



Making Medicines Affordable

# EUROPEAN GENERIC MEDICINES ASSOCIATION

## Biosimilar Medicines:

### 8<sup>th</sup> 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 and Member of the Medicines Evaluation Board*

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* - *Rasmus Rojkjaer, Head of Global R&D Biologics, Mylan, CH*

18:00 End of Day & Cocktail

#### 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](mailto:info@egagenerics.com) [www.egagenerics.com](http://www.egagenerics.com)

VAT: BE 0449 332 209



Making Medicines Affordable

# EUROPEAN GENERIC MEDICINES ASSOCIATION

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), Rasmus Rojkjaer (Mylan) and Sandy Eisen (Teva Europe)**

13:00 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](mailto:info@egagenerics.com) [www.egagenerics.com](http://www.egagenerics.com)

VAT: BE 0449 332 209



Making Medicines Affordable

## EUROPEAN GENERIC MEDICINES ASSOCIATION

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®** - **Rodeina Challand**, Clinical Director, Hospira UK Limited, UK
- 14:20 **Panel Discussion with Clinicians** - **Prof. Dr. med. Gerhard Lonnemann**, Professor of Internal Medicine and Nephrology and Internist and Specialist in Nephrology at the Centre of Nephrology and Hemodialysis, Langenhagen, DE, **Rodeina Challand** and **Dr. Sandy Eisen**
- 15:50 **Closing Remarks** - **Suzette Kox**, Senior Director Scientific Affairs, EGA
- 16:00 End of Symposium Coffee

WITH THE SUPPORT OF



GEDEON RICHTER



Advancing Wellness™



**SANDOZ**



MEDIA SPONSORS



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

[www.gpaconferences.com](http://www.gpaconferences.com) or [www.egagenerics.com](http://www.egagenerics.com)

Cristina Romagnoli - T: +377-93-501348 - F: +44-208-0825368 - E: [info@gpaconferences.com](mailto:info@gpaconferences.com)

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

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](mailto:info@egagenerics.com) [www.egagenerics.com](http://www.egagenerics.com)

VAT: BE 0449 332 209