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In A Global Context

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CONFERENCE CO – CHAIRED BY:

Marie Manley
Partner
Bristows

Helen Roberts
Legal Director
Sanofi-Aventis UK

"Excellent detailed and up to date presentations. A highly relevant and interesting programme."

Ian Hiscock, Eli Lilly and Company Limited

Third Annual

EU Pharma Law & Regulation

An Expert Guide to the Latest Legal and Regulatory Developments Impacting the Pharma Industry

The only industry led EU Pharma Law event

28 and 29 April 2008

Crowne Plaza St. James, London, UK

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- Combating the flood of counterfeit pharmaceutical goods – regulatory and legal strategies
- Advanced marketing and promotion strategies to maximise your pipeline whilst ensuring compliance
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- Developments in the US, UK and Europe on pricing, reimbursement and transparency
- How current legislative proposals will affect advanced therapies
- Key European developments in orphan drugs & communications in the field of rare diseases
- The Financial Penalties Regulation: how to be prepared for inspections

Plus: You will acquire essential skills from the successful Master Classes on
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see inside for full details

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This conference is THE essential one-stop shop providing you with the crucial tools and guidance to stay a-step-ahead of changes in IP, competition law and regulation impacting the pharma industry.

C5's event is the most detailed, in-depth and practical forum you can attend on how to conduct business without being confronted with potential infringement to legislation.

Our expert speakers will help you to take advantage of the opportunities available and maximise the protection afforded under Pharma legislation by addressing how to:

- work your way around the conundrums surrounding parallel trade and competition law
- predict the outcome of current litigation on pricing and transparency
- be prepared for the EU Penalties Regulation
- utilise technology in the fight against counterfeit goods

Get right up-to-date with key developments affecting Pharma:

- Strategies on how to maximise your product life cycle
- How to best protect your market share and combat tactics used by parallel importers
- Successfully navigating the rules on advertising to health professionals
- Effective interpretation of the Paediatric Regulation, Financial Penalties Regulation and Advanced Therapies Legislation

Be sure that your arguments are watertight and that your company is compliant with the latest pharma law and regulation.

PLUS add value to your attendance by signing up for the post conference Master Classes on:

A) Best Practices for Complying with EU and US Advertising and Promotion Requirements

B) A Practical Guide to FDA Requirements for Pharma Companies

WHO SHOULD ATTEND

Pharma/Biotech companies - Directors/Heads/Managers of:

- IP
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Solicitors and Attorneys specialising in:

- IP
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MONDAY 28 APRIL 2008

8:00 Registration and Coffee

9:00 Chair's Opening Remarks

Maria-Isabel Manley
Partner, Bristows

9:15 Current and Forthcoming Developments: The Essentials for Surviving 2008 and Beyond

Maria-Isabel Manley, Partner, Bristows

Arnold Friede, formerly General Counsel, Unilever U.S. food business; Former Associate Chief Counsel, FDA, New York

Dr Peter Feldschreiber, MHRA and Barrister, 4 New Square

- Recent EC legislation
- How will the increasing complexity and discretion of regulators affect the pharma legal and regulatory landscape?
- Interconnection between regulatory decisions and exclusivity rights
- The 'Pharma Package'
  - communications on the future of the single market in pharma for human use
  - strengthening and rationalising pharmacovigilance
  - Financial Penalties Regulation – similarities and differences with the anti-trust legislation
- EU Bolar developments:
  - lack of harmonisation in implementation among EU member states
  - what generic companies are currently entitled to do
- US developments:the Food and Drug Administration Amendments Act of 2007
  - key issues regarding REMS and new FDA Post-Marketing Authority
  - examining the clinical trial registry
  - voluntary "pre-review of DTC advertising"
  - the impact of an expert/scientific risk advisory board to medical advisory agencies
- Trends and Future

10:30 Global Marketing Authorisation: Is It Working?

