



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

Biosimilar Medicines

11th EGA International Symposium

coordinated by the
European Biosimilars Group, a Sector Group of the EGA

25 - 26 April 2013

The Tower Hotel
St. Katherine's Way, London E1W 1LD, UK

Thursday | 25 April 2013

Biosimilar Medicines - EGA International Symposium

08:00 Registrations pre-symposium workshop & welcome coffee

09:00 - 13:00 **PRE-SYMPOSIUM WORKSHOP "The US Biosimilar Pathway in 2013: Early Challenges, Current Trends and Possible Future Developments"**
(Applicable only to delegates who have registered separately for the workshop)

In contrast to last year's focus on biosimilar market considerations and the mechanics of the law establishing the US biosimilar pathway, this year's workshop will focus on the intersection of the US regulatory process and biosimilar intellectual property considerations. The workshop will integrate Anita O'Connor's FDA regulatory and scientific experience with Greenblum and Bernstein's patent expertise to address regulatory and patent issues relevant in 2013. Through interactive panel discussions and lectures, workshop attendees will receive a brief overview of the Biosimilar Act with a focus on what stakeholders should keep in mind as they navigate the US biosimilar pathway. The workshop will also include an overview of recent legal challenges relating to the Biosimilar Act, including the citizens petition filed by Abbott (now AbbVie) that seeks to prevent FDA from approving certain biosimilars in the US. Possible future developments contemplated by lawmakers, regulators, and biosimilar candidates will also be addressed.

organised by



GREENBLUM & BERNSTEIN, P.L.L.C.

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 www.egagenerics.com

VAT: BE 0449 332 209



- 13:00 Registrations & welcome buffet lunch sponsored by
- 14:00 **Session 1 - Market and legislative moves regarding biosimilars**
Chair | *Victor Lino Mendonça, Head of Pharmaceutical Policy and Health Economics, 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 with special focus on Europe**
Alan Sheppard, Global Head Generics, Thought Leadership, IMS Health, UK
- 14:40 **Biosimilar manufacturing landscape-opportunities and challenges**
Andrew Badrot, Partner, CMS Pharma, CH
- 15:10 **Biosimilars' utilisation and the role payers do play in driving uptake in Europe: an industry perspective**
Ken Walsh, Manager Global Pricing Biopharma, Sandoz International
- 15:40 **Panel discussion with session speakers**
- 16:00 **Coffee break**
- 16:30 **Session 2 - Best practices around Europe supporting uptake of biosimilars: shaping the future**
Chair | *Paul Greenland, Vice President - Biologics, Hospira UK Limited and Chair of the EGA Biosimilars Market Access Group*
- Zoom on countries' experiences with biosimilars:**
- 16:30 **Biosimilars in the UK**
Warwick Smith, Director General, BGMA (British Generic Manufacturers Association)
- 16:45 **Biosimilars in Germany**
Udo Müller, Global Medical Director Oncology - Global Medicines Group - Global Medical Affairs, TEVA Germany representing ProGenerika (German Generic Medicines Association)
- 17:00 **Biosimilars in Italy**
Michele Uda, Director General, Assogenerici (Italian Generic Medicines Association)
- 17:15 **Biosimilars in France**
Frédéric Collet, Country Head France, Sandoz representing GEMME (French Generic Medicines Association)
- 17:30 **Panel discussion with session speakers**
- 18:00 **End of day cocktail**



Friday | 26 April 2013

Biosimilar Medicines - EGA International Symposium

- 08:00 Networking coffee
- 09:00 **Session 3 - Biosimilars' frameworks in the EU and the USA: closing the gap?**
Chair | Joerg Windisch, Chief Science Officer, Sandoz Biopharmaceuticals, AT and Chair of the EGA-European Biosimilars Group (EBG)
- 09:00 **EU KEYNOTE ADDRESS: Biosimilar monoclonal antibodies in the EU: Where are we and where are we heading?**
Christian Schneider, Danish Health and Medicines Authority, Chair of the EMA Biosimilar Medicinal Products Working Party (BMWP) and Committee for Advanced Therapies (CAT)
- 09:20 **EMA perspectives on the revision of the overarching biosimilar guideline and quality guideline**
Camille Vleminckx, Scientific Administrator in the Oncology, Haematology and Diagnostics Section of the Safety and Efficacy of Medicines Sector (Human Medicines Development and Evaluation unit), EMA
- 09:40 **US KEYNOTE ADDRESS: Regulatory perspective on the requirements for biosimilar development and approval in the United States**
Steven Kozlowski, Director, Office of Biotechnology Products, CDER, US FDA
- 10:00 **Immunogenicity assessment for biosimilar monoclonal antibodies**
Paul Chamberlain, NDA Advisory Board Member and NDA Expert Immunogenicity
- 10:20 **Panel discussion with session speakers and Karl Heinz Emmert**, Head Biosimilar Development, Teva Germany and Vice-Chair of the EGA-European Biosimilars Group (EBG)
- 11:00 Coffee break
- 11:30 **Session 4 - Biosimilars in clinical practice**
Chair | Ildiko Aradi, Head, Clinical Development of Biologics, Gedeon Richter Hungary and Vice-Chair of the EGA-European Biosimilars Group (EBG)
- 11:30 **Biosimilars: What clinicians should know**
Martina Weise, MD, BfArM, DE and Vice-Chair of the EMA Biosimilar Medicinal Products Working Party (BMWP)
- 11:50 **Opportunities that Norway sees for the future with the introduction of biosimilar monoclonal antibodies and the hurdles to overcome**
Steinar Madsen, MD, FACP (Hon), Medical Director, Department of Drug Information, Norwegian Medicines Agency
- 12:10 **Panel discussion with session speakers, Dr. Christian Schneider & Dr. Nuno Miranda**, Director of the National Program for Oncologic Diseases (PT)
- 13:00 Buffet lunch



EUROPEAN GENERIC MEDICINES ASSOCIATION

Making Medicines Affordable

- 14:00 **Session 5 - Challenges ahead: naming, identification, global development**
Chair | *Karl Heinz Emmert, Head Biosimilar Development, Teva Germany and Vice-Chair of the EGA-European Biosimilars Group (EBG)*
- 14:00 **Problems with terminology for biosimilars**
Robin Thorpe, Fellow of the Royal College of Pathologists, Head of Biotherapeutics Group, National Institute for Biological Standards and Control, UK
- 14:20 **Naming and traceability**
Gillian Woollett, Senior Vice President, Avalere Health, USA
- 14:40 **Safe prescription, safe dispensing and identification of all biologicals in the context of the reopened biosimilars INN debate**
Suzette Kox, Senior Director Scientific Affairs and Coordinator of the EGA-European Biosimilars Group (EBG), EGA
- 15:00 **Final Q&A and wrap up discussion with regulators**
- 15:30 **Closing remarks**
Suzette Kox, Senior Director Scientific Affairs and Coordinator of the EGA-European Biosimilars Group (EBG), EGA
- End of Symposium coffee

EVENT SPONSORS



For further information please visit: www.egagenerics.com