



FRANKINCENSE

European Herbal Practitioners Association's Newsletter

August 2006

Regulation Update

Professional Regulation

The new Working Group (WG) on acupuncture, herbal medicine and traditional Chinese medicine had its first meeting on 22 June in Leeds. Membership of the WG includes practitioners, educationalists, lay and a number of observers representing wider stakeholder interests. Also on the WG are the Chairs of three key stakeholder groups, the Acupuncture Stakeholder Group, the Chinese Medicine Working Group and the EHPA, representing the interests of acupuncture, TCM and herbal medicine respectively. A lot of the work from the WG will be delegated to these three stakeholders.

The terms of reference of the WG are:

1. to consider the implications of the broader reviews (Chief Medical Officer, Sir Liam Donaldson on medical regulation and Andrew Foster on non-medical regulation, both as a consequence of the Shipman enquiry – see section on DH Reports) for regulation of acupuncture, herbal medicine and TCM practitioners.
2. to prepare the way for formal regulation by identifying issues and proposing options in relation to education and training, registration, fitness to practise and other aspects of regulation.
3. to co-ordinate stakeholder comments on specific proposals for legislation.

The June meeting included presentations from the DH on the need to regulate and from the Health Professions Council on how regulation might work. The work plan for the WG was also considered.

On 31 July, the WG Chair met with the three Stakeholder Chairs and representatives of the MHRA to progress joint working across the professions towards regulation. This included discussion with the MHRA on the reform of Section 12 (1) of the Medicines Act 1968, which it is anticipated will be in place at the onset of statutory regulation for these professions. The MHRA is planning to publish a number of discussion papers covering the various aspects of this proposed reform. In addition, the Stakeholder Chairs considered distribution of further work delegated from the main WG and relevant funding issues.

The next meeting of the Working Group is 19 September.

New DH Reports: Foster & CMO Reviews

In July, the Department of Health published two reports following the recent reviews of the statutory regulation of healthcare professionals in the UK. Sir Liam Donaldson, Chief Medical Officer, led a review of the regulation of the medical profession and Andrew Foster, former Head of Workforce, led the review of the regulation of non-medical professionals. The Department of Health is consulting on the recommendations contained in the reports, with a closing date of 10 November 2006. Links to these three documents are available on the EHPA website: www.euroherb.com.

Safety Issues from MHRA

Cimicifuga racemosa

The MHRA is reviewing the possibility of a link between the use of black cohosh (*Cimicifuga racemosa*) and liver disorders. Black cohosh, an ingredient of herbal products, is commonly used to treat menopausal symptoms and is widely available in the UK.

This possible link has been identified by the MHRA's Commission on Human Medicines (an amalgamation of the Medicines Commission and the Committee on the Safety of Medicines) and the Herbal Medicines Advisory Committee. Both have reviewed all available data and concluded that it suggests an association between black cohosh and risk of liver disorders.

Following advice from both committees, it is now voluntarily agreed that companies will add warnings to the labels of OTC black cohosh products. In addition, the MHRA has asked that practitioners verbally alert patients prescribed black cohosh to look out for any adverse events associated with its use.

Kava Ban

The Committee on Safety of Medicines' (CSM) Expert Working Group (EWG) on the safety of Kava was established in March 2002 to investigate the ongoing safety concerns about liver toxicity suspected to be associated with the use of herbal medicinal products containing Kava. Despite presentations to the CSM by the EHPA and the BHMA, the EWG, the CSM and the Medicines Commission determined that Kava was associated with an unacceptable risk of idiosyncratic hepatotoxicity which could not be minimised or prevented by any regulatory measures other than the removal of Kava products from the market.

In light of the advice of the Medicines Commission, Ministers decided to make an order under section 62 of the Medicines Act 1968. The Medicines for Human Use (Kava-Kava) (Prohibition) Order 2002 (Statutory Instrument 2002 No. 3170) ("the Prohibition Order") was made on 18 December 2002 and came into force on 13 January 2003. Equivalent regulatory action was taken to prohibit Kava in foods.