Olivier Lemaire, Director and Senior Counsel, GSK Brussels

- Discussing the notion of global marketing authorisation
- Examining the particular case of "fixed combinations"
- Addressing uncertainty as to when should a company get exclusivity
- What happens to medical products before they have acceded?
- Does GMA apply to biosimilars?
- Comparing and contrasting data exclusivity in the US and EU

11.00 Morning Refreshments

11:15 Imitation is not the Sincerest Form of Flattery – Combating the Flood of Counterfeit Pharmaceutical Goods

Robert B. Nicholas, Partner and Chair, FDA Practice Group, McDermott Will & Emery LLP (Washington, DC)

- Examining what policies to have in place to prevent counterfeiting
- How counterfeiting seeds into distribution and how to combat it
- What are the obligations of the EU and member states in the fight against counterfeit goods?
- What are the pharmaceutical companies' responsibilities?
- Evaluating the US safety standards agreement with China
- What is China's responsibility – stemming the flow of counterfeit goods?
- Tackling the issue of company liability
- Technological advances to track counterfeit goods
- Optimising your company's relationship with customs

12:15 Key Legal and Contractual Considerations for Clinical Trials

Nermeen Varawalla, MD, DPhil (Oxon), MBA, Vice President Investigator Relations, Scientific & Medical Affairs, PRA International

Gerry Kamstra, Partner, Bird & Bird

- Ensuring watertight contractual relations
  - who bears the responsibility?
  - how should draft the agreement?
  - what to worry about
  - how to avoid conflict of interests
  - drafting requirements under different jurisdictions
- ABPI Agreement
- Tips and highlighted problems with the running of clinical trials
- Clinical Trials in the US
- Complying with FDA requirements in Europe
- Key legal issues to be aware of in the globalisation of clinical trials
- Drug development: industry trends and their implications
  - drivers of change: product pipelines, drug safety concerns and rise of emerging markets
  - growth of outsourcing and off-shoring; quest for health outcomes data
  - regulatory and legal implications of the changing clinical development landscape
  - challenges for sponsors and service providers

1:00 Networking Lunch

2:15 Interpreting Recent Developments under the Paediatrics Regulation

Peter Bogaert, Partner & Head, Life Sciences, Convington & Burling

Neil Edwards, Managing Director, Sirius Regulatory Consulting Ltd

- Update on the rules and recent experience
  - where do we stand on the regulation and its application in practice?
  - what interpretation problems have arisen?
  - how to ensure that the underlying policy objective (providing new data in exchange for a reward) is reached?
- How to prepare the application for a PIP
  - how detailed should the PIP be?
  - how should points of uncertainty be addressed?
- Scope of the paediatric obligations
  - new medicines
  - line extensions for patented products
- Conditions for the paediatric reward
- Overall strategic considerations
  - timing
  - scope of product development
  - orphan medicines
- Specific issues concerning paediatric clinical trials

3:00 Afternoon Refreshments

3.30 Navigating the Intersection between Competition Law and Pharma Law: Have the Rules Changed?

Sheyenne Scriven, Senior Legal Counsel, Novartis Pharma AG

Pat Treacy, Partner, Bristows

- Where is the intersection, and what signals should we follow?
- Have the rules of the road changed?
  - parallel trade and supply
  - pricing
  - patents: obtaining, enforcing and settling
- How to avoid a major accident at this intersection
- Competitive aspects of stock management programmes
- Interpreting the court's decision in the *AstraZeneca* case

4:30 Life Cycle Management Strategies and Best Practices

Steven Bennett, Partner, Lovells

Christof Bull, PhD, Senior Patent Attorney
European Patent Attorney, Merk Serono International SA

- Pfizer, GSK and AstraZeneca's strategies: Are they working?
- Current challenges to life cycle management strategies
  - indication expansion
  - patent extension
  - delivery mechanisms
  - reformulation
- Recent developments in case law: *Boehringer Ingelheim, AstraZeneca* and *GSK*
  - generic and the innovator
  - parallel traders
  - what amounts to abuse?
- Considering life cycle management programmes
  - deciding how best to deploy the intellectual property and regulatory tools at a company's disposal to protect its investment

