Global Animal Health Conference

Global Availability of Veterinary Medicines - Providing a Climate for Science and Innovation

Event #11106
23-24 March 2011
European Medicines Agency, Canary Wharf, London, United Kingdom

Programme Co-Chairs

Barbara Freischem, Executive Director, International Federation for Animal Health (IFAH), AISBL, Belgium

David Mackay, Head of Unit Veterinary Medicines and Product Data Management, European Medicines Agency, EU

Programme Committee

Rene Aerts, Vice-President R&D Biologicals, Intervet-Schering-Plough Animal Health, The Netherlands

Ellen de Brabander, Chief Scientific Officer and Head of Global R&D, MERIAL Limited, USA

Elisabeth Erlacher-Vindel, Deputy Head of Scientific and Technical Department, The World Organisation for Animal Health (OIE), France

Kornelia Grein, Head of Sector Veterinary Medicines, European Medicines Agency, EU

Rick Hill, Director, Center for Veterinary Biologics USDA, Animal and Plant Health Inspection Service, Veterinary Services, USA

Anja Holm, Senior Scientific Officer, Department of Veterinary Medicinal Products, Danish Medicines Agency, Denmark, and Chair of the Committee for Medicinal Products for Veterinary Use (CVMP)

Jeffrey C. Mariner, Veterinary Epidemiologist, International Livestock Research Institute (ILRI), Kenya

Jan Slingenbergh, Senior Officer, Infectious Diseases, Emergency Prevention Systems (EMPRES), Food and Agricultural Organisation of the United Nations (FAO), Italy

Steven D. Vaughn, DVM Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, U.S. Food and Drug Administration, USA

Wilhelm von Trott zu Solz, representing Boehringer Ingelheim Animal Health, Germany

Who Will Attend

Professionals with an interest in the latest scientific developments in animal health from the pharmaceutical industry, academia, regulatory and governmental agencies worldwide.

Overview

This conference provides an excellent platform to discuss the opportunities and challenges of ensuring an adequate supply of up-to-date medicines to meet the needs of animals around the world. The conference will also recognise the one world, one health concept which underlines that health in animals promotes health in humans.

Key Topic - Availability

Defining the problem
- What do we mean by availability and what should we do about it?
- Developed versus less-developed world
- Maintain existing products versus bringing new products to market

Role of veterinary medicines in disease control
- Vaccines - Current approaches
- Antimicrobials – Maintaining appropriate access for veterinary use

Regulation of medicines - Lessons from applying better regulation principles
- MUMS (The Minor Use and Minor Species) versus 'full' market products
- What is 'better regulation' and what benefits does it bring to regulators and industry?
- Cooperation in the less developed world
- Lessons from regional cooperation
- VICH 4 and the outreach programme

Innovation – Encouraging new products to market
- Status report on innovation
- Regulators approach to stimulating innovation
- Building alliances to promote innovation
- Feedback on successes and key learnings

Learning Objectives

This conference will enable participants to keep abreast of advances in research and development in working towards an environment that is both predictable and exciting for the availability of new and innovative veterinary medicines.

About the DIA

The DIA is a neutral, global, professional, member-driven association of nearly 18,000 biotechnology, pharmaceutical, clinical or medical, academic and regulatory professionals, students and patient representatives. Through its international meetings, training courses, online learning and myriad of networking opportunities, the DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies, and services to improve health and well-being worldwide. Headquarters are in Horsham, PA, USA, with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India, and Beijing, China. For more information, visit www.diahome.org or call the DIA in Europe +41 61 225 51 51.

About EMA

The European Medicines Agency is a decentralised agency of the European Commission whose main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

About IFAH

IFAH (International Federation for Animal Health) is the federation representing manufacturers of veterinary medicines, vaccines and other animal health products worldwide. It represents both corporate members and national as well as regional animal health associations. These associations comprise both local medium-size enterprises (SMEs) and international companies.

IFAH Healthy Animals Healthier World | EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH | DIA® www.diahome.org

WEDNESDAY | 23 MARCH 2011

08:00 REGISTRATION

09:00 Session 1

OPENING SESSION
Session Chairs:
Barbara Freischem, Executive Director, International Federation for Animal Health (IFAH), AISBL, Belgium
David Mackay, Head of Unit Veterinary Medicines and Product Data Management, European Medicines Agency, EU

Opening Address
Andreas Pott, Acting Executive Director, European Medicines Agency, EU

Opening Address
Barbara Freischem, Executive Director, International Federation for Animal Health (IFAH), AISBL, Belgium
David Mackay, Head of Unit Veterinary Medicines and Product Data Management, European Medicines Agency, EU

Availability of Veterinary Medicines
Eric Maree, President of the IFAH Board of Directors, Chairman of the Executive Board of Virbac S.A., France

09:45 Session 2

THE NEED FOR VETERINARY MEDICINES IN A GLOBAL CONTEXT
Session Chairs:
Jeffrey C. Mariner, Veterinary Epidemiologist, International Livestock Research Institute (ILRI), Kenya
Wilhelm von Trott zu Solz, representing Boehringer Ingelheim Animal Health, Germany

