



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

1st EGA Pharmacovigilance Discussion Forum EU Pharmacovigilance: A Moving Target

| 30th January 2008 |

Radisson SAS Royal Hotel

47, rue du Fossé-aux-Loups - 1000 Brussels, Belgium

Wednesday 30th January 2008

08:00 Registration and Networking Coffee

Session I **The Future EU Pharmacovigilance Environment**
Chair | *Suzette Kox, Senior Director Scientific Affairs, EGA*

09:00 **Opening Address by Suzette Kox, Senior Director Scientific Affairs, EGA**

09:15 **What are the Key European Commission's Legislative Proposals to Strengthen and Rationalise the EU Pharmacovigilance Environment?** | *Peter Arlett, European Commission Enterprise and Industry DG Pharmaceuticals Unit, EU*

09:45 **What is the Generic Industry's Viewpoint Regarding the New Legislative Proposals?** | *Wendy Huisman, Chair of EGA Safety & Pharmacovigilance Working Group and EV EWG Member, Teva Europe, NL*

10:15 **Panel Discussion with session speakers, Thierry Roisin, AFMPS BE, Pim van der Giesen, MEB NL, Günter Hermann and Thys Kruger from industry**

11:00 Coffee Break

Session II **EU Harmonised Birthdates and Periodic Safety Update Reports**
Chair | *Günter Hermann, Senior Director Pharmacovigilance PLIVA EU, Germany*

11:30 **What is the Status of the EU Harmonised Birthdates' Initiative and Best Practice Guide for Submission of PSURs?** | *Pim van der Giesen, Medicines Evaluation Board, NL*

11:50 **Generic Industry's Contribution and Experience so far** | *Marina Belle, PSUR Manager, Sandoz International, DE*

12:20 **Q&A Session**

13:00 Buffet Lunch

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Session III EudraVigilance & Inspection Environment

Chair | *Wendy Huisman, Chair of EGA Safety & Pharmacovigilance Working Group and EV EWG Member*

- 14:00 **The EudraVigilance Project: Today and in the Future** | *Sabine Brosch, Deputy Head of Sector Pharmacovigilance and Post-Authorisation Safety and Efficacy, EMEA, EU*
- 14:30 **Generic Industry's Perspective** | *Augusto Filipe, EudraVigilance EWG Member, Farmoz, PT*
- 15:00 **AFSSAPS Experience and Recommendation concerning Pharmacovigilance Inspections** | *Emmanuelle Pinès, Pharmacovigilance Inspector, AFSSAPS, FR*
- 15:30 Coffee Break

Session IV Risk Management in the EU

Chair | *Suzette Kox, EGA*

- 16:00 **European Risk Management Strategy: Achievements to Date and Priority Areas for the Future** | *Sabine Brosch, Deputy Head of Sector Pharmacovigilance and Post-Authorisation Safety and Efficacy, EMEA, EU*
- 16:30 **Risk Management for Generic Medicines: Open Questions** | *Thys Kruger, Medical Director Ranbaxy Europe, UK*
- 17:00 **Questions from the Floor and Discussion**
- 17:30 End of Forum and Cocktail Reception

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 15th January 2008 & are subject to availability