Assess the impact of 1107 on generic and off patent registrations with essential feedback from 5 Member States

INFORMA LIFE SCIENCES'

CROP PROTECTION: OFF PATENT PRODUCTS AND GENERICS

Creating revenue generating opportunities for R&D and generic companies by overcoming commercial, regulatory and legal hurdles

8-9 November 2011, Renaissance Hotel Brussels, Belgium

Member State Feedback on 1107/2009:

- Tracy Roberts, **Chemicals Regulation Directorate, UK**
- Anne Marie Dillion, **Department of Agriculture, Ireland**
- Maarten Trybou, *Head of Service Pesticides and Fertilizers,* **Federal Public Service of Public Health, Food Chain Safety and Environment, Belgium**
- Maria Gaspari, *Registration Manager, Department of Pesticides,* **Ministry of Rural Development and Food, Greece**
- Dr Pavel Minár, *Head of Plant Protection Products Section,* **State Phytosanitary Administration, Czech Republic**

Key Industry Players Include:

- Garth Drury, *Head of Global Regulatory & Government Affairs,* **Rotam, France**
- Dr Michael J. Carroll, *Global Registration Manager,* **Dow AgroSciences, UK**
- Dr Richard Garnett, *EMEA Crop Protection Regulatory Affairs Lead,* **Monsanto Europe, Belgium**
- Maria Antonakou, *Head of Registration and Field Trials Department,* **Hellafarm SA, Greece**
- Jürgen Wenzel, *Regulatory Affairs,* **HELM AG, Germany**
- Dr Matthew Phillips, *Partner,* **Phillips McDougall, UK**
- Stéphane Delautre-Drouillon, *Secretary General, Association of Users and Distributors of AgroChemicals in Europe,* **AUDACE, France**
- Graham Dickinson, *Director, East Europe Commercial,* **ProCam, UK**

Key Benefits of Attending:

- ✔ Examine the impact of **data protection under the new regulation** on the registration of off patent and generic products; industry feedback from Rotam plus an in-depth panel discussion
- ✔ Hear feedback on the **zonal authorisation process post June 14** from southern and central zones; presentations from Member States plus Hellafarm share their experience of submitting a zonal dossier
- ✔ Dow AgroSciences describe strategies for efficient **re-formulation of old molecules** to create new products and barriers for generics
- ✔ Find out how to profit from **new markets including Asia and Central America**; gain a greater understanding of regulatory pathways, business opportunities and entrance barriers
- ✔ Learn about the **latest market intelligence** of the agrochemical industry; market analysis of 2011 and predictions for 2012

New for 2011

EVENING SEMINAR, DISCUSSION AND DINNER: 8 NOVEMBER 2011

Generics, Off Patent Products and Changing Regulatory Frameworks in Asia

Seminar Leader:
Dr Vasant Patil, *Regulatory Affairs Director,* **CropLife Asia, Singapore**

POST-CONFERENCE WORKSHOP: 10 NOVEMBER 2011

Essential EU Agrochemical Law for Non-Lawyers - Bridging the Legal and Regulatory Interface

Seminar Leaders:
Claudio Mereu, *Partner,* **Field Fisher Waterhouse, Belgium**
Noel Akers, N.J. Akers & Co, UK

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"Very good opportunity to meet the regulators and discuss ongoing and future issues"
APC, Delegate 2010

Day 1: Tuesday 8 November 2011

08:30 Morning Coffee and Registration

09:00 Introduction from the Chair
Steve Kozlen, *Europe Region Manager,* **Sharda and Kozlen Consulting,** Belgium

1107/2009: THE IMPACT ON GENERICS AND OFF PATENT REGISTRATIONS

09:10 **Transition to the new regulation for off patent and generic products**
- Overview of EU legislation
- Comparison of 91/414 and 1107/2009
- The new review process
- Changes to data protection
- Data sharing/arbitration rules

Tracy Roberts, Chemicals Regulation Directorate, UK

09:45 **Data protection and sharing under 1107/2009**
- Transition from 91/414/EEC and consequences for re-registration
- Key changes under Regulation 1107/2009
- Data sharing
- Identifying protected data
- Planning registration strategy for generics

Terry Tooby, *Regulatory Consultant,* **Terry Tooby Consulting,** UK

10:20 Morning Coffee and Exhibition Viewing Time

10:50 **Data protection under the new regulation 1107/2009 – Generics industry feedback**
- Context
- Does the new regulation improve market access for post-patent companies?
- Adoption and interpretation in Member States
- Arbitration/legal options
- Outlook

Garth Drury, *Head of Global Regulatory & Government Affairs,* **Rotam,** France

11:25 **Data protection under the new regulation 1107/2009 – Legal perspective**
- Legal framework and the impact for generic/off patent companies
- Commercial negotiations for generics
- How have the rules changed?
- How do the regulators deal with data protection?

