



FRANKINCENSE

European Herbal Practitioners Association's Newsletter

June 2005

EHPA Accreditation Board

The EHPA Accreditation Board was established in 2000 and consists of independent educationalists from higher education, practitioners of herbal medicine drawn from EHPA member professional associations, two members who are representative of accredited institutions, and other professionals representing the wider interests of the community.

Initially the board invested significant time devising, consulting, publishing and putting in place its accreditation system (subsequently commended by the Herbal Medicine Regulatory Working Group), and began working closely with educational institutions in 2001/2.

Since then, three degree level programmes have been fully accredited (having subsequently met any conditions set by the board following the accreditation visit) at: the Northern College of Acupuncture, York, the London College of Traditional Acupuncture & Oriental Medicine (LCTA), and the College of Integrated Chinese Medicine (CICM), Reading.

At the time of writing, the University of Lincoln and the University of Westminster have programmes in Western Herbal Medicine and Chinese Herbal Medicine respectively that have achieved provisional accreditation. Each will be fully accredited when conditions set following the accreditation visit have been met by the due date. A number of other institutions are working towards accreditation, with two more reports due to be considered at our July meeting.

The EHPA criteria for accreditation are explicit, transparent and rigorous, and only those institutions able to provide evidence that the criteria can be met have their programme accredited. In addition, a number of policies and procedures have been developed including visiting guidelines for panel members. Other issues such as criminal record checks, admission of students with disability and fitness to practise are currently being debated and help to inform the accreditation process.

The board is continuing to build on its achievements to date and this year sees the start of our programme of annual reviews for accredited programmes, in addition to publication of an updated accreditation handbook, induction for

recently appointed board members, and a training day for panel members nominated by professional associations. We intend to establish regular meetings between board members and staff of all institutions accredited by, or working towards EHPA accreditation, and are in the process of consulting institutions about their preferred way of organising this.

The work of the board could not continue without the significant time and expertise given by board and panel members. Their contribution is both acknowledged and greatly appreciated as we work together in order to promote standards of education and training for the benefit of patients, students, practitioners and the wider community - thanks very much everybody!!

New Health Minister

Rt Hon Jane Kennedy MP has been named Minister of State for Quality and Patient Safety.

The new Minister's remit will include clinical quality, patient safety and clinical negligence. Responsibilities include standards, inspection and performance; patient safety, including the National Patient Safety Agency (NPSA); clinical governance and quality issues; clinical negligence; MRSA; reducing bureaucracy; National Institute of Clinical Excellence (NICE); genetics; Medicines and Healthcare products Regulatory Agency (MHRA) and medicines; pharmaceutical industry and pharmacy; R&D; counter fraud; and Departmental management.

As part of patient safety, Jane Kennedy will oversee the regulation of herbal medicine, acupuncture and TCM practitioners. In her capacity of overseeing the MHRA, she will also be responsible for reform of Section 12(1) of the Medicines Act of 1968 (i.e. one to one prescription of herbal medicine).

New CAM Specialist Library

The NHS National electronic Library for Health is currently developing a Complementary and Alternative Medicine Specialist Library (NeLCAM). The Library's mission is to provide clinicians with access to the best current know-how and knowledge to support healthcare-related decisions. Patients, carers and the public may also use the site, but NHS

Direct Online provides the best public gateway to health information. All resources on the site are free to use and the majority can be accessed by all users. For more information, visit the Library website: <http://www.nelh.nhs.uk/>

From MHRA:

New guidance on medicinal product definitions

Users and distributors of products containing herbal ingredients can now check whether those ingredients have a general or medicinal use - and therefore be subject to government regulation - in a new guide recently launched by the MHRA.

More than 600 common, and not so common, plants are listed in the MHRA's product guidance - enabling suppliers to check which category of usage the specific part of the plant they are using might fall into.

