Business Information
In A Global Context

Gain real life insight from 14 senior in-house representatives

C5's 7th Conference on

EU Pharma Law and Regulation

Latest Updates and Best Practice Approaches for main focus areas:
Pricing & Reimbursement, Promotion and **Patent Strategies**

22 – 23 February 2012 | Le Méridien Piccadilly Hotel | London, UK

Get Essential Information from Regulators & Industry Representatives:

European Commission
MHRA
ABPI

From In-House Experts:

Pfizer (Italy)
Novo Nordisk (Denmark)
Bristol-Myers Squibb (UK)
Novartis (Switzerland)
Merck & Co (UK)
Sanofi (France)
Pfizer (UK)
Johnson & Johnson (Belgium)
Astellas Pharma (UK)
Ipsen Innovation (France)
Vifor Pharma (Switzerland)
Astex Pharmaceuticals (UK)
Gilead Sciences (France)
GlaxoSmithKline (UK)

From International Legal Advisers:

Winston & Strawn (UK)
Clifford Chance (Germany)
White & Case (Belgium)
Taylor Wessing (UK)
Dechert (France)
CMS Cameron McKenna (UK)
Faus & Moliner Abogados (Spain)
Crowell & Moring (Belgium)
Bristows (UK)
Sidley Austin (USA)
Arnold & Porter (UK)
Lützeler Klümper Wachenhausen (Germany)
Fasken Martineau (UK)
Mannheimer Swartling (Sweden)
PriceSpective (UK)

The Hottest Issues and Main Challenges for 2012:

- **Establishing a successful pricing & reimbursement strategy**
  - Fully understand the latest EU initiatives
  - Analyse first experiences with AMNOG
  - Learn how to overcome hurdles when dealing with NICE
  - Discuss the Transparency directive review
- **Hear from the regulator on pharmacovigilance implementations and where firms need to improve**
- **Clarifying advertising and promotion regulations:**
  - Address the challenges of cross border promotion
  - Manage the legal and compliance risk of social media
  - Identify all your off-label promotion risk areas
- **Analysing latest SPCs decisions for orphan & paediatrics, fixed-dose combination products and biosimilars**
- **Keeping abreast with competition law developments**
  - Examine recent case law
  - Discuss practical aspects and trends of reverse settlements

PLUS, attending our pre-conference courses will help you to remain one step ahead of your competitors in this highly complex and challenging legal landscape. Tuesday, 21 February 2012:

Workshop A:
Legal Aspects of Pricing & Reimbursement Decisions *Maximise your P&R strategies by taking advantage of the complex and diverse EU regulatory environment*

Workshop B:
Advertising & Promotion of Medicines Across the EU – *Gain valuable insights to recent regulatory developments and emerging best practices*

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Based on Industry Feedback We've Tailored This Event to Examine the Most Pressing Topics under a Microscope!

In times of growing competition in the pharma industry for tighter healthcare budgets, where firms are facing stricter national pricing and reimbursement laws as well as increased government scrutiny, it is – now more than ever – crucial for legal professionals to keep abreast with regulatory developments as well as to benchmark against industry best practice.

This focused and practical conference on **EU Pharma Law & Regulation** brings together numerous eminent in-house counsel from the world's largest pharma and biotech companies, top legal practitioners and regulatory experts in an outstanding speaker faculty. Based on their first-hand experience, the distinguished panel will provide you with invaluable practical and strategic guidance on the most current regulatory and legal developments in the EU pharma sector.

We have listened to your feedback and have made some significant changes to this event with the aim to make it more applicable and relevant to your needs. Instead of covering the whole spectrum of legal and regulatory changes in the EU, we will drill down into specific challenges associated with: *Pricing & Reimbursement, Communication & Promotion, Pharmaceutical Package, Competition Law, Parallel Trade, Patent Strategies and Clinical Trials.*

Come away with conference materials that you can share with your team and integrate into your practice immediately.

Plus! Maximise your learning with the practical and intensive Pre-Conference Workshops on: **Tuesday, 21 February 2012:**

Workshop A: Legal Aspects of Pricing & Reimbursement Decisions
This practical workshop has been especially designed for legal experts to optimize their company's pricing & reimbursement strategies by taking advantage of the highly complex and heterogenic legal landscape in Europe.

