



Royal  
Pharmaceutical  
Society  
of Great Britain



A 2 <sup>1</sup>/<sub>2</sub> day international symposium on

## ***Pharmacovigilance of herbal medicines: current state and future directions***

**Wednesday 26 to Friday 28 April 2006**

at the Royal College of Obstetricians and Gynaecologists,  
Regent's Park, London, UK

### **FINAL PROGRAMME**

#### **Key topics:**

- Adverse effects of herbal medicines
  - Interactions between herbal and conventional medicines
  - Molecular basis of herbal adverse drug reactions (ADRs)
  - Detecting and assessing signals of herbal safety concerns
- Spontaneous reporting of suspected herbal ADRs: national and global perspectives
  - Herbal-sector—initiated schemes for reporting herbal ADRs
  - Industry and regulatory perspectives on herbal ADRs and ADR reporting
- Applying pharmacoepidemiological methods to investigating safety of herbal medicines
- Impact of traditional herbal medicinal products directive on pharmacovigilance of herbal medicines
  - Communication of herbal safety concerns
  - Risk management strategies for herbal medicines
  - Pharmacogenomics and herbal medicines
  - Nomenclature and quality of herbal medicines



**E/S/C/O/P**



**Organised by** the Royal Pharmaceutical Society of Great Britain (RPSGB) in conjunction with the Uppsala Monitoring Centre (WHO-UMC), the International Society of Pharmacovigilance (ISoP), the Gesellschaft für Arzneipflanzenforschung (GA; Society for Medicinal Plant Research), the European Scientific Cooperative on Phytotherapy (ESCOP), the School of Pharmacy, University of London, UK, the School of Pharmacy, University of Auckland, New Zealand, and the Academy of Pharmaceutical Sciences, UK.

### **Background and purpose of the meeting:**

Herbal medicines are widely used in health-care in both developed and developing countries. However, in recent years, there have been several high-profile herbal safety concerns that have had an impact on the public health, and there is increasing recognition of the need to develop pharmacovigilance (safety monitoring) systems for herbal medicines. Pharmacovigilance for herbal medicines is, in many respects, in its infancy and monitoring the safety of herbal medicines presents unique challenges.

This meeting aims to provide a comprehensive and critical overview of the current state of pharmacovigilance activities for herbal medicines at the national and global levels. It will explore in depth the challenges that pharmacovigilance of herbal medicines presents, consider relevant emerging issues and what steps could and should be taken to improve safety monitoring for herbal medicines in the future.

### **Who should attend**

This conference will be of interest to individuals working in medicines regulation, National Pharmacovigilance Centres, the herbal medicines and conventional pharmaceutical industry and academia, as well as complementary and conventional health-care providers, including medical herbalists, doctors, pharmacists and nurses, and journalists.

### **Submitted abstracts**

Submitted abstracts on relevant topics have been invited and the deadline has now passed. A session will be dedicated to short oral presentations of selected submitted abstracts. Accepted abstracts will be published in *Drug Safety*.

### **Registration**

Delegate fees are £275.00 for members of the associated organisations, academics and government employees, and £350.00 for non-members and industry employees (exclusive of VAT at 17.5%). The fee for *bona fide* students is £145 (exclusive of VAT). The on-site registration fee is £450 + VAT for all delegates. Fees are inclusive of course documentation, refreshments and lunches during the Conference.

### **Chairman**

Joanne Barnes, Associate Professor in Herbal Medicines, School of Pharmacy, University of Auckland, Auckland, New Zealand (j.barnes@auckland.ac.nz)

### **Scientific Organising Committee:**

Professor Rudi Bauer, Institute of Pharmaceutical Sciences, Department of Pharmacognosy, University of Graz, Germany, and President, GA

Dr Jan Bruhn, Inbio, Sweden, ESCOP Board

Professor Peter AGM de Smet, Scientific Institute Dutch Pharmacists, The Netherlands

Professor I Ralph Edwards, Director, Uppsala Monitoring Centre, Sweden

Simon Mills, Peninsula Medical School, Universities of Exeter and Plymouth, UK, and ESCOP Board

Professor Tony Moffat, School of Pharmacy, University of London, UK

Professor Giampaolo Velo, University of Verona, Italy, and President, ISOP

Dr John Clements, Science Advisor to the Royal Pharmaceutical Society, UK

### **Programme**

The Conference will open at 13.30 h on Wednesday 26 April and close at approximately 18.00 h on Friday 28 April 2006.

