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C5's 2nd Annual Forum on

European Pharma Regulatory Law

Emerging European Regulatory Developments Affecting
the Pharma Sector and Effective Strategies for Compliance
and Risk Management

21 - 22 September 2011 • Le Plaza Hotel, Brussels, Belgium

Experienced in-house counsel, top legal practitioners, and regulatory experts will provide you with both practical and strategic guidance on the most current regulatory developments impacting on the pharma sector, including:

- Interpreting the Pharmacovigilance rules and the impact on reporting obligations
- The rise of social media: balancing compliance obligations with effective marketing strategies
- Obtaining and maintaining an effective pricing and reimbursement structure
- The do's and don'ts in multi-jurisdiction clinical trials: where are we and where are we going?
- Reviewing your pharma regulatory requirements and the interaction with competition law
- Adopting an effective product labelling model to combat anti-counterfeiting
- Successfully obtaining SPCs and extensions of regulatory data protection: extending your market exclusivity
- Avoiding product liability litigation by reviewing your global labelling practices

Plus, add further practical value to your experience by attending the programme's post-conference workshop on:

Adopting Effective Risk Management Strategies to Avoid Product Liability Claims

Friday, 23 September 2011

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Pharma companies have faced increased regulatory enforcement in Europe in the recent past. The Pharma Sector inquiry, combined with the impact of the EU Pharma Package have meant that European companies must continually adopt new processes, strategies and reporting practices to comply with the obligations imposed under the evolving legislation. In particular, the marketing of pharma products has become subject to an increasingly complex web of legislation and regulation, resulting in the need for further guidance from regulatory authorities on the use of social media in today's global market.

The 2011 European Pharma Regulatory Law forum will focus on recent developments affecting the pharma industry in Europe and will also assess the impact of US developments on European companies. Our outstanding panel of experts will examine the crucial regulatory competencies needed to comply with the authorities and avoid potential costly sanctions. In addition, members from the key European and US regulators will address the fundamental amendments to the ever-changing rules and regulations and how your pharma practices will need to change.

Plus! Maximise your learning with the Post-Conference Workshop on:

Friday, 23 September 2011

Adopting Effective Risk Management Strategies to Avoid Product Liability Claims

This workshop will equip you with the key practical and strategic tools you need to construct effective risk management plans that comply with drug safety standards in today's challenging pharma industry. The workshop moderators will walk you through drafting effective risk management plans that will provide you with the tools and proven strategies you need to avoid costly product liability claims. You will also learn about how to implement Risk Evaluation Management Strategies (REMS) for inclusion in your US drug portfolios.

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/pharmaforum

WHO SHOULD ATTEND?

The 2nd Annual Forum on European Pharma Regulatory Law is a must for:

- Managers, directors and in-house counsel from the pharma, biotech and healthcare industries having responsibility for:
 - Regulatory affairs
 - Drug development and approval processes
 - Pharmaceutical law and regulation
 - Licensing and M&A
 - Medical affairs
- Lawyers, patent attorneys and consultants to the pharma, biotech and healthcare industries whose practices focus on:
 - Pharmaceutical law and regulation
 - Regulatory compliance
 - Patent litigation
 - Licensing and M&A
- Regulatory professionals from national and international regulatory bodies
- Clinical Research Organisations (CRO's) that conduct clinical research for the pharma and biotech industries
- Investment bankers and venture capitalists whose clients and portfolio companies operate in the pharma and biotech industries

CONFERENCE CHAIRS:

Dr. Alexander Natz
Head of Brussels Office, Federation of Pharmaceutical Industry

Maarten Meulenbelt
Partner, Sidley Austin LLP

EXPERT FACULTY:

Arundel McDougall
Partner, Ashurst LLP

Dr. Alexander Natz
Head of Brussels Office, Federation of Pharmaceutical Industry

Carla Schoonderbeek
Partner - Public & Regulatory, NautaDutilh

Catherine Longeval
Partner, Van Bael & Bellis

Charlotte Unger
Scientific Director Environment
Medical Products Agency, Sweden

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Ian S. Forrester Q.C.
Partner, White & Case LLP