- Incite into interim injunctions pending appeal: new law, new weapons?
  - recent decisions of the UK Court of Appeal in *Pozzoli* (June 2007) and the Patents Court decision in *Servier v Apotex* (July 2007)
  - what is the test applied for the grant of an interim injunction in the UK as compared to other EU jurisdictions?
  - what is the likelihood of an interim injunction being extended pending appeal in the event a patent is found invalid or not infringed?
  - how recent case law in the UK has changed the position as regards both the grant of leave to appeal and also the continuation of an interim injunction pending such appeals
- Patent Linkage: assessing to what extent there is patent linkage in different jurisdictions?
- Reviewing recently approved drugs/new indications
- Analysing appropriate dosage regimes
- Clinical trials and special patient populations
- Combinations, application forms and devices, manufacturing and process claims, formulations, enantiomers, metabolites, second generation products, crystalline and amorphous forms

5:30 **Closing Remarks of the Chair and Conference Adjourns to Day Two**

TUESDAY 29 APRIL 2008

8:30 **Coffee**

9:00 **Chair's Opening Remarks**

Helen Roberts, **Legal Director, Sanofi-Aventis UK**

9:15 **Pricing and Reimbursement: Identifying and Tackling the Critical Issues**

Keiron Sparrowhawk, **Partner, PriceSpective**

Carla Schoonderbeek, **Partner & Head of Life Sciences Group, NautaDutilh (Amsterdam)**

Bart van der Lelie, **Director Corporate Affairs, Schering-Plough**

- Recent developments in key markets: United Kingdom, France, Germany
- Commercial influences
  - brands, generics, parallel imports
  - interchangeability
  - classification
  - primary and secondary care
- Renegotiation of the PPRS
- OFT proposal – is this a case of naivety over experience?
- Risk sharing agreements - who is taking the risk and is this a slippery slope from which there is no return?
- The funding of pharmaceuticals – are Europe' s problems more about funding than pricing?
- The *AstraZeneca* Appeal
- Examining Pfizer's direct distribution arrangement
  - to what extent is one forced to supply?
- Outcome of the Commission's investigation into alleged anti-competitive conduct by *Boehringer Ingelheim*.
- Pricing and cross border referencing
- The reimbursement arena
  - compliance with standards
  - drug efficacy, effectiveness and efficiency determinations – are they working?
    - pro's and cons of a European mutual recognition approach
  - burden of proof: assessment by independent institutions or science in political context?
  - how to determine the value?
    - systematic assessment of drugs versus decision body taking a decision

10:15 **No More Mr *'Nice'* Guy: Recent Developments on Transparency In The US, UK and key European Jurisdictions**

Paulina Kieszkowska-Knapik, **Partner, Baker & McKenzie Gruszczycski & Partners Attorneys at Law LP**

Brian Lovatt, **C.E.O, Vision Healthcare Consultancy**

- How is the EU Transparency Directive interpreted by different jurisdictions?
- IQWiG, HAS, NICE all HTA's but different
- Is the US system going to be US-NICE ?
- What is the point of a pricing and reimbursement process when countries employ other cost containment processes?
- Critique of NICE
- Analysing future outlook
- Recent case law – *Eisai* and *Pfizer* cases
- Complaints about non-compliance with transparency requirements

11:00 **Morning Refreshments**

11:15 **Biosimilars – Legal Framework, Scope and Recent Developments**

Dr Brian Tempest, **Chief Mentor & Executive Vice Chairman of the Board, Ranbaxy Laboratories**

Yoseph Shaaltiel, **E.VP, R&D, Protalix Ltd**

- Getting access to the market for biosimilars
- Recent decisions and approvals
- Comparison of US and EU position
- Should one tolerate the substitution with biotechnologies to biosimilars?
- Could an abridged regulatory process really benefit generic manufacturers?
- Which companies are making the moves that are driving change?
- Which therapies are now on the biosimilar radar?
- Emergence in US of interest in having a generic bio-logic system
- Evaluating plant cell culture as a pharmaceutical protein expression system
- Examining plant made glucocerbrosidase
  - biochemistry
  - toxicology
  - clinical development
- Expanding your knowledge on the challenge from India:
  - market drivers
  - competition is rising
  - branded generics
  - intellectual property
  - M&A and private equity
  - East West alliances

