Timely and important feedback from 7 National Regulators

Veterinary Medicines: Generics, Patents and Parallel Import Summit

Developing cost effective strategies to meet regulatory requirements and decrease time to market

3-4 July, 2007, Hilton Amsterdam, The Netherlands

Expert speakers to help improve your knowledge and provide greater understanding:

1. Practical Regulatory Advice from 7 National Regulators

Prof Reinhard Kroker, *Head Division,* **BVL, Germany**
Cornelia Ibrahim, *Head of Department-Support and Surveillance after Authorisation,* **BVL, Germany**
Asbjørn Brandt, *Head of Department,* **Danish Medicines Agency, Denmark**
Dr Gabriel Beechinor, *Director of Veterinary Medicines,* **Irish Medicines Board, Ireland**
Szilvia Speidl, *Deputy Director,* **Directorate of Veterinary Medicinal Products, Hungary**
Dr Ilian Getchev, *Director of* **Institute for Control of VMP, Bulgaria**
Caroline Evans, *Pharmacovigilance Assessor ,* **VMD, UK**

2. Real Life Business & Regulatory Insights

Mr Korevaar, *Managing Director,* **Eurovet, The Netherlands**
Alan Sheppard, *Executive VP Europe Generics,* **Dr Reddy's Laboratories, UK**
Asim Banerjee, *VP Animal Health,* **Wockhardt Ltd, India**
Cait Brennan, *Veterinary Regulatory Affairs Manager,* **Chanelle Pharmaceuticals Manufacturing Ltd, Ireland**
Anne Nallen, Nallen Regulatory Consulting *(Formely Head of Regulatory Affairs ,* **Cross Vetpharm Group, Ireland)**

3. Essential Legal Updates

Noel J Akers, *Principal and Founder,* **N J Akers & Co, UK**
Elisabethann Wright, *Counsel,* **Hogan and Hartson, LLP, Belgium**

Join us to collaborate and discuss the most topical issues:

- ✔ First hand information from national regulators to help you understand how competent authorities are making use of the provisions for registering generic products under the new directive
- ✔ Getting to grips with the new regulation: Feedback from regulatory affairs managers on getting products to market under the new system
- ✔ Understanding the changing requirements for safety data - what and how much information is required: Target animal safety guidelines, higher tier risk assessments, user safety assessments and residue studies, pharmacovigilance data and inspections
- ✔ In depth analysis of the patent system
- ✔ Legal feature session - Real life case studies on recent litigation, analysis of the outcomes and the potential future impact of such decisions
- ✔ Must attend parallel import briefing - Latest feedback from real life cases

Pre Conference Workshop - 2 July 2007

Patent Law and Practice in Veterinary Medicines

An intensive one-day course designed to provide a detailed analysis of patent law in Europe. Course highlights include: Introduction to patent law • Standards for patentability • Terms of patent protection • Patent infringement • Licensing • Patent Rights • Challenging patent validity • Patent specifications as sources of information

Course Leader: **Noel Akers, NJ Akers & Co Ltd**

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YOUR 3 STEP CHECKLIST TO SUCCESS:
1. A unique opportunity to gain valuable insight and practical advice from 7 national regulators

Pre-Conference Workshop: 2 July 2007

Patent Law and Practice in Veterinary Medicines

09.00 Registration 09.30 Start 16.30 End of Workshop

Session 1: **Introduction to Patent Law**
The first session introduces the concept of a patent and sets out the nature of a patent as a legal right. To place the modern practice of patent law into perspective, the history of the major patent systems around the world is summarised. Finally, this session reviews the major national, regional and international laws, conventions and treaties governing patents, completing the groundwork for the following sessions.

Session 2: **Standards for Patentability**
It is essential to understand what can and cannot be protected by a patent. Session 2 reviews the law relating to patentability and the exceptions to patentable inventions, in particular the patenting of new uses of known compounds, an area in which veterinary medicine inventions have helped shape the law. The session concludes by reviewing the standards of novelty, inventive step and industrial applicability required in order to obtain a valid patent for a veterinary medicine product.

Session 3: **Term of Patent Protection**
This session will review the term of patent protection afforded by the law and the possibilities for patent term extensions under the Supplementary Protection Certificate (SPC) provisions in Europe. An understanding of these provisions is essential for a generic company looking to market a patented product after the patent term has expired.

