Business Information
In A Global Context

C5's 3rd Forum on

EU Pharma Regulatory Law

EMA Insight into Pharmacovigilance Implementation: What is Working?

Minimising Risks by Ensuring Compliance with Critical Evolving Regulatory Developments

25 & 26 September 2012 | Le Méridien Hotel | Brussels, Belgium

Pose Your Questions Directly to Key Regulators & Pan-European Associations:

European Commission
European Medicines Agency
National Board of Health, Denmark
European Generic Medicines Association
European Healthcare Fraud & Corruption Network
EU Privacy Association
DAHTA
EUCOPE
LYSIAC
HALMED

In House Perspectives:

Gilead Sciences (France)
Sanova Pharma (Austria)
Ablynx N.V. (Belgium)
Merck Serono (Germany)
Novo Nordisk A/S (Denmark)
Novartis International AG (Switzerland)
Johnson & Johnson (Belgium)
Esteve (Spain)

- **Policy makers**: get first hand updates
- **Key regulators**: ask about their initiatives and priorities
- **Pharmacovigilance**: benchmark your implementation strategies
- **HTAs**: what is the impact on your portfolio?
- **Anti-Corruption**: change your company practices to avoid sanctions
- **Social Media**: minimise legal risks
- **Clinical Trial Directive**: understand the proposals
- **Competition law**: align your business with recent decisions
- **SPCs**: which areas await clarification?
- **Licensing Deals**: avoid pitfalls

Monday 24 September 2012 at 1.30 pm:

A Step by Step Guide to Creating Successful Partnerships between Diagnostic and Drug Companies

Up to 18.5 CPD

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2012 is shaping up to be a critical year for European pharma regulation with innovators and generic companies needing to react quickly to incorporate imminent changes and amendments to key European legislation and directives. Given the highly competitive and lucrative nature of the industry, it is increasingly important for time-starved pharma corporate counsel and their legal advisers, to get the latest information in two, practical, content-rich days.

At **C5's 3rd European Pharma Regulatory Law Forum,** the distinguished faculty will give sophisticated and comprehensive solutions to the key challenges facing the industry at present, including:

- Representatives from the **EMA**, the **European Generic Medicines Association**, the **European Commission**, the **EU Privacy Association** and **EUCOPE** will unravel the complexity to enable you to implement the Pharmacovigilance Rules effectively, anticipate the amendments to the Data Protection and Clinical Trials Directives and fulfil the requirements of the new Falsified Medicines Directive to safeguard the integrity of your medicine supply chain
- **Novartis Pharma AG** and **Gilead Sciences** will analyse the lessons learned from the Mediator case and how to manage the risks of off-label promotion
- The **President** of the **European Healthcare Fraud & Corruption Network** will provide guidance on how to update your company practices and avoid sanctions in light of increased Anti-Bribery enforcement activity
- **Novo Nordisk A.S.** and the **Head of the Pharma Regulation Practice at Taylor Wessing** will advise you how to minimise legal risks by maintaining robust social media strategies and supervising use effectively
- How to optimise your pricing and reimbursement strategies across diverse member states to counter cost containment strategies with the **Head of Government Affairs in Europe for Novartis International AG**, the Director of LYSIAC and legal counsel from **Garrigues Law Firm**
- A comprehensive round up of the latest decisions regarding the scope of SPCs and the areas that still need to be clarified after the Medeva train of cases and the Novartis case by **Esteve**, the **Head of the Regulatory Department at Bristows and the Head of the IP and Life Sciences Practices at CMS Cameron McKenna**

Take back valuable insights to your organisation and use this to ensure that you comply with the requirements of the regulators and avoid costly penalties. Representatives from key regulators will explain the rationale behind the latest regulations and will answer your queries regarding the rapidly changing regulatory landscape. Don't miss this outstanding opportunity to learn from and network with those at the forefront of pharma regulatory law in the EU market.

Plus, enhance your experience by attending:

The Pre-Conference Working Group on Monday 24 September 2012 at 1.30 pm:
A Step by Step Guide to Creating Successful Partnerships between Diagnostic and Drug Companies

This working group will provide an overview of the reasons why drug and diagnostics companies form partnerships, the advantages and pitfalls of forming partnerships, the issues arising from diagnostics and common challenges encountered and things to look out for. A leading expert will talk about the factors you should consider when choosing a partner and the types of contracts you should use and key provisions to insert. Case studies and real life practical examples will be used to highlight key points.

Participants will receive a comprehensive set of valuable materials prepared by the speakers specifically for this event. These are materials that you will be able to use again and again.