What Are the Needs for Veterinary Medicines at a Global Level?
Jan Slingenbergh, Senior Officer, Infectious Diseases, Emergency Prevention Systems (EMPRES), Food and Agricultural Organisation of the United Nations (FAO), Italy

Recent OIE Initiatives and Resolutions Relating to Veterinary Medicines and their Expected Impact on Availability and Use
Elisabeth Erlacher-Vindel, Deputy Head of Scientific and Technical Department, The World Organisation for Animal Health (OIE), France

4 Key Contributions of Veterinary Medicines to Society
Wilhelm von Trott zu Solz, representing Boehringer Ingelheim Animal Health, Germany

10:45 COFFEE BREAK

11:15 Session 2 (continued)

THE NEED FOR VETERINARY MEDICINES IN A GLOBAL CONTEXT
Session Chairs:
Jeffrey C. Mariner, Veterinary Epidemiologist, International Livestock Research Institute (ILRI), Kenya
Wilhelm von Trott zu Solz, representing Boehringer Ingelheim Animal Health, Germany

Experience with Regulating Innovative Products and Technologies
Eva Bennet-Jenkins, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority (APVMA), Australia

The Role of Veterinary Medicines in Building Trust in Safe Food – "Food Security"
Jeff Waage, Director, London International Development Centre (LIDC), United Kingdom
Jonathan Rushton, Senior Lecturer, The Royal Veterinary College, United Kingdom

What Is Needed to Promote Availability?
Albert Douffissa, Veterinarian – Expert in Distribution of Veterinary Medicines in Central African Markets, Cameroon

Consolidation of the Animal Health Industry and its Impact on Availability
Joachim Hasenmaier, CEO, Boehringer Ingelheim, Germany

Panel Discussion

13:00 LUNCH

14:00 Session 3

REGULATION APPROPRIATE FOR NEEDS
Session Chairs:
David Mackay, Head of Unit Veterinary Medicines and Product Data Management, European Medicines Agency, EU
Ellen de Brabander, Chief Scientific Officer and Head of Global R&D, MERIAL Limited, USA

Presentations from the following speakers and a round table discussion
- Gary Bosch, Global Head, Research & Development, Novartis Animal Health, Switzerland
- Baptiste Dungu, Senior Director, Research & Development, Global Alliance for Livestock Veterinary Medicines (GALVmed), United Kingdom
- Rick Hill, Director, Center for Veterinary Biologics USDA, Animal and Plant Health Inspection Service, Veterinary Services, USA
- Anja Holm, Senior Scientific Officer, Department of Veterinary Medicinal Products, Danish Medicines Agency, Denmark, and Chair of the Committee for Medicinal Products for Veterinary Use (CVMP)
- Jeffrey C. Mariner, Veterinary Epidemiologist, International Livestock Research Institute (ILRI), Kenya
- Steven D. Vaughn, DVM Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, U.S. Food and Drug Administration, USA

Discussion, Explanation of Break Out Sessions

15:30 COFFEE BREAK

16:00 Session 3 (continued)

REGULATION APPROPRIATE FOR NEEDS
Session Chairs:
David Mackay, Head of Unit Veterinary Medicines and Product Data Management, European Medicines Agency, EU
Ellen de Brabander, Chief Scientific Officer and Head of Global R&D, MERIAL Limited, USA

Discussion in Break Out Sessions

Group 1: What are the main obstacles to availability and how can they be overcome?
Rhona Banks, Director Regulatory Affairs, Triveritas

Group 2: What is 'better regulation' and how can it be promoted?
Anja Holm, Senior Scientific Officer, Department of Veterinary Medicinal Products, Danish Medicines Agency, Denmark and Chair of the Committee for Medicinal Products for Veterinary Use (CVMP)

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited the 'Global Animal Health Conference' with 12.5 credits. All participants are eligible for these credits.

Group 3: In what areas does a common regulatory approach between regions make sense and what can be done at an international level to promote convergence of approach?
Steven D. Vaughn, DVM Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, U.S. Food and Drug Administration, USA

Reporting from Break Out Groups and Plenary Discussion

17:30 END OF DAY ONE

19:00 CONFERENCE DINNER

THURSDAY | 24 MARCH 2011

08:30 **Session 4**

INNOVATION IN VETERINARY MEDICINES AND APPROPRIATE REGULATION
Session Chairs:
Barbara Freischem, Executive Director, International Federation for Animal Health (IFAH), AISBL, Belgium
Steven D. Vaughn, DVM Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, U.S. Food and Drug Administration, USA

Innovation in Veterinary Medicine: Needs and challenges
Jeffrey Simmons, President, Elanco Animal Health, USA

Embracing New Innovation in Veterinary Drug Evaluation
Steven D. Vaughn, DVM Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, U.S. Food and Drug Administration, USA

Innovative Medicines at the European Medicines Agency - Experience and challenges
Falk Ehmann, Scientific Support and Projects, Human Medicines Development and Evaluation Unit, European Medicines Agency, EU