Workshop B: Advertising and Promotion of Medicines Across the EU
This interactive workshop will help you to stay abreast with the latest regulatory developments and enforcement actions for marketing pharmaceutical products in Europe. Our expert presenters from different jurisdictions will provide valuable insights into industry best practice and clarify regulatory guidelines through practical case studies.

WHO SHOULD ATTEND?

The 7th EU Pharma Law & Regulation conference is a must for:

- From the pharmaceutical, biotechnology and healthcare industry:
  - General Counsel / Head of Legal Affairs
  - In-House Counsel
  - Head of Regulatory Affairs / Government Affairs / Regulatory Counsel / Compliance
  - Head of Competition Law / Patent & IP Counsel
  - Business Development / Licensing Officer
  - Medical Affairs
  - Head of Market Access / Pricing
- External counsel, lawyers, patent attorneys and consultants to the pharmaceutical, biotechnology and healthcare industries
- Officers and regulatory professionals from national and international regulatory bodies

Reserve your place at this invaluable conference today! Register now by calling +44 (0) 20 7878 6888 or registering online at www.C5-Online.com/eupharma

CONFERENCE CHAIRS

Maarten Meulenbelt
Partner, **Sidley Austin (Belgium)**

Gareth Morgan
Partner, **Winston & Strawn**

EXPERT FACULTY

Karolyn Fletcher
Legal Director, **Bristol-Myers Squibb**

Jerry Temko
Senior Vice President and General Counsel
Astellas Pharma Europe

Bryan Black
Senior Legal Counsel, **Novartis**

Paul Catchpole
Value and Access Director, **ABPI**

Alexey Kislitsyn
Director International Legal Affairs, **Gilead Sciences**

Chris Verleye
Senior Counsel, **Johnson & Johnson**

Coleen Klasmeier
Partner, **Sidley Austin (USA)**

Peter R. Thomsen
Sr. Manager IP-Litigation & Global Head IP-Policy, **Novartis**

Lyn Leaper
IP Counsel, **Astex Pharmaceuticals**

Jorge Wernli
VP Pricing & Government Affairs, **Vifor Pharma**

Jordi Faus
Partner, **Faus & Moliner Abogados**

Marco Sugarelli
Legal Affairs Associate Director, **Pfizer**

Ulrich Reese
Partner, **Clifford Chance**

Anne-Laure Marcerou
Partner, **Dechert**

Shelley Gandhi
Unit Manager – Signal Management Group
Vigilance & Risk Management, **MHRA**

Helén Waxberg
Partner, **Mannheimer Swartling**

Tim Worden
Partner, **Taylor Wessing**

Adela Williams
Partner, **Arnold & Porter**

Sean-Paul Brankin
Partner, **Crowell & Moring**

Mark Powell
Partner, **White & Case**

Franck Schwartz
Senior Director, Safety and Compliance, **Ipsen Innovation**

Heike Wachenhausen
Lützeler Klümper Wachenhausen Rechtsanwälte

Nick Beckett
Partner, **CMS Cameron McKenna**

Maria Manley
Partner, **Bristows**

James Horgan
Assistant Counsel, European Patents, **Merck & Co**

Paul Ranson
Partner, **Fasken Martineau**

Victoria Kitcatt
Assistant General Counsel, European Regulatory Law, **Pfizer**

Keiron Sparrowhawk
EU Partner, **PriceSpective (UK)**

Gro Laier
Deputy QP PV, **Novo Nordisk**

Speaker tbc
European Commission

Pre-Conference Workshops: 21 February 2012

Workshop A: 8.30am to 12.00pm

Legal Aspects of Pricing & Reimbursement Decisions

Maximize your P&R strategies by taking advantage of the complex EU regulatory environment

Keiron Sparrowhawk
EU Partner, **PriceSpective** (UK)

The workshop leader will walk you through the complex, highly regulated European landscape of pricing, reimbursement and market access and will provide innovative strategies to define, drive and capture value for biopharmaceutical and medical technology assets. Using a unique integrated approach to value strategy the leader will outline practical and strategic tips for achieving optimal levels of price and access. Topics to be discussed will include:

