHRA has expressed the view that there would appear to be no legal reason for taking a different approach from that taken with industrially produced

remedies which happen to be sold over-the-counter.

- **Herbalist makes up non-industrially produced remedies**, e.g. from unprocessed ingredients. Use Section 12(1). Public health protection strengthened by herbalists' Code of Conduct (analogous to pharmacists' code) setting out good practice, e.g. over the use of reliable suppliers. Disciplinary offence (up to and including removal from Register) in the event of breach of code.
- **Herbalist commissions a third party to make up an industrially produced remedy to the herbalist's specification to fulfil special needs (notably where there is no suitable licensed/registered herbal product available)** Article 5 of the Directive 2001/83/EC allows Member States to exclude from the provisions of the Directive "*to fulfil special needs medicinal products supplied in response to a bona fide unsolicited request, formulated in accordance with the specifications of an authorised health care professional and for use by his individual patients on his direct personal responsibility*". In principle, registered herbalists might be added to this so-called "Specials" regime. Schedule 1 to the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 currently applies to any order by a doctor or dentist of a medicinal product made up to their specification where the third party holds an appropriate manufacturers' licence.
- **Herbalist mixes different, industrially produced, finished herbal remedies**, for example, the herbalist might take and mix two different herbal medicines each of which holds a traditional use registration. The HMRWG is currently unclear as to whether registered herbalists might wish or need to use such a provision and the case for allowing herbalists to mix licensed or registered medicines requires further consideration.
- **Use of restricted (i.e. potent) herbal ingredients under Section 12(1)**. Following statutory regulation, use of herbs which currently are restricted to use following one-to-one consultation could in future be restricted to use following consultation by a registered herbalist. This would appear to have clear advantages in the protection of public health. Such a provision would probably have been included in the Order in 1977 had it been possible at that time to define a professional herbalist in law.

6.4 The labelling and advertising requirements, which would apply in relation to these various categories, is an issue that requires careful consideration.

## 7. Are there other current users of Section 12(1) besides herbalists likely to be on the statutory Register?

7.1 There may be numbers of practitioners from one or more of the various complementary and alternative medicine groups (or indeed not allied to any particular grouping) who regularly or occasionally make up herbal remedies under the legal cover of Section 12(1). Possible examples that have come to the attention of the HMRWG, include some aromatherapists, homeopaths, various other multidisciplinary CAM professionals from a range of different traditions, and certain shopkeepers who hold consultations and make up remedies for individual patients. While there will be some staff in some health food stores who hold consultations and make up herbal remedies under Section 12(1), the majority will be operating under Section 12(2) and they will be responding to customers seeking advice on buying over-the-counter herbal remedies, currently sold under Section 12(2), and in future under the proposed Traditional Herbal Medicines Product Directive. (Acupuncturists, particularly those practising TCM, often use herbalism as well, although it is possible, depending on the outcome of work in progress, that acupuncturists may achieve statutory regulation, possibly within a CAM Council alongside herbalists.)

7.2 The HMRWG's view, based on initial discussions with a range of interested parties from other CAM groupings, is that it is not straightforward to assess the scale and pattern of Section 12(1) activity by these groups. The MHRA has advised the HMRWG that determination of whether a product is a medicine is carried out on a product-by-product basis against the definition set out in European law<sup>1</sup>. Clearly any herbal product which is not classified as a medicine, is not being supplied under Section 12(1). Equally, many CAM practitioners may well supply medicinal herbal products under Section 12(2), or in future via the proposed Directive on Traditional Herbal Medicinal Products.

7.3 The HMRWG recommends that during further discussions or consultations on its proposals it would be helpful if other CAM groups could have further opportunity to identify the pattern of current usage of Section 12(1) by CAM practitioners.

<sup>1</sup> Definition of Medicinal Product from Directive 2001/83EC: Any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product.

## 8. Issues arising from any usage of Section 12(1) by practitioners not on statutory Register

8.1 Sections 4, 5 and 6 of this paper summarise public health concerns which may arise from Section 12(1) and possible ways in which statutory regulation of herbalists could be used to strengthen public health protection in relation to the operation of Section 12(1).

8.2 The HMRWG has considered various options for Section 12(1) operators not on a statutory Register.

### Regulatory options for Section 12(1) operators not on herbalist Register

- Look to minimise the occurrence of such a situation by some form of grandparenting arrangement for transition to the herbalist Register with a period of grace to give people time to meet full requirements of being on the Register.
- Where practitioners are potentially on several different CAM registers look for practical measures e.g. forms of mutual recognition, in order to minimise costs for people pursuing several CAM disciplines. (This option is less applicable if there is a wider CAM register.)
- Restrict Section 12(1) to practitioners on the herbalist or CAM Register. Provide some form of transitional rights for other existing operators in order to minimise adverse regulatory impact.
- Continued availability of Section 12(1) to anyone who wishes to use it to be accompanied by a **voluntary** code of good practice, e.g. covering issues such as use of reliable suppliers and keeping up a reliable list of users.
- Continued availability of Section 12(1) to anyone who wishes to use it, i.e. regardless of qualifications and experience.

