

# Biosimilar Medicinal Products A Reality in Europe

## 4<sup>th</sup> EGA Symposium on Biosimilars

Hotel Radisson SAS Portman  
22 Portman Square – London W1H 7BG, UK

18-19 May 2006

THURSDAY 18 May 2006

DAY I

12:00 Registration

13:00 Welcome Buffet Lunch

### Market Overview

**Session One** - Chair | Greg Perry, Director General, EGA

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

14:15 **EU Biological/Biotechnological Pharmaceutical Market in Europe**  
*Eva Edery, Senior Consultant, Europe, Global Pharma Strategy, IMS Health, UK*

14:40 **Investor's Point of View of the Biosimilar Market**  
*Frances Cloud, Director, Nomura Code Securities, UK*

15:05 **Healthcare Economics Perspective**  
*Tim Oldham, Acting Head EMEA, Vice-President, Business Planning & Operations Effectiveness, Mayne Pharma and Chair of EGA Biotechnology & Biosimilars Committee, UK*

### Q&A Session

15:45 - 16:15 Coffee Break

**Session Two** - Chair | *Tim Oldham, Acting Head EMEA & Chair of EGA Biotechnology & Biosimilars Committee*

16:15 **The Bolar Provision: a Safe Harbour in Europe?**  
*Kristof Roox, Partner, Crowell & Moring, Belgium*

16:35 **Developments in 'Follow-on' Biologics in the USA. Is a Global Approach Possible?**  
*Suzanne Sensabaugh, VP, US RA, and Senior Director for Global Biogenetics, Teva Pharmaceuticals Industries, USA*

### Q&A Session

17:15 **Round Table - Senior Executives' Perspective on the Future:** *Erich Kohler-BioGeneriX, Julian Attfield-GeneMedix, Geoff Ansell-Niche, Ajaz Hussain-Sandoz, Dieter Moecke-Stada, Suzanne Sensabaugh-Teva*

18:00 End of Day I

19:00 Conference Cocktail



Making Medicines Affordable

FRIDAY 19 May 2006

DAY II

08:00 Networking Coffee

### Session Three - Legal & Regulatory Framework

Chair | *Suzette Kox, Senior Director Scientific & Regulatory Affairs, EGA*

09:00 Keynote Address: *Thomas Lönngren, Director European Medicines Agency*

09:20 European Legal Environment on Biosimilars

*Nicolas Rossignol, European Commission, Enterprise & Industry Directorate-General, Pharmaceuticals*

09:40 EMEA Perspectives on Evolution of the Guidelines, Current and Future - *Peter Richardson, Department Pre-Authorisation of Medicines for Human Use, Quality of Medicines, EMEA*

10:00 Pre-/Clinical Development of Omnitrope<sup>®</sup>, the first biosimilar approved: Sandoz' experience  
*Alexander Berghout, Head Clinical Research and Development, Biopharmaceuticals, Sandoz*

10:20 Q&A Session with Session Speakers

11:00 - 11:30 Coffee Break

### Session Four - Science

Chair | *Ajaz Hussain, Vice President & Global Head of Biopharmaceutical Development, Sandoz*

11:30 Pharmacodynamics/Pharmacokinetics of Therapeutic Proteins and Biosimilars  
*Fritz Sörgel, Professor, School of Medicine, University Essen and Head of Institute for Biomedical and Pharmaceutical Research, Nürnberg-Heroldsberg, Germany*

12:00 Immunogenicity Considerations for Biosimilar Products  
*Sandy Eisen, Chief Medical Officer, TEVA Europe, UK*

12.30 Further Considerations on the Erythropoietin Guideline  
*Paul Chamberlain, Director - Biopharmaceuticals, Drug Development Programs, MDS Pharma Services, France*

13:00 Buffet Lunch

### Session Five - Post Approval Issues

Chair | *Sandy Eisen, Vice President for Portfolio and Scientific Affairs, TEVA Europe*

14:00 Risk Management, the New EU Guidance  
*Stella Blackburn, Department Post-Authorisation of Medicines for Human Use, EMEA*

14:30 Naming, Labelling, Interchangeability and Traceability of Biosimilars  
*Suzette Kox, Senior Director Scientific & Regulatory Affairs, EGA*

15:00 - 15:30 Coffee Break

15:30 Pricing, Reimbursement and Substitution for Biosimilars: A National Authority's Perspective  
*Vincent Houdry, Member of Comité Economique des Produits de Santé, France*

15:45 Patients' Perspective  
*Jo Harkness, Policy & External Affairs Director, International Alliance of Patients' Organizations*

16:00 Clinician's Perspective - *Prof. Dr. Colin Brown, University of Sheffield, UK*

16:15 Round Table and Q&A Session with Speakers Chaired by *Tim Oldham*

17:00 End of Symposium and Drinks Reception till 18:00

Registrations, subjected to availability, are opened on [www.gpaconferences.com](http://www.gpaconferences.com)

Symposium Fee for EGA Members: 638 GBP + 17.5% VAT

Symposium Fee for Participants from Eastern Europe: 849 GBP + 17.5% VAT - Symposium Fee for Non EGA Members: 1118 GBP + 17.5% VAT

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