



Biosimilars

Ensuring quality, safety, and performance of follow-on biologics

11th - 13th November 2008, Radisson Plaza-Warwick Hotel, Philadelphia, USA

Key Speakers

Linda R. Horton, Partner, **Hogan & Hartson**

Dr Rustom Mody, Director & Head – Strategic Research, R&D and Quality, **Intas Biopharmaceuticals**

Elona Baum, Director, Policy and Management Operations, Regulatory/Quality/Compliance, **Genentech**

Lore Unt, Counsel for Intellectual Property, **Federal Trade Commission (FTC)**

Tom Saylor, Chief Executive Officer, **Arecor**

Diane Edquist Dorman, Vice President for Public Policy, **National Organization for Rare Disorders (NORD)**

Marc Martens, Senior Associate, **Bird & Bird**

Dr Arnon Chait, President and CEO, **Analiza**

James Harris, Chief Effective Officer, **Healthcare Economics**

Dr Antony C Tridico, Partner, Biotechnology/Pharmaceutical Practice Group, **Finnegan Henderson**

Arnold I. Friede, Counsel, **McDermott Will & Emery**

Robin Howard, Director, **Simon-Kucher & Partners**

Cecil Nick, Vice President Biotechnology, **Parexel**

Dr Jacco Keja, Managing Director and Practice Leader, **Quintiles Global Consulting Services**

Dr Helmut Brunar, VP Research & Business Development, **Kwizda Pharma**

Dr Jorge Mestre-Ferrandiz, Senior Economist, **Office of Health Economics**

Pre-Conference Interactive
Workshop

Led by:

Arnold I. Friede

Counsel

McDermott Will & Emery LLP

Tuesday
11th November
2008

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Biologics are the fastest growing segment of the pharmaceuticals market. What is the future for follow-on biologics?**Dear Colleague,**

With a variety of different reasons for and against the development of biosimilars within the USA, generic manufacturers, originators and payers have differing views as to how this should come about. Visiongain is delighted to host the 4th Annual Biosimilars conference in Philadelphia this November. This 3-day event will provide you with practical insights into the scientific developments and regulatory challenges that will influence the success of biosimilars/follow-on biologics market. Enabling you with a platform to discuss the issues effecting the market, such as product selection and payer acceptance in a broader industry context. Consideration will be given to the evaluation of unwanted immunogenicity of follow-on biologicals, from preclinical development, through clinical trials, and into the post-registration period to minimise the risks associated with immunogenicity in recipients of therapeutic products. This meeting has received excellent feedback in previous years and this year's programme will be no exception.

Reasons to register today

- Identify the trends that will shape future market development of follow-on biologics
- Explore the current market and regulatory environment for biosimilars in Europe and the relevance to US legislation
- Examine the emerging market landscape for biosimilars in India and China
- Understand interchangeability/substitutibility policies
- Discuss unwanted immunogenicity issues for biosimilars
- Analyse the market impact of biosimilars from the Payers perception
- Examine the pre-marketing hurdles and post-marketing challenges faced by biosimilar/follow-on biologics developers:
- Utilise new and established analytical tools for demonstrating comparability
- Assess how is the landscape evolving for biosimilar medicines

I look forward to meeting you at the conference

Best regards



Andrea Charles
Head of Conferences

Who should attend?

Branded Biotechnology & Generic Pharmaceutical Companies, Drug Regulators, Healthcare Agencies, Government Departments, Contract Research/Bio manufacturing Organisations, Regulatory Affairs, Pharmacovigilance

VPs, Directors, Heads, Managers of:

Legal Counsel
Intellectual Property
Regulatory Compliance
Pharmacovigilance
Drug Safety & Risk Management
Quality Affairs/ Quality Control
New Product Development
Process Science
Business Development
Business Operations
Scientific Affairs
Commercial Affairs
Marketing
Analytical Characterisation
Process Control and Analytical Technologies
Clinical Immunology
Biopharmaceuticals/ Biotherapeutics
Principal Scientist
Chief Scientific Officer

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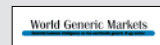
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For further information please visit: www.espicom.com/wgm



A business review of, and commentary on, the developments that are shaping this rapidly evolving and often contentious sector of the generic drug industry. This well written quarterly review will help you navigate through the twists and turns of the emerging biosimilar market. Packed with the latest industry and regulatory developments, company profiles and keen insightful commentary, it is essential reading for everyone involved or interested in biosimilars.