Ministers made a specific commitment to review the available evidence two years after the prohibition had been made. To fulfil this commitment, a public consultation (MLX319) exercise was completed between January and April 2005. The available worldwide spontaneous reporting data and the published literature were also reviewed. The EWG met again to consider all the available data in October 2005 and concluded that the prohibition order on Kava remained justified and proportional. This review, published in July 2006, can be read in full at www.mhra.gov.uk

EMEA Consultation

The European Medicines Agency has published a concept paper on the quality of combination herbal medicinal products/traditional herbal medicine products EMEA/HMPC/CHMPC/CVMP/58222/2006. This paper can be viewed on the EMEA website www.emea.eu.int. The consultation period closes 30 September 06.

Education & Accreditation Update

Ayurveda

Through the first half of this year, the three Ayurvedic professional associations working together within the EHPA (APA, MAPA and AMA) developed a new Ayurvedic element of the EHPA curriculum. A significant amount of work has gone into this document and it will be going out for peer review later this month.

Accreditation Board Annual Reviews

The Accreditation Board has recently completed this year's annual reviews of institutions offering EHPA accredited programmes. The visiting review teams attempted to include some members of the original accrediting panel in order to promote continuity and consolidate positive working relationships between the Board and the Institution. There was evidence of good practice which the Board will be disseminating and some developmental points that require further action.

Clinical Hours

During the course of the Board's annual review process, the importance of minimising variations in the quality of the students' clinical experience was reinforced during visits, as was the importance of ensuring that hours matched the Board's definition of what can count as a 'clinical hour'. This exercise,

coupled with questions raised about the number of clinical hours during the work on the Ayurvedic curriculum, led the Education Committee, chaired by Philip Lockett, to set up a sub committee to look at the issues in more detail. Additional input to the review will be provided by the Accreditation Board, especially the work on qualitative and quantitative factors which influence the quality of the clinical learning environment. The sub committee will report progress to the Education Committee at the next meeting.

This review will ultimately inform the Education Committee's decision as to whether to increase the existing number of clinical hours in the Curriculum, and by how much.

Finally, the Education Committee and Accreditation Board are indebted to the British Acupuncture Council for permission to use their excellent Standards documents as part of the review process.

Traditional Medicines Congress, USA

Various associations of traditional medicine practitioners in the USA have united under the Traditional Medicines Congress (TMC). This umbrella organisation was established in 2004 to initiate a cooperative process to exchange ideas about the future of traditional medicines in the United States and to protect and develop their respective practices within the US legislative and regulatory framework. The TMC aims to achieve appropriate recognition of all traditional systems of medicine and to establish their voluntary regulation.

The TMC has also produced a document entitled *A Regulatory Model for Traditional Medicines: Guiding Assumptions and Key Components*. This document and more info on the TMC's work are available on www.traditionalmedicinescongress.com.

Report from HerbFest, Gloucestershire

The Association of Master Herbalists marked its 10th Anniversary in July this year by hosting a three-day open conference called Herbfest. Held at Greenandaway, Gloucestershire, an open-air conference centre, the event took place under an assortment of canvas, including marquees, yurts and Bedouin-style tentage. Organic vegetarian food was provided throughout, and services and conveniences were scrupulously and impressively ecologically correct.

The event boasted three days of workshops, seminars and herb walks from a panel of luminaries from a variety of backgrounds, traditions and professional association including, among many others, Andrew Chevallier (NIMH), Sebastian Pole (APA), Jill Davies (AMH) and Tamara Kircher (RCHM).

2006 Diary Dates

FIH Feasibility Steering Group meeting, London	31 August
Herbal Forum	11 September
British Acupuncture Council Annual Conference, Cirencester	16-17 September
EHPA Education & Council meeting, London	18 September
DH Steering Group meeting for Acupuncture, Herbal Medicine & TCM. Leeds	19 September
Chinese Medicine Working Group meeting, London	21 September
FIH Regulation Conference	27 September
EHPA Accreditation Board meeting, London	2 October
EHPA Education & Council meeting, London	13 November
EHPA Accreditation Board meeting, London	11 December
13 th Annual Symposium on Complementary Health Care, Exeter	12-14 Dec