Session 4: **Patent Infringement**
Patents are an enforceable legal right and knowing how and when to combat infringers is important in realising the full value of that right. Session 4 covers patent infringement, what constitutes infringement, Bolar Exemption from infringement, enforcing patent rights, and the remedies available against infringers. This session will also look at the doctrine of exhaustion of rights as it affects patent infringement in Europe, a key aspect of patent law for generics companies in the EU.

Session 5: **Licensing Patent Rights**
Patents are business assets and their commercial exploitation often requires licensing to be undertaken. To realize the full potential of a patent portfolio, an understanding of licensing is essential. This session reviews the licensing of patent rights, the governing laws and regulations, royalty payments and the form of licensing agreements.

Session 6: **Challenging Patent Validity**
The patents of others can represent major obstacles to your freedom to conduct your business. Accordingly, knowing how to challenge the validity of competitor patents and remove that obstacle is very valuable. Session 6 covers invalidating patents, the grounds for invalidity and the manner in which validity can be challenged.

Session 7: **Patent Specifications as Sources of Information**
Patent specifications are a valuable source of technical information. This session looks at the ways in which patent information can help your business, in terms of developing new and improved technology and also monitoring the activities of others.

Course Leader : Noël J. Akers

Noël is a Chartered Patent Attorney and European Patent Attorney. He is also a Registered Trade Mark Agent in the UK and admitted to practice before the European Community Trade Mark Office. He graduated from the University of Nottingham with a degree in Chemical Engineering, before qualifying in the patent and trade mark profession. Noël has worked with a number of international corporations and law firms. In particular, he spent a considerable length of time practicing European patent law in the United States, where he was involved in a series of major patent litigation cases with actions in both Europe and the US. As a consequence, Noël developed a specialty in coordinating patent procurement and litigation in cases involving actions in the US and Europe.

Noël has acted as an expert on European patent law and provided expert testimony in a number of US patent litigations, in particular provided evidence on aspects of patentability under European patent law and the law of privilege in the UK.

Immediately prior to establishing N.J. Akers & Co., Noël was a partner with Howrey, a major US law firm, managing the patent department of its London Office.

Day One: Tuesday 3 July 2007

08.15 Registration & Coffee

08.55 Chairmans Introduction

KEYNOTE SESSION

09.00 **Generics in Europe: The Challenges and the Opportunities - Strategy and Vision**
- Will generic products be the new wave of growth for the animal health industry?
- Can generic products increase the availability of veterinary products in member states?
- Opportunities and challenges for generics in the animal health industry

Mr Korevaar, *Managing Director,* **Eurovet Animal Health,** The Netherlands

09.40 **Emerging Markets-A Threat or Opportunity?**
- Market dynamics
- Factors for success
- Opportunities for Indian companies in Europe

Asim Banerjee, *VP Animal Health,* **Wockhardt Ltd,** India

10.20 **Out Of Industry Case Study: Two Legs vs Four - Evolution from Human Generics**
- Evolution of the human generic market - what have been the biggest changes, what lessons have been learnt along the way?
- Understanding todays market, the challenges and the potential solutions - What are the potential opportunities and long term prospects?

Alan Sheppard, *Executive VP Europe Generics,* **Dr Reddy's Laboratories Limited,** UK

11.00 Morning Coffee

Latest Updates and Experiences with the New Directive

11.30 **Regulation of Generic Veterinary Medicines: Understanding the Provisions for Registering Off Patent Products under the New Directive**
For this session we have brought together 5 national regulators to discuss and debate national attitudes, procedures and experiences for the registration of off patent products. In this session each speaker will present a 25 minute paper to allow delegates to compare the procedures and attitudes in different member states. This session will be followed by an interactive Q&A session.
- How are member states making use of provisions for the registration of generic products under the new directive?
- Interpretation of the new guideline of 2004 for generics
- Implementation of new directive in national laws
- Which cases do regulators really want studies for and what paperwork and documentation are required?
- Requirements for bridging or hybrid products-what are the rules?
- Dossier requirements and practical advice for dossier submissions
- Experiences to date

Prof Reinhard Kroker, *Head Division,* **BVL,** Germany

Dr Gabriel Beechinor, *Director of Veterinary Medicines,* **Irish Medicines Board,** Ireland
Asbjørn Brandt, *Head of Department,* **Danish Medicines Agency,** Denmark