12:00 **Networking Lunch**

1:15 **Parallel Trade: The Latest Developments and the Most Critical Issues**

Jacquelyn MacLennan, **Partner, White and Case LLP**

Charlotte Hugon, **Corporate Counsel, UCB Group, Brussels**

- ECJ judgments in Greece with reference to GSK's reduction in supply to Greek wholesalers
  - will the Greek wholesalers case establish whether the implementation of such a programme by a dominant company could be a breach of Article 82?
- The supply quota mechanism
- Cutting health cost vs stimulating innovation
- Generic challenges for obtaining quick access to the market
- Pricing reimbursement mechanism
- *AstraZeneca*, *GSK* and *Pfizer* cases and stock management
- Developments in France
- GSK Spain
- AstraZeneca – company in dominant position – how much scope does it have with regard to abuse of power
- Article 82 and the *Boehringer Ingelheim* case
- Developments in The US
  - the Dorgan Bill – what happens once it is implemented?
- Direct pharma method of distribution

2:00 **Advanced Marketing and Promotion Strategies to Maximise Your Pipeline While Ensuring Compliance**

Alison Brown, **Partner, Arnold & Porter LLP**

Dr Peter Mayer, **Partner, Simons & Simons**

- EU Directives and legislative background
- Advertising medicines to consumers
  - the UK experience
  - the regulatory framework – how it works in practice
  - the PAGB and other codes of practice

- EFPIA Code
- IFPMA Code

- Comparing and contrasting the systems in place in key European jurisdictions
- Successfully negotiating and drafting advertising and marketing agreements
- What does the future hold for distributers?
- SPI code of conduct
- Information to patients
  - what do you provide to patients and where does it cross over to advertising?
  - what should they be able to but on the internet and where should they be restricted?
- Off label use
  - promoting off-label use while complying with the law
  - Problem with sales persons – how do you stop them illegal off-label use?
- The use of trade dress
- Relationship with the medical professionals

2:45 Afternoon Refreshments

3:00 **How Current Legislative Proposals Will Affect Advanced Therapies**

Dr Gareth Morgan, **Associate, Taylor Wessing LLP**

Declan O'Brien, **Managing Director, IFAH**

Roger Cook, **Director, NOAH**

- Examining the new tissue and blood product legislation
- Evaluating the impact of the legislation on the regulation of collection, use and sterility of tissue and blood
- GMP and GDP standards
- Dealing with the adoption of the ADR (Advanced Therapeutics Regulation)
- What is the structure of the new regime for Advanced Therapy products?
- Identifying the types of products within the scope of the ADR
- Interaction with other EU legislation

4:00 **Key European Developments in Orphan Drugs & Communications In the Field of Rare Diseases in Europe**

Suzanne Smith, **General Counsel & Company Secretary Phoqus Pharmaceuticals plc**

- Why do orphan drugs get special treatment?
- What are the incentives to encourage pharma companies to develop orphan drugs?
- Orphan blockbusters
- How the clinical and regulatory development work in practice
- The race for market exclusivity
- What if your product doesn't win the race?
- Similarities and differences with the US Orphan Drug Act
- Pointers for due diligence
- The future: update on the European Commission's Communication on rare diseases

4.30 **The EU Financial Penalties Regulation: How To Be Prepared For Inspections**

Dr Alexandra McConnell, **Senior Associate, Clifford Chance LLP**

Dr Peter Feldschreiber, **MHRA and barrister, 4 New Square**

Alexandre Mencik, **Senior Legal Counsel, Amgen**

- Regulatory Investigations:
  - how to handle an investigation
  - precautionary internal investigations
  - crisis management
  - lessons from competition law
- Spin-off civil liability claims: follow-on damages actions and collective redress proposals at EU level
- Public Health isues for non-compliance
- Underlying rationale of the Penalties Regulation from the regulatory standpoint: pharmacovigilance; counterfeit medicines, clinical trials, unlawful advertising
- Role of member state regulators in EMEA investigations
- Examining the new proposed pharmacovigilance legislation