For further information please visit: www.espicom.com/bios



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About visiongain:

Visiongain is a specialist business information company focused on providing cutting edge products and services across the Pharmaceutical/Biotech, Telecommunications, Defence and Finance sectors, which include reports, conferences, online daily news and offline news analysis and bespoke consultancy. With a commitment to innovation and excellence, visiongain offers flexible solutions to meet our clients' business intelligence needs, providing the right information at the right time to facilitate the commercial decision-making process. Our pharmaceutical products include Pharma Business Daily, the leading daily email newsletter for the pharmaceutical, biotech and healthcare industries, and a range of independent, high-quality, in-depth reports covering focused and topical areas of concern. Our pharmaceutical conferences address the hottest commercial, regulatory and technical topics and provide an ideal forum for debate and networking for pharmaceutical professionals from around the world.

For further information, please visit: www.visiongain.com

Sponsorship and exhibition opportunities:

This event offers a unique opportunity to meet and do business with some of the key players in the pharmaceutical and biotech industries. If you have a service or product to promote, you can do so at this event by:

- Hosting a networking drinks reception
- Taking an exhibition space at the conference
- Advertising in the delegate documentation pack
- Providing branded bags, pens, gifts, etc.

If you would like more information on the range of sponsorship or exhibition possibilities for visiongain's 4th Biosimilars event, please contact:




Patricia Gallegos

Tel: +44 (0)20 7549 9952

Email: patricia.gallegos@visiongainglobal.com

Pre-Conference Interactive Biosimilars Workshop

Led by:  **Arnold I. Friede**
Counsel
McDermott Will & Emery LLP

Timings: 10:00 - 10:30 Registration and refreshments
10:30 - 15.30 Workshop
Timing includes refreshment breaks

Workshop Format

The purpose of the workshop is to allow delegates to engage in knowledge sharing with their peers in a smaller, less formal environment than the main conference. As such the audience size will typically be no more than 20 participants in order to enable maximum interaction between the workshop leader and delegates. The format is also more interactive, with less emphasis on 'lecture-style' presentations and more emphasis on case studies, group discussions, exercises and Q&A sessions.

Workshop agenda

- Background and context
 - United States V. Generix Drug Corp. (1983)
 - Drug Price Competition And Patent Term Restoration Act Of 1984 "Hatch-Waxman Act"
 - 505(b)(2)
- Pathways for Biosimilars Act
- Contents of application
- Waivers of certain requirements
- Additional Information
- FDA action on biosimilar application
- "Interchangability" (I.E. Substitutability) separate and distinct from biosimilarity.
 - Standards
 - FDA Guidelines
- General rules
- Exclusivity for first interchangeable biosimilar
- Reference product exclusivity.
- Timing of biosimilar filings.
- Guidance documents
- Naming
- Patents
 - Exchange of patent information

About your workshop leader



Arnold I. Friede:

Arnold I. Friede is counsel to the law firm of McDermott Will & Emery LLP based in its Washington, D.C. office. Arnie is a member of the Firm's Health Law Department. Arnold I. Friede is a widely respected food and drug law counselor and advocate with significant advertising law, health care law, First Amendment, environmental, and commercial and transactional experience. He has a long history of direct involvement in successfully representing clients in FDA-regulated matters beginning as an Associate Chief Counsel in the FDA Chief Counsel's Office, as well as a broad spectrum of senior in-house legal experience across multiple FDA-regulated industries.

