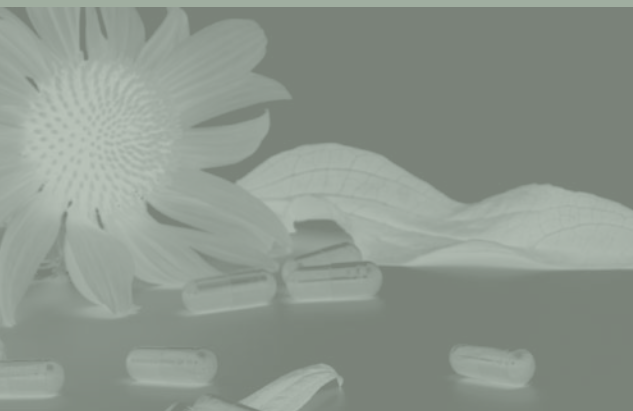


Traditional herbal medicines masterclass

Practical advice on registering a
traditional herbal medicinal product (THMP)



**Royal
Pharmaceutical
Society**
of Great Britain

Friday 13 November 2009 at the
Royal Pharmaceutical Society of Great Britain, London

OBJECTIVES

Whilst EU Directive 2004/24/EC is available, together with many other published EU guidelines also relevant to the field of herbal medicines, it is still very difficult to work through the practical steps required to register your own product as a traditional herbal medicinal product (THMP) in the EU.

This masterclass will bring together those professionals who have much experience in the herbal medicines sector and the regulators at the health authority with an aim to:

- Provide advice on a practical level to those registering a traditional herbal medicine.
- Share the experience of the UK MHRA in the assessment of applications.
- Allow delegates to consider and learn from real-life scenarios through interactive sessions.

The programme is designed by the authors of **A Practical Guide to Licensing Herbal Medicinal Products** - a recently launched PhP publication, which will be available for purchase at a substantial discount on the day. For further details on the organisers and the book please visit www.thmpd.eu.

PROGRAMME

Conference Chair: Peter Bradley, British Herbal Medicine Association (BHMA)

- 09.00 Registration and coffee
- 09.30 **Welcome and introduction by the Chair**
Peter Bradley, BHMA
- BHMA
 - BHMA and ESCOP Publications
- 09.45 **Why register a product as a traditional herbal medicine**
Elizabeth Williamson, University of Reading
- Alternatives for registration (THM, WEU, full MA or food/supplement/cosmetic)
 - Benefits and disadvantages of registration
- 10.20 **Practicalities of planning a submission**
Thomas Brendler, PlantaPhile Ltd.
- Compiling a registration documentation - the basics and the process
 - Key requirements (proof of tradition, quality, safety, claims)
 - CTD
 - Resources required and potential costs
- 11.05 Coffee
- 11.30 **Compiling a Module 3 (chemistry and manufacturing)**
Stefan Spiess, Gruenwalder GmbH
- GAP & GMP issues
 - Herbal substance(s) / compound(s) / herbal product
 - Analytical/pharmaceutical development (methods and validation)
 - Manufacturing
 - Stability

WHO SHOULD ATTEND

The workshop is aimed at:

- Manufacturers, distributors and importers of herbal products
- Regulatory specialists and consultants
- QPs and QPPs
- QA managers
- Scientists involved in natural product formulations
- NGOs and government agencies
- Pharmacists
- Herb growers, processors and extract manufacturers
- Investors and financial advisors in the field of natural products

VENUE

The Royal Pharmaceutical Society is conveniently located in central London with easy access from Waterloo, Vauxhall and Victoria rail and tube stations.

12.10 **Compiling a Module 1 (product information)**

Ann Godsell, Ann Godsell Regulatory

- Summary of product characteristics
- EMEA monographs and community list
- Labeling, package inserts and readability testing
- Pharmacovigilance system

12.50 **MHRA experiences with assessment of THR applications**

Linda Anderson, Medicines and Healthcare products Regulatory Agency (MHRA)

- Product information
- Chemistry and manufacturing
- Safety and traditional use

13.30 Lunch

14.30 **Parallel rotating workshop sessions**

Interactive workshops designed to give delegates the opportunity to interact with speakers and resource persons in smaller masterclasses. Case studies on practical issues will be used to stimulate discussion and delegates will be able to raise specific questions in a less formal setting. Three parallel sessions will be run twice during the afternoon. Delegates can choose any **two** masterclasses and are encouraged to submit questions in advance to be answered in the relevant class.

Workshop 1: Traditional use and safety

Workshop 2: Quality and stability

Workshop 3: Claims and labeling

16.00 **Workshop feedback and closing remarks**

All speakers and resource persons

16.15 Close

REGISTERING A TRADITIONAL HERBAL MEDICINE – FRIDAY 13 NOVEMBER 2009**REGISTRATION FORM**

Delegates will be registered upon receipt of the completed form and will liable to pay the fees. Payment must be made before the start of the conference. Fees inclusive of lunch and refreshments.

REGISTER BY FRIDAY 4 SEPTEMBER 2009 AND SAVE UP TO 15% (EARLY BIRD FEE)

	EARLY BIRD	FULL FEE
NON-MEMBER	<input type="checkbox"/> £325	<input type="checkbox"/> £375
MEMBER OF RPSGB OR BHMA	<input type="checkbox"/> £225	<input type="checkbox"/> £275

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Dietary Requirements				Booking ref.			

METHOD OF PAYMENT

☐ Bank transfer (Sort Code 60 60 04 Account Number: 70378193. National Westminster Bank, 91 Westminster Bridge Road, London SE1 7ZB) Quoting ref MMS EVT 437

☐ Debit/Credit card ☐ Maestro ☐ Mastercard ☐ Visa ☐ Amex

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Please return this form with your payment to: Events Coordinator,
 Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN
 Fax: 020 7572 2506 Email: events@rpsgb.org (Tel: 020 7572 2640)

NB. IF YOU DO NOT RECEIVE A CONFIRMATION OF YOUR PLACE VIA EMAIL WITHIN 5 WORKING DAYS OF SUBMITTING YOUR REGISTRATION FORM PLEASE LET US KNOW

Terms and Conditions

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