International Society of Pharmacovigilance

New Challenges in Clinical Safety, Pharmacovigilance and Vaccine Vigilance

Training Course, 10 & 11 February 2005, Barcelona

Venue: Fundació Doctor Robert, Universitat Autònoma de Barcelona,
Sant Antoni Maria Claret 171 - 08041 Barcelona- Spain
www.fdrobert.org

This high level two-day seminar will assess what are the new challenges in pharmacovigilance and how society should meet them. The programme will include the following topics:

- The changing roles and responsibilities of a safety officer
- Monitoring patients' safety and health during clinical trials and recommendations of CIOMS VI
- What are the optimal pre- & post-authorisation safety conditions for a drug to be a successful candidate: is there a new Investigational Framework with ICHE2E?
- Current and future perspectives for education and training in pharmacovigilance
- Developing tools and skills in pharmacovigilance: Applying benchmarking to coding, data-mining, exploring and finding risks, and defining safe use of the drugs and developing pragmatic approaches
- Social communication: the role of patients and patients' associations with special reference to orphan drugs
- The marketing of pharmacovigilance: how to be more attractive for professionals, pharmaceutical and biotech companies, patients, mass media. Do we need Erice Declaration re-activation?
- Vaccine vigilance: what is different as regards definition, collection, analysis, reporting?
- Challenges in the pharmacovigilance of oncolytic treatments.

There will be practical exercises and ample opportunity to exchange views and ideas in discussions both following individual presentations and after the panel discussion at the end of the seminar. The aim is to produce an outline of widely acceptable recommendations.

The course will run on the February 10th at 09.00 through to 18.00 (1.5 hours' lunch) and continue on February 11th at 09.00 through to 17.00 (1.5 hours' lunch).

Speakers and chairpersons will be:
M. Antonia Astorga (Sanofi-Aventis), Conxita Barajas (Bayer), Jürgen Beckmann (BfArM), Chalbi Belkahia (Tunisia National Centre of Pharmacovigilance),
Ralph Edwards (WHO), Paula Marquez (PharmaMar), Elisabeth Loupi (Sanofi-Aventis), Ronald Meyboom (UMC), Tomas Moraleda (MSSO), Ana Maria Corrêa-Nunes (INFARMED), Peter Schultz (Amgen), Josep Torrent (COMP-EMEA), Giampaolo Velo (Clinical Pharmacology Unit- Verona University)

Full details and registration forms available from the ISoP Administration office

The cost for 2-days seminar (10 February & 11 February):

500 Euros for ISoP members (Industry)
350 Euros for governmental, academic, retired or student members of ISoP
750 Euros for non-members of ISoP (includes one year's membership to run until 31.12.2005)
500 Euros for governmental, academics, retired or student non-members of ISoP (includes one year's membership to run until 31.12.2005; proof of status required)

The cost includes lunch with drinks and coffee break but does not include accommodation, dinner or travel.

Single rooms/night are available at a special rate with the following hotel:
Hotel Amrey Sant Pau (**55.58 euros + 7% tax)**
Sant Antoni Maria Claret, 173 (Esquina Sant Quinti) - 08041 Barcelona (Spain)
Tel: +34 93 433 51 51 - Fax: +34 93 433 41 51
E-mail: santpaureservas@grupoamrey.com
www.amrey-hotels.com
★ Bookings and payment should be made directly with the hotel quoting **'ISoP'**
(Please note: rate available until 31 December 2004)

Payments
Payment in Euros (payable to: International Society of Pharmacovigilance)
Bank transfers and Credit/Debit Card - **VISA and MasterCard only accepted**.

International Society of Pharmacovigilance, PO Box 32974, London SW19 8YG, UK (Administration address)
Tel and fax: +44 (0)20 8286 1888 – email:administration@isoponline.org – Internet: www.isoponline.org

The aim of the International Society of Pharmacovigilance is to provide an international forum for all those with an interest in the clinical, scientific and regulatory aspects of drug safety, - and not only full-time pharmacovigilance professionals. Our Society consists of members from industry, governmental agencies, research and academic bodies.