Ilaria Passarani
Senior Health Policy Officer, The European
Consumers' Organisation

Dr. Janet Soreth
Deputy Director, Europe Office,
US Food & Drug Administration

Joachim Schwerin
Head of Competition Team, DG Enterprise
and Industry, European Commission

John Chave
Secretary General, Pharmaceutical Group
of the European Union

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Biologicals

Paul England
Professional Support Lawyer
Simmons & Simmons LLP

Penny Gilbert
Partner, Powell Gilbert

Dr. Peter Feldschreiber
Barrister, Four New Square

8.30 **Coffee and Registration**

9.00 **Chair's Welcome**

Maarten Meulenbelt
Partner, Sidley Austin LLP (Belgium)

9.10 **Interpreting the Pharmacovigilance Rules and the Impact on Reporting Obligations**

Carla Schoonderbeek
Partner, NautaDutilh (The Netherlands)

- How are pharma companies adopting the new rules into their internal processes?
 - highlighting the practical experiences
- How will changes in reporting obligations affect pharma companies?
 - changes to the drafting of commercial agreements and related SDEAs
 - how do European safety reporting systems interrelate with the US and other jurisdictions?
 - how to set up a practical multi-jurisdiction contract management system to cope with pharmacovigilance obligations
 - how to deal with inspections
- How are the different member states interpreting the rules?
- Getting the balance right between the rules on reporting adverse events and the rules on protecting personal data
- Continuous risk benefit assessment and off-label use
- Requirements for additional clinical studies
 - obligations to conduct clinical studies post approval
 - how often will new clinical studies be required?
 - how will it work in practice?
 - cost and time challenges

10.00 **Reviewing your Pharma Regulatory Requirements and the Interaction with Competition Law**

Dr. Joachim Schwerin
Head of Competition Team, DG Enterprise and Industry, European Commission (Belgium)

Ian S. Forrester Q.C.
Partner, White & Case LLP (Belgium)

- How can the European Commission promote the competitiveness of European industry?
- Principles governing the regulation vs. competition law interface
 - public policy interests
 - investment incentives and IPR protection
- Settlement agreements
 - the merits and demerits of settling patent litigation
 - "reverse settlements" and "value transfers" under Articles 101 and 102
 - any guidelines for resolving current questions?
- Impact of the new European Commission guidelines on horizontal co-operation agreements
 - R&D agreements
 - co-marketing and co-promotion agreements
 - cross-licensing and technology agreements
 - the horizontal guidelines and rules on technology transfer

- The AstraZeneca appeal
 - redefining categories of abuse
 - guidance for the future
- Implementing strategies to respond to parallel trade
 - developing an effective direct distribution model
 - supply chain re-design and the consequences for exports
 - withdrawing products from the market: the implications
 - the legal obligations of suppliers and resellers

10.45 **Refreshment Break**

11.10 **The Inclusion of Environmental Aspects into the EU Legislation on Good Manufacturing Practice (GMP)**

Charlotte Unger
Scientific Director Environment, Medical Products Agency (Sweden)

- The increase in the production of pharma products in low-cost countries
 - how will it affect the environment and patient health?
 - establishing an understanding from both society and industry
- Public awareness and the demand for action
- How can pharma companies promote patient health without inclusion of the environmental aspects?
- Broadening the perspective: achieving effective management of common resources via sustainable development for pharmaceuticals
 - economic growth
 - social cohesion
 - environmental protection
- The proposals for legislative changes from the Swedish government

11.45 **Obtaining and Maintaining an Effective Pricing and Reimbursement Structure**

Alexander Natz
Head of Brussels Office, Federation of Pharmaceutical Industry BPI (Belgium)

Cord Willhofs
Partner, Ehlers, Ehlers & Partners (Germany)

Maarten Meulenbelt
Partner, Sidley Austin LLP (Belgium)

