



# FRANKINCENSE

European Herbal Practitioners Association's Newsletter  
2005

April

## Publication of the Regulation Outcomes from the DH & MHRA

In March 2004, the Department of Health consulted on proposals to regulate herbal medicine and acupuncture practitioners. The consultation period closed in June 2004. The Department has analysed the responses received and has now launched a report on the consultation. The Department of Health plans to publish draft legislation for further consultation in autumn 2005.

Over 1,000 copies of the consultation were distributed to interested individuals and organisations and a total 698 responses were received to the consultation. Responses to the Department of Health's consultation paper 'Regulation of herbal medicine and acupuncture' show 98.5 per cent support for a UK-wide system of statutory regulation of herbal medicine and acupuncture from those responding. Key areas of debate included the type and name of the proposed regulatory Council, protected titles, collaborative regulation and the composition of the council.

Health Minister Lord Warner said: "The existing legislation in this area is weak. It fails to provide patients and the public with adequate protection and does not offer a guide as to the competence of the practitioner. The majority of responses to the consultation indicated strong support for our plans to improve patient and public protection by introducing statutory regulation. Statutory regulation will improve patient and public protection by setting clear standards of training and competence for practitioners. It will also enhance the status of the herbal medicine and acupuncture professions."

The medicines watchdog, the Medicines and Healthcare products Regulatory Agency, also published responses to their draft plans to tighten regulation of herbal remedies.

See full results of DH results at [www.dh.gov.uk/Consultations/ResponsesToConsultations/fs/en](http://www.dh.gov.uk/Consultations/ResponsesToConsultations/fs/en) and for MHRA at <http://medicines.mhra.gov.uk/inforesources/publications/mlx299outcome.pdf>

## Update on the Regulation of Herbal Practitioners

Following the publication of the results of the consultation on the regulation of herbal medicine and acupuncture, the Department of Health held a one day workshop in March for a small group of herbal medicine and acupuncture practitioners to discuss the results of the consultation and also to consider next steps. As laid out in the DH report, the next phase of the regulatory process will be to set up a joint acupuncture and herbal medicine working group to consider some of the detail of the joint regulation of the two professions and to make recommendations to the Shadow Council which will be set up by the DH in 2006.

## New Patient Guide from the Foundation for Integrated Health

A new guide that provides practical information to help people find safe, well-regulated complementary healthcare practitioners was launched in February by The Prince of Wales's Foundation for Integrated Health. "Complementary Healthcare: A Guide for Patients" has been written by The Foundation in conjunction with many leading UK patient organisations, healthcare professionals and complementary practitioners.

*The Guide*, which has been part-funded by the Department of Health, provides practical information for the increasing number of people across the country who are visiting complementary practitioners. The 50-page booklet details 16 of the most popular complementary therapies including acupuncture, aromatherapy and herbal medicine. It lists general precautions; points to be aware of before having treatments; further sources of information, including those on the Internet and emphasises the need for all patients to discuss any potential complementary treatments with their GPs. Get a copy by emailing: [jo@fihealth.org.uk](mailto:jo@fihealth.org.uk)

## "Herbalist" convicted of illegal supply of medicines

On 18 March, the proprietor of 'The Herb Garden' in Leigh on Sea, Essex, Ms Anna Yang was found guilty of the supply of Chinese medicines to members of the public as 'herbal only' when they contained

non-herbal ingredients including Fenfluramine Hydrochloride, a banned drug associated with causing valvular heart disease and pulmonary hypertension. Ms Yang claimed to be a qualified Doctor and surgeon in China and promoted these goods, not only in her shop but also on the Internet. Fenfluramine Hydrochloride was formerly a prescription only medicine, which had its marketing authorisation withdrawn in 1997 because of its potential adverse effects on the heart and lungs.

Officers from the MHRA visited Yang's shop on several occasions between 2001 and 2002 and seized many products, which on analysis were found to be medicinal products containing *Fenfluramine*, *Aristolochia*, *Glibenclamide* and *Ephedrine*. All except Ephedrine are prescription only medicines and all are in breach of the Medicines Act 1968.

*Aristolochia* is a herbal substance, which has been banned from sale throughout most of Europe and has been the subject of prohibition in the UK since July 1997. The toxic component Aristolochic Acid has caused the death of a number of persons in Belgium and has led to kidney failure (Nephropathy) in at least two women in the UK.

It is the responsibility of the retailer to know precisely what is in the products that they sell. The MHRA has made it clear that suppliers like Anna Yang who ignore the grave injury that can be caused to innocent purchasers by selling supposed herbal products containing potentially harmful drugs and are in breach of the Medicines Act of 1968 will be investigated and prosecuted.

Having pleaded guilty to 10 offences under the Medicines Act 1968, Anna Yang was fined £30,000 and ordered to pay £20,000 prosecution costs. She was also ordered to do 80 hours of Community Service. The sentence passed by the court should act as a deterrent to others who have little regard for their customer's health or the Medicines Act.

