



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

3rd EGA Pharmacovigilance Discussion Forum

20 January 2010

Radisson SAS Hotel
22 Portman Square, London W1H 7BG, UK

Wednesday 20 January 2010

- 08:00 Registration and Networking Coffee
- 09:00 **Session I - In the Spotlight: The European Commission Pharmacovigilance Legislative Proposals**
Chair | *Suzette Kox, Senior Director Scientific Affairs, EGA*
Opening Address by *Suzette Kox, Senior Director Scientific Affairs, EGA*
- 09:05 **Where are we in the Process and what are the Sticking Points?** | *Suzette Kox, Senior Director Scientific Affairs, EGA, BE*
- 09:20 **Patients and Consumers' Perspective and Counterproposals** | *Ilaria Passarani, Head of the Health Department, BEUC, the European Consumers' Organisation, BE*
- 09:40 **Experience with Patients Direct Reporting and How Best to Address Patient Advocacy Groups' and Social Health Insurers' Concerns Regarding the EC Legislative Proposals** | *Mick Foy, MHRA, UK*
- 10:00 **Position of The Netherlands on the Pharmacovigilance Package** | *Birte van Elk, MEB, Dutch Representative for the Pharmacovigilance Package in the Council of Ministers*
- 10:15 **Panel Discussion on the Pharmacovigilance Package with Session Speakers, Mia Trolle Borup, Danish Medicines Agency, DK - Julia Pallos, Head of Pharmacovigilance Department, National Institute of Pharmacy, HU - Wendy Huisman, Teva Europe, NL**
- 11:00 Networking Coffee Break
- 11:30 **Session II - Cutting Red Tape While Ensuring Patients Safety: Periodic Safety Update Reports, PSUR Work Sharing Scheme and Core Safety Profiles**
Chair | *Gernot Schreiber, Head Global Pharmacovigilance and EU Qualified Person for Pharmacovigilance, Sandoz International, DE, and EGA Representative at the EudraVigilance Steering Committee*
Generic Medicines Industry's Perspective | *Wendy Huisman, EU Qualified Person for Pharmacovigilance, Teva Europe, NL, Chair of EGA Safety & Pharmacovigilance Working Group and EudraVigilance Expert Working Group Member*

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EU Perspective: Achievements and Next Steps | *Mia Trolle Borup, Chair of the EU PSUR Work Sharing Project, EU*

Discussion and Q&A | *Session Speakers, Ilaria Passarani, Head of the Health Department, BEUC and Inge Bøgh Jansen, Director Pharmacovigilance Drug Safety, Actavis, DK*

13:00 Networking Buffet Lunch

14:00 **Session III - Latest Moves in the Pharmacovigilance Environment**

Chair | *Augusto Filipe, Director Medical Department, Farmoz, PT and EudraVigilance Expert Working Group Member*

Impact of Health Level 7 on Electronic Transmission of Individual Case Safety Reports (E2B), Compliance Reports and Key Developments within Eudravigilance | *Paolo Alcini, Head of Section Data Collection and Management of the Pharmacovigilance and Risk Management Sector, EMA, EU*

14:30 **Questions & Answers**

14:45 **Pragmatic Approach to the Detailed Description of Pharmacovigilance System (DDPS)** | *Axel Thiele, Pharmacovigilance Department, BfArM, DE*

15:05 **Good Pharmacovigilance Practice Risk Based Inspections** | *Andrew Cochrane, Inspector, MHRA, UK*

15:30 **Questions & Answers**

16:00 End of Forum Drink

For further information

www.gpaconferences.com or www.egagenerics.com

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