Take away new commercial and regulatory strategies to successfully manage and grow your off patent portfolio

INFORMA LIFE SCIENCES' 3RD ANNUAL

CROP PROTECTION: POST PATENT PRODUCTS, IPR AND PARALLEL TRADE

Practical Commercial and Regulatory Advice for R&D and Generic Companies Looking to Exploit the Revenue Generating Capabilities of Off Patent Molecules

18 - 19 November 2008, Crowne Plaza City Centre, Amsterdam, The Netherlands

www.informa-ls.com/crop

Industry Feedback

James Bristow, Rotam Group Agrochemical Division

Mike Caroll, Dow AgroSciences

Chris Orpin, Dow AgroSciences

Key Business Insights

Dr Matthew Phillips, Phillips McDougall

Dr Nigel Uttley, Enigma Marketing Research

Janelle Kay, Pyxis Regulatory Consulting

The Most Up-To-Date Regulatory Information & Advice

Darren Flynn, Pesticides Safety Directorate, UK

Pascale Robineau, AFSSA, France

Mathias Uteb, BVL, Germany

Inge Rol, Ctgb, The Netherlands

Maarten Derudder, Federal Public Service of Public Health, Food Chain Safety & Environment, Belgium

Milena Koprivnikar Bobek, Phytosanitary Administration, Slovenia

Top Level Legal Know-How

Claudio Mereu, Field Fisher Waterhouse LLP

Charles Whiddington, Field Fisher Waterhouse LLP

Marjan Noor, Howrey LLP

Prof Willem Hoyng, Howrey LLP

Nick Beckett, CMS Cameron McKenna LLP

2008 Conference Highlights:

- ✔ **OPENING KEYNOTE** – James Bristow, General Manager-International, Rotam Group Agrochemical Division, Hong Kong
- ✔ Two Extended and Interactive Member State Panel Sessions:
  1. **Registration of Off-Patent Products** – Feedback from 6 Member States: UK, Germany, France, The Netherlands, Belgium and Slovenia
  2. **Parallel Trade** – Hot topics include national opinions on common origin and import for own use, enforcement and control mechanisms for parallel authorisations, tackling mis-use and counterfeiting
- ✔ **Latest market intelligence** – Make up, performance and growth areas: identifying the next generation of off patent products
- ✔ **Essential EU Agrochemical Law** – Access to data, competition law & patent law explained, commercial implications assessed
- ✔ **Review of European Case Law** – CTB vs. Bayer plus 2 ECJ Judgments- France vs. Commission plus Imports for Own Use

New for 2008 **PRE CONFERENCE WORKSHOP**

Generic Registrations in the United States

Monday 17 November 2008

- Indepth analysis of the US market
- Practical advice on submitting generic applications in the US
- Data compensation in practice

Course Leader: **Janelle Kay,** *Principal Consultant,* **Pyxis Regulatory Consulting, USA**

New for 2008 **POST CONFERENCE WORKSHOP**

Maximising Returns Through Reformulation: Old Molecules New Opportunities

Thursday 20 November 2008

- Practical tips on identifying which molecule and which formulation
- Strategies for product development and registration
- Benchmarking reformulation performance

Course Leader: **Nicola Mitchell,** *CEO & Founder,* **Life Scientific, Ireland**
Sharon Brady, *Regulatory Affairs Manager,* **Life Scientific, Ireland**

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PRE CONFERENCE WORKSHOP

Generic Registrations in the United States

Monday 17 November 2008

09.00 Registration 09.30 Start 16.30 End of Workshop

The process and strategies for successful registration of generic pesticides in the United States will be covered in this extended session. Attendees will learn about the EPA and its methods as well as techniques to expedite the registration process with EPA. Finally, the session will focus on data compensation and what can be expected in this process, including a review of the arbitration process, decisions, and the potential ramifications of those decisions.

Workshop Outline

Session One: Background
- History
- Regulations
- Terms
- Types of registration

Session Two: Process
- Data development requirements
- Labeling
- EPA review process and interaction

Session Three: What's Next?
- Re-registration/Registration Review/Data Call-Ins
- EPA maintenance
- State registration
- Market access

Session Four: Data Compensation
- Task Forces
- Procedures expected outcome
- Arbitration process
- Industry perspective

KEY REASONS TO ATTEND

✔ Indepth analysis of the US market including a thorough evaluation of opportunities that exist for companies working with post patent molecules and generic products

✔ Practical advice on submitting generic applications in the US - valuable insight and real life strategies to obtain your marketing authorisations

✔ Data compensation in practice- discover how this works in the US

✔ Dedicated Q&A with our expert workshop leader to ensure that you get answers to your most pressing questions

Course Leader: **Janelle Kay,** *Principal Consultant,* **Pyxis Regulatory Consulting,** USA

POST CONFERENCE WORKSHOP

Maximising Returns Through Reformulation: Old Molecules New Opportunities

Thursday 20 November 2008

09.00 Registration 09.30 Start 16.30 End of Workshop

This workshop aims to outline product life cycle management options, in particular the re-invention of existing, generic molecules and portfolios, to improve a molecule's competitive profile, expand a molecule's scope and / or extend a molecule's patent life e.g., combination products, new formulation technology (e.g., nano-encapsulation, aqueous formulations), new uses, safener technology, seed treatments, straight reverse engineered generics to complement portfolios, etc.