### HMRWG Recommendations concerning other CAM professionals using Section 12(1) not on statutory Register

- The HMRWG has some reservations on public health grounds about the desirability of an indefinite continuation of a position where people are operating a business entailing holding personal consultations and making up and supplying medicinal products without a reliable assurance that such operators are working under adequate professional accountability.

This potentially is the position if there are some CAM operators not on any statutory Register operating under Section 12(1). However, for a number of reasons, the HMRWG does not consider it realistic, for the foreseeable future, to restrict use of Section 12(1) to those on a statutory Register. There is considerable uncertainty as to how many other CAM professionals, shop keepers and so on, are using Section 12(1). There are issues about the extent to which a wider CAM Council, if this is established, may extend in time to cover other CAM operators who happen to be Section 12(1) users and there are potentially very significant issues of regulatory impact for practitioners who may be operating very small, even one person, businesses.

- The view of the HMRWG is that, for the time being, the most realistic and feasible approach would be to allow continued use of Section 12(1) by operators not on the herbalist or CAM Register while encouraging the growth of voluntary self-regulation to give the public assurance. This would be on the understanding that the situation would then be kept under review, particularly as to whether responsible self-regulation was providing sufficient public health protection. This would be a relatively flexible approach keeping the longer term options open.
- In relation to a possible scheme of self-regulation, the HMRWG believes that there should be appropriate training and audit of these CAM operators using Section 12(1) provision.
- Educational provision from age 16 is offered by a variety of UK institutions ranging from sixth form colleges through colleges of further education to higher education institutions. A variety of levels of achievement are recognised from BTEC through HNC/HND, NVQs, foundation degrees, degrees and higher degrees. The training portfolio available to train the full compass of those using Section 12(1) provision including fully trained professionals (e.g. herbalists and aromatherapists), herbal dispensers, assistants, and counter staff should utilise these existing educational resources. Levels of responsibility associated with each qualification should be clearly defined and the importance of appropriate referral to a more qualified person is properly explained and audited in practice. The use of National Professional Standards may help this process.
- In the same way that the roles, responsibilities and training for herbal practitioners, to be registered under the Herbal Council or CAM Council will be defined, it is in the interests of public safety that appropriate levels of training and qualification of herbal dispensers and assistants, as well as those

managing health food stores, are similarly clearly defined and provided. The public must be assured that guidance received in the use of herbal remedies at all levels is reliable and safe and that the herbal remedies themselves have the necessary assured quality. For example, a counter assistant in a health food store should be trained to advise members of the public that they should consult a professional if they are intending to use a variety of herbs as well as over the counter and /or prescription medicines. If customers require more professional guidance they should be referred to an appropriately trained health professional.

- Initial advice on herbal remedies is generally sought from herbal professionals and staff working in both pharmacies and health food stores. It is essential that staff receiving such enquiries are trained to respond appropriately. Over-the-counter, pre-packaged products are currently provided under the aegis of Section 12(2) of the Medicines Act 1968. However, it is anticipated that the proposed new EU Directive on Traditional Herbal Medicinal Products, designed to replace Section 12(2) provision, will shortly regulate appropriate labelling of such pre-packaged herbal products. The proposed Directive will require registered traditional herbal medicinal products to carry relevant indications and other information about the safe use of the product.
- The recognition by all workers in the herbal sector of the limits of their competence when providing guidance to customers and/or patients about the taking of herbal medicines is crucial to the effective provision of primary care in the community. The objective must be to ensure rapid referral of people requiring professional diagnosis and treatment as soon as possible. Training of support staff should be appropriate to their roles and responsibilities, and needs to be considered in the context of both patient care and educational provision. Clear guidelines are required regarding training and ongoing professional assessment and validation so that the public can rely on advice and help received regarding herbal treatment. It would appear sensible for such guidelines to take account of and develop from existing training schemes such as those endorsed by the British Herbal Medicine Association and the Health Food Manufacturers Association.

**In summary, the HMRWG recommends that Section 12(1) should continue to be available for the foreseeable future for CAM practitioners not on a statutory Register under voluntary self-regulation that has clearly flagged standards of training and validation.** In time, in the light of experience it may be in

the public interest that all those using Section 12(1) provision should be brought under control of the Herbal Council or CAM Council. It may well also be seen to be in the public interest for aromatherapists to attain similar statutory self regulation to that currently being sought by herbal practitioners. The Aromatherapy Regulatory Working Group is reviewing the current arrangements for the regulation of the aromatherapy profession.