- A **strategic response to the EU regulatory regimes** and initiatives for pricing and reimbursement
- **Health technology assessments (HTA) in the EU:** How should companies consider differences in evaluation criteria, limited comparability and transferability of HTA across countries in their strategies when launching a new product?
- **Legal and practical considerations for developing a pricing & reimbursement strategy:**
  - Regional differences
  - Performance based agreements/risk sharing agreements
  - Different reimbursement guidelines (e.g. for orphan drugs, paediatics)
  - Different evidence requirements for cost-effectiveness, innovative research, rare diseases, etc

Workshop B: 1.00pm to 4.30pm

Advertising and Promotion of Medicines Across the EU

Recent Regulatory Developments & Emerging Best Practice

Ulrich Reese
Partner, **Clifford Chance** (Germany)

Victoria Kitcatt
Assistant General Counsel, **Pfizer** (UK)

Pharmaceutical companies must stay up to date on the complex and evolving European regulatory environment governing promotional efforts and advertising. This workshop will examine the particular challenge of creating compliant promotional material and conducting advertising campaigns on a regional, pan-EU basis. Areas to be covered will include, but are not limited to:

- Overcoming the challenge of **divergent interpretations and enforcement systems** of the individual EU member states, within the framework of EU advertising legislation
- Clarifying the **latest judicial developments in the CJEU** and likely practical impact in this context
- **Designing a promotional campaign for the EU,** given the regulatory differences of EU members states – key challenges:
  - Compliance with Summary of Product Characteristics
  - Varying standards for data supporting promotional claims
    - Comparative advertising
    - Evidence-based: primary v secondary endpoints
  - Pan-EU journal advertising and websites
  - Essential Information (Abbreviated Prescribing Information)
- **Examples and case studies**

Conference Day One: 22 February 2012

8.30 **Coffee and Registration**

9.00 **Chair's Opening Remarks**

Maarten Meulenbelt
Partner, **Sidley Austin** (**Belgium**)

PRICING & REIMBURSEMENT

9:10 **Clarifying EU Initiatives in Pricing and Reimbursement**

This session will provide you with detailed insights into the latest legal discussions and regulatory guidelines on pricing and reimbursement in European countries. Gain practical insights on what to expect from and how to deal with the below national authorities:

GERMANY

Ulrich Reese
Partner, **Clifford Chance** (Germany)

- Examining first experiences with AMNOG
- Clarifying and updating on requirements and processes
- IQWiG's role in reimbursement decisions
- Best practice approaches for a successful market access and pricing strategy in Germany

UNITED KINGDOM

1. Industry Developments

Paul Catchpole
Value and Access Director, **ABPI**

- Evaluating the latest value-based pricing discussion
- Understanding the ABPI code for the regulation of added value
- How can pharma companies effectively persuade the government to reimburse their drug?
- Assessing current practice of risk sharing

2. Practical Insights

Karolyn Fletcher
Legal Director, **Bristol-Myers Squibb** (UK)

- Outline of the NICE appraisal process
- NICE appeals procedure, incl grounds for appeal
- Judicial appeal procedure
- Judicial review – points emerging from the cases

10:40 **Morning Coffee Break**

SPAIN

Jordi Faus
Partner, **Faus & Moliner Abogados** (Spain)

- Introducing the new national legislation: *Royal Decree Law 9/2011*
- Adapting cost-efficiency reviews
- No more preference for generic drugs
- Examining implications for the industry, e.g. with regards to parallel trade

11:40 **How to Establish a Successful Pricing & Reimbursement Strategy**

PANEL DISCUSSION

Keiron Sparrowhawk
EU Partner, **PriceSpective** (UK)

Helén Waxberg
Partner, **Mannheimer Swartling** (Sweden)

Jorge Wernli
VP Pricing & Government Affairs, **Vifor Pharma** (Switzerland)

PANEL DISCUSSION

- Discussing the review of the Transparency directive by the EU Commission and its implications for the pharma industry
- Regulation of added value – Is the UK model the way forward? How to adjust your strategy?
- Examining the practical importance of Risk Sharing Agreements
- European perspectives and coordination with regards to Health Technology Assessments
- Trends and future developments with regards to reference pricing and cost-effective pricing
- Assessing orphan drug challenges in Europe and opportunities for development
- Impact of pricing issues on R&D decisions

12:20 **Networking Luncheon**

COMMUNICATION & PROMOTION

13:20 **Advertising of Prescription Only Medicinal Products**

Bryan Black
Senior Legal Counsel, **Novartis** (Switzerland)