- The European Commission's approach to transparent pricing and reimbursement systems
 - what are companies' rights to be heard?
 - what are their appeal rights?
 - what are the potential impacts of the Commission's review of the transparency directive?
- Off-label use and incentives to doctors
 - to what extent can governments incentivise doctors to prescribe one drug over another?
 - the ECJ case ABPI v MHRA: demand side related measures
 - the impact of exclusivity rights in an off-label use environment
 - new German case law on Lucentis
 - how can pharma companies work with hospitals to deliver the entire range of services?
- The impact of the German AMNOG reforms on innovative products

- the new conditions for market access in Germany
- the impact for international reference pricing
- timelines for the procedure and key players
- impact on incremental research
- exemptions for orphan drugs
- preparation of the new value dossier
- market trends in the hospital sector and generic markets
- Current UK proposals for value-based pricing of products
 - what does value-based pricing mean?
 - how is the value-based price determined?
 - what type of data needs to be generated to establish clinical and cost effectiveness?
 - how to tailor the data to be consistent with the administration of drugs in other countries
- Striving for a consistent price across different jurisdictions
 - which countries are the most important for pricing and reimbursement?
 - the impact of the price negotiations in Germany (AMNOG) and UK value-based pricing
 - the new price cuts in Greece
 - what is the European Commission perspective on pricing and reimbursement and HTA coordination?
 - industry perspective on the process of the Clinical Added Value of Orphan Drugs (CAVOD)
- Developing effective strategies and costing models
 - how to include the pricing process in the lifecycle management plan
 - developing adequate costing models for each product
 - ensuring the costing models are not anti-competitive

12.45 **Lunch**

14.00 **The Evolution of Regulation and the Drug Approval System in the 21st Century**

Dr. Peter Feldschreiber

Barrister, Four New Square, Lincolns' Inn (UK)

- What are the recent developments for drug approvals in Europe?
- Parallel advice between Europe and the US
- How long does it take to get a drug approved?
 - is the process speeding up or slowing down?
- Determining the clinical benefit of taking a product to the next stage
 - is the drug likely to be reimbursed?
 - should more products be eliminated in Phase 2?
 - What will be the impact on the design of the trial?
- At what stage should pharma companies approach the pricing reimbursement authorities?
 - should approval be part of the phase 2 development process?
- How can pharma companies effectively persuade governments to reimburse their drugs?
 - Medical and Educational Good and Services (MEGS) in the UK
 - Joint Working – to what extent can the industry and NHS work together?
- Assessing current practices with relation to risk sharing
 - should governments only reimburse where a patient responds to a medicine?

14.40 **The Do's and Don'ts in Multi-jurisdiction Clinical Trials: Where Are We and Where Are We Going?**

Cristiana Spontoni

Partner, Squire, Sanders & Dempsey LLP (Belgium)

- What impact will the proposed legislative amendments have on clinical trials conducted in Europe?
 - what amendments are in the pipeline?
 - can a more centralised system reduce the burden on pharma companies?
- The shift towards a transparent approach to information on clinical trials
 - what information is/will become publicly available?
 - how to avoid accidental release of confidential patient information
- Drafting clinical trial agreements
 - what are the "hot" clauses in the contract?
 - how much "global" and how much "local" do you need to be?
 - satisfying FCPA/Anti-bribery obligations: compliance and payments
- Drafting Informed Consent Forms
 - what are the hot topics?
 - what about data protection aspects?
- Hot issues in contracting with Clinical Research Organisations (CROs)
 - how much outsourcing?
 - how much liability?
 - how much independence?
- Clinical trials in the emerging markets
 - which regions are increasingly being used to conduct clinical trials?
 - what are the advantages and challenges with conducting clinical trials in the emerging markets regions?
 - what are the reporting requirements?
 - how can you avoid compliance pitfalls?

15.20 **Refreshment Break**

15.45 **Adopting an Effective Product Labelling Model to Combat Anti-counterfeiting**

Alexander Natz

Head of Brussels Office, Federation of Pharmaceutical Industry (Belgium)

John Chave

Secretary General, Pharmaceutical Group of the European Union (Belgium)

- What are the key provisions in the new anti-counterfeit legislation affecting pharma companies?
- The impact for wholesalers, parallel traders and pharmacies
- Which measures are proposed to secure the safety of the supply chain?
- Overview about existing national systems and pilot projects
- Strategies to prevent counterfeit drugs coming onto the market
 - safety features (unique identifier, tamper proof evidence)
 - what will be the impact on drug prices?
- Which products will require mandatory safety features to satisfy improved health care practices?

