EUROPEAN GENERIC MEDICINES ASSOCIATION

Making Medicines Affordable

4th EGA Pharmacovigilance Discussion Forum

24 January 2011

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

Monday 24 January 2011

08:00	Registration and Networking Coffee
09:00	Session I - **In the Spotlight: The New EU Pharmacovigilance Legislation** Chair | *Suzette Kox, Senior Director Scientific Affairs, EGA*
09:00	Opening Address by *Suzette Kox, Senior Director Scientific Affairs, EGA*
09:05	**What are the New Responsibilities for the Member States?** | *Mick Foy, Manager - Signal Management Group, Vigilance and Risk Management of Medicines, MHRA, UK*
09:35	**Impact of the New Pharmacovigilance Legislation on the Work of the European Medicines Agency** | *Peter Arlett, Head of Sector for Pharmacovigilance and Risk Management, EMA, EU*
10:05	**What's New for Patients and HealthCare Professionals?** | *Linda McAvan, Labour UK MEP, European Parliament Rapporteur of the Pharmacovigilance Package*
10:30	**Questions & Answers** *with Session Speakers*
11:00	Networking Coffee Break
11:30	Session II - **Risk-Based Pharmacovigilance and Periodic Safety Update Reports** Chair | *Balwant Heer, VP, Global Head - Product Safety & Risk Management, EU QPPV Mylan, UK*
11:30	**Common Denominator of PSUR Work Sharing, and PSUR Risk-Based approach: What is the Future for Generic Medicines? Work Sharing or no more Periodic Safety Update Reports?** | *Menno van der Elst, Senior Assessor, Pharmacovigilance Department, MEB, NL*
12:00	**Generic Medicines Industry's Questions and Perspective** | *Inge Bøgh Jansen, Director Pharmacovigilance Drug Safety, Actavis and Vice-Chair of the EGA Safety & Pharmacovigilance Working Group*
12:30	**Discussion and Q&A** *with Session Speakers*
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 III - **EudraVigilance, Risk Management Plans and Referrals in the Changing Environment** Chair | *Augusto Filipe, Director Medical Department, Farmoz, PT and EudraVigilance Expert Working Group Member*
14:00	**Latest Key Developments within EudraVigilance and the Way Forward** | *Sabine Brosch, Business Lead in EudraVigilance and International Standardisation in Pharmacovigilance, EMA, EU*
14:30	**Questions & Answers**
14:45	**Pragmatic Approach towards Risk Management Plans for Generic Medicines, Pharmacovigilance Working Party Recommendations and Referrals** | *Wendy Huisman, EU Qualified Person for Pharmacovigilance, Teva Europe, NL, Chair of EGA Safety & Pharmacovigilance Working Group and EudraVigilance Expert Working Group Member*
15:15	**Interactive Overall Discussion Session on Implementation of the New Legislation** | *Mick Foy, Manager - Signal Management Group, Vigilance and Risk Management of Medicines, MHRA, UK, Menno van der Elst, Senior Assessor, Pharmacovigilance Department, MEB, NL, Industry's Speakers/Chairs and Audience* *Questions should be formulated generally and should be sent 2 weeks in advance to skox@egagenerics.com*
15:45	**Questions & Answers**
16:00	End of Forum Cocktail sponsored by EXTEDO eRegulatory Affairs

For further information please visit:

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