EUROPEAN GENERIC MEDICINES ASSOCIATION

Making Medicines Affordable

6th EGA Pharmacovigilance Discussion Forum

16 January 2013

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

Wednesday 16 January 2013

08:00	Registration and networking coffee
09:00	Session 1 – **Implementation of the new EU pharmacovigilance legislation** Chair | *Maarten Van Baelen, Medical Affairs Manager, EGA*
	Opening address | *Maarten Van Baelen, Medical Affairs Manager, EGA*
09:05	**EMA general state of play** | *Peter Arlett, Head of Sector for Pharmacovigilance and Risk Management, EMA, EU*
09:40	**The new pharmacovigilance fee regulation: an EGA perspective** | *Maarten Van Baelen, Medical Affairs Manager, EGA*
10:00	**Q&A**
10:15	**Member States general state of play** | *Mick Foy, Group Manager, Vigilance Intelligence and Research Group Vigilance and Risk Management of Medicines, MHRA - Birte van Elk, Dutch Representative for the Pharmacovigilance Package in the Council of Ministers, MEB*
10:50	**Panel discussion** *with session speakers and interaction with the floor on achieving harmonisation of implementation*
11:00	Networking coffee break
11:30	Session 2 – **New pharmacovigilance inspections environment** Chair | *Wendy Huisman, Chair of EGA Pharmacovigilance & Drug Safety Working Group*
	Inspections: practical examples and findings pre- and post-July 2012 | *Anya Sookoo, Expert Inspector, GCP & Pharmacovigilance, MHRA, UK*
12:00	**Implementation of the Pharmacovigilance System Master File for the generic medicines industry** | *Wendy Huisman, EU Qualified Person for Pharmacovigilance, Teva Europe, NL, Chair of EGA Pharmacovigilance & Drug Safety Working Group and EudraVigilance Expert Working Group Member*
12:30	**Q&A and discussion**
13:00	Networking buffet lunch

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14:00 Session 3 - **The new risk-based approach to pharmacovigilance**
Chair | *Michel Mikhail, Executive Vice President Corporate Regulatory Affairs, Fresenius Kabi*

Nationally authorised products - PSUR transitional arrangements and work sharing | *Anne Ambrose, VRMM, Medicines and Healthcare Products Regulatory Agency (MHRA) and Chair of PSUR Work Sharing Working Party*

14:30 **Risk Management Plans (RMPs) for generic medicines: a pragmatic approach** | *Philippa Guy, Head of Safety EMEA, Hospira*

15:00 **Periodic Safety Update Reports (PSURs) for generic medicines** | *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 **Wrap up panel discussion** *with Mick Foy, Group Manager, Vigilance Intelligence and Research Group Vigilance and Risk Management of Medicines, MHRA, industry session speakers and the floor*

16:00 Cocktail reception

For further information www.egagenerics.com

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