Arnie has had a distinguished career of highly responsible, diverse, and complex positions. He served in government as a law clerk in Federal District Court in Los Angeles, and then with the Federal Judicial Panel on Multidistrict Litigation in Washington, DC, and as an Associate Chief Counsel in the FDA Chief Counsel's Office in Rockville, Maryland. Afterwards with Richardson-Vicks in Wilton, Connecticut, and then with several divisions of Unilever United States, including as General Counsel of Unilever's U .S. food business in New Jersey, and then as senior corporate counsel with Pfizer in New York, Mr. Friede has been involved for nearly 35 years in a broad range of FDA and other agency-regulated businesses, including the life sciences, such as pharmaceutical and biotech, medical device, medical information, disease management, and over-the-counter drugs, as well as in the food, cosmetic, chemical and other industries. He has a breadth and depth of experience across an array of substantive legal areas and business operations.

About McDermott Will & Emery:



McDermott Will & Emery is a premier international law firm with a diversified business practice. Numbering more than 1,100 lawyers, we have offices in Boston, Brussels, Chicago, Düsseldorf, Houston, London, Los Angeles, Miami, Munich, New York, Orange County, Rome, San Diego, Silicon Valley and Washington, D.C. Extending our reach to Asia, we have a strategic alliance with MWE China Law Offices in Shanghai.

Our Firm has 70 years of experience serving a broad range of client interests. We understand the issues faced by corporate decision makers because many of our lawyers have held key government and in-house positions. We understand how economic, social and political issues affect operations because our lawyers have navigated the complex business and regulatory environment themselves.

<http://www.mwe.com>

09:30 Registration and refreshments

10:00 Opening address from the chair

10:10 **The biosimilar threat: Lessons learned from the European Union**

- Biosimilar market access: differences between the US and the EU
- Payer perception of biosimilars
- The impact of biosimilars: case studies from the EU
- Assessing the biosimilar threat for your company
- Finding the right strategic response

Robin Howard
Director, San Francisco Office
Simon-Kucher & Partners

10:50 **Biosimilars in the EU**

- EU legislative framework
- Actions to date under the EU framework
- Naming of biological medicines
- Interchangeability/substitutability issue
- Relevance to U.S. legislation

Linda R. Horton
Partner
Hogan & Hartson

11:30 Morning refreshments

11:50 Presentation to be announced

Dr Emily Shacter
Chief Biochemistry, Chief, Laboratory of Division of Therapeutic Proteins,
Office of Biotechnology Products, OPS CDER OPS, CDER
FDA*

12:30 **Examining the current legal and regulatory landscape for US marketing of follow-on biologics**

- U.S. patent provisions currently applicable to biologics undergoing FDA Review
- Proposed U.S. legislations
- Scope regarding comparable and interchangeable biologics
- Market exclusivities
- Resolution of patent infringement disputes
- Current status in Congress

Elona Baum
Director, Policy and Management Operations, Regulatory/Quality/Compliance
Genentech

13:10 Networking lunch

14:30 **Strategies for achieving the most effective patent protection**

- Patent strategies for protecting against biosimilars
- Regulatory issues to consider when seeking patent protection
- Claim drafting strategies
- Protecting from design arounds by using method and process claims
- Use of trade secret protection

Dr Antony C Tridico
Partner, Biotechnology/Pharmaceutical Practice Group
Finnegan Henderson

15:10 **The future role biosimilars can play in improving patient access to effective and affordable medicines**

- Celebrating the successes over the past 25 years
- Where will the next quarter century take us?
- How do we identify future opportunities?
- What are the challenges yet to be faced?

Diane Edquist Dorman
Vice President for Public Policy
National Organization for Rare Disorders (NORD)

15:50 Afternoon refreshments

16:10 **The market for biosimilars: evolution and policy options**

- Substitutability and Interchangeability
- An economic framework for analysing biosimilars
- Dynamic modelling of biosimilars
- What should payers do?

Dr Jorge Mestre-Ferrandiz
Senior Economist
Office of Health Economics

16:50 **Potential competition implications for generic biologics**

- How biologics competition may compare to small-molecule drug competition
- Competition implications of different biologics regulatory frameworks
- Lessons learned from Hatch-Waxman related to innovator and follow-on exclusivities
- Potential competition concerns with follow-on biologics

Lore Unt
Counsel for Intellectual Property
Federal Trade Commission (FTC)

17:40 Closing remarks from the chair

17:45 **Networking drinks**

Take your discussions further and build new relationships in a relaxed and informal setting.