12.45 Lunch

14.00 **Regulation of Generic Veterinary Medicines: Understanding the Provisions for Registering Off Patent Products under the New Directive (cont)**
Szilvia Speidl, *Deputy Director,* **Directorate of Veterinary Medicinal Products,** Hungary
Dr Ilian Getchev, *Director,* **Institute for Control of VMP,** Bulgaria

14.50 **Regulation of Generic Veterinary Medicines : Interactive Question and Answer Session**
Our panel of regulators will be on hand to answer any questions, provide clarification on grey areas and address any outstanding issues

15.10 Afternoon Tea and High Speed Networking

With high speed networking you can make more new business contacts in one session than most people make in 6 months!

- Network with other professionals, one to one, a few minutes at a time
- Leave with a pocket full of business cards and numerous new business connections
- Chances are you'll meet lots of people you wish you had more time with
- PLUS network with delegates from the co-located Strategic Alliances in the Animal Industry Conference

15.55 **Getting to Grips with New Legislation: Industry Experiences of Registering Products Under the New Directive**

- Article 13 applications
- Data requirements
- Concept of the Global Marketing Authorisation
- European Veterinary Reference Medicinal Product
- Referrals and Serious Risk
- Ecotoxicity

Anne Nallen, Nallen Regulatory Consulting, Ireland
(Formerly Head of Regulatory Affairs, **Cross Vetpharm Group,** Ireland)

16.35 **Case Study: Industry Experiences of Registering Products Under the New Directive**

- Main changes for generics European reference product
- Case study - mutual recognition procedure
- What this means for generics

Cait Brennan, *Veterinary Regulatory Affairs Manager,* **Chanelle Pharmaceuticals Manufacturing Ltd,** Ireland

17.15 **Getting Products to Market Q&A Session**

17.30 End of Day 1

Evening Seminar- Practical Advice on How to Submit Generic Applications in The USA

Registration 18.15 Seminar Start 18.30 Dinner 20.30

The seminar will cover the history and process of obtaining a generic animal drug approval in the United States. The background of the law and practice of the US animal drug approval process will be covered to provide an understanding of the currently approved procedure. Specifics on the generic animal drug process will be covered in detail, discussing eligibility requirements, exceptions that are permitted under the current guidance and the steps generally followed in the development process.

Outline:

1. Background of the animal drug approval process in the United States
2. Generic animal drugs: Underlying principles and regulations
3. Eligibility rules
4. Exceptions to the rules and suitability petitions
5. Manufacturing requirements
6. Current concerns and future issues

Dr David M Petrick, *President and Founder,* **Delta Consortium Regulatory Consulting Ltd,** USA

Day Two: Wednesday 4 July 2007

08.50 Chairmans Introduction

Understanding The Changing Safety Data Requirements and Identifying the Potential Impact on the Generics Industry

09.00 **Target Animal Safety Guideline Update**
Julian Braidwood, *Director,* **Triveritas,** UK

09.30 **Clarification of Ecotox Data Requirements for the Registration of Generic Veterinary Medicine Products**

- To what extent do generic companies need to provide ecotox data?
- What are the challenges that companies face in the generation of ecotox data?
- What are regulators looking for, what is required?
- What are the potential solutions and what studies should be done to avoid the phase 2 assessment?

To be announced please visit www.animalpharmevents.com/generics for further information

Pharmacovigilance for Off Patent Products: What do Generic Companies Really Need to Know?

10.00 **Experiences with the Revised Pharmacovigilance Legislation and Future Challenges**

- PSUR management and assessment
- First experiences from pharmacovigilance inspections
- Signal detection and analysis of pharmacovigilance data

Cornelia Ibrahim, *Head of Department – Support and Surveillance after Authorisation (Post Marketing) of Veterinary Medicinal Products,* **BVL,** Germany

10.30 **Practical Advice for Preparing for Inspections in the UK**
- Who will be inspected?
- When will inspections be conducted?
- What will the inspectors look at?
- Will all MAHs be treated the same?
- What are the outcomes of an inspection?