5.30 Closing Remarks of the Chair and Conference Ends

WEDNESDAY – 30 APRIL 2008
PRACTICAL MASTER CLASSES ON:

09:00am – 12:00pm

A Best Practices for Complying with EU And US Advertising and Promotion Requirements

Carla Schoonderbeek, **Partner & Head of Life Sciences Group, NautaDutilh (Amsterdam)**

Helen Darrcott, **Director of Legal and Regulatory Affairs, Proprietary Association of Great Britain (PAGB)**

Arnold Friede, **formerly General Counsel, Unilever U.S. food business; Former Associate Chief Counsel, FDA, New York,**

Lori Reilly, **Vice-President for Policy and Research, Pharmaceutical Research and Manufacturers Association (PhARMA)**

This session will combine knowledge sharing, role playing and practical advice. This is an excellent opportunity to learn best practices, share your ideas and proposals with your colleagues and to hear their thoughts and feedback.

Highlights of this master class include:

- Overview of laws and regulations and supervisory bodies controlling the advertising, marketing, and promotion of prescription drugs and biologics
  - what duties and responsibilities are governmental or self regulation bodies charged with?
  - what are its enforcement capabilities and jurisdiction?
  - identifying the role of the FTC in the advertising and promotion of drugs
- Advertising requirements for prescription v. non prescription products
  - what information must a drug advertisement include?
- Reviewing the steps which taken for the review of launch campaigns and promotional materials
- What constitutes a launch?
- Exploring the role of the label in advertising
- Specifying appropriate and inappropriate marketing and sales interactions when conducting medical research
  - analysing Phase IV study requests – motivation v. objective
- How is Internet and e-mail advertising regulated?
- Advertising and Promotion of Rx Drugs in the US?

2:00pm – 5:30pm

B A Practical Guide to FDA Requirements

Robert B. Nicholas, **Partner and Chair, FDA Practice Group McDermott Will & Emery LLP (Washington, DC)**

Melody Hughson, **Senior Director, Public Policy World Wide Public Affairs, Pfizer**

This master class shall look at the interaction and relationship between the FDA and European Agencies and will compare and contrast the different requirements for the drug approval process.

Topics to be discussed include:

- Overview of the FDA, structure and operations
- FDA regulation of drugs: Understanding the difference between "new drugs" and other drugs
- Research, development, and approval process for new drugs
- The investigational new drug application (IND) and the regulation of clinical research
- The new drug application (NDA)
- Accelerated approval (fast track)
- Dispute Resolution
- US Political and Legislative Outlook – 2008, Potential Impact on FDA
- Updates on pending legislative issues: follow-on biologics, patent reform, medicare physician fix (other potential issues include comparative effectiveness center, marketing practices reporting, etc)
- Health reform proposals of Presidential candidates
  - coverage of uninsured
  - other provisions impacting pharmaceutical industry
- Repeal of non-interference
- Importation
- Eliminate loopholes in Hatch-Waxman

EU Pharma Law & Regulation

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Time: 9.00am – 5.30pm Registration and distribution of documentation from 8.00am
Venue: Crowne Plaza, St. James
Address: 45-51 Buckingham Palace Gate, London. SW1E 6AF
Tel: + 44 (0) 20 7834 66 55 Fax: + 44 (0) 20 7630 75 87
Tube: St. James Park (Circle, District)

POST-CONFERENCE MASTER CLASS **A) TIPS AND BEST PRACTICES FOR COMPLYING WITH EU AND US ADVERTISING AND PROMOTION REQUIREMENTS**
Date: 30 April 2008
Time: 9.00am – 12.00pm Registration and distribution of documentation from 8.00am

POST-CONFERENCE MASTER CLASS **B) A PRACTICAL GUIDE TO FDA REQUIREMENTS FOR PHARMA COMPANIES**
Date: 30 April 2008
Time: 2.00pm – 5.00pm Registration and distribution of documentation from 1.00pm

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