



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

2nd EGA Pharmacovigilance Discussion Forum 28 January 2009

OKURA Hotel
Ferdinand Bolstraat 333 - NL-1072 LH Amsterdam

Wednesday 28 January 2009

- 08:00 Registration and Networking Coffee
- 09:00 **Session I - The New European Commission Pharmacovigilance Legislative Proposals**
Chair | *Suzette Kox, Senior Director Scientific Affairs, EGA*
Opening Address by *Suzette Kox, Senior Director Scientific Affairs, EGA*
- 09:15 **The Co-decision Procedure, Stakeholders & Timelines** | *Suzette Kox, Senior Director Scientific Affairs, EGA*
- 09:45 **Key Legislative Proposals Impacting the Generic Medicines' Industry** | *Wendy Huisman, EU Pharmacovigilance QP, Teva Europe, NL, Chair of EGA Safety & Pharmacovigilance Working Group and EudraVigilance Expert Working Group Member*
- 10:15 **The European Consumers' Organisation Perspective** | *Ilaria Passarani, Health Policy Officer, BEUC, BE*
- 10:30 **Panel Discussion with Session speakers and Ineke Crijns, Senior Clinical Assessor Pharmacovigilance, MEB, NL**
- 11:00 Networking Coffee Break
- 11:30 **Session II - Harmonised Birthdates, Periodic Safety Update Reports, PSUR Work Sharing Initiative, Literature Search and Risk Management Systems**
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 | *Marina Belle, PSUR Manager, Sandoz International, DE*
EU Perspective | *Mia Trolle Borup, Chair of the EU PSUR work sharing project*
Panel Discussion and Q&A | *Session Speakers, Line Michan, Pharmacovigilance Officer, Danish Medicines Agency, Sabine Brosch, Deputy Head of Sector Pharmacovigilance and Post-Authorisation Safety and Efficacy, EMEA, EU and Koos van der Plas, Manager, Pharmacovigilance Qualified Person, Apotex Europe*
- 13:00 Networking Buffet Lunch

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- 14:00 **Session III - EudraVigilance & Inspection Environment**
Chair | *Augusto Filipe, EudraVigilance EWG Member, Farmoz, PT*
EudraVigilance: Current Status and New Legal Proposal | *Sabine Brosch, Deputy Head of Sector Pharmacovigilance and Post-Authorisation Safety and Efficacy, EMEA, EU*
- 14:30 **Questions & Answers**
- 14:45 **The Pharmacovigilance Master File and Audits: Generic Industry's Perspective** | *Wendy Huisman, EU Pharmacovigilance QP, Teva Europe, NL, Chair of EGA Safety & Pharmacovigilance Working Group and EudraVigilance Expert Working Group Member*
- 15:05 **Pharmacovigilance Inspection** | *Carrie Scott, GPvP Operations Manager & Pharmacovigilance Inspector, MHRA, UK*
- 16:00 **Questions & Answers**
- 16:15 **End of Forum Drink**

For further information and to register on-line, please visit:

www.gpaconferences.com or www.egagenerics.com

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Registrations close officially on 16 January 2009 & are subject to availability