Workshop Outline

Session One: Which Molecule?
- Identifying opportunities
- Sourcing agrochemicals in China
- Patent navigation - novel formulations, synergistic mixtures, methods of manufacture, key intermediates, isomers
- Chemical equivalence

Session Two: Which Formulation?
- Combination products, new formulation technology (e.g., nano-encapsulation, concentrated, aqueous formulation), new uses, safener technology, seed treatments, straight reverse engineered generics to complement portfolios, etc.
- Comparative assessment
- Improved efficacy, safety, hazard classification, quality (stability), delivery and dosing (extended release)

Session Three: Getting to Market - Development and Registration
- Regulatory strategy
- Reference product and data protection
- Levering precedent / previous investments, through extrapolations, comparability/bridging scenarios and reasoned scientific case
- Costs and timelines
- Common pitfalls

Session Four: Benchmarking Reformulation Performance and Identifying Key Success Factors
- Assessing the ROI of reformulation
- Tactical and strategic objectives for product reformulation
- Benchmarking reformulation performance and identifying key success factors
- Competitive differentiation (improved treatment / extended release)
- Launch timing and sequencing
- Relative pricing
- Promotional activity

Course Leaders: **Nicola Mitchell,** *CEO & Founder,* **Life Scientific,** Ireland
Sharon Brady, *Regulatory Affairs Manager,* **Life Scientific,** Ireland

DAY ONE: 18 NOVEMBER 2008

08.15 Registration and Coffee

08.55 Chairman's Introduction

Opening Keynote Address

09.00 **Innovation with off Patent Molecules -Challenges, Opportunities, Strategies and Future Vision**
James Bristow, *General Manager-International,* **Rotam Group Agrochemical Division,** Hong Kong

Market Intelligence-Driving Growth Through A Better Understanding of Agrochemical Markets and Trends

09.35 **Current Position and Future Prospects for the Crop Protection Market**
- Market analysis - market breakdown and performance in 2007 and 2008
- Key factors affecting industry development
- Outlook to 2012

Dr Matthew Phillips, *Partner,* **Phillips McDougall,** UK

10.05 **Uncovering New Commercial Opportunities for Generics Through a Better Understanding of Patents and Data Protection Issues**
- Analysis of the current landscape for off patent products
- Identifying the next generation of off patent products
- The importance of thorough patent and data protection analysis
- Will an off patent product become a generic?

Dr Nigel Uttley, *Managing Director,* **Enigma Marketing Research,** UK

10.35 Morning Coffee

11.10 **International Perspective: Opportunities in the US for Off Patent Products**
- Market overview
- Basics of the application process
- Registration strategies
- Trends in data compensation processes

Janelle Kay, *Principal Consultant,* **Pyxis Regulatory Consulting,** US

Review of Novel Formulation Development and Regulatory Strategies

11.40 **Formulation Development and Registration**
- Designing new formulations to avoid regulatory problems
- Reverse engineering for "me too" formulations – benefits and limitations
- Changing existing formulations – "minor changes"
- Building the case to support formulation changes

Mark Bell, *Manager Formulation Development,* **Battelle UK Ltd,** UK

12.10 Lunch

Update on European Agrochemical Regulatory Policy

13.30 **Analysis of Current Position on Plant Protection Product Regulation and The Revision of 91/414/EEC**
- Review programme - to be completed by the end of 2008
- Peer review procedures
- Impact of MRL Regulations
- Impact of the revision

Terry Tooby, *Regulatory Consultant,* UK

14.00 **Policy for Data Protection, Sharing and Compensation under Draft Regulation**
Claudio Mereu, *Partner,* **Field Fisher Waterhouse LLP,** Belgium

14.30 **Update on Annex 1 Renewals**
- Understanding the proposals for annex 1 renewals
- How will it work and what is expected?