### Possible pointers to continuing use of Section 12(1) by CAM operators not on a statutory Register

- The HMRWG doubt that it would realistically be feasible to regard such operators, as "authorised healthcare professionals" and therefore it would seem not possible to extend to them the legal cover to commission industrially produced herbal remedies from a third party or to mix together different industrially produced herbal remedies.
- The EU General Product Safety Directive could offer some additional protection, for example in requiring operators to have product recall arrangements. This by itself might be insufficient to ensure public safety however.
- In the interests of public health protection these operators could be excluded from using a specified range of potent herbal ingredients (an updated version of SI 2130/1977).

## 9. Other Issues

9.1 The issue has been raised with the HMRWG of the regulatory position if a CAM operator, such as a shopkeeper, is selling loose herbs for medicinal purposes but without there being a one-to-one consultation as would be required under Section 12(1). This would appear not to be an industrially produced medicinal product that requires a marketing authorisation or (in future) a traditional use registration. The issue may need further consideration as to whether this is an area for a residual provision in Section 12(2). Alternatively, this situation may suggest the need, on public health grounds, to ensure there is a consultation, as under Section 12(1). The regulatory position may be complicated as it will not necessarily be clear in individual cases as to whether the item is purchased for medicinal purposes. This issue will require further consideration.

9.2 The HMRWG considers that those practitioners on the statutory Register should be permitted to use traditional medicinal remedies of non-plant origin

provided that such remedies can demonstrate safe use and are subject to required standards of quality assurance. This is an issue that would require further detailed study and discussion between the MHRA, the traditional medicines sector and other interest groups (including public health experts). Among the issues for consideration would be: how traditional medicines should be defined in this context and what categories of non herbal ingredients should be covered; what mechanism should be used to identify which specific ingredients would be suitable on safety grounds; and what quality standards should be applied. The use of animal parts in medicines, for example, raises a number of important issues of safety and quality related to safety, in the light of experience with Transmissible Spongiform Encephalopathies (TSE).

## 10. Regulatory Impact

10.1 The Government attaches considerable importance to the issue of assessing the regulatory impact of any policy proposals that may impose costs or benefits on business, not least on small businesses. There will be a need for a regulatory impact assessment to be developed at an early stage in relation to proposals. As indicated above, some of those currently operating under Section 12(1) may be the ultimate in small business, that is one person operating part time.

## 11. Summary of Recommendations

11.1 SI 1971/1450. The Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 is outdated and should be repealed or substantially revised.

11.2 SI 1977/2130 The Medicines (Retail Sale and Supply of Herbal Remedies) Order 1977 needs updating and simplifying. In particular, it is recommended that under this particular SI, the supply of potent herbs not suitable for over the counter sale should be restricted to those practitioners with appropriate training who are on a statutory register.

11.3 It is recommended that herbalists and other suitably qualified health professionals on a statutory Register may request a third party to make up an industrially produced remedy to the herbalist's specification to fulfil special needs. In this such practitioners would be considered "authorised health

