



FRANKINCENSE

European Herbal Practitioners Association's Newsletter

September 2005

Regulation Update

Following the publication of the results of the consultation on the regulation of acupuncture and herbal medicine earlier this year, the DH intended to set up a joint working group of these two professions, together with Traditional Chinese Medicine, a tradition that spans the two professions, to make recommendations on the establishment of a Shadow Council.

Setting up this working group was initially delayed because of the general election and the subsequent appointment of a new Minister. Now, however, it seems that the possible implications of the Foster Review (see a piece on the Foster Review later in this newsletter) will delay it further, likely until early 2006. The Minister is due to be briefed shortly and following this, recruitment for members of the Joint Working Group will begin. We expect an announcement from the Department of Health about progress on this front by mid October.

Work by the MHRA on reform of S12(1) of the Medicines Act 1968 continues. One difficult issue to resolve will be how the MHRA manages those practitioners who use herbs but are not exclusively herbalists and will not be on the statutory register, e.g. naturopaths. Another area that needs addressing is whether registered herbal practitioners will be considered 'authorised healthcare professionals' and as such able to use a third party to manufacture unlicensed herbal remedies. Both of these issues were raised by the Herbal Medicine Regulatory Working Group and discussed in its report. See the full report at www.euroherb.com. The EHPA has made its position very clear to the MHRA that a way must be found to allow statutory regulated herbal practitioners to be recognised as 'authorised healthcare professionals'.

EMA and MHRA Consultations

The European Medicines Agency is currently consulting on a number of issues relating to the implementation of the THMPD, specifically as relates to quality, test procedures and acceptance criteria for herbal medicinal products, as well as on 'herbal drugs with serious risks'. See the EMA website: www.emea.eu.int. The latter document was originally produced in 1992 and was roundly condemned by the UK herbal community at the time as being unscientific and inaccurate.

The EHPA has already submitted a robust response to one document (CPMP/QWP/2820/00 Rev 1 AKA EMEA/CVMP/815/00 Rev 1) in time for the September 15th deadline and is preparing two further submissions for the remaining consultation documents due by 30th September. In addition, the EHPA has made a full and forthright response to the MHRA's Consultation Document on the implementation of the THMPD, MLX 325, pointing out that the Quality Control Guidelines proposed to be applied to traditional herbal medicinal products are unworkable and the costs of implementation of the Directive may see the demise of many small to medium sized herbal suppliers and manufacturers in the UK. This EHPA response can also be found on the EHPA website www.euroherb.com and see also "Progress on THMPD" later in this newsletter.

Michael McIntyre made Honorary Doctor

On July 7th, Michael McIntyre, Chairman of the EHPA, was made an honorary doctor of Middlesex University for his services to the herbal medicine profession. As President of the NIMH in 1993, Michael helped to launch the first degree course in herbal medicine in the UK at Middlesex and later went on to teach there. Today the University offers degrees in Western herbal medicine, Traditional Chinese Medicine and most recently Ayurveda. Two years ago Michael was made an honorary visiting Professor of the University.

New Chief Executive at the Foundation for Integrated Health

Kim Lavelly has been appointed Chief Executive at FIH, effective Thursday 1st September 2005.

Kim Lavelly replaces Michael Fox, who joined The Prince of Wales's Foundation for Integrated Health in 1998, following the Foundation's inception in 1997.

Kim Lavelly has had a successful career in the 'not for profit' sector, in the Consumers' Association (now *Which?*) and most recently in Consumers International, an international federation of consumer organisations.

The EHPA wishes Kim every success in her new post.

New Accredited Courses

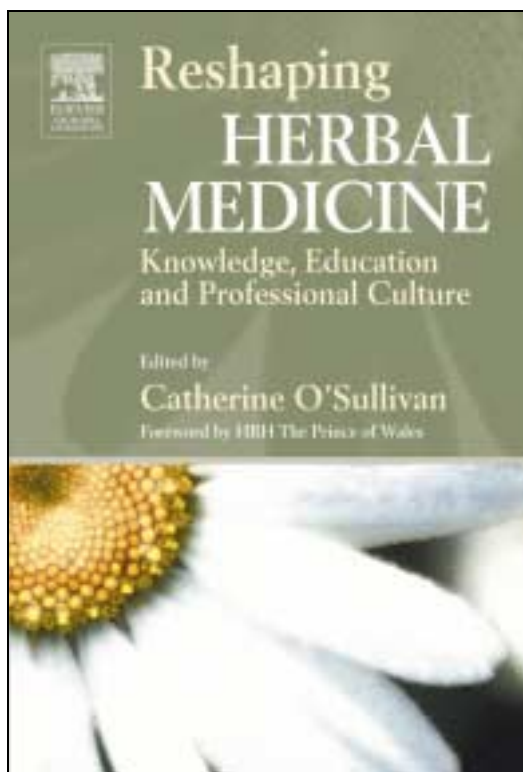
The EHPA is delighted to announce that the TCM programme at Middlesex University (www.mdx.ac.uk) and the TCM programme at the University of Westminster (www.wmin.ac.uk) have both achieved full EHPA accreditation.