Mike Caroll, *Global Registration Manager,* **Dow AgroSciences,** UK

15.00 Afternoon Tea

Getting Products to Market - Meeting the Demands of Regulatory Requirements

15.30 **Annex III Dossier Preparation- Adapting to Work Sharing Opportunities- Mancozeb Case Study.**
- Introduction to Mancozeb
- Impact of minimum effective dose and the challenges faced to gain GAP harmonization both within DAS and across the multi national customers purchasing Mancozeb for mixture products
- Need to develop a "risk envelope"
- The evolution of the core zonal dossiers for North and South Europe with country specific appendices to cover national risk assessments
- Potential to extend the number of uses
- Opportunities for work sharing - the need for pragamatism

Chris Orpin, *European and Pacific Mancozeb & Zoxamide Regulatory Manager,* **Dow AgroSciences,** UK

16.00 **Member State Feedback on Registration of Generic Products**

REGULATORS PANEL SESSION

In this extended session each speaker will present a short overview to outline national opinions and priorities for the registration of off patent products. This will be followed by a Q&A session. Topics for discussion include:
- Registration of generic products – how does this work at a national level and what are the dossier requirements?
- How do member states deal with minor changes to formulations?
- Data protection, sharing and compensation
- Options for vertebrae data and forced data sharing
- Control of impurities
- Re-registrations - Annex 3 data protection
- Mutual Recognition-interpretation, approaches and experiences to date

Darren Flynn, *Head of Approval, Secretariat Branch,* **Pesticides Safety Directorate,** UK
Pascale Robineau, *Director Crops and Environment,* **AFSSA,** France
Inge Rol, *Officer Legal Affairs,* **Ctgb,** The Netherlands
Maarten Derudder, *Engineer,* **Federal Public Service of Public Health, Food Chain Safety & Environment,** Belgium
Milena Koprivnikar Bobek, Phytosanitary Administration, Slovenia
Marcin Bieliński-Biliński, Ministry of Agriculture and Rural Development, Poland (subject to final confirmation)

17.15 End of Day One

DAY TWO: 19 NOVEMBER 2008

08.30 Registration and Coffee

08.55 Chairman's Introduction

Essential EU Agrochemical Law

09.00 **Access to Data and Competition Law**
- What conditions can data holders impose on generics companies?
- What is deemed reasonable?
- Arbitration systems for accessing data
- Competition Law – understanding how is it applied and impact on business

Claudio Mereu, *Partner,* **Field Fisher Waterhouse LLP,** Belgium
Charles Whiddington, *Partner,* **Field Fisher Waterhouse LLP,** UK

09.30 **European Patent Law**
- Overview of procedure in key jurisdictions
- Recent developments on procedural steps in patent actions
- Pan European comparison of recent decisions on validity and infringement
- Tactical decisions on choice of jurisdiction

Marjan Noor, *Partner,* **Howrey LLP,** UK

10.00 **Spotlight on Recent Case Law: CTB vs. Bayer**
Prof Willem Hoyng, *Managing Partner Europe,* **Howrey LLP,** The Netherlands

10.30 **Legal Round-Up Question and Answer Session**

10.45 Morning Coffee

Parallel Trade: Provisions and Member State Feedback and Opinion

11.15 **EU Legislation on Parallel Trade of PPPS and Feedback on ECJ Decisions**
- Proposed provisions in the draft regulation
- Comparison of Commission and Parliament proposals
- Discussion on the ECJ judgement in France vs. Commission
- Discussion on judgement on imports for own use

Mathias Uteb, *Legal Advisor,* **BVL,** Germany

11.45 **Parallel Trade, Preparing Products for Market: What Can Companies Do?**
- The commercial perspective
- The legal framework (including a review of recent case law)
- Branding strategies
- Stock management strategies

Nick Beckett, *Partner,* **CMS Cameron McKenna LLP,** UK

12.15 Lunch

13.30 **Member State Feedback on Parallel Trade**
In this extended session each speaker will present a short overview to outline national opinions and priorities in relation to parallel trade. This will be followed by a Q&A session. Topics for discussion include:
- National criteria in applications to obtain authorisation
- Attitudes on common origin as a requirement of authorisation
- Opinions on applications for import for own use
- Enforcement and control mechanisms for parallel authorisations
- Strategies to tackle mi-use and counterfeits

REGULATORS PANEL SESSION

Darren Flynn, *Head of Approval, Secretariat Branch,* **Pesticides Safety Directorate,** UK
Pascale Robineau, *Director Crops and Environment,* **AFSSA,** France
Inge Rol, *Officer Legal Affairs,* **Ctgb,** The Netherlands
Mathias Uteb, *Legal Advisor,* **BVL,** Germany
Maarten Derudder, *Engineer,* **Federal Public Service of Public Health, Food Chain Safety & Environment,** Belgium
Milena Koprivnikar Bobek, Phytosanitary Administration, Slovenia
Marcin Bieliński-Biliński, Ministry of Agriculture and Rural Development, Poland (subject to final confirmation)