The current programme can be found at [www.rpsgb.org/science](http://www.rpsgb.org/science)

### **For further information contact:**

Lisa Gilbert, Science Conference Secretariat, Royal Pharmaceutical Society. Email: [science@rpsgb.org](mailto:science@rpsgb.org); Phone: 0044 (0) 20 7572 2261, Fax: 0044 (0) 20 7572 2506

## Programme

### WEDNESDAY 26 APRIL 2006

- 1.00 REGISTRATION AND COFFEE
- 1.30- 2.10 Welcome  
**Gerald Alexander**, Vice-President of the Royal Pharmaceutical Society  
**Joanne Barnes** and Scientific Organising Committee
- 2.10 - 2.25 Opening address  
**Alasdair Breckenridge**, Executive Chairman,  
Medicines and Healthcare products Regulatory Agency, UK
- SESSION 1: Adverse effects of herbal medicines.**  
Chair: **Alasdair Breckenridge**
- 2.25 - 3.15 Strategies for risk management for herbal medicines  
**Phil Routledge**, CSM Cardiff, chair of Herbal Medicines Advisory Committee, UK
- 3.15 - 3.45 **Overview of herbal ADRs by system-organ-class**  
**Peter A G M de Smet**, Scientific Association Dutch Pharmacists, Netherlands
- 3.45 - 4.15 COFFEE; POSTER VIEWING
- 4.15 - 4.45 Drug-herbal interactions: mechanisms and clinical relevance  
**Shufeng Zhou**, Department of Pharmacy, National University of Singapore, Singapore
- 4.45 - 5.15 Chemical and molecular basis of *Aristolochia* and other herbal toxicities  
**H H Schmeiser**, Division of Molecular Toxicology, Heidelberg, Germany
- 5.15 - 5.45 Herbal medicines in pregnancy and breast-feeding  
**Pat McElhatton**, National Teratology Information Service, Newcastle, UK
- 5.45 – 7.00 WINE RECEPTION AND POSTER VIEWING

### THURSDAY 27 APRIL 2006

- 8.30 - 9.00 COFFEE; POSTER VIEWING
- SESSION 2: Challenges and solutions 1: Regulation of herbal medicines and implications for pharmacovigilance**  
Chair: **Tony Moffat**, University of London, UK
- 9.00 - 9.10 Welcome  
**Joanne Barnes** and Scientific Organising Committee
- 9.10 - 10.00 **Plenary 2:** The THMPD and the 2001 review of pharmaceutical legislation: implications for safety and pharmacovigilance of herbal medicines  
Speaker to be confirmed
- 10.00 - 10.30 Regulation of herbal practitioners in the UK: implications for safety and safety monitoring of herbal medicines  
**Linda Anderson**, Medicines and Healthcare products Regulatory Agency, UK
- 10.30 - 11.00 COFFEE; POSTER VIEWING
- Session 3: Challenges and solutions 2: nomenclature and quality of herbal medicines**  
Chair: **Rudi Bauer**, University of Graz, Austria
- 11.00 - 11.30 The WHO-UMC herbal ATC classification system  
**Mohammed Farah**, WHO-UMC, Sweden
- 11.30 - 12.00 The i-Plants project  
**Bob Allkin**, Royal Botanic Gardens, Kew, UK