- Clarifying the fundamental principles of EU law and industry codes
- Examining recent EU case law:
  - *MSD v Merckle GmbH (C-316/09)*
  - *Novo Nordisk (C-249/09)*
- Checklist for advertising material reviews: areas of important focus
- Anticipating and managing competitive challenges – at launch and beyond
- Addressing challenges of cross border promotion
- Providing effective legal advice to brand teams: some practical tips

14:00 **Social Media for Pharma: Managing the Legal and Compliance Risks**

Tim Worden
Partner, **Taylor Wessing** (UK)

- Identifying the key risks of social media use (Facebook, blogs for healthcare professionals, sponsoring patient networks)
- Worrying about adverse events: real issues or red herring?
- Examining the PMCPA guidance and its impact on the industry
- Establishing sensible strategies for managing the risks

14.40 **Off-Label Promotion: Lessons Learnt From the Mediator Case**

Anne-Laure Marcerou
Partner, **Dechert** (France)

Alexey Kislitsyn
Director International Legal Affairs, **Gilead Sciences** (UK)

- Analysing the latest cases in the EU and their implications for pharma companies
- What can be learnt from the Mediator case?
- Addressing French legislative changes regarding off-label prescription
- What can firms do to avoid off-label promotion allegations?

15:30 **Afternoon Refreshment Break**

16.00 **Managing the Risks of Off-Label Promotion**

INSIGHTS FROM US EXPERIENCE

Coleen Klasmeier
Partner, **Sidley Austin** (USA)

This practical presentation will offer insights and discuss industry approaches to off-label communication issues that are not addressed adequately by the applicable legislation and regulations or regulatory guidance. The following issues and risk management procedures will be addressed:

INSIGHTS FROM US EXPERIENCE

- Examining processes with regards to company dissemination of non-promotional scientific information, e.g.:
  - scientific congresses
  - publications
  - continuing education
- Medical, regulatory, and legal review of promotional labeling and advertising
- Separation of medical functions from commercial activities within a firm
- Global public affairs and corporate communications

16.50 **Managing Relations to Patient Groups and Healthcare Professionals while Staying Compliant with Bribery Regulations**

Marco Sugarelli
Legal Affairs Associate Director, **Pfizer** (Italy)

- How can pharma companies work with healthcare professionals?
  - Optimising interaction with patient groups: integrity and transparency
  - Good practice guidelines for working healthcare professionals
- Managing compliance risks with regards to UK Bribery Act
- FCPA implications and related risks for EU pharma companies

17:30 **Conference Adjourns to Day Two**

Conference Day Two: 23 February 2012

8:30 **Continental Breakfast**

9:00 **Chair's Opening Remarks and Recap of Day One**

Gareth Morgan
Partner, **Winston & Strawn** (UK)

PHARMACEUTICAL PACKAGE

9:10 **Pharmacovigilance Discussion: Regulatory Update & Implementation Review**

PANEL SESSION

Dr. Shelley Gandhi
Unit Manager-Signal Management Group
Vigilance & Risk Management of Medicines, **MHRA**

Franck Schwartz
Senior Director, Safety and Compliance
Ipsen Innovation (France)

Heike Wachenhausen
Lützeler Klümper Wachenhausen Rechtsanwälte (Germany)

Gro Laier
Deputy QP PV, **Novo Nordisk** (Denmark)

- Clarifying latest regulatory developments
- Reviewing implementation efforts – where do firms need to improve
- Achieving good vigilance practice
- How to improve your approach of dealing with the regulator (e.g. providing and structuring the information, reporting challenges)
- Dealing with different EU regulators
- Linking PV to Health Technology Assessment: what studies do pharma companies need to do to satisfy the authorities? What is expected?

9:50 **Examining the Legal Issues of PV in Connection with Product Liability Cases**

Adela Williams
Partner, **Arnold & Porter** (UK)

- Identifying pharmacovigilance challenges
- Addressing the implications for product liability
- What can be learned from recent cases, e.g. Mediator in France?
- Examining issues in relation to recalls
- What are the real impacts on the pharma industry?