Reserve your place today by calling **+44 (0) 20 7878 6888**, faxing your registration form to **+44 (0) 20 878 6885**, sending an email to **registrations@C5-Online.com** or registering at **www.C5-Online.com/eupharma**.

ATTENDEE PROFILE

For over a decade, our regular attendees have attended **C5**'s Pharma Series to hear the latest regulatory updates, benchmark their procedures and network with their peers.

Today's in-house counsel are required to advise on a broad range of issues relating to pharma regulatory law which will be covered by this comprehensive event.

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For more information about this program or our global portfolio, please contact:
Jo Menzer on **+44 (0)20 7878 6978** or
email **j.menzer@C5-Online.com**

PRE-CONFERENCE WORKSHOP
24 September 2012

1.30 **Registration and Coffee**

2.00 **A Step by Step Guide to Creating Successful Partnerships between Diagnostic and Drug Companies**

Richard Watts, **Director, Companion Diagnostic Partnerships, QIAGEN (UK)**

- What does the US legislation require in terms of diagnostics?
- What is the rationale behind the rules?
- Why partner with a diagnostics company?
- Challenges and complexities that commonly arise
  - successful strategies for overcoming those problems
- Who should you partner with? What factors should you consider in making your decision?
- What contracts should you use? What are the key provisions that you should include?
- Case study of a successful partnership arrangement: key factors for success

5.00 **Workshop Ends**

MAIN CONFERENCE | DAY 1, 25 SEPTEMBER 2012

8.00 **Registration and Coffee**

8.45 **Opening Remarks from the Chair**

9.00 **Unravelling the Complexity to Ensure Effective Implemention of Pharamacovigilance (PV) Legislation**

Tomasz Jablonski, **Legal Service, European Medicines Agency**

- Analysis of various implementation strategies adopted
  - strategies that work: key factors
  - where do companies need to improve?
  - identifying and minimising potential risks
  - guide to training your drug safety team on the new law
  - case studies of implementation strategies used by various companies
- Challenges and hurdles encountered during implementation and how to overcome them
- Achieving good vigilance practice: critical steps
- How to improve your approach of dealing with the regulators
- Linking PV to Health Technology Assessment: what studies do pharmaceutical companies need to do to satisfy the authorities? What is expected?
- Addressing concerns regarding post authorisation efficacy studies
- Steps market authorisation holders should take to ensure they are aware of post marketing studies
- Exploring joint FDA/EMA safety efforts

9.45 **Adopting Effective Risk Management Strategies to Avoid Product Liability Claims**

Mediator Case

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

- Identifying pharmacovigilance challenges & the implications for product liability
- Lessons to be learned from recent cases, e.g. the *Mediator* case in France
- Examining issues in relation to recalls
- Adopting effective risk management strategies to avoid product liability claims
  - constructing effective risk management plans that comply with drug safety standards
  - proven strategies to minimise the risk of costly product liability claims
  - how to implement risk evaluation management strategies (REMS) to include in your US drugs portfolio
- Adopting an effective product labelling model to combat anti-counterfeiting

10.30 **Morning Refreshments**

10.45 **Safeguarding the Integrity of your Medicine Supply Chain: Fulfilling the Requirements of the New Falsified Medicines Directive**

Julie Maréchal-Jamil, **Senior Manager, Quality & Regulatory Affairs, European Generic Medicines Association (Belgium)**

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 discussions
  - evaluating the implementation efforts so far
  - examining recent court cases
  - the revision of the Customs Regulation: analysing the proposed changes and potential challenges

11.45 **Anti-Corruption Enforcement Initiatives in Pharma: How to Change Your Company Practices to Avoid Sanctions**

Paul Vincke, **President, European Healthcare Fraud & Corruption Network (Belgium)**

- Impact of the UK Bribery Act had on the pharma sector
  - to what extent has it been applied properly?
  - how much business must companies do with the UK and how frequently?
- Strategies to address challenges encountered by the pharma industry during implementation
- Strengthening your compliance programme
- Impact of sector specific legislation which restricts what can be done
  - how pharma companies can work with healthcare professionals
  - good practice guidelines for professionals
- Inducements to doctors: what level of supervision has been undertaken by:
  - the pharma regulatory authorities, the Code of Practice authorities and the SFO?
- Implications of the *Vanguard* case in respect of promotion by third parties
- Managing compliance risks with regards to the UK Bribery Act
- FCPA implications and related risks for EU pharma companies

12.30 **Networking Lunch**

1.30 **Lessons Learned from the Mediator Case and How to Manage the Risks of Off-Label Promotion**

Juergen Dressel, **Head Patents, Litigations ex US, Novartis Pharma AG (Switzerland)**

