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# EUROPEAN GENERIC MEDICINES ASSOCIATION

## Biosimilar Medicines:

### 8<sup>th</sup> EGA Annual International Symposium

22 - 23 April 2010

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

Thursday | 22 April 2010

EGA Annual International Symposium on Biosimilar Medicines

12:30 Registrations & Welcome Buffet Lunch

**Session One | Biologics Market Overview and Latest US Legal Developments**

Chair | **Greg Perry**, Director General, EGA

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

14:30 **Biological/Biotechnological and Biosimilars' Market: the Global Outlook** - *Douglas M. Long, Vice President of Industry Relations, IMS Health, USA*

15:00 **USA Legal Developments, a Final Breakthrough?** - *Janet M. MacLeod, Partner, Crowell & Moring LLP, New York, USA*

15:45 Coffee Break

**Session Two | Increasing Patient Access while Ensuring the Sustainability of the Biosimilar Medicines' Industry**

Chair | **Paul Greenland**, Biosimilars Marketing Director - EMEA, Hospira UK

16:15 **Biological Therapies Economics and How to Increase Access to Biosimilar Medicines** - *Fraz A. Mir, Consultant Physician, Cambridge University Hospitals NHS Foundation Trust Addenbrooke's Hospital, UK*

16:45 **Biosimilar Medicines: a Health Technology Assessment's Perspective** - *Anne Dandon, Head of Medicines' Assessment, Haute Autorité de Santé, FR and Member of the Medicines Evaluation Board*

17:15 **Panel Discussion: Key Factors for the Sustainability of the Biosimilar Medicines' Industry** - *Giulia Del Brenna, Head of Unit, Competitiveness in the Pharmaceuticals Industry and Biotechnology, DG Enterprise, European Commission* - *Anne d'Andon, Head of Medicines' Assessment, Haute Autorité de Santé, FR* - *Peter Stenico, Head Commercial Operations, Western Europe, DEHO, Sandoz International, DE* - *Rasmus Rojkjaer, Head of Global R&D Biologics, Mylan, CH*

18:00 End of Day & Cocktail

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Friday | 23 April 2010

EGA Annual International Symposium on Biosimilar Medicines

08:00 Networking Coffee

**Session Three | The Biosimilarity Concept: Application to Complex, Large Molecules**

Chair | **Sandy Eisen**, Chief Medical Officer, Teva Pharmaceuticals Europe, UK, and Chair of EGA - European Biopharmaceuticals Group

09:00 **EMA Keynote Address - John Purves**, Head Quality of Medicines Sector, Human Medicines Development and Evaluation, European Medicines Agency, EU

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

10:00 **Distinguishing Aspects of the Canadian Regulatory Approach and Perspective on Subsequent-Entry Monoclonal Antibodies - Anthony Ridgway**, Senior Regulatory Scientist, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, Biologics and Genetic Therapies Directorate, Health Canada, Canada

10:30 Coffee Break

**Session Four | EU Regulatory Framework: Next Steps on the Horizon**

Chair | **Joerg Windisch**, Deputy Head Global Development, Head Global Technical Development, Sandoz Biopharmaceuticals, AT, and Vice-Chair of EGA - European Biopharmaceuticals Group

11:00 **European Medicines Agency's Post Authorisation Activities Regarding Biosimilar Products - Jan Petracek**, Risk Management, Sector Pharmacovigilance and Risk Management, Patient Health Protection, EMA, EU (inv)

11:30 **Guideline on Immunogenicity Assessment of Monoclonal Antibodies - Robin Thorpe**, Head Biotherapeutics Group, National Institute for Biological Standards and Control, UK

12:00 **Unconventional Approaches to Clinical Designs - Markku Toivonen**, Scientific Director, NDA Advisory Board, NDA Regulatory Science Ltd, UK

12:30 **Panel Discussion on the Challenges of Biosimilar Monoclonal Antibodies - Christian Schneider (PEI), Anthony Ridgeway (HC), Robin Thorpe (NIBSC), Markku Toivonen (NDA), Rasmus Rojkjaer (Mylan) and Sandy Eisen (Teva Europe)**

13:00 Buffet Lunch

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Session Five | Experience with Biosimilar Medicines in Clinical Practice: Building Trust for the Future

Chair | **Sandy Eisen**, Chief Medical Officer, Teva Pharmaceuticals Europe

- 14:00      **Setting the Scene: The First Two Years on the Market with Retacrit®** - **Islah Ahmed**, Global Medical Director, Hospira, Inc., USA
- 14:20      **Panel Discussion with Clinicians** - **Dr. David Goldsmith**, Nephrologist, Guy's and St Thomas' NHS Foundation Trust, London, UK, **Dr. Islah Ahmed** and **Dr. Sandy Eisen**
- 15:50      **Closing Remarks** - **Suzette Kox**, Senior Director Scientific Affairs, EGA
- 16:00      End of Symposium Coffee

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Registrations close officially on 9 April 2010 & are subject to availability

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