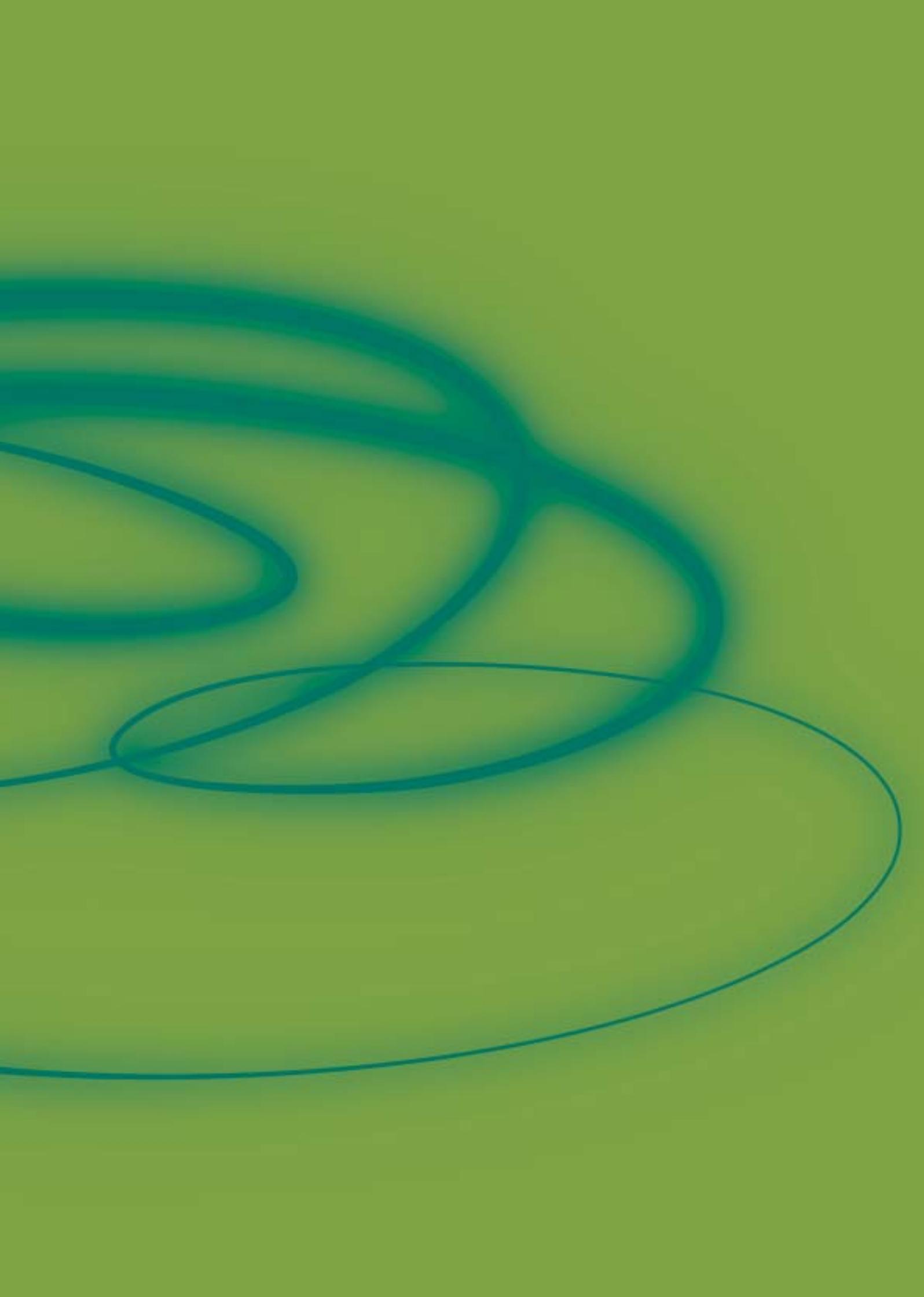
professionals" under Article 5 of EU Directive 2001/83/EC.

11.4 Further work should be undertaken to investigate the case for permitting registered herbalists to mix two or more industrially produced remedies.

11.5 Those CAM professionals making use of Section 12(1) provisions who are not statutorily regulated are urged to develop secure systems of voluntary self-regulation including independently audited, clearly defined, training standards, codes of ethics and

disciplinary procedures. The HMRWG foresees that in the long term all operators using Section 12(1) provision may be included in a wider CAM Council.

11.5 The HMRWG recommends that the scope of Section 12(1) should be extended to allow practitioners on the herbalist/shared Register to supply traditional medicinal remedies of a non-plant origin provided these remedies can demonstrate safe use and are subject to required quality assurance standards.



Recommendations on the Regulation of Herbal Practitioners in the UK  
Recommendations from the Herbal Medicine Regulatory Working  
Group including Recommendations on the Reform of Section 12(1)  
of the Medicines Act 1968

This report contains recommendations for the statutory regulation of herbal practitioners in the UK. It was prepared by the Herbal Medicine Regulatory Working Group (HMRWG), which was established in January 2002 by the Department of Health, The Prince of Wales's Foundation for Integrated Health and the European Herbal Practitioners Association. The HMRWG comprised an independent Chair and lay membership as well as delegates from the main professional bodies representing the herbal profession within the UK.

These proposals for the regulation of the herbal medicine profession have taken account of the regulatory systems in place for other health and social care professionals – both conventional and complementary and alternative. Professional regulation must be open, responsive and accountable, with the emphasis on the protection of patients and the public. Regulation of the herbal medicine profession will protect the public by setting and monitoring standards of professional training, conduct and performance.

**The European Herbal Practitioners Association (EHPA)** was founded in 1993 as a forum for professional associations representing herbal practitioners of various traditions. It works to foster unity within the profession, to promote the availability of herbal treatment and to raise standards of training and practice. The EHPA campaigns for the recognition of professional herbal practice throughout the EU as a speciality in its own right and to maintain the availability of a wide range of traditional herbal medicines for use by qualified herbal practitioners.

**The Prince of Wales's Foundation for Integrated Health**, originally named the Foundation for Integrated Medicine, was formed at the personal initiative of His Royal Highness The Prince of Wales, who is now its president. The Foundation's aim is to promote the development and integrated delivery of safe, effective and efficient forms of healthcare to patients and their families through encouraging greater collaboration between all forms of healthcare.

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