Anne-Laure Marcerou, **Partner, Life Sciences Department, Dechert (France)**

Alexey Kislitsyn, **Director EMEA Legal affaires, Gilead Sciences (France)**

- Key lessons to be derived from the *Mediator* case
  - the changes it triggered in French legislation
  - the likely impact elsewhere?
- Guidance for market authorisation holders on how to be aware of post marketing studies
  - scope of market authorisation holders' responsibility
  - towards a new obligation to monitor and prevent off-label use?
  - what are the penalties for non-compliance?
- Steps that companies can take to avoid off-label promotion allegations
- Tips on supervising company dissemination of non-promotional scientific information

2.30 **How to Minimise Legal Risks in the Pharma Sector by Maintaining Robust Social Media Strategies and Supervising Use Effectively**

Søren Thor Jensen, **Vice President & Assistant General Counsel, Pharma Law, Legal Governance & Global Legal GSC, Novo Nordisk A/S (Denmark)**

Tim Worden, **Partner and Head of Pharma Regulation Practice, Taylor Wessing (UK)**

- Identifying the key risks of social media use
  - establishing robust strategies for managing those risks
- Matters to consider when using these channels
  - how much responsibility do you have for things said by third parties?
- How to create & maintain an effective social media staff policy & tips on training staff
- Examining the PMCPA guidance and the implications
- Problems from the use of digital technology devices

3.15 **Afternoon Refreshments**

3.30 **Inside Guide: How to Ensure Compliance with the Anticipated Amendments to the Data Protection Directive**

Dr. Paolo Balboni, **Scientific Director, EU Privacy Association (Belgium)**

- What are the main changes introduced by the proposal for a new general data protection regulation?
  - an outline of the political priorities of the Cyprus Presidency
  - are there specific provisions concerning the processing of data relating to health and the processing of data for research purposes?
  - what are the particular implications of the regulatory changes on this sector?
- What are the main concerns at the EU and national level?
- How will this affect interactions with the US?
- Analysis of the proposals in relation to telemedicine
- How will the proposals affect non-EU companies?
  - how will this affect how US based entities that interact with EU consumers can collect, store and use consumer data?

Extended Q & A

4.30 **The Implications of Health Technology Assessments (HTAs) on Your Product Portfolio**

Dr. Hans-Peter Dauben, **Head, DAHTA German Agency for HTA**

- Understanding HTAs and how they are used
- What services do Health Technology Authorities offer?
- To what extent are HTAs being harmonised across Europe?
- Analysing approaches from regulatory bodies & their impact
- What are the latest developments regarding HTAs?
- How are HTAs working in practice in the EU?
- Key challenges and how can these be dealt with
- Addressing concerns relating to data privacy
- The effect of the trend towards smaller patient populations & targeted medicines
- Impact of HTAs on small and medium businesses (SMEs) in Europe

5.15 **Entering Into Pharma Licensing Deals: Tips, Traps and Techniques**

Alison Dennis, **Partner, Field Fisher Waterhouse LLP (UK)**

- Matters to consider when entering into licensing deals
  - what is the IP that you are acquiring and defining the field of use
  - practical and regulatory responsibilities: who is best placed to handle?
  - structuring royalty terms: what are the options and watch points?
  - indemnities: what do they REALLY mean?
  - termination provisions: where should the end of the line be and how to handle the end of relationships well through prior agreement

6.00 **Conference Adjourns**

MAIN CONFERENCE | DAY 2, 26 SEPTEMBER 2012

8.30 **Registration and Networking**

9.00 **Opening remarks from the Chair**

9.15 **How to Align Your Business Practices in Light of Recent Competition Law Judgments**

Henri Piffaut, **Directorate-General Competition, European Commission**

Dr. Werner Berg, **Partner, Crowell & Moring (Belgium)**

- Update on investigations and settlements by regulators & implications for the industry
- Important points to note from the *Astra Zeneca* decision
- Assessing the significance of the *Servier* case: to what extent is it likely that other health authorities will take action as a result of this judgment?
- Other pending cases to watch closely
- Overview of recent developments in parallel trade in France, Spain and Sweden

10.15 **A Big Year on the SPC Front: Is There Anything Else For the Court to Clarify?**

Dr Nicolas Vincent Ruiz, **Director Industrial Property, European Patent Attorney, Esteve (Spain)**

Marie Manley, **Partner & Head of the Regulatory Department, Bristows (UK)**

Nick Beckett, **Partner & Head of IP and Life Sciences Practice, CMS Cameron McKenna (UK)**

- An update on recent and pending decisions
- What is left after the Medeva train of cases and the Novartis case?
- Interaction between the SPC and the Paediatric Regulation

11.15 **Morning Refreshments**

11.30 **Optimising Pricing & Reimbursement Strategies across Diverse Member States**

