SMi present their 14th annual conference on...

Generics, Super-Generics, and Patent Strategies

Wednesday 11th and Thursday 12th May 2011
Millennium Gloucester Hotel, Central London, UK

KEY SPEAKERS
Pascal Brenneisen
Country Head
Sandoz UK

Jozef Belcik
Commercial Director, Branded Generics
AstraZeneca

Deepak Murpani
Vice President, Product Development
GenePharm Group

Manoj Paruthi
Senior Manager, Head Branded Generics
Hikma Pharmaceuticals

Ayhan Aslan
Director, International Commercial Division
MN Pharmaceuticals

Aman Trehan
Deputy General Manager-Intellectual Property
Cadila Health Care

CONFERENCE HIGHLIGHTS
- Investment opportunities and challenges in the Generics industry for the UK
- The development of Super-Generics
- European IP issues and global patenting strategies
- Generics in emerging markets
- Insights into European regulatory body procedures

With over half of the current blockbuster drugs on the market with a value of £241 Billion due to expire by 2015, there are incredible opportunities open to the new and existing global generic players.

PLUS TWO INTERACTIVE PRE-CONFERENCE WORKSHOPS
Tuesday 10th May 2011, Millennium Gloucester Hotel, Central London, UK

A: Valsartan: Negotiating the EU patent thicket for a blockbuster anti-hypertensive
Hosted by Duncan Curley, Director, Innovate Legal
8.30am – 12.30pm

B: Generics in the emerging markets: Boom or bubble?
Hosted by Paul Mendelsohn, CEO, Pharmawise
Co-hosted by Frances Cloud, Founder, Pharmacloud
1.30pm – 5.30pm

www.generic-pharma.co.uk
Register online and receive full information on all of SMi’s conferences
Alternatively fax your registration to +44 (0) 870 9090 712 or call +44 (0) 870 9090 711
8.30  Registration and coffee

9.00  Chairman’s opening remarks
Brian Tempest, Chairman, Hale & Tempest (Ex CEO Ranbaxy)

**OPPORTUNITIES AND REGULATIONS**

9.10  Investing in generic drug products through perfect product selection
- Limited or no API availability is the critical factor
- Balancing IP circumvention with formulation in product selection
- Product complexity must limit the competition
- Difficult studies to prove bioequivalence
- NPV must be highly positive
Richard Dicicco, Chairman, Harvest Moon Pharmaceuticals

9.50  Recent trends in EU competition policy
- The European Commission’s perspective
- Competition policy in a global context
- The detection, investigation and sanction of anticompetitive behaviour
- Future outlooks and foreseeable changes in competition policy
Paul Csizsár, Director, European Commission, Competition Directorate General

10.30 Morning coffee

11.00 The future of generics and reference pricing in Europe and its implications for the industry
- Reference pricing system
- Pricing and reimbursement
- The future of generics?
Ayhan Aslan, Director, International Commercial Division, MN Pharmaceuticals

11.40 Structural changes in the global pharmaceutical marketplace
- Healthcare challenges
- Big pharma changes
- Generic marketplace pressures
- The Indian pharma industry
Brian Tempest, Chairman, Hale & Tempest (Ex CEO Ranbaxy)

12.20 Networking lunch

**STRATEGIES AND DEVELOPMENT**

1.20 Insight on EU regulatory bodies
- Pitfalls of generic dossiers
- Overview of CHMP and CMDh referrals
- CHMP rules of procedure
Martin Votava, CHMP member (2007-10), Head of Pharmacology Department, Charles University

2.00 Big Pharma strategy in Generics
- Branded Generics (BGx) opportunity for big pharma
- Benefits of BGx for patients
- Approaches to succeed in BGx
- How to structure
- Where to focus
- Synergies to realise
- Key challenges to address
Jozef Belcik, Commercial Director, Branded Generics, AstraZeneca

2.40 The development of supergenerics
- Develop business strategies
- What are Supergenerics?
- Why are Supergenerics “super” than the generics – A scientific, IP and commercial perspective
- Supergenerics – The shareholder’s perspective
- How to identify Supergeneric opportunities?
- Case studies – Challenges, approach and strategies
- Future potential
Deepak Murpani, Vice President, Product Development, Genepharm Group

3.20 Afternoon tea

3.50 Regulatory options for generics through different licensing possibilities
- Players and trends in the generic market
- In-house development versus in-licensing: Pros and cons
- Risk factors for consideration
- Opportunities in development of supergenerics
Ivanka Atanasova, Chief Expert, Bulgarian Drug Agency (BDA)