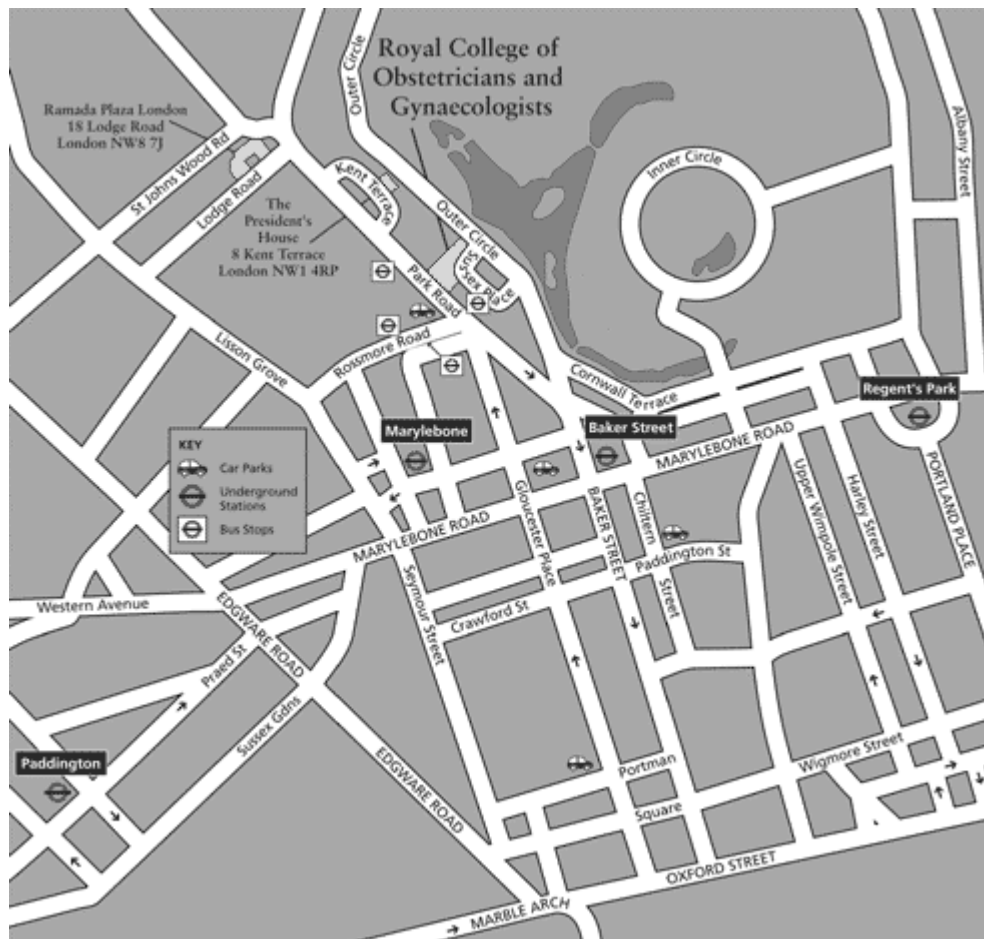
- 12.00 - 12.30 Authentication of Chinese herbal medicines; importance in safety and safety monitoring  
**Christine Leon**, Royal Botanic Gardens, Kew, UK
- 12.30 - 1.00 Quality of herbal medicinal products and implications for safety and efficacy  
**Arnold Vlietinck**, University of Antwerp, Belgium
- 1.00 - 2.00 LUNCH; POSTER VIEWING
- Session 4. Short oral submitted presentations**  
Chair: **Jan Bruhn**, ESCOP
- 2.00 - 3.15 Presentations from submitted abstracts
- 3.15 - 3.45 COFFEE; POSTER VIEWING
- Session 5. Complementary and alternative medicine systems: paradigms and perspectives on herbal ADRs and ADR reporting**  
Chair: **Bruce Hugman**, Communications Consultant to the UMC, Thailand
- 3.45 - 4.00 Adverse event reporting for prescribed herbal medicines. The National Institute of Medical Herbalists yellow card reporting scheme  
**Alison Broughton**, National Institute of Medical Herbalists, UK
- 4.00 - 4.15 U.K. Register of Chinese Herbal Medicine spontaneous reporting scheme  
**Tony Booker**, Register of Chinese Herbal Medicine, UK
- 4.15 - 4.30 UK aromatherapists perspective on ADRs and ADR reporting  
**Judith Howie**, International Federation of Aromatherapists, UK
- 4.30 - 4.45 Traditional healers' perspective on ADRs and ADR reporting  
**Alex Dodoo**, National Pharmacovigilance Centre, Ghana
- 4.45 - 5.00 Panel discussion  
**A Broughton, T Booker, J Howie, A Dodoo**
- 5.00 - 5.15 ESCOP perspective on ADRs and ADR reporting  
**Simon Mills**, ESCOP
- 5.15 - 5.30 Safety of herbal medicines, and herbal ADR reporting: perspective of a herbal medicine manufacturer  
**Stephan Köhler**, Schwabe Pharmaceuticals, Germany
- 5.30 - 5.40 Herbal ADRs and herbal ADR reporting: the pharmaceutical industry perspective  
**Richard Tiner**, The Association of the British Pharmaceutical Industry
- 5.40 - 5.50 Consumer perspective on ADRs and ADR reporting  
Speaker to be advised
- 5.50 - 6.00 Health-food stores' perspective on ADRs and ADR reporting  
Speaker to be advised
- 6.00 - 6.15 Panel discussion  
**S Köhler, S. Mills, R Tiner** and others to be confirmed
- 6.15 Close of session
- FRIDAY 28 APRIL 2006**
- 8.30 - 9.00 COFFEE; POSTER VIEWING
- 9.00 - 9.10 Welcome, **Joanne Barnes** and Scientific Organising Committee
- Session 6. Tools and Techniques (1) Spontaneous reporting of herbal ADRs**  
Chair: **Ralph Edwards** and **Joanne Barnes**

