EUROPEAN GENERIC MEDICINES ASSOCIATION

Making Medicines Affordable

Biosimilar Medicines: 10th EGA International Symposium

19 – 20 April 2012

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

Thursday | 19 April 2012	EGA International Symposium on Biosimilar Medicines

08:00 Registrations pre-symposium workshop & welcome coffee

09:00 – 13:00 **PRE-SYMPOSIUM WORKSHOP "Biosimilars In America: IP Strategy and Due Diligence"**
The workshop will explore the mechanics of the Biologics Act with an emphasis on how the Act relates to the involved intellectual property and how the intellectual property may impact the biosimilar applicant's strategy for entering the market
(only for delegates who have registered separately)

organised by G&B Greenblum & Bernstein, P.L.C.

13:00 Registrations & welcome buffet lunch

Session 1 - **Increased markets for biosimilars**
Chair | ***Greg Perry**, Director General, EGA*

14:00 **OPENING ADDRESS - *Gudbjorg Edda Eggertsdottir**, President Iceland & EVP Special Projects at Actavis and President EGA*

14:10 **Biological/biotechnological and biosimilars market:**

- **The global outlook**
  ***Alan Sheppard**, Global Head Generics, Thought Leadership, IMS Health, UK*
- **Shaping the opportunity**
  ***Antonio Iervolino**, Senior Consultant, IMS Consulting Group*

14:40 **Mergers & acquisitions and financial markets perspective of the biosimilars market - *Tommy Erdei**, CFA, Managing Director, Healthcare Investment Banking, Jefferies International Limited, UK*

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15:00 **Panel discussion on biosimilars market opportunities introduced by *Diem Nguyen***, *General Manager Biosimilars, Established Products Business Unit, Pfizer Inc.* - ***Session Speakers*** and ***Paul Greenland***, *Biosimilars Marketing Director – EMEA, Hospira, UK*

15:45 Coffee break

Session 2 - **Experience with the uptake of biosimilars**
Chair | ***Paul Greenland***, *Biosimilars Marketing Director – EMEA, Hospira, UK and Chair of the EGA Biosimilars Market Access Group*

16:15 **Biosimilars in Germany**
Prof. Bertram Häussler, *IGES Institut, Berlin, DE*

16:30 **Biosimilars in Sweden**
Gustaf Befrits, *Health Economist, Dental and Pharmaceutical Benefits Agency, Stockholm, SE*

16:45 **Biosimilars in the UK**
Dr. Kim Orchard, *Wessex Blood and Marrow Transplantation Unit, Department of Haematology, Southampton University Hospitals, Southampton, UK*

17:00 **Panel discussion with session speakers, national authorities and industry:**
Steffen Thirstrup, *Danish Medicines Agency and Co-Chair of DG Enterprise Project Group 5 on Market Access for Biosimilars* - ***Artur Chodkowski***, *Oncology Business Unit Head, Sandoz Poland* – ***Michele Uda***, *Health Economics Affairs Manager, Assogenerici and* ***Henk Eleveld***, *Adviser and Contractmanager Pharmacy, Menzis Health Insurance, NL*

18:00 End of day cocktail

Friday | 20 April 2012 — EGA International Symposium on Biosimilar Medicines

08:00 Networking coffee

Session 3 - **EU enlarged framework for biosimilars**
Chair | ***Joerg Windisch***, *Head Global Technical Development, Sandoz Biopharmaceuticals, AT and Chair of the EGA European Biopharmaceuticals Group (EBG)*

09:00 **KEYNOTE ADDRESS: Biosimilars - why terminology matters?**
Martina Weise, *BfArM, DE and Vice-Chair of the EMA Working Party on Similar Biological Medicinal Products (BMWP) of the Committee for Medicinal Products for Human Use (CHMP)*

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09:15 **Current EMA perspectives on the revision of the overall biosimilar guidelines**
***Peter Richardson**, Head of Biologicals Section, Quality of Medicines Sector, Human Medicines Development and Evaluation Unit, EMA*

09:45 **Final guideline on biosimilar monoclonal antibodies and immunogenicity guideline for monoclonal antibodies and future perspectives of the EU biosimilar medicines working party**
***Christian Schneider**, Danish Medicines Agency, Chair of the EMA Working Party on Similar Biological Medicinal Products (BMWP) and Committee for Advanced Therapies (CAT)*

10:15 **EGA perspective on the final guideline on biosimilar monoclonal antibodies and the revised general biosimilar guidelines**
***Karl Heinz Emmert**, Head Biosimilar Development, Teva Germany and Vice-Chair of the EGA European Biopharmaceuticals Group (EBG)*

10:30 **Panel discussion with session speakers**

11:00 Coffee break

Session 4 - **Regulatory approaches in key regions of the world**
Chair | ***Andrea B. Miller**, Sr. Vice President, Global Regulatory Affairs and Product Safety, Mylan*

11:30 **Regulatory guidelines for biosimilars in the USA**
***John M. Pakulski**, Senior Director and Head US Biopharmaceutical Regulatory Affairs, Sandoz Inc. and Chair of the Biosimilars Task Force of GPhA, USA*

12:00 **Regulatory guidelines for biosimilars in Japan**
***Teruyo Arato**, Division Director, Human Resources Development Division, Office of Regulatory Science Operations, Pharmaceuticals and Medical Devices Agency (PMDA), JP*

12:30 **Regulatory approaches to follow-on biologicals taken by major Latin American countries**
***Maria Fabiana Jorge**, President, MFJ International LLC., USA*

13:00 Buffet lunch

Session 5 - **Supporting biosimilar global development and international harmonisation of data requirements: a must for availability and access to high quality biosimilars worldwide**
Chair | ***Karl Heinz Emmert**, Head Biosimilar Development, Teva Germany and Vice-Chair of the EGA European Biopharmaceuticals Group (EBG)*

14:00 **EU approach to global development for biosimilars and international harmonisation**
***Nils Behrndt**, Deputy Head of Cabinet DG SANCO, European Commission*

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14:30 **Rolling out an international framework for biosimilar global development: EGA's perspective**
***Cornelia Ulm**, Senior Director Regulatory Affairs – Biologics, Mylan GmbH, CH and Vice-Chair of the EGA European Biopharmaceuticals Group (EBG)*

14:45 **International panel discussion on biosimilar global development with session speakers, *Christian Schneider**, Chair of the EMA BMWP, **Teruyo Arato**, Division Director at the PMDA JP, **John M. Pakulski**, Chair of the GPhA Biosimilars Task Force, USA and **Joerg Windisch**, Chair of the EGA-EBG*

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

End of symposium coffee

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