



FRANKINCENSE

European Herbal Practitioners Association's Newsletter

April 2006

Regulation Update

Professional Regulation

The Department of Health (DH) has recently appointed Professor Michael Pittilo to chair the new Working Group on the regulation of acupuncture, herbal medicine and TCM. This is good news for the profession as Prof Pittilo proved himself an excellent chair on the Herbal Medicine Regulatory Working Group and is very familiar with the herbal sector and its issues.

The DH has also recently called for nominations for membership of the new Working Group. The Group will comprise 12 professional members representing the following professions/traditions:

- Acupuncture (covering traditional and medical acupuncture)
- Herbal Medicine (covering all traditions)
- Traditional Chinese Medicine

There will also be four appointed lay members, two members representing the higher education sector and nine observers invited to participate in the Group.

The first meeting of the Group will be held on 22 June 2006 in Leeds.

Reform of S12.1

Following the launch of the Traditional Herbal Medicinal Products Directive, the MHRA is now concentrating its efforts on the reform of Section 12.1. Some of the issues under consideration include:

- Who if anyone, apart from regulated herbal practitioners, will have the right to prescribe herbal medicines under Section 12.1 of the Medicines Act 1968
- Whether regulated herbal practitioners could be considered authorised health professionals under the main European medicines directive (2001/83/EC) thus permitting them to have specific herbal medicines manufactured by a herbal manufacturer under Specials Licence (effectively therefore exempt from the need for a full marketing authorisation.)
- Whether the scope of S12.1 can be extended to include a limited range of non-plant traditional medicines

Safety Issues from MHRA

Concerns about misleading advertising

The MHRA raised concerns that consumers were at risk as a result of misleading claims about the safety of traditional Chinese medicines and recently complained to the Advertising Standards Authority (ASA). The ASA has upheld complaints about three leaflets advertising the services in traditional Chinese medicine clinics. Further information at www.mhra.gov.uk

The MHRA is encouraging herbal practitioner associations to ask their members to review their advertising against the provisions of the British Code of Advertising, Sales Promotion and Direct Marketing. Further information can be found at www.asa.org.uk.

Possible toxic ingredients in African Herbal Medicines

The Medicines and Healthcare products Regulatory Agency (MHRA) believes that certain African herbal remedies are on the UK market which could contain toxic herbal ingredients and lead to life threatening conditions.

Consumers are warned not to purchase or use two products, 'M2' and 'Energy 2000', believed to be available on the UK market and may contain the toxic herbal ingredients *Strophanthus sarmentosus* or *Aristolochia species*. *Aristolochia species* have been banned in unlicensed herbal remedies in the UK since 2001.

- *Aristolochia species* can cause kidney failure and cancer.
- *Strophanthus* species have a powerful action on the heart and could result in serious heart problems including abnormal heart rate and heart failure

Anyone who knows of any source of supply is asked to notify the MHRA: info@mhra.gsi.gov.uk; 020 7084 2000.

EMEA Consultations

The European Medicines Agency (EMA) is the European overarching body covering medicines legislation. The EHPA has been continuing to press the EMA's Herbal Medicinal Products Committee (HMPC)! within the EMA to reconsider the quality control guidelines for multi-herb products. As currently published, the quality control guidelines make the licensing of over-the-counter herbal products containing three or more herbs difficult from a scientific and economic point of view. We are pleased to report that there is some sympathy being expressed about the plight of multi-herb compounds by regulators and we have gratefully received considerable support from the Prince of Wales in seeking a reasonable solution to the problem of multi-herb products.

We are also closely monitoring the draft monographs on specific herbal medicines published by the HMPC. The EHPA has responded to the consultation documents on specific herbal monographs making the case for appropriate traditional herbal indications.

TMEC

The Traditional Medicines Evaluation Committee, an established EHPA sub committee is meeting regularly to review endangered herbs such as Kava and Black Cohosh to prevent the loss of these and other traditional herbal medicines.

TMEC is also working with the MHRA to review some non-herbal traditional medicines for possible inclusion under S12.1.

HMAC

The first meeting of the MHRA's Herbal Medicine Advisory Committee (HMAC) was held in February. The Committee's role is to give Ministers and the MHRA independent expert advice on the recently introduced registration scheme for traditional herbal medicines and on unlicensed herbal remedies supplied under Section 12 of the Medicines Act 1968.

Practitioner members include Tony Booker (RCHM), Alison Denham (NIMH), Shantha Godagama (AMA) and Simon Mills (NIMH/ CPP).