- 9.10 - 10.00      **Plenary 3:** Spontaneous reporting of herbal ADRs: the global experience  
**Ralph Edwards**, WHO- Uppsala Monitoring Centre, Sweden
- 10.00 - 10.30      Spontaneous reporting of herbal ADRs: experiences from Africa  
**Alex Dodoo**, Coordinator for the National Centre for Pharmacovigilance, Ghana
- 10.30 - 11.00      Spontaneous reporting of herbal ADRs: Chinese experience  
**Yixin Chen**, National Pharmacovigilance Centre, China
- 11.00 - 11.30      COFFEE; POSTER VIEWING
- 11.30 - 12.00      Spontaneous reporting of herbal ADRs: German experience  
**Ulrich Hagemann**, BfArM, Germany
- 12.00 - 12.30      International data mining for signals of herbal ADRs  
**Andrew Bate**, WHO- Uppsala Monitoring Centre, Sweden
- 12.30 – 1.00      Periodic safety update reports for herbal medicinal products: an industry perspective  
**Hartwig Sievers**, Phytolab, Germany
- 1.00 - 2.00      LUNCH; POSTER VIEWING  
**Session 7: Tools and Techniques (2). Applying pharmacoepidemiological tools in pharmacovigilance of herbal medicines**  
Chair: John Parkinson, London, UK
- 2.00 - 2.30      Potential of observational data in herbal pharmacovigilance  
**John Parkinson**, General Practice Research Database, London, UK
- 2.30 - 3.00      Modified PEM for herbal medicines: a feasible method ?  
**Deborah Layton**, Drug Safety Research Unit, Southampton
- 3.00 - 3.30      Evamed – a prescription-based electronic system for reporting adverse drug events in complementary medicine  
**Marion Schaefer**, Berlin
- 3.30 - 4.00      COFFEE; POSTER VIEWING  
  
**Session 8: Future directions**  
Chair: **Giampaolo Velo**, University of Verona, Italy
- 4.00 - 4.30      Pharmacy records and herbal medicines : problems and potential in pharmacovigilance of herbal medicines  
Speaker to be confirmed
- 4.30 - 5.00      Evidence for benefits of herbal medicines  
Speaker to be confirmed
- 5.00 - 5.30      Pharmacogenomics and herbal medicines  
**Munir Pirmohamed**, University of Liverpool, UK
- 5.30 - 6.00      Communication of herbal safety concerns  
**Bruce Hugman**, Communications Consultant to the UMC, Thailand
- 6.00 - 6.10      Closing ceremony: **Joanne Barnes** and Scientific Organising Committee

## Venue

The Conference “*Pharmacovigilance of herbal medicines: current state and future directions*” will be held at:

The Royal College of Obstetricians and Gynaecologists  
27 Sussex Place, Regent's Park, London NW1 4RG  
Tel: +44 (0) 20 7772 6200 Fax: +44 (0)20 7723 0575



**By Train:** Marylebone mainline rail station is only a ten-minute walk away and Paddington, Euston, King's Cross and St Pancras are also close by.

**By Tube:** The nearest Underground station is Baker Street (served by the Hammersmith & City, Bakerloo, Circle, Jubilee and Metropolitan lines).

**By Bus:** The area is also well served by a number of different buses, including the numbers: 13, 82, 113, 139, 189 and 274.

**By Car:** Car parking facilities are available at the NCP Park Road (24-hour) and on the Regent's Park Outer Circle (short-stay metered parking).