Most medicines are clearly identifiable as such and are subject to EU marketing authorisation procedures. But some products with herbal ingredients can be classified as medicines, food or cosmetics depending on the type of product and which part of the plant is used. The new MHRA guidance comprehensively lists known recorded medicinal, food, aromatherapy or cosmetic uses for a wide range of herbs frequently used in Western Europe and North America, and which parts are used medicinally.

The guide has been drawn up following extensive consultation with industry trade associations and the Food Standards Agency. Copies of the guidance are available from the MHRA website at www.mhra.gov.uk (from the home page scroll down to the herbal product guidance link).

MLX 324: License Fees

The MHRA is currently consulting on proposals to introduce fees relating to the implementation of Directive 2004/27/EC (2001 Review changes); Directive 2004/24/EC, the Traditional Herbs Directive; and, the introduction of a National Rules scheme for homeopathic products. See website for full consultation document www.mhra.gov.uk.

Implementation of the Directive on Traditional Herbal Medicinal Products (THMPD)

The THMPD became law throughout the European Union in April 2004 and has to be fully implemented by 2011. This process is now underway in the UK with many UK and foreign herbal companies seeking to get their formulations licensed under the new

Directive. The Herbal Forum is a gathering of representatives of the UK herb industry and (via the EHPA) practitioners that has been meeting the MHRA over the past three years. From these meetings and from briefing papers from the European Medicines Evaluation Agency (EMA)¹, it appears that the quality and safety guidelines that are required by the new Directive to qualify for THMPD registration are likely to significantly restrict the number of herbal products available over-the-counter. In particular, multiple herbal formulations are struggling to meet the quantitative analysis requirement that demands that products should be able to demonstrate that the finished herbal product contains the same quantity of active herbal material as was present to start with. The problem with this is that cheaper forms of chromatography are not sophisticated enough to be able to measure all the herbs in a finished product and so this quantitative analysis could turn out to be expensive, if it can be achieved at all.

To add to the difficulties, a number of other procedures are now required for all OTC medicinal products such as Patient Information Leaflets (PILS) which are costly to produce as well as a new requirement for every medicinal product label to carry information in Braille that will certainly add cost to packaging OTC herbal products. Another recently revealed ongoing cost to the herb industry is an EU requirement for all companies producing medicines (including herbal medicines) to use international medical terminology, MedDRA (the medical dictionary for regulatory activities). This is designed to allow the transmission of information related to many aspects of the regulation of medical products online e.g. regular adverse event reports to the MHRA and other EU medicines regulatory authorities. Although special financial arrangements are made for small and medium sized companies, there are still costs involved in complying with this requirement as there are for conducting stability tests for each herbal medicine sold OTC. To this must be added the cost of licensing a herbal product.

The EHPA, working with representatives of the UK herb and health food sector, is currently seeking to negotiate directly with the EMA Committee for Herbal Medicinal Products to see if there is room to manoeuvre with regard to some of these requirements. We hope to bring you news of this in the near future.

¹ E.g. *Note For Guidance on the Quality of Herbal Medicinal Products*, CPMP/QWP/2819/00; EMA/CVMP/814/00; 26/7/01.

RCGP sets up new CAM group

The Royal College of General Practitioners has set up a Complementary Medicine Advisory Group to provide support to GPs in their understanding, use and referral to disciplines and individuals working in CAM. The Committee is exploring practical ways to integrate GP practice and training with the work of CAM practitioners. Representatives from herbal medicine, acupuncture, osteopathy and chiropractic attended the first meeting on 23 May together with colleagues from the Department of Health and the Prince of Wales's Foundation for Integrated Health. Michael McIntyre is representing the EHPA.

European Food Supplements Directive Challenge

The Alliance for Natural Health, made up of consumers, practitioners, retailers and innovative food supplement companies, challenged the European Food Supplements Directive in the High Court in October 2003. The Alliance claims the Directive has the potential to ban some 75% of vitamin and mineral supplements. The case was successfully referred and expedited to the European Court of Justice in January 2004.

