



Making Medicines Affordable

THE EUROPEAN GENERIC MEDICINES ASSOCIATION

# Moving Forward with Biosimilar Products in Europe

| 3<sup>rd</sup> EGA Symposium on 'Biogenerics' |

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

26<sup>th</sup>-27<sup>th</sup> May 2005

THURSDAY 26<sup>th</sup> May 2005

DAY I

12:00 Registration

13:00 Welcome Buffet Lunch

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

14:00 Welcoming address: 'Moving Forward with Biosimilar Products in Europe'  
*Emile G.W.H. Loof, President EGA*

14:15 EU Competitiveness in Biotechnology and Biosimilar Products  
*James Copping, Unit Biotechnology, Competitiveness in Pharmaceuticals, Cosmetics, Enterprise Directorate General, European Commission*

14:45 EU Biological/Biotechnological Pharmaceutical Market in Europe  
*Eva Edery, Consultant, IMS Health, UK*

15:30 Coffee Break

**Session Two** - Chair | *Paul Edwards, Vice-President EGA*

16:00 Is there a Future for 'Biogenerics'? A Financial Analyst's Point of View  
*Tommy Erdei, CFA Director, Healthcare Banking, ABN AMRO*

16:30 How Can Companies Maximise Their Chances of Success in 'Biogenerics'?  
*Tim Oldham, Director Business Development & Strategic Marketing, Mayne Pharma Plc, UK*

17:00 A Global Perspective for Developing Biosimilar Medicines - The Sandoz Experience  
*Patrick Vink, Global Head Biopharmaceuticals, Sandoz, Austria*

18:00 End of Day I

19:00 Conference Cocktail Reception



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FRIDAY 27<sup>th</sup> May 2005

DAY II

08:00 Networking Coffee

**Session Three** - Chair | *John Greenwood, Director of Quality & Regulatory Affairs, GeneMedix & Chair of EGA Biotech Working Group*

09:00 **Provisions for Micro, Small and Medium-Sized Enterprises in the Centralised Procedure and Transition from Current to the Future Legal Basis for Biosimilar Applications**  
*Nicolas Rossignol, European Commission, Enterprise DG, Pharmaceuticals*

09:30 **Other Regulatory Developments in the European Union Related to 'Biosimilars'**  
*Suzette Kox, Senior Director Scientific Affairs, EGA*

10:00 **Assessing Patent and Legal Considerations for 'Biogenerics'**  
*Bert Oosting, Head Intellectual Property & Information Technology Group and the Pharmaceutical Group, Lovells, The Netherlands*

10:30 Coffee Break

11:00 **Regulatory Developments for 'Follow-on' Biologics in the USA**  
*Gordon Johnston, Vice President Regulatory Affairs Generic Pharmaceutical Association & Former Deputy Director, Office of Generic Drugs, FDA, USA*

11:30 **Confidentiality Arrangements between the EU (EC and EMEA) and the US FDA/DHHS**  
Implementation plan and its relevance to guidelines and applications for biosimilar products  
*Dr. John Purves, Head of Sector for Quality of Medicines in the Pre-authorisation of Medicines for Human Use Unit, EMEA*

12:00 **Scientific Advice Procedure for Biosimilar Medicinal Products**  
*Dr. Prof. Gottfried Kreutz, CHMP Member, Head of Department Clinical Pharmacology, BfArM, Germany*

12:30 **Question & Answer Session covering the morning session**

13:00 Buffet Lunch

**Session Four** - Chair | *John Greenwood, Chairman of EGA Biotech Working Group*

14:00 **Pre-clinical Requirements for Biosimilar Medicinal Products**  
*Dr. Hans-Karl Heim, Wissenschaftlicher Rat, Department Experimental Pharmacology & Toxicology, BfArM, Germany*

14:30 **Unwanted Immunogenicity**  
*Dr. Robin Thorpe, Head, Division of Immunobiology & Endocrinology, National Institute for Biological Standards & Controls (NIBSC), UK*

15:00 Stretch your legs break

15:15 **Statistical Aspects of Clinical Trials of Comparability**  
*Dr. John Whittington, Medical & Scientific Director, Mediscience Services, UK*

15:45 **Risk Management & Pharmacovigilance**  
*Dr. Xavier Kurz, Belgian Centre for Pharmacovigilance, Directorate General Medicinal Products, Belgium*

16:15 **Question & Answer Session with afternoon speakers and Dr. Prof. Jean-Hugues Trouvin, Chair of Biotechnology Working Party, CHMP – Member & Director of Evaluation of Medicinal & Biological Products, AFSSAPS, France**

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

Symposium Fee for EGA Members: 625 GBP + (17.5%VAT) - Symposium Fee for Non Members: 1095 GBP + (17.5%VAT)  
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