## RCHM Approved Suppliers Scheme

The Register of Chinese Herbal Medicine (RCHM), a member of the EHPA, has developed an approved supplier scheme that currently includes ten approved suppliers and a selection of loose herbs, herb powders and products.

This means that the herb or herb product has come from a company that has committed itself to a programme of Quality Development, where Quality Systems are being introduced and Good Manufacturing Practice (GMP) and is being observed by employees at all levels. This programme of continuous improvement is then independently verified using qualified and experienced auditors and technical experts. Practically this means that,

as far as is possible, when you give a herbal medicine to a patient, when using an Approved Supplier, you can be sure of the following:

- That the herbal medicine has originated from a reputable source and has undergone all necessary testing. After arriving in the UK, documented procedures are in place to ensure the herbal medicine can be readily identified and will be correctly labelled if re-packaged.
- The herbal medicine has been stored in a suitable environment, where temperature and humidity are constantly monitored and contamination risks are minimised.
- The staff that handle the herbs are being trained in Good Manufacturing Practice. They have training records and well defined areas of responsibility.
- In the event of a product recall from either the manufacturer or a Government agency, the supplier has the means to identify from their batch records to whom the herbs have been distributed and to contact the practitioner or patient directly to give advice on the appropriate course of action.
- In case of complaint, the approved supplier has a documented complaints procedure that is transparent and provides information regarding the result of the complaint.

The MHRA has welcomed the RCHM initiative to create this procedure and has indicated that it is keen to work with the RCHM and its practitioners to ensure the continuing development of the approved suppliers scheme to ensure high standards of quality assurance and control for the Chinese herbal medicine sector.

Michael McIntyre, Chair of the EHPA, said 'I fully support the work of the RCHM in trying to raise the standards of quality control of herbal products in the UK.'

## Ayurvedic Practitioners Association

The EHPA is delighted to announce the formation of the Ayurvedic Practitioners Association (APA), a unifying body for Ayurvedic professionals in the UK, which has been recently established for the following purposes:

- to represent Ayurveda, as an independent and comprehensive traditional system of medicine;
- to promote and protect the practice of authentic Ayurveda with a view to improving the health and well being of people in the UK and Europe;

- to develop the profession, and help to create, promote and protect global unity among Ayurvedic professionals.

The APA has been created as a forum to represent UK Ayurvedic professionals with a view to uniting the Ayurvedic community. It intends to engage actively in a constructive dialogue with all regulatory authorities and policy makers. Thus the APA is aiming to provide reliable support, assistance

and advice to the Government in its efforts to regulate traditional medicine systems in the UK. The APA is also planning to enter into discussions with the Department of Health to explore the possible integration of Ayurveda into future UK national care strategies. For more information about the APA, contact [info@apa.uk.com](mailto:info@apa.uk.com).

## 2005 Diary Dates

Herbal Forum	11 April
MHRA Seminar: DTHMP Pharmacovigilance Requirements <i>Register with the MHRA: <a href="mailto:conferences@mhra.gsi.gov.uk">conferences@mhra.gsi.gov.uk</a></i>	12 April
Herbal Stakeholders Meeting	22 April
CPP CPD Series: Phytotherapeutics for Infertility, University of Reading <i>Contact the CPP: Pamela Bull, <a href="mailto:pamela.bull@btopenworld.com">pamela.bull@btopenworld.com</a></i>	24 April
EHPA Accreditation Board Meeting	25 April
Conference: Developing Research Strategies, University of Southampton <i>Contact Email: <a href="mailto:compmed@soton.ac.uk">compmed@soton.ac.uk</a> or telephone: (02380) 241073</i>	28 April
Ayurveda Practitioners Association Regulation Update	6 May
EHPA Education Meeting & Council Meeting	9 May
Conference: 'Integrated Health: Coming of Age', Royal Society of Medicine, <i>Contact: <a href="http://www.rsm.ac.uk">www.rsm.ac.uk</a></i>	17-18 May
Conference: Diversity and Debate in Alternative and Complementary Medicine <i>Contact: Christine Barry, <a href="mailto:Christine.Barry@brunel.ac.uk">Christine.Barry@brunel.ac.uk</a></i>	28 June-1 July
EHPA Accreditation Board Meeting	4 July
EHPA Education Meeting & Council Meeting	11 July
12 <sup>th</sup> Annual Symposium on Complementary Health Care, Peninsula Medical School <i>See website: <a href="http://www.pms.ac.uk/compmed/symposium">www.pms.ac.uk/compmed/symposium</a></i>	19-21 Sept
CPP CPD Series: The value of Traditional Use of Herbal Medicine, Banbury <i>Contact the CPP: Pamela Bull, <a href="mailto:pamela.bull@btopenworld.com">pamela.bull@btopenworld.com</a></i>	25 July