- financial impact for the OTC and Rx sector
- special treatment for generics?
- the importance of the European Commission's delegated Acts
- timelines and procedures for white lists and black lists
- 2-D matrix barcodes on each package as part of an end-to-end-control system
- the importance of the tamper proof evidence

16.30 **Implementation of the UK Bribery Act and how Pharma Company Practices will need to Change**

Neill Blundell

Partner, Eversheds LLP (UK)

- What procedures and systems will pharma companies need to adopt to ensure compliance and minimise risks?
 - training methods
 - reporting structures
 - risk assessments and audit procedures
 - responsibility for the conduct of third parties: sub-contractors and distributors
- What will be the impact on UK pharma companies?
 - what will be the impact on companies engaging in business in the UK?
 - defining "doing business in the UK": how much and how regularly?
- Inducements to doctors – what level of supervision will be undertaken by:
 - the pharma regulatory authorities?
 - the Code of Practice authorities?
 - the Serious Fraud Office?

17.15 **Chairman's Closing Remarks and End of Day One**

MAIN CONFERENCE DAY TWO
22 SEPTEMBER 2011

9:00 **Chair's Welcome**

Alexander Natz

Head of Brussels Office, Federation of Pharmaceutical Industry BPI (Belgium)

9.05 **The Rise in Social Media: Balancing Information to Patients and Advertising to Ensure Compliance**

Ilaria Passarani

Senior Policy Officer, The European Consumers' Organisation BEUC (Belgium)

Catherine Longeval

Partner, Van Bael & Bellis (Belgium)

- Information to patients vs. advertising
 - what can pharma companies include in information about prescription drugs to the general public?
 - what are the regulations on pharma company interaction with health service providers?
- The role of social media
 - what information can pharma companies publish?
 - when is it considered advertising to the public?
 - who is liable for activity on blogs, forums, etc.?
 - how to ensure privacy and data protection
- The move towards harmonised rules

- what are the proposed rules on how pharma companies can provide information to the public?
- what is the position of the European parliament and what is likely interpretation by the member states?
- how to ensure enforcement and compliance
- Summary of Product Characteristics (SMPCs)
 - ensuring that advertising activities are consistent with the SMPC: Novo Nordisk
 - what are the respective challenges when referring to data in the SMPC or new data?
 - can a drug be used for secondary benefits where they are listed in the SMPC but not approved for that use?
- The move towards a more centralised system
 - the decline in pharma sales representatives and the move towards key account management
 - ensuring corporate social responsibility in the pharma sector

9.55 **Avoiding Product Liability Litigation by Reviewing your Global Labelling Practices**

Dirk Hellner

Associate Vice President Legal Product Management and Defence, Sanofi (France)

Arundel McDougall

Partner, Ashurst LLP (UK)

- Legal basis for product liability litigation in Europe
- What is a defect?
 - defect including failure to warn
- Who needs to be informed?
 - learned intermediary versus patient information
 - what if patients do not read the PIL?
- The importance of labelling consistency
 - what is product labelling?
 - main differences between EU and USA labelling rules
 - managing product labelling in a pharmaceutical company: how to achieve labelling consistency between countries?
 - tools for labelling harmonization
 - why can labelling inconsistencies not be avoided?
- How to implement labelling decisions?
 - how to update the prescriber/patient information?
 - the US paperless labelling initiative: the future for product labelling?
- How to properly document the labelling process?
 - why should in-house legal counsel be involved in the labelling process?
 - why is documentation important for the litigator?
 - how does the litigator deal with labelling inconsistencies between countries?
 - why are product liability claims more difficult to defend in the US and UK, as opposed to continental Europe?