Bart van der Lelie, **Director, LYSIAC (Netherlands)**

Andras Fehervary, **Head Government Affairs Europe, Novartis International AG (Switzerland)**

Dr. Alexander Natz, **Secretary General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) (Belgium)**

Jose Fernandez-Ranada, **Partner & Head of Life Sciences Department, Garrigues (Spain)**

- Update on the latest legal developments and regulatory guidelines
  - what are your options in responding to state cost containment measures?
  - examining actions across Europe to reduce prices paid by government customers
- A comparison between the pricing and reimbursement strategies in different member states
  - who are the main regulators responsible for setting the pricing and reimbursement strategies?
  - where do the key differences lie in strategies?
  - what is the impact on pharma companies?
  - impact of Germany on international reference pricing
  - the new country basket in Germany
- Best practice approaches for a successful market access and pricing strategy
  - how to manage pricing and reimbursement regimes in Europe to gain the most effective market access & ROI
- Revision of the EU Transparency Directive
  - what are the current challenges for the implementation of the EU Transparency Directive in national law and the effective enforcement of its principles?

12.30 **Networking Lunch**

1.30 **How to Overcome Challenges relating to Current Good Manufacturing Practice (GMP) Requirements**

Maurits Lugard, **Partner, Sidley Austin (Belgium)**

- An overview of the GMP laws and the implications for manufacturers
- Proposals for legislative changes from member states and the outlook for the next year
- The impact of the US drive to ensure that foreign companies are GMP compliant
  - steps to take to meet the US requirements
- Implications of increased emphasis on manufacturing in new counterfeit goods rules
- Matters for in house lawyers to consider

2.15 **Demystifying the Scope and Potential Impact of Proposed Legislation on Biosimilars to Enable You to Make Strategic Decisions Now**

Frank Landolt, **Vice President Intellectual Property and Legal, Ablynx N.V. (Belgium)***

Dr. Anthony C. Tridico, **Partner, Finnegan, Henderson, Farabow, Garrett & Dunner (Belgium)**

- Introduction to biosimilars
- An overview of the regulatory legal framework - US vs. Europe
- Understanding the new US guidelines provided by the FDA
- Details of the EMA guidelines
- Case studies on the EMA's approach
- Comparison of the market regarding biosimilars in the US and the EU: what does this mean for the industry?
- Navigating the interplay between regulatory and patent protection
- Strategies for preparing for a biosimilar challenge

3.15 **Afternoon Refreshments**

3.30 **Market Access: Regulatory Considerations when Entering the Russian and CEE Market**

Roswitha Reisinger, **Area Legal Counsel for Central and Eastern Europe, Eli Lilly Regional Operations**

Siniša Tomic, **European Affairs Counsellor, Halmed (Agency for Medicinal Products & Medical Devices) (Croatia)**

Alexey Trusov, **Partner, Baker & McKenzie CIS (Russia)**

- An overview of the regulatory climate in Russia and the CEE
- Current trends in the regulatory policy in this region
- Details of the regulatory framework in Croatia as an EU accession country and other countries in the region
- Specific focus on:
  - promotional activities
  - pricing of medicinal products and medical devices
  - antitrust and unfair competition
- Issues to consider when entering this market

4.30 **The Review of the Clinical Trial Directive**

Georgios Amexis, **Regulatory Affairs Manager, Merck Serono (Germany)**

Dr. Alexander Natz, **Secretary General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) (Belgium)**

Cristiana Spontoni, **Partner, Squire Sanders (UK) LLP**

- Harmonisation on the level of the approval process
- The role of ethics committees
- The Voluntary Harmonisation Procedure and its influence
- Overview of the new proposal of the European Commission
- What is the impact on non-interventional studies?

5.30 **Conference Ends**

Cross Border Panel

C5's 3rd Forum on

EU Pharma Regulatory Law

Minimising Risks by Ensuring Compliance with Emerging Regulatory Developments

25 & 26 September 2012 | Le Méridien Hotel | Brussels, Belgium

Business Information In A Global Context

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ADMINISTRATIVE DETAILS

Date: 25 & 26 September 2012
Time: 8.00 am – 5.45 pm
Venue: Le Méridien Brussels Hotel
Address: Carrefour de l'Europe 3, Brussels, 1000, Belgium
Telephone: +32 (0)2 548 4211

An allocation of bedrooms is being held for delegates at a negotiated rate until 23 August 2012. To book your accommodation please call Venue Search on tel: +44 (0) 20 8541 5656 or e-mail beds@venuesearch.co.uk. Please note, lower rates may be available when booking via the internet or direct with the hotel, but different cancellation policies will apply.

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