

World Generic Medicines

Congress Americas 2009

17 – 20 November 2009, The Westin Grand, Washington DC, United States

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Hear from



**The Honorable
Henry Waxman**
Member of Congress
United States



Stefan Sveinsson
Executive Vice President
Research & Development
Actavis Group



William Kennally
Area President North America
Established Products
Pfizer



Amit Patel
Senior Vice President &
Head North America Generics
Dr Reddy's Laboratories



Markus Meier
Assistant Director,
Healthcare Division
Federal Trade Commission

More highlights Page 3 >>
Full programme Page 4 - 6 >>

Excellence



The business of affordable medicines

Hear from and meet top generic pharmaceutical leaders:
including Actavis, Dr Reddy's Laboratories, Hospira, Mylan & Sandoz
pages 4 and 5 >>

The future of generic medicines:
consider fresh ideas from industry leaders shaping the generics landscape
pages 4 and 5 >>

Highly interactive pre and post conference workshops:
the evolution of the generic medicines industry and the legal environment
for generic medicines page 6 >>

Pre & post conference workshops

17 November 2009 The evolution of the
generic medicines industry

20 November 2009 Legal environment for
generic medicines

All details page 6 >>

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“Good selection of topics, excellent presenters/speakers”

Director of Operations, **Egis Pharmaceuticals**

“Very informative, enlightening presentations”

President, **Pharex Health Corp**

“Good quality speakers, well organised, great venue, topical content”

Chief Executive Officer, **Dr Reddy's, South Africa**

Benchmark your generics strategy alongside the industry's best

World Generic Medicines Congress Americas 2009 is the must attend meeting for those striving for excellence in the generic pharmaceutical industry. In this setting the industry's elite will meet and focus their attention on the important topics of the day including the major challenges in the sector, the evolving scientific, regulatory and policy environment, the expanding global platform and ensuring business success in the quest to provide affordable medicines.

The World Generic Medicines Congress series has an international profile and is already established as the generic medicine meeting of choice, attracting high numbers of industry leaders. Register to guarantee your place amongst the industry thought leaders and decision makers innovating the sector!

Generic medicines in the US and internationally

The global economic downturn has challenged the pharmaceutical industry and affected demand, though the market has remained relatively buoyant in these times of struggle and has fared far better than many other industries. The generic medicines market has continued to prosper with a faster pace of growth than pharma, as healthcare providers utilize generics in cost efficient plans and the industry responds well to the changing competitive landscape. The US generic market is worth an estimated \$60 billion in 2009 and has remained promising as drastic changes occur. The USA's reforming healthcare system significantly supports and encourages the use of generic medicines as a cost effective, safe and efficient source of healthcare.

The meeting provides an in-depth analysis of generic medicine strategy, policy and case studies from a number of emerging markets – which continue to out perform the mature markets – providing a unique overview of affordable medicines within an international platform.



Interact with industry experts in the panel sessions

The congress will review the status of the industry with a focus on its successes as well as ensuring the market continues to thrive today and tomorrow.

The World Generic Medicines Congress Americas 2009 is a must-attend event for generic professionals striving to excel in the industry

This meeting will set the scene for you, providing an in depth overview of the generic medicines market; address scientific innovation in the industry; update you with important policy and regulatory developments; analyze the resulting impact of these developments; review the global environment with a focus on the prosperous emerging markets; review the unique strategy and evolving legislative setting for biosimilar pharmaceuticals and examine the financial performance of the sector.

World Generic Medicines Congress Americas 2009 is set to bridge the gap between international generic manufacturers, big-pharmaceutical manufacturers, regulatory bodies, policy decision makers and financial organisations. The programme finds the perfect balance between high quality scientific content, strategy-led presentations from an expert speaker panel, solutions-based discussion sessions on the most pertinent issues affecting the generics industry and extensive networking opportunities.



8 REASONS

Why you should attend World Generic Medicines Congress Americas 2009:

Comprehensive agenda; we have over 20 unique and informative sessions, keep track on our website for developments

Actavis, Dr Reddy's Laboratories, Hospira, Sandoz, Mylan, Aspen & Pfizer; hear industry insights from our expert speaker panel including top generic and pharmaceutical representatives!

Quality content! We listen to you and your peers to ensure our program confronts the topics you want to hear

Policy experts including representatives from **the FTC, US Congress, the FDA and the United States Patent and Trademark Office**

Extensive global reach; we have speakers from America, Europe, Africa and Asia to give a much needed view of the international generic landscape

Pre and post conference workshops, focused networking sessions, panel discussions, delegate led questions. **Tailor the packed congress to meet your own information and networking needs**

Proven track record! Continuing and evolving from the success of 2007 and 2008 in Europe and America, this event promises to be bigger and better than ever!

