



EUROPEAN GENERIC MEDICINES ASSOCIATION
Making Medicines Affordable

2nd EGA SYMPOSIUM ON 'BIOGENERICS'

Friday 28th May 2004

Radisson SAS Portman Hotel
22 Portman Square
London W1H 7BG

Chaired by John Greenwood

Director of Regulatory Affairs GeneMedix and Chair of the EGA Biotech ad-hoc Working Group

9.30 Welcoming address

Rory O'Riordan, President of the European Generic medicines Association - EGA

9.40 Current and future legal basis for similar biological medicinal products

- Current legal basis outlined in Directive 2003/63/EC (Annex I of Directive 2001/83/EC)
- Legal basis outlined in the future pharmaceutical legislation ('Pharma Review')
- Legal basis for stand-alone mixed applications i.e. own data, comparability data and reference to bibliographical data
- Applications cross-referring to ex-concertation products in the centralised procedure
- Bolar provision and application to similar biological medicinal products

Nicolas Rossignol, Enterprise DG unit F2 Pharmaceuticals, Regulatory framework and Market authorisations, European Commission

10.10 New and developing issues affecting similar biological medicinal products

- Future data exclusivity provision in the Centralised Procedure
- Global marketing authorisation concept and biological medicinal products
- Issue of Small and Medium-sized Enterprises in the Centralised Procedure
- Environmental Risk Assessment
- Risk Management Strategy
- Clinical Trial Directive 2001/20/EC

Suzette Kox, Senior Scientific & Regulatory Affairs Advisor EGA

10.40 Update on the scientific and legal situation regarding 'biogenerics' in the USA

William F Haddad, Chairman/CEO, Biogenerics, Inc, USA

11.15 Coffee/tea break

11.45 Guideline on Comparability of Medicinal Products containing Biotechnology-derived Proteins as Drug Substance: Non-clinical and clinical issues

Focus on the relevance of clinical data for biosimilar products

Barbara van Zwieten-Boot, CPMP Member, The Netherlands

12.15 Immunogenicity and biosimilar medicinal products

Paul Chamberlain, Director Biopharmaceuticals, Drug Development Programs, MDS Pharma Services, UK

13.00 Lunch

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14.00 The challenge of demonstrating comparability of biological medicines following process change within the scope of the New ICH Q5E Guideline Step 2 document and the CPMP Comparability guideline-quality issues: a Consultant's assessment

Cecil Nick, Senior Regulatory Consultant, Worldwide Regulatory Affairs, Parexel International Ltd., UK

14.30 Experience gained so far with FDA and Health Canada

Paul Chamberlain, Director Biopharmaceuticals, Drug Development Programs, MDS Pharma Services, UK

15.00 A 'Biogeneric' Company's strategy to market

- Why should a company wish to produce these products?
- Terminology for biogenics
- Why do we have to demonstrate comparability with the innovator?
- How do we demonstrate comparability?
- Characterisation testing of Active Ingredient
- Pre-clinical studies
- Clinical studies
- Specifications
- Immunogenicity

John Greenwood, Director of Regulatory Affairs, GeneMedix plc, UK

15.30 Stretch your legs break

15.45 Audience Interactive Panel Discussion with CPMP Members and Speakers on the developments of biosimilar medicinal products and the data required and experience with scientific advice: chaired by John Greenwood

Paul Chamberlain, **Bill Haddad**, **Cecil Nick**, **John Purves**/EMEA, **Jean-Hugues Trouvin**/CPMP Member France, **Barbara van Zwieten-Boot**/CPMP The Netherlands

16.30 Enlarged Europe and the 'Bolar' provisions

- Bolar clause in new Pharma Directive:
 - Picking apart the clause:
 - Submission of MAA
 - application of paragraphs 1-4
 - "consequential practical requirements"
 - without prejudice to "the law relating to" IP and commercial property
 - scope of activities?
 - "necessary studies and trials"
 - (activities allowed in MS under current law/jurisprudence)
 - Biogenics
 - Geographical extension (EEA relevance)
 - Implementation strategies
- Accession countries' Bolar
 - Outside of *acquis*
 - Approach in different countries (within WTO Dispute framework)
- How will national law interact with Pharma
- Exportation?
 - intra-Community
 - outside (Canada)
- Eventual Bolar in Community Patent

David Koch, Senior Advisor-Contracts and IP, Sicor-Teva Switzerland

17.00 Chairman's conclusions

End of symposium drinks till 18.00

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