15.00 Afternoon Tea

15.30 **A Stakeholder Perspective on Parallel Trade**
- Experiences of working with EU member states
- Impact of the Common Origin decision
- Impact of voluntary withdrawal on parallel registrations
- Phase-out periods for parallel products

Jan Schlauer, *VP,* **International Plant Protection Association**

16.00 **Updates on Industry Efforts to Tackle Counterfeits in the Agrochemical Industry**
Rocky Rowe, *Advisor Trade Issues,* **European Crop Protection Association,** Belgium

16.30 Final Q&A Session and Chairman's Closing Remarks

16.45 End of Conference

CROP PROTECTION: POST PATENT PRODUCTS, IPR AND PARALLEL TRADE

Conference Overview

Informa Life Sciences' 3rd annual **Crop Protection: Post Patent Products, IPR and Parallel Trade** conference is a unique forum bringing together all parties involved with the further development and registration of off patent crop protection molecules. This year's agenda has been designed equip you with the key market intelligence, commercial insights and practical advice you need to best navigate the European regulatory system and successfully obtain marketing authorisations for your products.

5 Key reasons to attend

1 **Leading speaker panel.** Bringing you together with the top level commercial, regulatory and legal professionals; ensuring you benefit from expert opinions and practical, unbiased, advice.

2 **Direct access to national regulators from 6 Member States.** Join us for two extended, interactive, panel sessions; delivering first-hand insights from our regulators to completely update you on national procedures and attitudes to generic product authorisations and parallel imports. Hear from and put your questions to the PSD, UK, Federal Public Service of Public Health, Food Chain Safety & Environment, Belgium, AFSSA, France, Ctgb, The Netherlands, Phytosanitary Administration, Slovenia, BVL Germany

3 **Essential new information.** Agrochemical market trend analysis, next generation off patent product identification, impacts of the revised 91-414, case law, latest updates including ECJ judgements
NEW FOR 2008. Novel formulation development and regulation PLUS EU agrochemical law essentials; getting to grips with competition and patent law, understanding its application and business impacts.

4 **Benefit from 2 new conference workshops:**
1- Generic Registrations in the United States
2- Maximising Returns Through Reformulation: Old Molecules New Opportunities

5 **Access senior level professionals from across the globe.**
Dedicated networking sessions makes this event the perfect event to catch up with old colleagues and meet new business contacts.
Learn from and share experiences with over 90 attendees including Commercial Manager, Developmental Manager, Director of Business Development, General Manager, Global Generic Affairs Manager, Global R&D Manager, Global Registration Manager, Head of Marketing, Head of Product Chemistry, Head of Quality Control, Managing Director, Managing Patent Attorney, Portfolio Manager, Product Manager, Product Registration Manager, Registration Officer, Regulatory Affairs Manager, Sales Manager, Strategic Development Manager, Strategic Marketing Manager, Team Leader, Technical Manager.

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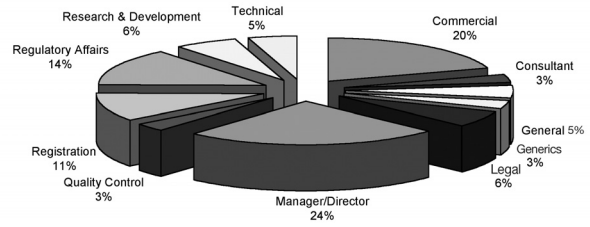
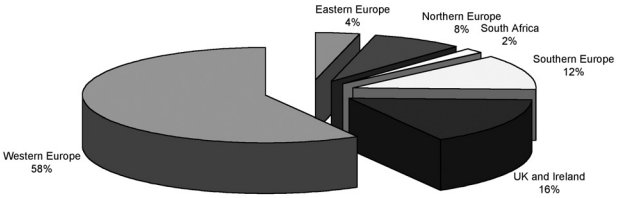
Commercial Opportunities: Call for Sponsors and Exhibitors

If you provide regulatory services or solutions to the agrochemicals industry the **3rd annual Crop Protection: Post Patent Products, IPR and Parallel Trade** conference will bring you face-to-face with your target market giving you a unique opportunity to gain exposure for your services, meet potential new business contacts and catch up with existing or previous customers.

Access senior level professionals



Gain exposure for your company before a global audience



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Delegate feedback from the 2007 conference:
– "Excellent practical conference…" (Dow AgroSciences)
– ".. good balance of input from regulators and companies" (Bayer CropScience AG)
– "Excellent platform to get updates and to make business contacts" (tec2trade)

For more information on how you could benefit from this event and to discuss the full range of lead generating, networking and branding opportunities that exist please contact:

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