Extensive networking opportunities; make contact, plan who to meet and arrange meetings prior to the conference, take part in multiple networking sessions, continue and build those relationships following the event

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Health Network Communications is an international events company dedicated to providing conferences, training courses and seminars for the life science community.

A-list of industry experts



The evolving industry landscape and consolidation in the generics industry

Stavros Nicolaou, Senior Executive, **Aspen Pharmacare** and Chairman, **Pharmisa**



Globalization of Indian generics – an emerging market perspective

Vikash Salig, Chief Executive Officer, **Dr Reddy's Laboratories South Africa**



Global review of generic biological medicine

Patrick Vink, Senior Vice President, Global Head of Biologics, **Mylan Inc**



The role of regional companies in the emerging MENA markets

Mazen Darwazah, Vice-Chairman, **Hikma**



Reverse payment settlements: the status of judicial decisions and legislative proposals

Tom Rosch, Commissioner, **FTC**



Scientific considerations in the evaluation of follow-on protein products

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



Significant recent developments in the law as it relates to patents & the pharmaceutical industry

Mark Bowditch, Patent Attorney, **Sandoz**

"Well prepared and informative presentations. Relevant selection of topics"

Business Development Manager, **Pharmathen Pharmaceuticals**

"Covered a broad range of issues affecting the generic industry"

Senior Economist, **PMPRB**

17 top industry and policy experts under one roof and counting...

Your event contact is Prithibah Irving
+44 (0) 207 608 7055

pairving@healthnetworkcommunications.com

Day One Wednesday 18 November 2009

8.00 Registration & coffee

GENERIC MEDICINE INDUSTRY LANDSCAPE

8.50 Opening remarks from the chair

9.00 Role of generic medicines in the provision of affordable and effective healthcare



- Government initiatives to lower healthcare costs
- Generic consumption prognosis in the worldwide economical crisis with declining sales for pharmaceuticals
- Providing affordable medicine in a fiercely competitive environment with constant price erosion


Stefan Sveinsson, Executive Vice President Research & Development, **Actavis Group**

9:30 Pfizer's drive to provide affordable, quality medicines to under served patients



- Why Pfizer is turning to multi-source markets for future growth
- How Pfizer will compete in the challenging multi-source space
- Pfizer's contribution to affordable healthcare strategies

William Kennally, Area President North America Established Products, **Pfizer**

10.00  **PANEL SESSION** Ask our keynote morning speakers your burning questions10.20  **SPEED NETWORKING** and morning refreshments

11.10 Congressional update and Q&A session on Hatch-Waxman Reforms



The Honorable Henry Waxman,
Member of Congress,
United States of America

11.40 United States healthcare reform and comparative effectiveness: examination of the resulting impact on the generics sector

Speaker to be confirmed

12.10 Update on the Federal Trade Commission's actions involving generic medicines

- Recent developments in brand-generic patent litigation settlement cases
- Actions to prevent generic drug companies from hindering generic competition
- Views concerning the competitive implications of authorized generics
- Findings from the drug company agreements filed with the FTC under the Medicare Modernization Act of 2003

Markus Meier, Assistant Director, Healthcare Division, **Federal Trade Commission**

12.40 Lunch

1.40 The blurring line between innovator and generic pharma

- Big pharma trend for partnering into, acquiring, or launching a generic or emerging markets presence
- Generic companies are increasingly developing, manufacturing and/or commercializing specialty drugs, new chemical entities, and biologics
- Are the traditional descriptors of innovator vs. generic still applicable? Will we see a new breed of pharma and business models in the future?

Amit Patel, Senior Vice President & Head North America Generics, **Dr Reddy's Laboratories**

2.10 Driving generic utilization through aggressive patient engagement

- Strategies a payer can leverage to increase generic utilization in any patient population
- Leveraging comparative generic pricing information in patient communication tools to promote affordable purchase patterns
- Outcomes related to the implementation of a "generics tool kit" on several payer clients
- Clinical messages which can support and supplement the increase of generic drug utilization

Matthew Gibbs, Chief Clinical Officer, **Medco Health Solutions**

2.40 How can outsourcing partners aid efficiency and performance in the generics industry?

- Why generic companies are ideal candidates for outsourcing; demand volatility, price and economic volatility, need for supply chain excellence
- Need for flexibility, minimizing risk and lowering cost

Mark Wiesman, Chief Operating Officer, **DDN**

3.10 Afternoon refreshments

INTERNATIONAL MARKET FOCUS

3.40 African pharma – dependency or self sufficiency?

- The pharma supply in Sub-Saharan Africa
- Healthcare funding in Africa
- The nature of drug procurement in the Sub-Saharan region
- What is the best pharma model for the region?
- Meeting the challenge of developing and expanding pharmaceutical capacity on the continent
- Aspen's suggested model

Stavros Nicolaou, Senior Executive, **Aspen Pharmacare** and Chairman, **Pharmisa**

4.10 Globalization of Indian generics – an emerging market perspective

- Evolution of the Indian pharmaceutical industry
- Key drivers for globalization
- The impact on emerging markets including South Africa, Venezuela and Russia
- What does the future hold?

