



Traditional Herbal Medicines
Opportunities and Challenges for the Future

Symposium
Centre for Pharmacognosy and
Phytotherapy

The School of Pharmacy,
University of London

27th February 2007,
10am— 5pm

Traditional Herbal Medicines

Opportunities and Challenges for the Future

Maplethorpe Theatre, The School of Pharmacy,
University of London

Prof. Michael Heinrich (Chair)

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Organizers:



The School of Pharmacy, University of London
Centre for Pharmacognosy and Phytotherapy



British Herbal Medicine Association (BHMA)



Academy of Pharmaceutical Sciences (APSGB)



Society for Medicinal Plant Research (GA)



International Society for Ethnopharmacology
(ISE)



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Introduction

Herbal Medicines, which have always been a popular health care choice in the UK, have in recent years come under increased scrutiny regarding the products' quality and safety. Most importantly, the European Union recently established a simplified registration procedure for traditional herbal medicinal products for human use (Directive 2004/24/EC), which requires all unlicensed products to be registered.

Background

Under Directive 2004/24/EC, the applicant must submit bibliographical or expert evidence to prove that the herbal medicinal product (or an equivalent medicinal product) has been in medicinal use as a traditional medicinal product in the European Union for a period of at least thirty years (or 15 years in the EU plus 15 years outside of the EU). It will not be possible to make claims about a product's efficacy but only about its traditional use. A bibliographic review of the safety data, a justification for the simplified application and a dossier describing quality assurance need to be submitted. Lastly, these products are subject to the requirements of pharmacovigilance. Importantly, this Directive also establishes that the quality of a medicinal product is independent of its traditional use. Therefore all general principles of quality control, good manufacturing practice and good distribution practice also apply to traditional herbal medicinal products for human use.



Purpose of the Symposium

This new simplified regulatory framework offers multiple opportunities but will also require new approaches both in the industry and in academia. The symposium is specifically addressed to the herbal products industry and all speakers will highlight what is needed for successful applications under this scheme. It will also focus on the specific needs of the industry (like multi-herbal preparations: and how to comply with the requirements for quality and pharmacovigilance). Lastly, the potential for industry-university collaborations will be explored.

General Introduction (10.00 - 10.15)

- Prof. Anthony Smith (Dean, The School of Pharmacy), Tim Dye (William Ransom & Son plc), Prof. Michael Heinrich (Centre for Pharmacognosy and Phytotherapy, The School of Pharmacy)

Traditional Herbal Medicines - The General Framework (Chair Michael Heinrich) (10.15 - 11.45)

- Dr. Richard Middleton, BHMA - *Are herbs medicines? The future of the UK's herbal industry*
- Richard Woodfield, MHRA - *Bringing herbal medicine into effective regulation: what progress has been made in the UK and what are the prospects for turning this objective into practical reality?*
- Prof. Werner Knoess, BfArM, Germany - *Licensing herbal medicines - the German perspective*

Quality and Safety (Chair José Prieto) (12.00 - 13.30)

- Dr. Linda Anderson, MHRA - *Quality of HMPs*
- Colin Newbold, Essential Nutrition Ltd - *Quality control of HMPs - an industry perspective*
- Dr. Romanus Lehnfeld and Dr. Hartwig Sievers, Fa PhytoLab GmbH & Co. KG, Germany - *Safety and pharmacovigilance of HMPs*

The challenges for the future (Chair Tim Dye) (15.00 - 16.30)

- Dr. Keith Helliwell, William Ransom & Son plc - *Good manufacturing practice - challenges for the herbal industry*
- Prof. Phil Routledge, University of Cardiff - *Can herbal medical products be regulated?*
- Prof. Michael Heinrich, Centre for Pharmacognosy and Phytotherapy, The School of Pharmacy - *Closing remarks*
- **Informal gathering in the new Molecular Pharmacy Building**
(16.30 -)



Registration Fees (Including VAT)

- ◆ Delegate £100 []
- ◆ Member of one of the participating organisations
(APSGB, BHMA, ISE, GA): £ 50 []
- ◆ Students (with certificate from supervisor) and members
of the University of London's KKS network
(Kew-Kings-Square network): free []

Registration for all delegates:

Name: _____

Company/Institution: _____

Address: _____

Tel: _____ Fax: _____

Email: _____

Please make cheques payable to BHMA.

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Card Number: _____ Expiry Date: _____

Receipt required? Yes [] No [] Signature: _____

Please return this form by 10th January 2007. A supplement of £50. - will be charged after this date.

Completed Registration forms with cheque or credit card payments should be posted to the address below:

**Dr. R. W. Middleton
British Herbal Medicine Association
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For registration enquiries, please contact:

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Additional registration forms can be obtained from:

<http://www.bhma.info/>

<http://www.pharmacy.ac.uk/THM.html>