4.30 A new business model is needed to adequately serve EU generic companies
- On time delivery
- Data exclusivity
- DCP slots
- Affordable prices
- Critical mass of dossiers
Ineke Braat, CEO, PanGenerika

5.10 Chairman’s closing remarks and close of day one

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Register online at www.generic-pharma.co.uk • Alternatively fax

**Delegate Breakdown**

- UK
- Europe
- US
- Middle & Far East

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**Previous attendees**
Delegates at our previous Generics, Super-Generics, and Patent Strategies conferences have come from a wide range of international locations, and represented a diverse range of current opinions regarding the current challenges facing the global Generics marketplace.

Stimulating debate and discussions also arose amongst some of the largest international primary and generic pharmaceutical organisations.

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Supported by
8.30 Re-registration and coffee

9.00 Chairman’s opening remarks
Richard Dicicco, Chairman, Harvest Moon Pharmaceuticals

**LEGISLATION AND INTELLECTUAL PROPERTY**

9.10 Patent strategies and generic pharma sector: US, European and Indian perspective
- Background of US, European and Indian patent system
- Patent litigation landscape: US, Europe and India
- Insight of global pharmaceutical market
- Hatch Waxman Act and Indian pharma industry: Implications and future prospects
- Impact of TRIPS on Indian patent system and Indian pharmaceutical sector: Opportunities and challenges
Aman Trehan, Deputy General Manager-Intellectual Property, Cadila Healthcare

9.50 Launching a generic product on the EU market: Patent issues
- Patent expiry dates and SPCs
- How to anticipate paediatric extensions to SPCs
- Dealing with ‘use’ claims
- Case study: Losartan in the UK.
Duncan Curley, Director, Innovate Legal

10.30 Morning coffee

**GLOBAL PERSPECTIVES**

11.00 IP challenges for generic companies
- Brief overview – EU Patent system
- Patent strategies employed by Pharma companies
- Delay tactics
- Data exclusivity vs. Data protection
- Copyright and trademarks
Lorna Brazell, Partner, Bird & Bird

11.40 Investment opportunities and challenges in the Generics industry for the UK
- How to add value to customers - Clinicians, doctors, pharmacists, patients & commissioning bodies in the context of new Government policies
- How to offer value for price
- What are potential differentiating factors with focus on access to affordable medicines
Pascal Brenneisen, Country Head, Sandoz UK

12.20 Networking lunch

1.20 Generics in emerging markets: Middle East & North Africa – Opportunities & challenges
- MENA Markets – Evaluation of business opportunities available
- Regulatory Challenges while working in MENA
- Changing landscape - Upcoming additional requirements
Manoj Paruthi, Senior Manager, Head Branded Generics, Hikma Pharmaceuticals

2.00 Emerging markets beyond BRIC
- An untapped opportunity
- CIS, Vietnam, SSA
- How innovators take the lead in Generics
Bernd Stoiber, Consultant, Lead Training (Ex Head of Mass Markets, Novartis)

2.40 Afternoon tea

3.10 The risk of entering China with branded generics in 2011
- Overview of the Chinese market
- Current pharmaceutical distribution process flow
- Foreign entries into China pharmaceutical distribution
- Impact of expanding healthcare access on branded generics
- Leading multinationals in China
- Insights and issues
Margaret Hsiao, President, Harvest Moon Pharmaceuticals

3.50 The Chinese Pharmaceutical Industry Approaches Europe: Opportunities & Obstacles
- Overview of the Chinese pharmaceutical landscape
- API’s & Formulation Development
- Small molecules & follow-on biologics
- Alternative scenarios of market penetration
Bruce Murdoch, Commercial Director, Stravencon

4.30 Chairman’s closing remarks and close of conference
Overview of Workshop

The aim of this Executive Briefing is to discuss the patent estate for the API valsartan. Supplementary protection certificates for valsartan will expire in various European jurisdictions in 2011.

This briefing is aimed at manufacturers of generic pharmaceutical medicines who may be targeting valsartan for future development for European markets.

The various patent families will be examined and strategies will be suggested for addressing some of the patent issues discussed.