10.45 **Refreshment Break**

11.10 **The Current US Approval Process in Light of Recent Regulatory and Legislative Developments**

Dr. Janice Soreth

Deputy Director, Europe Office, U.S. Food & Drug Administration (FDA) (provisionally confirmed)

Daniel A. Kracov

Partner, Arnold & Porter LLP (US)

- What does the new FDA legislation provide?
 - the impact of the amendments on US and European pharma companies
- Strategies for getting products approved in the US by the FDA
 - for a generic pharma companies: how and when is the generic drug approval system expected to change in the US?
 - for biologic pharma companies: how will the US implement their approval system for biosimilar products?
 - how much data is required to permit a drug to be marketed?
 - how much data is required for accelerated approvals?
 - Avastin: outcome of the appeal hearing
- The interchange between the FDA and the EMA
 - how does the FDA influence the EMA?
 - how does the EMA influence the FDA?
 - is it likely to become easier or more difficult to enter the US pharma market?
- The new follow-on biologics regime
 - what are the requirements?
 - how is it working in practice?
 - what type of data does the FDA require the generic biosimilar to produce to approve the product?
 - the impact of the authorisation in practice: to what extent are biosimilars comparable to the originator product?
 - effect on reimbursement: do doctors, healthcare insurers or patients perceive it to be the same product, or are they different and to what extent?
- Assessing the impact of proposed amendments to the Prescription Drug User Fee Act (PDUFA)
 - what are the likely changes to the FDA approval process as a result of the proposed amendments?
 - proposed registration fee system for US applications: how will it affect the way pharma companies conduct their work?
 - proposed registration fees for generic drugs: performance targets
- Patient Centred Research Outcomes Institute (PCROI)
 - the US shift towards the European health technology assessment system
- FDA enforcement actions
 - what will be the outcome of pending investigations?
 - what sophisticated compliance structures can be pharma companies design to ensure they avoid:
 - advertising for unapproved uses?
 - impermissible financial relationships with the medical profession?

12.10 Overcoming Obstacles to eHealth and Personalised Medicine

Grant Castle

Partner, Covington & Burling LLP (UK)

- Assessing the current regulatory status of:
 - medicinal products
 - medical devices
 - software
 - health services
- Implications for R&D programs
- The likely impact on existing products
- Implications for market access
 - prescription, price, and reimbursement status
 - risk-sharing/outcome guarantee schemes

- Regulation of “added value”
 - interactions with healthcare professionals
 - interactions with patients, including DTC issues
 - interactions with health service providers
- Procurement considerations
- Related issues:
 - clinical or medical research
 - pharmacovigilance, including PASS considerations
 - data privacy
 - healthcare regulation and access to patients/patient records

12.50 Lunch

14.10 Successfully Obtaining SPCs and Extensions of Regulatory Data Protection: Extending Your Market Exclusivity

Olivier Lemaire

Director Legal Affairs, GlaxoSmithKline Biologicals (Belgium)

Penny Gilbert

Partner, Powell Gilbert (UK)

Gareth E. Morgan

Partner, Winston & Strawn LLP (UK)

Supplementary Protection Certificates (SPCs)

- What is the “basic patent”?
 - combination products
- What constitutes the first marketing authorisation in Europe?
 - Synthon v Merz
 - Generics v Synaptech
- What constitutes the “product”?
 - veterinary products
 - greater purity and enantiomeric products
 - new formulations

Regulatory Data Protection (RDP)

- How to obtain RDP for new active substances
 - overview of the procedures for obtaining marketing authorisation
 - the definition of a “new active substance”
 - what is the correct test to apply?

Incentives for Already Authorised Actives

- How is the European Commission providing incentives for companies to develop old compounds for new indications?
- Will a new indication benefit from the same level of incentives as the first?
 - patent protection
 - SPCs
 - regulatory exclusivity
 - new therapeutic indications bringing a significant clinical benefit
 - new indication for a well-established substance

Other Obligations, Incentives and Rewards

Paediatric Obligations

- When does a paediatric study need to be conducted?
 - exceptions, waivers and deferrals
- Paediatric Investigation Plans (PIPs)
 - the approach of the Paediatric Committee
- Paediatric Use Marketing Authorisation (PUMA)

P A N E L S E S S I O N

- Practical experience and success in obtaining paediatric extensions for SPCs

Orphan Drugs

- Introduction to orphan drug market exclusivity and its key advantages
 - how do you obtain the additional 2 years of market exclusivity?
- Potential risks to ongoing market exclusivity
 - review of market exclusivity at year 5
 - how can you lose market exclusivity?