An Opinion from the Court's Advocate General declared '*... that the Directive infringes the principle of proportionality because basic principles of community law, such as the requirements of legal protection, of legal certainty and of sound administration have not been properly taken into account. The Directive is, therefore, invalid.*' The European Court of Justice has now declared that the judgment will be handed down on 12 July 2005.

The Alliance is hoping the judgement will give rise to an amendment to the Directive that will result in greater clarity for consumers and manufacturers of food supplements across Europe. For more information see the Alliance's website: www.alliance-natural-health.org.

NEW Ayurvedic Degree Courses at Middlesex University

Middlesex University has just announced that it will be running a full range of Ayurvedic degree courses starting in September 2005.

Dr Mauroof Athique, Director of the College of Ayurveda, was delighted that his two-year project to get the first UK-based BSc and MSc programmes in Ayurvedic Medicine underway has succeeded. Middlesex University has a great reputation for being the first UK University to offer BSc courses in Herbal Medicine and Chinese Medicine and now the first to offer a BSc in Ayurvedic Medicine.

The three-year BSc (Hons) Complementary Health Science (Ayurveda) undergraduate degree course followed by a one-year PG Diploma course and one-year MSc course clearly sets the high standard appropriate for the education and training of competent Ayurvedic practitioners. Within the course structure there are modules that deal with India's unique, traditional medical system, as well as Western medical components and up to 1000 hours of supervised clinical training.

In addition, Middlesex University is offering a conversion course for medically trained doctors who may wish to use Ayurvedic modalities in their diagnosis and treatment of patients. Anyone wishing to enrol onto these courses should contact Middlesex University www.mdx.ac.uk, the College of Ayurveda ayurvedacollege@msn.com or the Ayurvedic Practitioners Association www.apa.uk.com.

Visit to Ireland May 2005

On May 21st, Michael McIntyre Chair of the EHPA met with members of the Irish Herbal Practitioners Association in Dublin. The meeting was fruitful identifying a number of policy areas where herbalists across Europe could usefully work together. In particular, it was agreed to lobby the UK and Irish authorities to ensure that the implementation of the Traditional Herbal Medicinal Products Directive should take into account the complexity of herbal medicines so that the financial burden of establishing quality controls would not effectively undermine the viability of small to medium herbal businesses in Ireland and the UK. It was also agreed to keep each other up to date with progress in Ireland and the UK towards statutory regulation of herbalists.

2005 Diary Dates

Homeopathy Awareness Week: Men, Women & Homeopathy <i>Contact: Society of Homeopaths, www.homeopathy-soh.org</i>	14-21 June
Parliamentary Group for Integrated & Complementary Healthcare: Complementary Medicine in Primary Care, House of Commons <i>Contact: info@euroherb.com</i>	21 June
MHRA Conference: Herbs Advertising, London <i>Contact: conferences@mhra.qsi.gov.uk</i>	23 June
Herbal Forum	27 June
Conference: Diversity and Debate in Alternative and Complementary Medicine Nottinham University <i>Contact: Christine Barry, Christine.Barry@brunel.ac.uk</i>	28 June-1 July
EHPA Accreditation Board Meeting	4 July
EHPA Education Meeting & Council Meeting	11 July
CPP CPD Series: The value of Traditional Use of Herbal Medicine, Banbury <i>Contact the CPP: Pamela Bull, pamela.bull@btopenworld.com</i>	25 July
Herbal Stakeholders	12 August
URHP Seminar: Chasing the Dragon's Tail: Herb-Drug Interactions <i>Contact: Guy Waddell, guywaddell@aol.com</i>	10-11 Sept
EHPA Accreditation Board Meeting	12 Sept
EHPA Education Meeting & Council Meeting	19 Sept
12 th Annual Symposium on Complementary Health Care, Peninsula Medical School <i>See website: www.pms.ac.uk/compmed/symposium</i>	19-21 Sept