



Making Medicines Affordable

First EGA Symposium on “Biotech Generics”

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Friday 23 May 2003

The Rembrandt Hotel

11 Thurloe Place - London SW7 2RS UK

Chaired by

John Greenwood, Director of Regulatory Affairs GeneMedix & Chair EGA Biotech WG

10.30 Welcome Note and Overview of the Political/Legal Environment for Comparable/Similar Off-Patent Biotechnology-derived Medicinal Products

- EGA and EU developments at the level of the European Commission, European Parliament and Council Working Group
- IGPA and ICH developments

Suzette Kox, EGA Senior Scientific & Regulatory Affairs Advisor

11.00 Strategies to Market: Understanding the headway being made in developing and licensing Generic Biologics

- Identifying the market and understanding the potential hurdles
- Access to cell lines that are high yielding and produce ‘comparable’ products
- Ability to manufacture at low cost without compromising quality
- Managing the regulatory hurdles
- Remaining competitive in a dynamic market

Paul Edwards, CEO GeneMedix - UK

Consultant’s Point of View: The route to comparable biological medicines

- Is the current regulatory view based on sound Quality, Safety & Efficacy concerns?
- Are the perceived risks from multi-source biotech products real?
- How much supporting data are required to adequately characterise against the comparator?
- What is the legal basis for bio-comparable medicines?
- What routes are open to filing with limited data?
- Where do we go from here?

Cecil Nick, Senior Regulatory Consultant, Worldwide Regulatory Affairs PAREXEL International - UK

12.15 Coffee Break

12.30 Comparability of Medicinal Products Containing Biotechnology-derived Proteins as Drug Substance

- Essential vs. biological similarity
- Legal vs. scientific aspects
- Comparability programmes
- Emerging EU guidance
- International harmonisation

Pekka Kurki, CPMP Member and Chairperson of the Ad-Hoc Working Group on (Pre)-clinical comparability of Biotechnology Products, EMEA

13.15 Lunch

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14.15 Unwanted Immunogenicity of Biological Products

- Immunogenicity evaluation in comparability studies
- Types of essays used & their characteristics
- Examples of findings with cytokines
- Importance of unwanted immunogenicity for biological products

Robin Thorpe, Head of Immunobiology, NIBSC National Institute for Biological Standards and Control UK

Audience Interactive Panel Discussion on the Challenges and Prospects for Comparable/Similar Biotechnology-derived Medicinal Products

Panellists: Paul Edwards, Cecil Nick, Pekka Kurki, John Purves, Robin Thorpe, Robert Zeid

15.15 Coffee Break

15.30 Structure Activity Relationship: Concepts and Applications

- Assessing comparability on the basis of product characteristics to safety & efficacy
- Overview of analytical, bioequivalence, and clinical requirements
- Overview of SAR for varying biotech product classes
- Overview of surrogate endpoints and utility of clinical bridging studies vs. post-market surveillance

Robert Zeid, Principal Consultant, TLI Development - NC/USA

Third Part Patents - a block or just a hurdle?

- Infringement exemptions in EP - research exemption and "Bolar"
- Process patents - infringement and validity issues

Nicola Baker-Munton, Managing Director, Stratagem IPM Ltd - UK

16.45 Closing notes from the Chair of the day

Conference ends at 17.00



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Please note all prices are inclusive of coffee breaks & lunch. The VAT is compulsory.

- My Company/Association is a Member of the EGA and will pay the Member Fee of (£420.00 + 17.5%VAT) = **£493.50**.
- My Company/Association is not a Member of the EGA and will pay the normal Non-Member Price of (£520.00 + 17.5%VAT) = **£611.00**.

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Cancellation policy: cancellations must be made before 23 April 2003. After this point we are NOT able to refund your fee. Should you be UNABLE to attend a substitute delegate is welcome at no extra charge.

Signature: Date and Place:

For Accommodation please contact directly the Hotel
Tel: +44 20 7589 8100 Fax: +44 20 7225 3476
Bedrooms at 130 £ are reserved until the 25 April 03

*If you need any information please contact:
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