09:30	Registration and refreshments	13:10	Networking lunch
10:00	Opening address	14:30	The next generation of biosimilars <ul style="list-style-type: none"> • The spectrum of complexity • The next biosimilar targets • Monoclonals as biosimilars • Efficient global programs <div style="border-left: 2px solid black; padding-left: 10px; margin-top: 10px;"> <p>Cecil Nick Vice President Biotechnology Parexel</p> </div>
10:10	Examining the emerging market landscape for biosimilars in India <ul style="list-style-type: none"> • Climatic changes in India favouring biosimilar development • Advantages of outsourcing the development of biosimilars to India • Quality perspective • Experiences on the development of two biosimilars for the regulated markets <div style="border-left: 2px solid black; padding-left: 10px; margin-top: 10px;"> <p>Dr Rustom Mody Director & Head – Strategic Research, R&D and Quality Intas Biopharmaceuticals</p> </div>		
10:50	Development of G-CSF biosimilar: a win-win-win situation on three continents <ul style="list-style-type: none"> • Overview of global regulatory environment, progress made with biosimilars in EU/USA, socioeconomic impact, general market musing • Case study GCSF-biosimilar: business model, analysis of Kwizda, Intas & Apotex motivations, next steps • Selection criteria for niche, orphan & super-orphan approach, financial considerations, corporate milestones, future perspectives <div style="border-left: 2px solid black; padding-left: 10px; margin-top: 10px;"> <p>Dr Helmut Brunar VP Research & Business Development Kwizda Pharma</p> </div>	15:10	Understanding pricing and reimbursement issues <ul style="list-style-type: none"> • An overview of the pricing and reimbursement environment for biologics and generics • Lifecycle management options for originators • Possible pricing strategies needed to remain competitive <div style="border-left: 2px solid black; padding-left: 10px; margin-top: 10px;"> <p>Dr Jacco Keja Managing Director and Practice Leader Quintiles Global Consulting Services</p> </div>
11:30	Morning refreshments	15:50	Afternoon refreshments
11:50	Biosimilar commercialisation opportunities and challenges in the US <ul style="list-style-type: none"> • Identify the key factors that emerging firms should contemplate when considering biosimilar development <p>Key topics for discussion</p> <ul style="list-style-type: none"> • Product selection • Regulatory considerations • Marketing opportunities • Payer acceptance <div style="border-left: 2px solid black; padding-left: 10px; margin-top: 10px;"> <p>James Harris CEO Healthcare Economics LLC</p> </div>	16:10	New and established analytical tools for demonstrating comparability <ul style="list-style-type: none"> • Robust tools focusing on functional product properties are essential for smooth regulatory approval • Modern techniques are available for demonstrating comparability of biologics independent of their source and production platforms • Thorough and convincing analytical comparability study may greatly assist in narrowing the scope of clinical comparability requirements <div style="border-left: 2px solid black; padding-left: 10px; margin-top: 10px;"> <p>Dr Arnon Chait President and CEO Analiza</p> </div>
12:30	Understanding the regulatory framework surrounding the development of biosimilars <ul style="list-style-type: none"> • Introduction – Timeline for development of biosimilars • Generic vs biosimilars • EU legislative framework • EU Guidelines • Strategic issues in EU <ul style="list-style-type: none"> - INN - Substitution - Non biotech - Old approvals in New Members States - Other issues <div style="border-left: 2px solid black; padding-left: 10px; margin-top: 10px;"> <p>Marc Martens Senior Associate Bird & Bird</p> </div>	16:50	Biosimilar/follow-biological products – USP perspective <div style="border-left: 2px solid black; padding-left: 10px; margin-top: 10px;"> <p>Dr Tina Morris Director, Biologics & Biotechnology USP*</p> </div>
		17:30	Chair's closing remarks
		17:40	End of conference

*invited