Claudio Mereu, *Partner,* **Field Fisher Waterhouse,** Belgium

12:00 **Panel discussion: Data protection**
Garth Drury, *Head of Global Regulatory & Government Affairs,* **Rotam,** France
Claudio Mereu, *Partner,* **Field Fisher Waterhouse,** Belgium
Terry Tooby, *Regulatory Consultant,* **Terry Tooby Consulting,** UK

12:35 **Spotlight presentation**
Informa Life Sciences' Crop Protection: Off Patent Products and Generics event brings together key figures from across the AgChem community. If you would like to share your views, offer your services or demonstrate your product to leading decision-makers in this field, why not take the opportunity to host this spotlight session? For details please contact:
Chamatkar Sandhu, *Business Development Executive*
Email: **chamatkar.sandhu@informa.com** Tel: **+44 (20) 7017 7278**

13:05 Lunch and Exhibition Viewing Time

14:15 **Feedback on the Annex I Renewal (AIR) project**
- What will be required under 1107?
- Will generics now be scrutinized more heavily?
- What are the timelines?
- What are the barriers for generics?

Anne Marie Dillion, Department of Agriculture, Ireland

14:50 **Central zone: Examining the zonal authorisation process with off patent product and generic products**
- Development of guidance docs
- Use of the dRR, is it working? Is it strong enough?
- What are the agreed timeframes and are they working?
- Harmonisation between zones
- Examining risk envelopes
- The zonal approach and issues arising

Maarten Trybou, *Head of Service Pesticides and Fertilizers,* **Federal Public Service of Public Health, Food Chain Safety and Environment,** Belgium

15:25 Afternoon Tea and Exhibition Viewing Time

15:55 **Southern zone: Examining the zonal authorisation process with off patent product and generic products**
- Experience so far in the assessment of zonal applications by generic companies
- Application of the risk envelope approach by generics: Problems and identification from applications made so far
- Agreements made on working practices within Southern zone steering group
- Southern zone: Specific national data requirements

Maria Gaspari, *Registration Manager,* **Department of Pesticides, Ministry of Rural Development and Food,** Greece

16:30 **Registration of PPPs produced with off patent/generic products for the Greek market – Generics industry feedback**
- Factors affecting a Greek company formulating and registering its own PPPs
- Experience from preparing a zonal registration dossier for a product produced by companies based in several southern MS
- Registration demands for PPPs based on generic products with proved identicallity but with differentiated additives
- Authorisation of PPPs produced for the restricted market of Greece

Maria Antonakou, *Head of Registration and Field Trials Department,* **Hellafarm SA,** Greece

17:05 **Member State panel discussion: The zonal approach**
Maria Gaspari, *Department of Pesticides, Hellenic Ministry of Rural Development and Food,* **Ministry of Agriculture,** Greece
Maarten Trybou, *Head of Service Pesticides and Fertilizers,* **Federal Public Service of Public Health, Food Chain Safety and Environment,** Belgium
Maria Antonakou, *Head of Registration and Field Trials Department,* **Hellafarm SA,** Greece

17:40 Closing Remarks from the Chair

17:50 End of Day 1 followed by Evening Seminar, Discussion and Dinner

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Evening Seminar, Discussion and Dinner: Tuesday 8 November 2011

Generics, Off Patent Products and Changing Regulatory Frameworks in Asia: Challenges, Opportunities and Global Impact

Registration 18:15 • Start 18:30 • Networking Dinner 20:30

Over the past 20 years generic manufacturers have gained significant markets in Asia as well as impacted other geographies, namely Africa, Americas and Europe. Many countries in Asia have either changed or revised their old CPPs regulatory framework, incorporating some of the principles of regulations from the developed world. This initiative of updating the old regulation in Asia bodes well both for the growers and industry. However the outcome will only be known after seeing how these new updated regulations will be enforced.

Content of the seminar:
- Markets in Asia
- Possible impact of changing regulations
- What is good and what is not so good?
- Future trends
- Challenges and opportunities for stake holders

Benefits of attending seminar:
- Understand evolving regulatory frameworks across Asia
- Learn how these changes could impact CPPs in 2020 and beyond
- Assess agriculture sustainability challenges for stake holders
- Discuss what industry can do
- Examine expectations from Regulators

Seminar Leader:
Dr Vasant Patil, *Regulatory Affairs Director,* **CropLife Asia,** Singapore

"The meeting gathered key players in the field of crop protection off-patent products and these companies shared their knowledge" **Brorungitek, Delegate 2010**

Day 2: Wednesday 9 November 2011

09:00 Introduction from the Chair

MARKET INTELLIGENCE: THE AGROCHEMICAL INDUSTRY

09:10 **Current position and future prospects for the crop protection market**
- Agrochemical market analysis for 2011 and predictions for 2012
- Key factors affecting the crop protection industry
- Future outlook

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

09:55 **Can Chinese companies overcome the barriers to EU market entry?**
- Primary patents and Supplementary Protection Certificates (SPCs)
- Secondary patents – mixture, process etc
- Data protection
- Potential market entry strategies