***Pharmacovigilance of herbal medicines: current state and future directions***

Wednesday 26 to Friday 28 April 2006, London, UK

**REGISTRATION FORM**

Conference Fees are inclusive of course documentation, informal reception, and refreshments and lunches during the Conference. Reduced Fees apply to bona fide members of RPSGB, the Academy of Pharmaceutical Sciences and the affiliated organisations.

<input type="checkbox"/>	<b>Members fee</b>	<b>£ 275.00</b>	<b>VAT</b>	<b>£ 48.13</b>	<b>Total</b>	<b>£ 323.13</b>
<input type="checkbox"/>	<b>Student</b>	<b>£ 145.00</b>	<b>VAT</b>	<b>£ 25.37</b>	<b>Total</b>	<b>£ 170.37</b>
<input type="checkbox"/>	<b>Full Fee:</b>	<b>£ 350.00</b>	<b>VAT</b>	<b>£ 61.25</b>	<b>Total</b>	<b>£ 411.25</b>
<input type="checkbox"/>	<b>On-site registration fee</b>	<b>£ 450.00</b>	<b>VAT</b>	<b>£ 78.75</b>	<b>Total</b>	<b>£ 528.75</b>

Delegates will be registered strictly in order of receipt of the completed Registration Form and will be liable to pay the appropriate fee upon registration.

DELEGATE SURNAME .....(BLOCK CAPITALS)

TITLE (Miss/Mrs/Ms/Mr/Dr/Prof) ..... FORENAMES .....

ADDRESS .....

POSTCODE ..... COUNTRY .....

TEL. No. .... FAX No. ....

E-Mail address: .....

I confirm that I am a member of RPS, APS or an affiliated organisation and claim the reduced fee

I am a member of (state organisation and membership number, if relevant).....

**METHOD OF PAYMENT** [please check one box]

Cheque in GB Pounds Sterling drawn on a British Bank and payable to "The Royal Pharmaceutical Society" ensuring that all bank charges are paid by the sender

Bank Transfer: Sort Code 60 60 04. Account Number: 7037 8193 quoting reference CAS/ SYM/ 416 National Westminster Bank, 91 Westminster Bridge Road, London SE1 7ZB, UK

Credit Card:    Mastercard                       Visa                       Eurocard                       AMEX

Card Number: .....

Exact Name on Card: .....

Expiry Date: . / . . . . . Signature: ..... Date: .....

CARDHOLDER'S NAME .....(BLOCK CAPITALS)

ADDRESS .....

POSTCODE ..... COUNTRY .....

Completed Registration Forms should be sent to: Lisa Gilbert, Science Programme Manager, RPSGB, 1 Lambeth High Street, London SE1 7JN, UK. Fax: 0044 20 7572 2506  
The VAT Registration Number is: UK 223 0296 92

## Accommodation

Please note that delegates are responsible for making their own bookings for accommodation.

<b>Name &amp; address</b>	<b>Telephone</b>	<b>Fax</b>	<b>Rating</b>
Georgian House Hotel 87 Gloucester Place W1H 3PG	020 7935 2211	020 7486 7535	◆◆◆ (3 diamonds)
Hart House Hotel 51 Gloucester Place W1H 3PE	020 7935 2288	020 7935 8516	◆◆◆ (3 diamonds)
The Americana Hotel 172 Gloucester Place NW1 6DS	020 7723 1452	020 7723 4641	◆◆◆ (3 diamonds)
Four Seasons Hotel 173 Gloucester Place NW1 6DX	020 7432 3224	020 7432 3225	◆◆◆◆ (4 diamonds)
Regents Park Hotel 154-156 Gloucester Place NW1 6DT	020 7258 1911	020 7258 0288	★★ (2 stars)
Dorset Square Hotel 39 Dorset Square NW1 6QN	020 7723 7874	020 7724 3328	★★★★ (4 stars)
Jarvis Marylebone Harewood Row NW1 6SE	020 7262 2707	020 7262 2975	
The Danubius <i>(formerly Ramada Plaza London)</i> 18 Lodge Road NW8 7JT	020 7722 7722	020 7483 2408	★★★★ (4 stars)
The Landmark London 222 Marylebone Road NW1 6JQ	020 7631 8000	020 7631 8080	★★★★★ (5 stars)

All the accommodation listed above is within 600 yards of the Royal College of Obstetricians and Gynaecologists.