This Briefing will enable you to:

- Gain insight into the EU patent landscape for valsartan
- Understand innovator patent filing practices and tactics
- Develop strategies for circumventing potential patent obstacles
- Discuss and exchange experiences with fellow professionals

Agenda

8.30 Registration and coffee
9.00 Welcome and Introduction
9.20 Valsartan compound patent overview
9.40 Patents to physical properties of valsartan
10.20 Morning coffee
10.40 Method of use patents - Therapeutic indications
11.30 Valsartan in combination products
12.00 Discussion and questions
12.30 Close of executive briefing

For more information and updates visit the conference website at www.generic-pharma.co.uk

About the Workshop Leader:

Dr Duncan Curley is an English solicitor and the founder of Innovate Legal. He obtained his PhD in Medicinal Chemistry at University College, London in 1992.


Duncan now principally advises on patent issues for companies operating in the generic pharmaceuticals sector.
Overview of Workshop
Recent M&A deals in the emerging markets have seen big pharma paying ever increasing multiples for generic assets in countries with strong growth prospects but populations with low purchasing power. Generics companies have also been trying to enter these markets, but with more complex strategies.

We also take a practical look at how best to build a successful branded generic business in the emerging markets, including strategies to deal with the biggest challenges that new entrants are likely to face.

Session Objectives
The session will examine the challenges and opportunities in the emerging markets, and help participants to develop successful strategies for market entry. The speakers will present content in a practical and interactive session, and the opportunity for attendees to join the debate.

- Emerging markets - where are they and why are they so interesting? Does the term mean the same thing to Big Pharma and generic companies? How are the markets changing?
- How do Big Pharma and generic companies compete in the emerging markets?
- How can new entrants overcome the challenges and develop the opportunities in emerging markets?

Agenda
13.30 Registration and coffee
13.35 Overview of the global emerging markets – Size, growth trends, key players. Definition of emerging markets from a generic perspective
14.15 Evolution of the structure of the markets – Pricing and reimbursement, emergence of unbranded generics, barriers to entry
15.00 Analysis of recent M&A transactions and discussion of likely future opportunities
15.45 Tea break
16.00 Discussion and Questions
17.30 Close of Executive briefing

For more information and updates visit the conference website at www.generic-pharma.co.uk

About the Workshop Leader:
Paul is Managing Director and founder of Pharmawise Ltd, a Specialist Consultancy Company focused on the Generic Pharma Sector. Paul Mendelsohn has 20 years of experience in the Pharmaceutical Generic Industry, working internationally to build and develop companies. Paul was Director of New Business development at Ivax Europe and before that Head of global business development at Merck Generics. Paul started life in the generics industry in sales and marketing of APIs and dossiers. Paul also headed up the Generics Division of Waymade Healthcare Plc and was Director of the British Association of Generic Distributors (BAGD). Paul was also cofounder of entrepreneurial venture capital organization and has a degree in Pharmacy and an MBA from Ashridge (UK)

Frances Cloud graduated from Magdalen, Oxford, in Biochemistry and immediately joined Savory Milln as a UK pharmaceuticals analyst. Following its takeover by Swiss Bank Corporation, she took up a role in pan-European pharmaceuticals coverage at MI before moving to Nomura in 1994. At Nomura, she initially specialised in central European pharmaceuticals companies before shifting to a broader role covering the European generic drug sector. Frances left Nomura in April 2009 and set up her own company, Pharmacloud. This offers consultancy services to the generic industry and also produces regular research on the generics sector, with a particular focus on those companies operating in Europe. Frances is very well known as an analyst and expert on the European generics sector and has been involved in many of the M&A transactions that have taken place in the sector in recent years. She is also a frequent speaker at conferences. Frances is a CFA charterholder.

About Pharmawise
Pharmawise are a global consulting firm of leading specialists in the generic pharmaceutical industry. Our combination of deep expertise and astute implementation has helped many of the world’s leading companies gain competitive advantage in this fast-growing market. We provide expert-led advisory, our consultants having gained hands-on experience at senior levels across the sector. We specialize in both strategic and tactical consultancy across commercial, operational and technical domains. If your growth strategy involves acquiring new business, offering new products, entering new markets or simply seeking the advice of the sector’s most adept practitioners, speak to Pharmawise. www.pharma-wise.com
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IBAN GB48 LOYD 3000 0900 9364 18

Cheque
We can only accept Sterling cheques drawn on a UK bank.

Credit Card
☑ Visa ☑ MasterCard ☑ American Express

All credit card payments will be subject to standard credit card charges.

Card No: _________________________________/_______________________________
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