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

10:30 Morning Coffee and Exhibition Viewing Time

MAXIMISING COMMERICAL OPPORTUNITIES

11:00 **Glyphosate products in a generic market: Quality and variability**
- In the EU there are now many registered Glyphosate products, and approved parallel imports
- Different products were sampled and analysed for Glyphosate content and the surfactant content
- Compared to the standard, 50% contained less Glyphosate, sometimes below the content allowed by the FAO specification
- Surfactant concentration was generally well below that of the standard and some products contained only trace levels
- The results of the survey demonstrate the need to buy trusted brands to ensure product quality and effective weed control, and suggest that wider monitoring needs to be undertaken

Dr Richard Garnett, *EMEA Crop Protection Regulatory Affairs Lead,* **Monsanto Europe,** Belgium

11:35 **Examining the distributors portfolio and post patent products**
- AgChem market from a distributor perspective
- Cover product life cycles
- Key products coming off patent
- Market segmentation; patented, proprietary post-patent and generic
- Product choices
- Options: R&D, parallel and generic
- How do ProCam decide on products?
- Winners and losers
- Conclusion and path forward

Graham Dickinson, *Director, East Europe Commercial,* **ProCam,** UK

RE-FORMULATION OF OLD MOLECULES

12:10 **Efficient re-formulation of old molecules: Industry case study**
- Examining the change in formulation to create a new product
- Approval from the regulators
- New data protection
- Barriers for generic companies
- Maximising your returns

Dr Michael J. Carroll, *Global Registration Manager,* **Dow AgroSciences,** UK

12:45 Lunch and Exhibition Viewing Time

EMERGING MARKETS

13:55 **The new FAO specification system - Chances and threats for the generic industry in emerging markets**
- What is new?
- Are generic companies affected?
- What do countries need for implementation of the system?
- How does it work and who benefits?

Jürgen Wenzel, *Regulatory Affairs,* **HELM AG,** Germany

14:30 **Business opportunities and entrance barriers in Central America**
- New business opportunities for whom?
- What do customers expect from a new player?
- What are the entrance barriers?
- How to develop a successful strategy

Dr Felix Thürwächter, *Head of Business Development,* **HELM AG,** Germany

PARALLEL TRADE

15:05 **Examining parallel trade - A Regulator's perspective**
- Changes from the Directive 91/414/EEC
- Experiences post 14 June 2011
- Labelling and packaging requirements
- Transparency and traceability

Dr Pavel Minář, *Head of Plant Protection Products Section,* **State Phytosanitary Administration,** Czech Republic

15:40 Afternoon Tea and Exhibition Viewing Time

16:10 **Practical impact of regulation 1107/2009 post 14 June 2011 on parallel trade**
- Article 52 – implications for European traders
- Current parallel trade situation in selected countries-what has changed?
- Impact of regulation 1107/2009 on generics: Market access, competition and prices
- Open questions and current problems

Dr Miroslav Orober, *Managing Director,* **Dr. Orober Consulting,** Germany

16:45 **From the Treaty of Rome to Article 52**
- The judicial construction of Europe
- Proportionality, consistency and legal certainty
- The single market for PPP and agricultural produce
- Public health and the protection of the environment
- Defining guidelines for Article 52

Stéphane Delautre-Drouillon, *Secretary General, Association of Users and Distributors of AgroChemicals in Europe,* **AUDACE**, France

17:20 Closing Remarks from the Chair

17:30 End of Conference

Post-Conference Workshop: Thursday 10 November 2011

Essential EU Agrochemical Law for Non-Lawyers - Bridging the Legal and Regulatory Interface

Registration 09:00 • Start 09:30 • End 16:30

Session one: Commercial and antitrust aspects of the Letter of Access
- Can the receiver of the LoA see the data or is it just made available to the CA for the purposes of processing the applications for authorisation?
- If there is only one manufacturer of an active can the manufacturer refuse to give the LoA to a potential competitor?
- How long does the LoA last?
- Competition law aspects: Negotiating a LoA - what price can be charged – what restrictions are usually applied? Is this acceptable?
- Practical experience with arbitration and antitrust proceedings

Session two: Generating a good supply agreement
- How are they generated?
- What should it look like?
- What can you legally ask a customer/supplier to do?

Session three: European patent law
- Overview of patent systems in Europe
- Strategy for seeking patent protection
- Term of patent protection and extensions
- Enforcing patents in Europe

Session four: Challenging patent validity
- Forums for challenging the validity of patents in Europe
- Opposition before the European Patent Office
- Invalidity proceedings before national courts
- Strategy for challenging patent validity

Session five: Legal round up 2010/2011

Workshop Leaders: **Claudio Mereu,** *Partner,* **Field Fisher Waterhouse,** Belgium
Noel Akers, N.J. Akers & Co, UK

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