New Publication

The EHPA is delighted to announce the publication of a new book *Reshaping Herbal Medicine*. The new book was edited by the EHPA's former Education Committee Chair and HMRWG member, Dr Catherine O'Sullivan, and includes contributions by many leading lights in the profession: Nick Lampert, Alison Denham, Peter Conway and many more.

The book draws on unique, previously unpublished, professional expertise regarding the reshaping of herbal medicine in the UK. It outlines the outcomes of recent examinations of its position within the healthcare system, and poses challenging questions about the direction of future herbal medicine policy within the UK.

Published by Elsevier.



Foster Review

Sir Andrew Foster, Director of Workforce, has been asked, in light of the Shipman Enquiry and the Chief Medical Officer Review of Revalidation and the GMC, to consider and provide advice to the Secretary of State about the regulation of the non-medical healthcare workforce, which includes dentists, osteopaths, nurses, pharmacists, etc.

While the herbal/traditional medicine profession has yet to be statutorily regulated, these Reviews will likely shape the future of healthcare regulation. The two reviews will consider the following:

- Revalidation and appraisal
- Initial and ongoing fitness for purpose
- Best practice in fitness to practice
- New and extended roles
- Regulation of health and social care support workers
- Review of functions and structure of the GMC
- Review of number of regulators

The Foster Review is to publish its findings by the end of the year, along with the CMO's report. Membership of the Review includes representatives from the regulatory bodies, the Department of Health, devolved administrations and the NHS.

The EHPA was invited to attend a Foster Review Reference Group part way through its proceedings to learn more about progress and to contribute to the discussions. The EHPA will participate in a further review day in early November by which time the main findings of the Foster Review are likely to have taken shape.

In addition, the EHPA responded to the Foster Review 'Call for Ideas' paper which can be viewed at www.euroherb.com.

Chinese Medicine Working Group

Earlier this year, the Department of Health established the CMWG in an effort to get the many different groups representing Chinese Medicine practitioners to work more closely together to ensure that this tradition is speaking with a single voice.

Progress on THMPD

Implementation of the Directive by the UK Government is set for 30 October 2005. As the date approaches, the EHPA has been in regular contact with the MHRA, either directly or through the Herbal Forum, to highlight a number of areas of concern around the implications of the Directive. Some of these are outlined below:

- Large costs for manufacturers who must meet GMP standards and obtain a Manufacturing Licence, particularly difficult for small businesses
- Quality standards for complex, multi ingredient herbal products will be very difficult to meet
- Registration fees are high (up to £40k for each product registration) and again will be difficult for small businesses to meet

- If the requirements of the Directive become so burdensome that local growers and manufacturers go out of business, this will have a knock on effect for practitioners who will have difficulty obtaining their products.

The EHPA will continue to work with the industry to ensure that these concerns are brought to the attention of the MHRA and the EMEA. See EHPA responses to recent consultations on medicines legislation at www.euroherb.com.

Food Supplements Directive

In the UK the Food Supplements Directive (FSD) has been seen as a threat to the long-established and flourishing market in vitamins & mineral supplements (VMS). The pretty-well unanimous

negative assessment of the FSD by UK manufacturers and suppliers of food supplements spurred the industry to challenge the Directive at the European Court of Justice. Opinion is divided about the ramifications of the recent judgment (12/7/05) of the ECJ arising out of this challenge. On the one hand it is perceived in a negative light by the Health Food Manufacturers Assn, the National Assn of Health Stores and other UK campaigners. In marked contrast, the Alliance for Natural Health (ANH) is much more upbeat about the judgement. What seems clear however is that there is not yet enough detailed information from the regulators as to the exact meaning and scope of the FSD (see briefing paper on this subject at www.euroherb.com)

2005 Diary Dates

Small Growers & Producers Meeting	5 October
CPP CPD Event: Phytotherapy and Alzheimer's Disease, London Contact Pamela Bull, pamela.bull@btopenworld.com	8 October
RCHM AGM, Regents College London	23 October
Parliamentary Group Reception	26 October
Herb Futures Meeting, Ripley, Surrey	27 October
EHPA Council and Education Committee meetings	14 November
EHPA Accreditation Board meeting	21 November
Herb Futures Meeting, Ripley, Surrey	12 December