Accreditation Update

Annual Review

This year's round of annual review visits to institutions offering EHPA accredited programmes is almost complete. Accredited programmes are reviewed on an annual basis to ensure the standards required by both the Education Committee and the Accreditation Board are maintained.

Institutions are asked to submit an annual report to the Board which must include amongst other things, commentary on any recommendations made at the time of accreditation. The report helps to identify

areas for discussion with staff and students during the visit and wherever possible, the Board tries to maintain continuity by asking the original accreditation team to participate in the review.

The Board will be evaluating this year's annual review process and invites feedback from all participants in order to help us decide how the process can be improved/streamlined prior to the 2006-7 cycle.

Education Network Meeting

The next meeting of the Accreditation Board will be on May 23rd at the Kings Fund, London, and an Education Network meeting will follow. The Network includes representatives of institutions offering EHPA accredited programmes and members of both the EHPA Education Committee and Accreditation Board. The purpose of the meeting is to meet colleagues and discuss educational matters of mutual interest.

Clinical Hours

A subcommittee of the Education Committee has been established to review both the quantity and quality of clinical hours required in educational programmes. EHPA member professional associations from each tradition were invited to nominate participants. Whilst the need for additional hours over and above the current minimum of 450 has been raised, it is widely recognised that providing a set number of hours does not in itself ensure a satisfactory learning experience for students.

The Board takes the view, for example, that the quality of the clinical environment, the anticipated clinical learning outcomes of the programme and the ways in which outcomes are assessed are all essential aspects to be considered in addition to the quantity of hours provided. Thus qualitative as well as quantitative issues are incorporated into the current accreditation process.

Accreditation Handbook

The revised and updated second edition of the EHPA Accreditation Handbook is now available on the website. In order to make it more user friendly the Board's accreditation criteria have been subdivided into sections reflecting the stages of the accreditation process: the Statement of Intent, the Full Submission Document and subsequent accreditation panel visit.

Thank you

A big "thank you" to everyone who has participated in this year's various Board activities, reviews and accreditation events – you each commit a significant amount of time and effort to the EHPA accreditation process and it is greatly appreciated.

Irish Update

Workshop

On 4 February, the EHPA held a successful workshop in Dublin together with our Irish colleagues. The workshop covered a number of topics including

- professional regulation
- implementation of the THMPD
- herbal monographs from the HMPC
- future collaboration opportunities

National Herbal Council

A new National Herbal Council, comprising five herbal practitioner groups, was established at the end of 2005. The first chairperson will be Dr Celine Leonard.

The practitioner groups are:

- Irish Register of Chinese Herbal Medicine
- The Association of Chinese Herbalists in Ireland
- Irish Association of Master and Medical Herbalists
- Irish Medical Herbalists Organisation
- Irish Register of Herbalists

The Council now represents in excess of 90% of practising medical herbalists in Ireland. The Council has agreed minimum training standards for its member organisations and will be moving towards statutory regulation under the Department of Health's "Allied Professions" regulation scheme in the near future.

In February, the Council launched a web based National Herbal Register, which provides details of each and every practitioner member of the council organisations. Visit the new register at www.nationalregisterofherbalists.com

Collaboration with other health professionals

The EHPA continues to participate in the committees on CAM run by the Royal College of General Practitioners and the Royal College of Physicians.

2006 Diary Dates

Chinese Medicine Working Group meeting	20 April
Modernisation of Traditional Chinese Medicines: a UK Perspective <i>Brunel University</i> , www.westfocus.org.uk	26 April
Pharmacovigilance of Herbal Medicines, London <i>Royal Pharmaceutical Society</i> , www.rpsqb.org	26-28 April
EHPA Council and Education Committee meetings Parliamentary Group	15 May 17 May
EHPA Education Network	23 May
EHPA Accreditation Board meeting	23 May
Chinese Medicine Working Group meeting	24 May
Herbal Forum	5 June
Traditional Medicines Evaluation Committee meeting	5 June
Acupuncture, Herbal Medicine and Chinese Medicine Working Group meeting, Leeds	22 June
iCAM short course: CAM Practitioners in the NHS, London <i>University of Westminster</i> , www.wmin.ac.uk/sih/icam	22-24 June
Evolving Regulatory Framework for Herbal Medicinal Products, Vienna www.ibc-lifesci.com/herbals	27-28 June
Herb Futures	10 July
CPP Seminar: Perceptions of Herb Quality – with emphasis on the Respiratory System at <i>Henry Doubleday Research Association, Warwickshire</i> , www.phytotherapists.org	24 July
HerbFest, Gloucestershire	24-26 July