



EUROPEAN GENERIC MEDICINES ASSOCIATION

Biosimilar Medicines:

8th EGA Annual International Symposium

2 - 3 September 2010

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

Thursday | 2 September 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	New US Patient Protection and Affordable Care Act: What's in for Biosimilars? - Keith Harrison , Partner, Crowell & Moring LLP, Washington, USA
15:45	Coffee Break Session Two Increasing Patient Access while Ensuring the Sustainability of the Biosimilar Medicines' Industry Chair Elke Grooten , Director Pharmaceutical Policy, EGA
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 d'Andon , Head of Medicines' Assessment, Haute Autorité de Santé, FR
17:15	Panel Discussion: Key Factors for the Sustainability of the Biosimilar Medicines' Industry - Christophe Roeland , Policy Officer, DG ENTR Unit F5 Competitiveness, 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 - Bram van Dijck , Head of Hospital & Specialty Business Europe, TEVA Pharmaceuticals Europe BV
18:00	End of Day Cocktail

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Friday | 3 September 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 , Former 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, 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	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
10:30	Coffee Break Session Four EU Regulatory Framework: Next Steps on the Horizon Chair Joerg Windisch , 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 - Sabine Brosch , Business Lead in EudraVigilance and International Standardisation in Pharmacovigilance, EMA, EU
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 Ridgway (HC), Robin Thorpe (NIBSC), Markku Toivonen (NDA), Cornelia Ulm (Mytan) 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 Clinical Experience with Retacrit® - **Rodeina Challand**, Director of Clinical Programmes, Hospira Ltd, UK
- 14:15 Clinical Experience with TevaGrastim® - **Udo Mueller**, Medical Director, Teva Global Biogenerics
- 14:30 Clinical Experience with Omnitrope® - **Shreeram Aradhya**, Head Global Clinical Development and Medical Affairs, Sandoz Biopharmaceuticals
- 14:45 Panel Discussion with **Gerhard Lonnemann**, Professor of Internal Medicine and Nephrology and Internist and Specialist in Nephrology at the Centre of Nephrology and Hemodialysis, Langenhagen, DE and with Session Speakers
- 15:30 Key Messages and Open Questions from the Symposium - **Cecil Nick**, Vice President (Biotechnology), PAREXEL Consulting, Uxbridge, UK
- 15:45 Closing Remarks - **Suzette Kox**, Senior Director Scientific Affairs, EGA

End of Symposium Coffee

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For further information and to register on-line, please visit:

www.gpaconferences.com or www.egagenerics.com

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Registrations close officially on 20 August 2010 & are subject to availability

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