15.20 Refreshment Break

15.40 **Guidance on the Regulations Applicable to Advanced Therapy Medicinal Products**

Didier Caizergues

Head of Regulatory Affairs Department, Genethon (France)

Julian Hitchcock

Consultant Lawyer, Field Fisher Waterhouse LLP (UK)

- Gene therapy legislation and practical experiences
 - when do you qualify as a gene therapy?
- TSU-engineered products run out of their transitional period by the end of 2012
- How can pharma companies prepare for filing of their applications with the EMA?
- What should be included in an application?
- Timing of the registration process
 - TiGenix's ChondroCelect drug

16.30 **Privilege and Discovery in Pharma Litigation**

Paul England

Professional Support Lawyer
Simmons & Simmons LLP (UK)

- Disclosure in pharma litigation
 - what UK disclosure rules requires of in-house counsel and their lawyers
 - differences to US discovery rules
- What are the limitations of privilege for in-house counsel in UK litigation?
- The Akzo Nobel debate – what privilege protection does in-house counsel have in European Commission investigations?
- Litigation privilege in pharma litigation
 - a comparison with legal advice privilege
 - special problems with experts
- How can pharma companies mitigate privilege and disclosure risks?

17.15 **Chairman's Closing Remarks and End of Conference**

POST-CONFERENCE WORKSHOP 23 SEPTEMBER 2011

9:00 – 12:30

ADOPTING EFFECTIVE RISK MANAGEMENT STRATEGIES TO AVOID PRODUCT LIABILITY CLAIMS

This workshop will provide you with in-depth guidance on devising strategic risk management plans to ensure your internal processes and drug standards comply with drug safety requirements across Europe and the US.

This workshop will equip you with the key practical and strategic tools you need to obtain sustainable market access in Europe and the US to avoid costly product liability claims.

8.30 **Coffee and Registration**

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

Workshop Moderator:

Dr. Heike Wachenhausen

Lützeler Klümper Wachenhausen Rechtsanwälte (Germany)

European approach: Risk Management Plans (RMPs)

- What products require an RMP to be developed?
- What level of reporting is required?
 - what is the criteria?
- Impact on product liability for pharma companies
- The likelihood of a shift towards the REMS approach followed in the US

US approach: Risk Evaluation Management Strategy (REMS)

- What products will require a REMS to be developed?
- When will the REMS plan need to be developed and implemented?
- The impact on pharma companies of adopting a REMS
 - potential for serious adverse events
 - potential misuse/abuse
 - comprehensive risk management strategies
 - registries, physicians and pharmacists to require training
 - databases for patients reporting to the FDA on how a product is being used and off-label use
- How complex are the strategies?
- The FDA approach to the REMS legislation

Morning Refreshment Break to be included

12.30 **End of Post-Conference Workshop**

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Emerging European Regulatory Developments Affecting the Pharma Sector and Effective Strategies
for Compliance and Risk Management



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Time: 8:30 - 17:30

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Payment is due in full upon your registration. Full payment must be received prior to the event otherwise entry will be denied. All discounts will be applied to the Main Conference Only fee (excluding add-ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to individuals employed by the same organisation.

TERMS AND CONDITIONS

You must notify us by email at least 48 hours in advance if you wish to send a substitute participant. Delegates may not "share" a pass between multiple attendees without prior authorisation. If you are unable to find a substitute, please notify C5 in writing no later than 10 days prior to the conference date and a credit voucher will be issued to you for the full amount paid, redeemable against any other C5 conference. If you prefer, you may request a refund of fees paid less a 25% service charge. No credits or refunds will be given for cancellations received after 10 days prior to the conference date. C5 reserves the right to cancel any conference for any reason and will not be responsible for airfare, hotel or any other costs incurred by attendees. No liability is assumed by C5 for changes in programme date, content, speakers or venue.

INCORRECT MAILING INFORMATION

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