EUROPEAN GENERIC MEDICINES ASSOCIATION

Making Medicines Affordable

5th EGA Pharmacovigilance Discussion Forum

18 January 2012

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

Wednesday 18 January 2012	
08:00	Registration and networking coffee
09:00	Session 1 – **In the spotlight: implementation of the new EU pharmacovigilance legislation** Chair | *Suzette Kox, Senior Director Scientific Affairs, EGA*
09:00	**Opening address** | *Suzette Kox, Senior Director Scientific Affairs, EGA*
09:05	**Implementing measures in order to harmonise the performance of the pharmacovigilance activities** | *Florian Schmidt, Legal Officer, DG Sanco/D3, European Commission*
09:25	**Update from the European Medicines Agency and the legislation implementation project** | *Peter Arlett, Head of Sector for Pharmacovigilance and Risk Management, EMA, EU*
10:00	**The ISO IDMP and Individual Case Safety Report (ICSR) standards** | *Anja van Haren, EudraVigilance Coordinator, CBG-MEB, NL*
10:20	**Questions & answers** *with session speakers*
11:00	Networking coffee break
11:30	Session 2 – **Implementation steps of new legislation by industry: what, when, how?** Chair | *Inge Bøgh Jansen, Director Pharmacovigilance Drug Safety, Actavis and Vice-Chair of the EGA Pharmacovigilance & Drug Safety Working Group*
11:30	**Hints to industry, a member state's perspective** | *Mick Foy, Manager - Signal Management Group, Vigilance and Risk Management of Medicines, MHRA, UK*
12:00	**From PSUR work-sharing to single assessments - Implications for established substances** | *Anne Ambrose, VRMM, Medicines and Healthcare Products Regulatory Agency (MHRA) and Chair of PSUR Work-Sharing Group, UK*
12:30	**Panel discussion with Industry**
13:00	Networking buffet lunch

EUROPEAN GENERIC MEDICINES ASSOCIATION
Rue d'Arlon 50, B-1000 Brussels, Belgium
T: +32-(0)2-736 8411 F: +32-(0)2-736 7438
E: info@egagenerics.com www.egagenerics.com
VAT: BE 0449 332 209

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14:00	Session 3 - **Changing pharmacovigilance environment for member states, pharmacovigilance inspectors and industry** Chair | *Balwant Heer, VP, Global Head - Product Safety & Risk Management, QPPV EEA, Mylan and EGA Representative at the EudraVigilance Steering Committee*
14:00	**What are the differences for inspection pre- and post-July 2012?** | *Anna Toth, Pharmaocvigilance Inspector, Department of Pharmacovigilance, Medical Products Agency, Sweden*
14:30	**Implementation of new pharmacovigilance legislation: are we prepared for transparency? A member state perspective** | *Doris Irene Stenver, Chief Medical Officer, Danish Medicines Agency (DKMA), Denmark*
15:00	**What does the new EU PV legislation mean at local and European level? An EU QPPV perspective** | *Wendy Huisman, EU Qualified Person for Pharmacovigilance, Teva Europe, NL, Chair of EGA Pharmacovigilance & Drug Safety Working Group and EudraVigilance Expert Working Group Member*
15:30	**The CMDh proposal how to handle administrative simplifications, particularly related to the change of QPPV** | *Sandra Petraglia, IT CMDh Member, AIFA*
15:45	**Q&A and discussion** *with session speakers & Inge Bøgh Jansen, Director Pharmacovigilance Drug Safety, Actavis*
16:00	Cocktail reception
16:30	**ADD-ON WORKSHOP: Implementation plan for new pharmacovigilance legislation in a generic medicines company** | *Jan Petracek, CEO, European Pharminvent Services, CZ*
18:00	End of workshop

For further information and to register on-line, please visit:
www.gpaconferences.com or www.egagenerics.com

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