THE EUROPEAN GENERIC MEDICINES ASSOCIATION

Biosimilar Medicines: Opportunities for Sustainable Healthcare

5th EGA Symposium on Biosimilars

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

3rd - 4th May 2007

THURSDAY 3rd May 2007 **DAY I**

12:30 Registrations & Welcome Buffet Lunch

Session One - Market Overview
Chair | Greg Perry, Director General, EGA

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

14:15 **Keynote Address** *Nicolas Rossignol, Administrator, European Commission, Enterprise & Industry Directorate-General, Pharmaceuticals*

14:40 **EU Biological/Biotechnological Pharmaceutical Market in Europe**
Eva Edery, Senior Consultant, Europe, Global Pharma Strategy, IMS Health, UK

15:05 **Biosimilar Products: a Viable Option?**
Chris Swann, Market Briefings Analyst, Espicom Business Intelligence, UK

Discussion

15:45 - 16:15 Coffee Break

Session Two - International and EU Legal Developments
Chair | Sandy Eisen, Chief Medical Officer, TEVA Europe and Vice-Chair EGA Biotechnology & Biosimilars Committee

16:15 **FDA's Perspective on Comparable and Interchangeable Biological Products**
Dr. Keith O. Webber, Deputy Director, Office of Pharmaceutical Science, Centre for Drug Evaluation and Research (CDER), Silver Spring, USA (VIA SATELLITE CONNECTION)

16:45 **Questions and Answers**

17:00 **Perspectives on the Waxman Legislation and EU Implications**
Gillian R. Woollett, Chief Scientist, Engel & Novitt LLP, USA

17:30 **Key Lessons from the First Successful Biosimilar Application in the EU: Omnitrope® - A Legal Perspective**
Julia Barth, Global Head Legal Product Development, Sandoz International GmbH

17:45 **Q&A session**

18:00 End of Day & Conference Cocktail

Making Medicines Affordable

FRIDAY 4th May 2007 DAY II

08:00 Networking Coffee

Session Three – INN Naming of Biosimilar Medicines

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

09:00 **EMEA Keynote Address**
John Purves, Head of Sector, Pre-authorisation Evaluation of Medicines for Human Use, Sector Quality of medicines, EMEA

09:15 **EGA Position on INN Naming of Biosimilar Products**
Marcy Macdonald, Director of Global Regulatory Affairs, Hospira Inc.

09:35 **Development on WHO INN Naming Policy and Application to Biosimilar Products**
Professor Derek Calam, Chairman INN Expert Group, WHO

09:55 **European Commission Position on INN Naming for Biosimilar Medicinal Products**
Nicolas Rossignol, Administrator, European Commission, Enterprise & Industry Directorate-General, Pharmaceuticals

10:45 **Discussion**

11:00 - 11:30 Coffee Break

Session Four – Science & Technology

Introduction of speakers | Suzette Kox, EGA
Chair | Ajaz Hussain, Vice President & Global Head of Biopharmaceutical Development, Sandoz

11:30 **Characterisation of Glyco-Proteins: the Latest Technologies**
Ram Sasisekharan, Professor of Biological Engineering and Health Sciences & Technology, Harvard- Massachusetts Institute of Technology, USA

12:10 **Outcome of Workshop on PAT and Principles of Design Space for Biological Products**
Peter Richardson, Pre-authorisation Evaluation of Medicines for Human Use, Sector Quality of medicines, EMEA

12:30 **Process Analytical Technology (PAT) and Application to Biosimilar Development**
Ajaz Hussain, Vice President & Global Head of Biopharmaceutical Development, Sandoz and Vice-Chair EGA Biotechnology & Biosimilars Committee

Q&A session

13:00 Buffet Lunch

Session Five – EU and International Regulatory Developments

Chair | Sandy Eisen, Chief Medical Officer, TEVA Europe and Vice-Chair EGA Biotechnology & Biosimilars Committee

14:00 **Update on EMEA Guidelines Regarding Biosimilar Products**
Peter Richardson, Pre-authorisation Evaluation of Medicines for Human Use, Sector Quality of medicines, EMEA

14:30 **WHO Regulatory Guidance for Biosimilar Products**
Jeewon Joung, WHO Quality, Safety and Standards

Q&A Session

15:00 - 15:30 Coffee Break

Session Six – Stakeholders' Point of View on Market Entry of Biosimilar Medicines

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

15:30

Thomas Bols, Director Government Affairs Europe, Amgen, Belgium
Sandy Eisen, Chief Medical Officer, TEVA Europe
Timothy F Statham OBE, Chief Executive National Kidney Federation UK
Roger Tredree, Chief Pharmacist, St. George's Healthcare NHS Trust, UK
Anna Bucsics, Deputy Head, Department of Pharmaceuticals, Main Association of Austrian Social Security Institutions and Past President of the Medicine Evaluation Committee (MEDEV)

16:30 **Discussion**

17:00 End of Symposium

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