EUROPEAN GENERIC MEDICINES ASSOCIATION

Making Medicines Affordable

Biosimilar Medicines:

9th EGA International Symposium

14 - 15 April 2011

Millennium Hotel London Mayfair
44 Grosvenor Square, London W1K 2HP, UK

Thursday | 14 April 2011 — **EGA International Symposium on Biosimilar Medicines**

12:30 Registrations & Welcome Buffet Lunch sponsored by SANDOZ

Session One | Markets are Moving Up
Chair | ***Didier Barret***, *EMEA President, France CEO, Mylan and President EGA*

14:00 **Opening Address - *Didier Barret*, *EMEA President, France CEO, Mylan and President EGA***

14:10 **European Biosimilars - How to Enhance the Competitiveness of this EU Industry - *Greg Perry*, *Director General, EGA***

14:25 **Biological/Biotechnological and Biosimilars' Market: the Global Outlook - *Alan Sheppard*, *Global Head Generics, Thought Leadership, IMS Health, UK***

14:55 **Biosimilars: From here to Profitability: What was Accomplished and What is yet to be Done? - *Ronny Gal*, *Specialty Pharma Analyst, Sanford Bernstein, USA***

15:30 Coffee Break

Session Two | International Developments: Biosimilars Go Global
Chair | ***Greg Perry***, *Director General, EGA*

16:00 **US Patient Protection and Affordable Care Act: What is the Overall Current FDA Thinking? - *Janice M. Soreth*, *MD, Deputy Director, FDA Europe Office, Office of International Programs***

16:30 **The Emerging Biosimilars Landscape in Asia Pacific - *Paul Greenland*, *Biosimilars Marketing Director - EMEA, Hospira, UK and Chair of the EGA Biosimilars Market Access Group***

17:00 **Global Development Programs: a Prerequisite for Worldwide Availability, Affordability and Patient Access to Biosimilars - *Ameet Mallik*, *Global Head, Sandoz Biopharmaceuticals, DE***

17:30 **Panel Discussion on Global Development Programs Increasing Availability of Biosimilar Medicines and Patient Access - *Session Speakers and Peter Richardson*, *Head of Biologicals, Sector Quality of Medicines, European Medicines Agency (EMA)***

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18:00 **Official Launch of EGA Biosimilars Handbook Edition 2011**
- Presentation of the handbook - ***Suzette Kox***, *Senior Director Scientific Affairs, EGA*
- Health Economic Benefits of Biosimilars - ***Paul Cornes***, *MD, Bristol Oncology Centre, Royal United Hospital Bath, Bath, UK*

18:30 End of Day Cocktail

Friday | 15 April 2011 — **EGA International Symposium on Biosimilar Medicines**

08:00 Networking Coffee

Session Three | The Evolving EU Framework (1)
Chair | ***Joerg Windisch***, *Head Global Technical Development, Sandoz Biopharmaceuticals, AT and Chair of the EGA European Biopharmaceuticals Group*

09:00 **Keynote Address - *Professor Bruno Flamion***, *Immediate Past Chair Scientific Advice Working Party (SAWP), CHMP; Professor Clinical Pharmacology, University of Namur, BE and Chair of the Belgian Committee for Reimbursement of Medicines (CTG/CRM)*

09:30 **Perspectives of the EU Biosimilar Medicines Working Party (BMWP) - *Christian Schneider***, *CHMP Member, Head of Division EU Cooperation/Microbiology, Paul Ehrlich Institute, DE and Chair of the EMA Working Party on Similar Biological Medicinal Products (BMWP)*

10:00 **EGA Perspective on Draft Guideline on Biosimilar Monoclonal Antibodies**
Islah Ahmed, *Global Medical Director, Hospira Inc.*

10:30 **Questions and Answers Session**

11:00 Coffee Break

Session Four | The Evolving EU and International Framework (2)
Chair | ***Cornelia Ulm***, *Senior Director Regulatory Affairs - Biologics, Mylan GmbH, CH and Vice-Chair of the EGA European Biopharmaceuticals Group*

11:30 **EGA Perspective on Draft Guideline on Immunogenicity Assessment of Monoclonal Antibodies - *Tom May***, *Research R&D Fellow, Hospira Inc.*

12:00 **Risk Management for Biologicals in the Context of the New EU Pharmacovigilance Legislation - *Jan Petracek***, *CEO, European Pharminvent Services, CZ*

12:30 **Global Development of Biosimilars: How can Science Inform Policymaking? - *Nikhil Mehta***, *Vice President, Biologics, Global Regulatory Affairs, Merck and Co., USA*

13:00 Buffet Lunch

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Session Five | Interchangeability and Substitution

Chair | ***Udo Müller**, Global Medical Director BioGenerics - Global Branded Products, TEVA Pharmaceutical Industries Ltd.*

14:00 **The Original "Interchangeable Biosimilars": The Substitutability of Pre- And Post-Manufacturing Change Biologics & their Implications for Interchangeable Biosimilars** – ***John M. Engel**, Esq., Managing Partner, Engel & Novitt, LLP, Washington, D.C., USA*

14:30 **Biosimilars, Information Gap and Barriers to Substitution**
***Arnold Vulto**, Deputy Head Hospital Pharmacy, Professor of Hospital Pharmacy and Practical Therapeutics at Erasmus University Medical Center Rotterdam, NL and Editor-in-Chief at the European Journal of Hospital Pharmacy*

15:00 **Panel Discussion with Session Speakers, *Steinar Madsen**, MD, FACP (Hon), Medical Director, Department of Drug Information, Norwegian Medicines Agency & **Anthony Grosso**, Formulary and Medicines Management Pharmacist, University College London Hospitals NHS Foundation Trust, London, UK*

15:30 **Closing Remarks - *Suzette Kox**, Senior Director Scientific Affairs, EGA*

End of Symposium Coffee

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