ANIMAL PHARM EVENTS

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HEAR FROM & NETWORK WITH NO LESS THAN 11 REGULATORS!!

Informa Life Sciences' 5th Annual:

Regulation of Veterinary Medicines in Europe 2009

Addressing key regulatory challenges and legislative amendments for veterinary innovator, generic and biological products

4-5 March 2009 • Movenpick Hotel • Prague • Czech Republic

www.informa-ls.com/regvetmed

New comprehensive agenda in an expanded one-track format – no need to miss any sessions – ensures you leave fully updated and aware of the implications of the key regulatory developments for originator, generic and biological submissions

Dear Colleague,

Animal Pharm and Informa Life Sciences are delighted to provide you with full details of the 5th Annual Regulation of Veterinary Medicines in Europe 2009 conference. To fully address your concerns at this critical time - with many companies dealing with costly referrals and recent legislative amendments impacting current and future practices - we have packed even more into the agenda than ever before to bring you a programme tackling regulatory strategies for innovator, generic and biological products.

New for 2009...

- ✓ **REFERRAL PROCEDURE FOCUS SESSION** – Learn about the referral process from the Chair of the CMDv, Esther Werner. Understand the common triggers for a referral, if it is possible to avoid one and if not how to reduce its impact on your budgetary plans.
- ✓ **THE EUROPEAN REFERENCE PRODUCT AND GENERIC PRODUCT REGISTRATIONS FOCUS SESSION** – Develop successful strategies for registering auto-generics or generic products in countries where the originator is not – PLUS invaluable tips for proving bioequivalence.
- ✓ **ADVICE ON PERFORMING THE ENVIRONMENTAL RISK ASSESSMENT FROM THE REGULATORS** – Hear directly from the regulators how to produce a successful ERA, understand common submission problems and how to overcome them.
- ✓ **THE NEW VARIATIONS PROCEDURE** – Understand exactly how this hotly anticipated new legislation will impact current procedures

In addition to this, Regulation of Veterinary Medicines in Europe will address ALL the important questions every regulatory affairs professional is concerned with:

- + **Feedback from the regulators on the MRP and the DCP** – How many dossiers have been submitted and using which procedures? What are the common hurdles that industry has faced with the registration procedures and how are these overcome?

Continued overleaf

FOR MORE INFORMATION ON **THE REGULATION OF VETERINARY MEDICINES** OR TO MAKE A BOOKING, SIMPLY TEL: +44 (0) 207 017 7481 OR EMAIL: **REGISTRATIONS@INFORMA-LS.COM** QUOTING 'CQ8092'

- **Where are we with implementation?** – Discuss the successes and how to overcome the hurdles of harmonised registration procedures across Europe
- **How will electronic dossier submissions work?** – Which agencies will accept E-dossier submission? Exactly how harmonised will the procedure be? Will it save you time?
- **What is the future of animal health regulation in Europe?** - Learn what the future regulatory developments in Europe will be with presentations from key European regulators
- **Will the PSUR pilot scheme be rolled out across Europe?** - Discover how successful this pilot was and if will it be rolled out throughout Europe

MEET THE REGULATORS INCLUDED IN OUR EXPERT SPEAKER LINE-UP!

1. **Lesley Johnson,** *Head of Pharmaceuticals and Feed Additives,* **Veterinary Medicines Directorate,** UK
2. **Esther Werner,** *Chair CMDv, Head of Veterinary Bacteriology,* **Paul-Ehrlich-Institut,** Germany
3. **Gérard Moulin,** *Deputy Director,* **ANMV/AFSSA,** France
4. **Bettina Rechenberg,** *Head of Section "ERA of Pharmaceuticals, Washing and Cleansing Agents, Nano Materials",* **Federal Environment Agency (UBA),** Germany
5. **Alex Tait,** *Senior Environmental Safety Assessor,* **Veterinary Medicines Directorate,** UK
6. **Silke Hickmann,** *Environmental Risk Assessor,* **Federal Environment Agency (UBA),** Germany
7. **Per Helboe,** *Senior Director, Licensing Division,* **Danish Medicines Agency,** Denmark
8. **Carmen Jungback,** *Head of Veterinary Virology,* **Paul Ehrlich Institut,** Germany
9. **Michèle Dagorn,** *Head of Pharmacogivilance Unit,* **ANMV/AFSSA,** France
10. **Eva Zubrová,** *Pharmacovigilance Assessor / Inspector,* **Institute for State Control of Veterinary Biologicals and Medicaments,** Czech Republic
11. **Gesine Hahn,** *Senior Assessor and Head the Veterinary Assessment,* **Federal Office of Consumer Protection and Food Safety (BVL),** Germany and Member of the **EMEA/CVMP Efficacy Working Party (EWP)**

PLUS 3 CUSTOM-DESIGNED, INTERACTIVE WORKSHOPS AND SYMPOSIUM:

1. **Legal and Regulatory Strategies for Veterinary Medicines** – Tuesday 3 March 2009 - Led by a panel of legal experts. For full details go to **www.informa-ls.com/regvetmed**
2. **Environmental Risk Assessment of Veterinary Medicines** – How the Regulators do it – Evening of Wednesday 4 March 2009 – Led by -**Alex Tait,** *Senior Environmental Safety Assessor,* **Veterinary Medicines Directorate,** UK
3. **Proving Bioequivalence for Veterinary Medicinal Products** – Friday 6 March 2009 – Led by **Pascal Richez,** *Chairman,* **TransPharm,** France

I look forward to welcoming you to what promises to be an exciting event in 2009.

Kind regards,

Gemma Cook
Senior Conference Producer
Informa LifeSciences

The most comprehensive Animal Health Regulatory Affairs professionals' conference, **Regulation of Veterinary Medicines in Europe 2009** has been exhaustively researched with industry and regulatory input, ensuring it addresses the concerns of you and your colleagues – **CONSULT YOUR PRIORITY COPY OF THE BROCHURE FOR FULL AGENDA DETAILS INCLUDING OUR EXPERT SPEAKER LINE-UP!**

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