What Types of New Innovations Can we Expect in the Future?
Ellen de Brabander, Chief Scientific Officer and Head of Global R&D, MERIAL Limited, USA

Discussion

10:00 COFFEE BREAK

10:30 **Session 4 (continued)**

INNOVATION IN VETERINARY MEDICINES AND APPROPRIATE REGULATION
Session Chairs:
Barbara Freischem, Executive Director, International Federation for Animal Health (IFAH), AISBL, Belgium
Steven D. Vaughn, DVM Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, U.S. Food and Drug Administration, USA

Risk Management and Public Fears – How to secure trust and public support?
Steve Kopperud, Executive Vice President, Policy Directions Inc., USA

Particular Challenges Represented by Biologically Active Molecules in Food-producing Species
Nikolaus Križ, Development and Evaluation of Veterinary Medicines, European Medicines Agency, EU
Mahesh Kumar, Executive Director, Global Biologics Research, VMRD, Pfizer Animal Health, USA

One World, One Health
Rene Aerts, Vice-President R&D Biologicals, Intervet-Schering-Plough Animal Health, The Netherlands

What are the Impediments to Authorisation of New Veterinary Medicines and How can They Best be Overcome?
Panel Discussion

12:30 LUNCH

13:30 **Session 5**

MAINTAINING AVAILABILITY OF EXISTING PRODUCTS
Session Chairs:
Kornelia Grein, Head of Sector Veterinary Medicines, European Medicines Agency, EU
Rene Aerts, Vice-President R&D Biologicals, Intervet-Schering-Plough Animal Health, The Netherlands
Challenges with Retaining Existing Antimicrobials
Ludwig Klostermann, Bayer Animal Health GmbH, Germany

Other Challenges to Maintaining Availability of Veterinary Medicines
Peter Holdsworth, Chief Executive Officer, Animal Health Alliance, Australia
Gabriel Beechinor, Director of Veterinary Medicines, Veterinary Medicines Department, Irish Medicines Board, Ireland

The Veterinarians View on Global Needs for Veterinary Medicines
Rens van Dobbenburgh, AUV, The Netherlands

Legislative Framework to Support Availability
Martinus Nagtzaam, European Commission, Belgium

15:20 **Session 6**

MEETING THE ANIMAL HEALTH NEEDS FOR THE 21ST CENTURY
Session Chairs:
Rick Hill, Director, Center for Veterinary Biologics USDA, Animal and Plant Health Inspection Service, Veterinary Services, USA
Elisabeth Erlacher-Vindel, Deputy Head of Scientific and Technical Department, The World Organisation for Animal Health (OIE), France

16:00 END OF CONFERENCE

REGISTRATION FORM

Global Animal Health Conference

23-24 March 2011 | European Medicines Agency, Canary Wharf, London, United Kingdom

ID # 11106

DIA www.diahome.org

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes lunch and coffee breaks

CATEGORY	Fee
Industry	€ 950.00 ❑
Government/academia/non profit (full-time)	€ 475.00 ❑
Conference Dinner, Wednesday night, 23 March 2011 at 19:00 at the EMA	€ 55.00 ❑

Group discounts, student fees and special discount for SME (status confirmed by EMA) available. Please contact DIA Europe for details.

TOTAL AMOUNT DUE: €_____ **NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT**

11106DIAWEB

RESPONSIBILITY/INTEREST AREA | Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line.

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__ Clinical Data Management/ eClinical
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__ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Manufacturing
__ Medical Communications
__ Medical Writing
__ Non-clinical
__ Outsourcing
__ Comparative Effectiveness/Health Technology Assessment/ Evidence-based Medicine
__ Pharmacology
__ Pricing/Reimbursement
__ Project Management
__ Professional Education, Training & Development
__ Public Policy/Law/ Corp. Compliance
__ Quality Assurance/Quality Control
__ Regulatory Affairs
__ Research & Development
__ Statistics
__ Strategic Planning
__ IT/Validation

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'S BUSINESS CARD HERE

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PAYMENT METHODS - Credit cards are the preferred payment method.

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❑ Cheques should be made payable to: DIA and mailed together with a copy of the registration form to facilitate identification to: DIA, Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland

❑ Bank transfers: When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." including your name, company, Meeting ID# 11106 as well as the invoice number to ensure correct allocation of your payment.
Payments must be net of all charges and bank charges must be borne by the payer.

Persons under 18 are not allowed to attend DIA meetings.

CANCELLATION POLICY

All cancellations must be in writing and received with DIA Europe office by 17:00 CET on 15 March 2011

Cancellations received by the date above are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/non-member) = € 200.00. Government/Academia/Non-profit (Member/non-member) = € 100.00. Tutorial cancellation: € 50.00. Registered attendees who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registered attendees are responsible for cancelling their own hotel reservations. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe is not responsible for airfare, hotel or other costs incurred by registrants.

Transfer Policy
You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute registrants will be responsible for the non-member fee, if applicable. Please notify DIA Europe office of any such substitutions as soon as possible.

IMPORTANT: Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.

HOW TO REGISTER

DIA Europe Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

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