Caroline Evans, *Pharmacovigilance Assessor,* **Veterinary Medicines Directorate (VMD),** UK

11.00 Morning Coffee

Legal Feature Session

11.40 **The Patent System in Europe and its Implication for the Generics Industry**
- An overview of the European patent system:
  - national vs. EPO
  - a summary of the European patent system
- What may be covered by a patent for a veterinary medicine:
  - novel compounds
  - further use patents
  - formulations
- The term of patents and patent term extensions:
  - patent term
  - supplementary protection certificates (SPCs)
- Challenging patent rights:
  - principles
  - forum and forum choices
  - timing

Noel J Akers, *Principal and Founder,* **N J Akers & Co,** UK

12.10 **The EU Bolar Provision**
- Implementation of the provision
- What does it permit: stockpiling, support for foreign filing, validation runs?
- National differences in scope across EU
- Implication of these differences to generic product manufacturer and studies
- Lessons to be learnt from the US

A Representative, Taylor Wessing, UK

12.40 Lunch

14.00 **Overview and Learnings of Experiences with Global Authoristations**
A Representative, Hogan and Hartson, LLP, Belgium

14.30 **Parallel Import : A Legal Perspective**
- Human vs. veterinary parallel trade
- IP-aspects vs. regulatory aspects
- Selection of landmark and recent case law ECJ (freedom of movement)
- "Kohlpharma" - MRP still required for generics?
- New legal basis - article 65(4) Directive 2001/82/EC

Kristoof Roox, *Partner,* **Crowell and Moring,** Belgium

15.00 Afternoon Tea

15.30 **Recent Litigation in Veterinary Medicines: Lessons Learnt and Potential Impacts**
The case law of the European Court of Justice has traditionally played the role of clarifying and interpreting EU legislation. However, the recent modifications to the Community Code demonstrate a reverse of this tradition. The European Commission acknowledged that the amendments to the provisions of the Code concerning generic products were influenced by the case law of the Court in this area. This session examines questions raised before the Court in a number of areas. Would the attendees have arrived at the same decision as the Court had they been hearing the case?
- Commission Decision approving Flexicam:
  - What method should be used to calculate exclusivity periods?
  - What powers does the European Commission have to approve generic products?
- Case C-431/04 Massachusetts Institute of Technology:
  - What are the criteria that are taken into account in determining what products are entitled to a Supplementary Protection Certificate?
- Case C-368/96 Generics:
  - What exactly is a generic?
  - Did the revision of the Community Code introducing a global authorisation alter the impact of this judgement?
- Case C-112/02 Kohlpharma:
  - Is it really anything new in generic approvals?
- Case T-13/99 Pfizer:
  - The application of the precautionary principle

Elisabethann Wright, *Counsel,* **Hogan and Hartson, LLP,** Belgium

16.30 **Panel – Discussions on the Main Strategies Employed for the Defence of Innovative Products and Attacks for Generic Companies**
Elisabethann Wright, *Counsel,* **Hogan and Hartson, LLP,** Belgium
Kristoof Roox, *Partner,* **Crowell and Moring,** Belgium
Noel J Akers, *Principal and Founder,* **N J Akers & Co,** UK

17.00 End of Conference

Co-located conference

Informa Life Sciences 2nd Annual Veterinary Medicines: Generics, Patents and Parallel Import Summit is co-located with

Strategic Alliances in the Animal Health Industry

3 - 4 July 2007, Hilton Amsterdam, Amsterdam, The Netherlands
www.animalpharmevents.com/alliances

Now in its second year, this is the annual meeting place for business development and alliance management executives from the animal health industry, as well as senior executives from biotech and technology companies

Conference Highlights include:
- Discover large pharma's internal strategy for licensing opportunities: What do they look for in a licensing partnership?
- Benefit from 3 practical case studies on successfully establishing alliances in India, China and Japan. Hear first hand from Bayer Healthcare, Animal Health India, Rokeby Biomed Ltd and Novartis Animal Health
- Interactive practical session to focus on real world scenarios that occur during alliances

Speakers at this event include:

Mark Haxell, *Associate Director,* **Pfizer Animal Health,** UK • **Dr Christian Schirvel,** *Group Director for Business Development,* **Vetoquinol,** France • **Rajesh Aggarwal,** *Country Division Head for Animal Health,* **Bayer Healthcare - Animal Health India,** India • **Dr Keita Kajiwara,** *Head of Registration & Development,* **Novartis Animal Health K.K,** Japan • **Dr Sze-Wee Tan,** *Chief Executive Officer and Managing Director,* **Rockeby biomed Ltd,** Singapore

*******Special Offer for Veterinary Medicines: Generics, Patents and Parallel Import delegates********

Delegates who register for the Veterinary Medicines: Generics, Patents and Parallel Import Summit can attend sessions in this conference free of charge. All networking breaks are co-ordinated to facilitate increased networking opportunities.