10:40 **Morning Coffee Break**

11:00 **Update on Anti-Counterfeits Regulation and the Implications for the Industry**

Chris Verleye
Senior Counsel, **Johnson & Johnson** (Belgium)

- Assessing the proposed Directive on Falsified Medicines and its new initiatives to help safeguard the medicines supply chain and protect patients:
  - Update on the latest discussion
  - Evaluating the implementation efforts so far
- Examining recent court cases
- The revision of the Customs Regulation: Analysing the proposed changes and potential challenges

COMPETITION LAW

11:40 **Examining Recent Competition Law Cases**

Sean-Paul Brankin
Partner, **Crowell & Moring** (Belgium)

- Updating on recent investigations by the regulators and their implications for the industry
- Discussing the *Reckitt Benckiser* decision
- Analysing the *Boehringer* settlement
- Uncovering the *NHS vs. Servier* case
- And address other cases in the pipeline

12:20 **Practical Aspects and Trends of Reverse Settlements**

PAY FOR DELAY PANEL

Sean-Paul Brankin
Partner, **Crowell & Moring** (Belgium)

Mark Powell
Partner, **White & Case** (Belgium)

Speaker tbc
European Commission

- Evaluating the latest regulatory discussion on EU and national level
- Are pay-for-delay agreements anti-competitive or is it the free market in operation?
- Forecasting the impact on the industry
- Assessing practical challenges:
  - Where can controversy arise?
  - How can you reduce your risk?

13:00 **Networking Luncheon**

PARALLEL TRADE

14:00 **Parallel Trade in the Euro Zone Crisis**

Nick Beckett
Partner, **CMS Cameron McKenna** (UK)

- Analysing the latest developments in two competition law disputes relating to pharmaceutical parallel trade:
  - the *Glaxo* case on dual pricing
  - the *AstraZeneca* case concerning abuse of a dominant position
- Examining the new regulation on plant protection and the express provisions on parallel trade
- Update on legal and regulatory developments regarding parallel trade in Europe:
  - *Greece:* How are the price cuts by the Greek government influencing reference prices throughout Europe?
  - *Italy:* Examining case law regarding repackaging
  - *Poland:* How can firms overcome obstacles in protecting their trademarks?
  - *UK:* Discussing recent developments and initiatives dealing with shortage of medicines

PATENT STRATEGIES

14.40 **Supplementary Protection Certificates**

Maria Manley
Partner, **Bristows** (UK)

Peter R. Thomsen
Sr. Manager IP-Litigation & Global Head IP-Policy
Novartis (Switzerland)

1. What's hot in the SPC field?
- An update on recent and pending decisions
- Discussing current controversies

2. Spotlight on Combination Products
- Examining challenges and grey areas
- Analysing the Medeva case and the implications for industry

3. SPCs and the Paediatric Regulation
- Assessing the SPC extension in practice
- Where does the uncertainty lie?

4. Biosimilars
- What is patentable subject matter in relation to biologics?
- Discussing recent case law
- How is biotech patenting developing?

15:30 **Afternoon Refreshment Break**

16:00 **In-House Counsel Panel Discussion: Patent Trends and Strategies**

IN-HOUSE PANEL SESSION

Jerry Temko
Senior Vice President and General Counsel
Astellas Pharma Europe (UK)

James Horgan
Assistant Counsel, European Patents, **Merck & Co** (UK)

Lyn Leaper
IP Counsel, **Astex Pharmaceuticals** (UK)

- Sharing best practice approaches in establishing a defense strategy
- Assessing recent decisions and trends in pharmaceutical patent cases and their consequent impact on the company's patent life cycle strategy
- Preparing for a changing landscape when big drugs are getting of their patents

CLINICAL TRIALS

16:40 **Clinical Trials: Overcoming Legal and Regulatory Challenges**

Paul Ranson
Partner, **Fasken Martineau** (UK)

- What do the new changes to the revised Clinical Trials Directive mean in practice
- Identifying typical legal and compliance pitfalls
  - Challenges when with dealing with CRO
  - Best practice to site contract clauses
  - Considering alternative options
- Ensuring funding and financial grants to clinical trials

17:20 **Conference Concludes**

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Business Information In A Global Context

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ADMINISTRATIVE DETAILS

Date: 22-23 February 2012
Time: 8.30 - 17.30
Venue: Le Méridien Piccadilly Hotel
Address: 21 Piccadilly, London, W1J 0BH, United Kingdom
Telephone: +44 (0)20 7734 8000

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