



Making Medicines Affordable

# EUROPEAN GENERIC MEDICINES ASSOCIATION

## 7<sup>th</sup> EGA Annual Symposium on Biosimilar Medicines

“Towards Global Development and Monoclonal Antibodies”

23 - 24 April 2009

Waldorf Hilton Hotel  
Aldwych London WC2B 4DD, UK

Thursday | 23 April 2009

EGA Symposium on Biosimilar Medicines

12:30 Registrations & Welcome Buffet Lunch

Session One | **Market Overview** - Chair | *Greg Perry, Director General, EGA*

14:00 Opening Address | *Greg Perry, Director General, EGA*

14:30 **Biological/Biotechnological Pharmaceutical and Biosimilar Market** - *Alan Sheppard, Global Head Generics, Thought Leadership, IMS Health, UK*

15:00 **Investor's Point of View** - *Ronny Gal, Specialty Pharma Analyst, Bernstein Research, USA*

15:45 Coffee Break

Session Two | **Legal and Market Environment for Biosimilar Medicines** - Chair | *Marcy Macdonald, Director, Global Regulatory Affairs, Hospira, USA*

16:15 **USA Developments Regarding a Legal Framework and Latest Developments in Canada** - *Juliana M. Reed, Director, Office of Government Affairs, Hospira, USA*

16:45 **Biosimilar Medicines: a Health Economist's Perspective** - *Peter Wieninger, Head of Department of Medicines, Main Association of Austrian Social Security Institutions and MEDEV Member*

17:15 **Panel on Market Experience with Biosimilar Medicines**  
*Bram van Dijck, Head of Hospital & Specialty Business Europe, Teva Pharmaceuticals Europe*  
*Paul Greenland, Biosimilars Marketing Director - EMEA, Hospira UK*  
*Udo Meurle, Head Global Strategic Marketing, Sandoz International*

18:00 End of Day & Cocktail

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Friday | 24 April 2009

EGA Symposium on Biosimilar Medicines

08:00 Networking Coffee

**Session Three | The European Union Paving the Road** - Chair | *Suzette Kox, Senior Director Scientific Affairs, EGA*

09:00 **Perspective and Activities of the EU Biosimilar Medicines Working Party (BMWP)** - *Christian Schneider, CHMP Member, Acting Head, Division EU Cooperation/Microbiology, Paul Ehrlich Institute Germany and Chair of the EMEA Working Party on Similar Biological Medicinal Products (BMWP)*

09:30 **Update on EMEA Activities Regarding Biosimilar Products and Guidance and the EMEA's Initiative about Benefit-Risk Assessment** - *Falk Ehmann, Secretariat of the EMEA Working Party on Similar Biological Medicinal Products (BMWP), Pre-Authorisation Evaluation of Medicines for Human Use, Sector Safety and Efficacy of Medicines, EMEA, EU*

10:00 **EU Risk Management Plans and Legislative Proposals Impacting Biopharmaceuticals** - *Jan Petracek, Risk Management Team, Sector Pharmacovigilance and Post Authorisation, Safety and Efficacy of Human Medicines, EMEA, EU*

10:30 Coffee Break

**Session Four | Towards Global Development of Biosimilar Products** - Chair | *Sandy Eisen, Chief Medical Officer, Teva Pharmaceuticals Europe, and Chair of EGA - European Biopharmaceuticals Group (EBG)*

11:00 **WHO Guideline for Abbreviated Licensing Pathways for Certain Biological Therapeutic Products: Status and Next Steps** | *Hye Na Kang, Scientist, Quality, Safety and Standards/IVB/FCH, World Health Organization, CH*

11:30 **Global Development, a CRO's perspective** - *Cecil Nick, Vice President (Biotechnology), PAREXEL Consulting, Uxbridge, UK*

12:00 **Global Development, the Way Forward: The EGA's Perspective** - *Ingrid Schwarzenberger, Sandoz Biopharmaceuticals Development, Head Regulatory Affairs Biopharmaceuticals, Sandoz, Austria*

12:15 **Panel Discussion with Speakers and Christian Schneider, CHMP Member and Chair of BMWP and Bruce Clark, Vice President, Regulatory and Medical Affairs, Apotex, Canada**

12:45 **EMEA Keynote Address** | *Thomas Lönngren, Executive Director, EMEA, EU*

13:00 Buffet Lunch

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**Session Five | Towards Biosimilar Monoclonal Antibodies - Chair | Bruce Clark, Vice President, Regulatory and Medical Affairs, Apotex**

14:00 **Monoclonal Antibodies - Taking Biosimilar Medicines to the Next Level | Andreas Premstaller, Head Technical Development, Biopharmaceutical Operations Kundl, Sandoz Austria**

14:30 **Towards Biosimilar Monoclonal Antibodies: A CRO's Perspective - Anita O'Connor, Senior Director for Biopharmaceutical Development, MDS Pharma Services, USA**

15:00 Coffee Break

**Session Six | Introduction of Biosimilar Medicines into Clinical Practice - Chair | Dr. med. Sandy Eisen, Chief Medical Officer, Teva Pharmaceuticals Europe, and Chair of EGA - European Biopharmaceuticals Group (EBG)**

15:30 **Are Special Recommendations for the Use of Biosimilar Medicines Needed? Panel Discussion with Prof. Colin Brown, Professor Emeritus of Renal Medicine and Transplantation, UK - Prof. Dr. med. Christoph Renner, University Hospital Zürich, CH - Dr. med. Michael Muenzberg, Global Head of Medical Affairs, Sandoz International and Dr. med. Udo Mueller, Medical Director, Teva Global Biogenerics**

17:00 End of Symposium

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