"A good and practical update on all aspects of veterinary generics"

(DS Regional Manager, Fort Dodge, Animal Health Generics 2006)

This years "Veterinary Medicines: Generics, Patents and Parallel Import" conference comes at a critical point as companies start to experience the practicalities of working with the new directive and feel the pressure of remaining compliant with the new regulatory guidelines for off patent products. We have once again developed a programme that addresses the needs of the industry and promises to be "the must attend event" for business professionals looking to increase market share and stay one step ahead of the competition in the animal health generics industry.

5 Key reasons to attend

1- The only event to present authority and industry opinions
First hand information and practical advice from : Eurovet Animal Health • Wockhardt Ltd • Dr Reddy's Laboratories Limited • Chanelle Pharmaceuticals Manufacturing Ltd • BVL • Irish Medicines Board • Danish Medicines Agency • Hungarian Directorate of Veterinary Medicinal Products • Bulgarian Institute for Control of VMP • VMD

2- Essential new information and interactive format:
23 information packed sessions provide practical information for delegates to take away and apply whilst dedicated Q&A sessions and informal networking provide an opportunity to get answers and potential solutions to some of the challenges that companies face

3 – Get answers to and debate the most topical issues

- ✓ What are the current challenges and future prospects for the generics industry?
- ✓ How are member states making use of provisions for the registration of generic products under the new directive?
- ✓ What are the real life experiences of regulatory affairs managers of working with the new legislation?
- ✓ What will be the impact of the changes in data requirements for the generics industry?
- ✓ What do generics companies really need to know about pharmacovigilance?
- ✓ What is the current situation with regards to the patent system, Bolar provisions, global authorisations and parallel import?

4 - New for 2007- Choice of 2 Conference Symposia: Maximise your time away from the office by taking advantage of our add on symposia
Pre-Conference Workshop – Patent Law and Practice in Veterinary Medicines
Evening Seminar – Practical Advice on How to Submit Generic Applications in the USA

5- Unrivalled Networking Opportunities: Share and benefit from the experiences of over 80 participants from 19 countries representing Europe, North America, Asia, Africa and the Middle East in 2006. Make more business contacts – network with delegates from the co-located conference " Strategic Alliances in the Animal Health Industry" and take part in the free speed networking sessions

4 Easy Ways to Save Money on Your Registration

You can save money if:

1. You represent an academic or not for profit organisation
2. You are travelling from a new member state or accession country
3. You wish to attend more than one add on symposium
4. You are attending the event with colleagues (substantial group discounts)

To obtain your discount please call Mike Sawicki, Tel: +44 (0)20 7017 5269, email: mike.sawicki@informa.com

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If you provide services or solutions to the animal health industry the 2nd annual Veterinary Medicines: Generics, Patents and Parallel Imports 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.

In 2006 over 80 participants from 19 countries including Australia, Belgium, Bulgaria, Canada, Denmark, France, Germany, Israel, Italy, Japan, New Zealand, Poland, Portugal, Republic of Ireland, Spain, Switzerland, The Netherlands, UK and USA attended the meeting. The conference attracted a senior level international audience from a range of job functions including: President, Vice President, Director Regulatory Affairs Senior Regulatory Manager, Registration Specialist/Officer/ Manager, Regulatory Affairs Manager and Registration and Development Manager.

For further 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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2 Day Pass: Conference & Evening Seminar	3-4 June 2007	CQ8024CY	£1249 + VAT (19%) = £1486.31	☐	£1349 + VAT (19%) = £1605.31	☐	£1449 + VAT (19%) = £1724.31	☐
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Full pass: Conference & evening seminar & pre-conference workshop	2-4 June 2007	CQ8024CXY	£1649 + VAT (19%) = £1962.31	☐	£1749 + VAT (19%) = £2081.31	☐	£1849 + VAT (19%) = £2200.31	☐

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