Vikash Salig, Chief Executive Officer, **Dr Reddy's Laboratories South Africa**

4.40 The role of regional companies in the emerging MENA markets

- Consolidation of the MENA markets
- The future of healthcare expenditure
- How MENA markets will reform

Mazen Darwazah, Vice-Chairman and MENA Chief Executive Officer, **Hikma Pharmaceuticals**

5.10 Changes in the drug distribution environment in Europe: impact on generics companies

- Opportunities and risks for generics companies in Europe
- Changes in the distribution environment in Europe
- Consequences for generics companies

Michael Lonsert, Head of Manufacturer Solutions, **Celesio**

5.40 Drinks reception hosted by Kaplan Gilman & Pergament LLP

8.00



The Gala Dinner, hosted by DDN is an opportunity to relax and network over drinks and great food with your fellow conference attendees. **Places are limited – in order to confirm your place you need to book early.**

Day Two Thursday 19 November 2009

8.00 Breakfast briefing hosted by Parexel Join in this engaging discussion and complementary breakfast session which will give you the opportunity to gain new and practical insights at this thought provoking and informative session. Check the website for further details >>

8.50 Opening remarks from the chair

9.00 Financial perspective of the generics market: 12 months on how the world has changed

- Trading multiples
- Mergers and acquisitions
- Regulatory environment and healthcare reform
- Emerging markets new entrants from large pharma
- Sector outlook next 24 months

Cathrin Petty, Partner, **Apax Partners**

9.30 Reverse payment settlements: the status of judicial decisions and legislative proposals

- Judicial decisions: Cardizem, Schering, Tamoxifen, Cipro, Cephalon and Androgel
- Legislative proposals: per se illegality and the case-by-case approach
- A proposed middle ground

Tom Rosch, Commissioner, **FTC**

10.00 Morning refreshments

IP, LEGAL STRATEGY & PATENT REFORM

10.30 Developing a comprehensive policy for biosimilars: a challenge with many moving parts
Remy Yucel, Director Technology Centre, **United States Patent and Trademark Office**

10.45 Significant recent developments in patent law as it relates to patents & the pharmaceutical industry

- Patents and the new follow-on biologics pathway
- Losing or extending the 30-month stay
- Triggering and forfeiting the 180-day exclusivity
- The latest on the biotech front: in re Kubin and Ariad vs. Lilly
- Business method patents in the pharmaceutical context
- Process limitations count: Aventis vs. Amphistar

Mark Bowditch, Patent Attorney, **Sandoz**

11.15 Antitrust implications of settling a Hatch-Waxman ANDA case

- Settlement structures - avoiding significant antitrust scrutiny
- Through the eyes of the FTC - what constitutes a reverse payment? Is there difference between a cash payment and other forms of consideration?
- Can the ANDA applicant validly protect its 180-day exclusivity period in the context of a settlement?
- How can one determine whether a payment is likely to be challenged?
- What are the major arguments in favor / against FTC's positions?
- Potential role of the U.S. Supreme Court in Hatch-Waxman settlements

Andrew Berdon, Partner, **Quinn Emanuel Urquhart Oliver & Hedges LLP**

11.45 Generic product selection in view of recent decision of the federal circuit

- Courts decisions effect on product selection
- What is enough to render a method patent invalid?
Rasmussen vs. SmithKline, Impax Labs vs. Aventis

- New life for obviousness in patent challenge litigation: Pfizer vs. Apotex, Aventis v. Lupin
- Change in the Law of Infringement for product-by-process claims: Abbott vs. Sandoz

Edward Pergament, Partner, **Kaplan Gilman & Pergament LLP**

12.15  **Legal insight: how to ensure access, management and protection of IP as business models and markets evolve**

Chair: Remy Yucel, Director Technology Centre, **USPTO**

Panellists:

Stephen Auten, Vice-President Legal IP, **Sandoz**

Edward Pergament, Partner, **Kaplan Gilman & Pergament LLP**

Andrew Berdon, Partner, **Quinn Emanuel Urquhart Oliver & Hedges LLP**

Mark Bowditch, Patent Attorney, **Sandoz**

12.45 Lunch

1.45 Global review of generic biological medicine

- Market development over the coming years: what is the opportunity?
- Regulatory developments around the world
- Biosimilars vs. biobetters: what's the difference and how does it impact strategy?
- How to develop a successful business model

Patrick Vink, Senior Vice President, Head of Global Biologics, **Mylan GmbH**

BIOSIMILAR MEDICINES

2.15 Scientific considerations in the evaluation of follow-on protein products

- Scientific considerations in assessing similarity and differences between biotechnology products produced by different manufacturers

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

2.45 Pharmacovigilance and biosimilars: ensuring patient safety

- Increasing demand on low price medicines, both in the US and other nations
- Potential opportunity for price reductions vs. the originator biopharmaceuticals
- New guidance and regulations
- Immunogenicity

Parexel client to be confirmed

3.15 Diversifying into generic biologics: entering into the biosimilars market

- Business rationale for investment in generic biologics
- Capabilities needed to successfully develop, manufacture and market biosimilars
- The competitive landscape
- Market factors influencing uptake of biosimilars

Cole Pinnow, Vice President, Global Specialty Pharmaceuticals, **Hospira**

3.45 Closing comments from the chair and afternoon refreshments

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Meet and talk about the business issues on your brain.



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See page 8.

Pre & post conference workshops

Tuesday 17 November 2009

The evolution of the generic medicines industry

Abstract

This workshop opens discussion channels between senior generic authorities. You will analyse the industry, spot trends, evaluate the effect of the economic downturn and forecast the industry's future.

Objectives

Expand your knowledge of the industry in a practical and interactive session, with an in-depth analysis of recent financial performance, regional trends and focus on the future.

Overview

9.00 Industry overview and analysis

- Analysis of the size, scope background and major influences on the global generics industry today

11.00 Key strategic drivers pushing generic uptake

- Global review of generic medicine
- US focus: Obama's health reform, the resulting effect on the generics industry, FTC input and health policy developments

12.00 Lunch

1.00 Industry consolidation

- With so much recent M&A activity, are these partnerships the best way forward? Financial and strategy considerations
- Big pharma: friend or foe?

2.30 The generic industry of tomorrow

- In such a turbulent environment, what can we predict about tomorrow's generic industry?
- Survival strategies and considerations for the future

Meet your workshop leaders

Frances Cloud, Founder, **Pharmacloud** has 15 years of industry experience as an equity analyst, investment banker and sector researcher and has extensive experience analyzing industry trends and the resulting financial implications on companies.

Malcolm Ross, Managing Director, **Generapharm-Consulting** has been in the industry for 30 years and worked within Teva, Par and Taro. His background is technical on the generic R&D side and strategic product life cycle management.

Friday 20 November 2009

Legal environment for generic medicines

Abstract

This workshop encourages open discussions with industry experts and fellow professionals. Delve into the topics you want to hear more about, the global IP challenges and considerations.

Objectives

To gain an in-depth understanding of the legal issues related to generic medicines. You will grasp the legal environment of generic medicines, patent landscape, antitrust issues, key legal issues related to biogenerics, authorized generics and the resulting legislation considerations.

Overview

9.00 Overview of the global generic landscape

11.00 Patent intelligence for generic activity

- Take an in depth look at patents in the generic industry including patent types and processes, the nature and coverage of patent protection, patent expiry issues, antitrust issues, exclusivity and patent protection provisions of the Hatch-Waxman Act
- Patent considerations specific to biosimilar medicines

12.00 Lunch

1.00 IP on the global platform

- IP challenges, the role of IP within the generic medicine industry and the commercial considerations affected by IP
- IP policy for generic medicines on an international platform: considering the major similarities and differences between the US and other key markets including Europe
- Patent reform and resulting legislation in the US
- Global IP legislation

2.30 Interactive Q&A

- Discuss what has been addressed in the day and an open opportunity to ask those final burning questions you may have

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Becoming a sponsor or exhibitor

Since launching in 2007, the *World Generic Medicines Congress* series has attracted a staggering number of senior generics industry personnel. These conference attendees are your potential clients, and are looking for the solutions that you can provide.

If you are a CRO, generic manufacturer, law firm or business intelligence company and you want to promote yourselves to the right people within the global generics industry then this event is the perfect platform on which to do so.

Your direct route to market

The 2nd annual *World Generic Medicines Congress Americas 2009* is the meeting of choice for senior decision makers in the global generics arena and is the perfect platform to meet with clients and build mutually beneficial partnerships. It is where world class vendors and solution providers can showcase products and expertise to this targeted audience. This is your chance to be part of the most cost effective marketing solution in generic medicines. Reduce the time taken to meet new

customers, lower the costs of advertising and maximise the return on your investment.

A few short questions for you

- Do you want to meet and influence high profile decision makers within the international generic pharmaceutical industry?
- Are you able to help companies further their approach to generic manufacture?
- Do you want a fast track to gaining competitive advantage and increased market share?

If your answer is yes to any of these questions, you should be participating at this event.

To sponsor contact
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Meet and do business with generics industry decision makers.

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World Generic Medicines Congress Americas 2009

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Gala Dinner

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