

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)

Juan Lubroth, Senior Officer, Food and Agricultural Organisation of the United Nations (FAO), Italy

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

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.



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

09:00 Opening Address

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

Opening Address

European Parliament representative invited

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?

Juan Lubroth, Senior Officer, Food and Agricultural Organisation of the United Nations (FAO), Italy

Recent OIE Initiatives and Resolutions Relating to Veterinary Medicines and Their Expected Impact on the Availability and Use of Veterinary Medicines

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

One World, One Health

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

The Role of Veterinary Medicines in Building Trust in Safe Food – “Food Security”

Industry speaker invited

What Is Needed to Promote Availability?

Albert Doufissa, Merial's Agent for Central Africa, Africa

Globalisation of the Animal Health Industry and its Impact on Availability

Joachim Hasenmaier, CEO, Boehringer Ingelheim, Germany

The Veterinarians View on Global Needs for Veterinary Medicines

World Veterinary Association representative invited

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

- Institute of Veterinary Drug Control (IVDC), China representative invited
- Global Alliance for Livestock Veterinary Medicines (GALVmed), United Kingdom representative invited
- 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

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

17:30 END OF DAY ONE

19:00 CONFERENCE DINNER

THURSDAY | 24 MARCH 2011

09:00 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

Continuing Education Information

DIA meetings and trainings are generally accredited by the SwAPP (Swiss Association of Pharmaceutical Professionals), Commission for Professional Development (CPD) and SGPM (Swiss Society of Pharmaceutical Medicine). All participants are eligible for these credits.

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

The Human Medicines Sector Approach to the Challenge

European Medicines Agency representative invited

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**10:30 COFFEE BREAK****11:00 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

Industry speaker invited

European Medicines Agency representative invited

Experience with Regulating Innovative Products and Technologies

Canadian Food Inspection Agency representative invited

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

Panel Discussion

13:00 LUNCH**14:00 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

Legislative Framework to Support Availability

Martinus Nagtzaam, European Commission, Belgium

Challenges with Retaining Existing Antimicrobials

Michael Londershausen, Head of R&D, Bayer Animal Health GmbH, Germany

Other Challenges to Maintaining Availability of Veterinary Medicines

Peter Holdsworth, Chief Executive Officer, Animal Health Alliance, Australia

European Medicines Agency representative invited

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

Unless otherwise disclosed, DIA Europe acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA Europe.

Speakers and agenda are subject to change without notice. Recording of any DIA Europe tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA Europe.

HOTEL INFORMATION

The DIA has blocked a limited number of rooms at the following two hotels:

Hilton London Docklands Riverside

265 Rotherhithe Street - SE16 5HW London - United Kingdom

Tel: +44 (0)20 7231 1001 - Fax: +44 (0)20 7231 0599

Email: reservations.docklands@hilton.com

www.hilton.com

at the rate of:

£ 149.00 per room inclusive of breakfast, exclusive of VAT

To book a room, please click on the hotel link available on the DIA website. Please fill in corporate account number: GDIAC. Rooms are available on a first-come first-serve basis.

The hotel is situated opposite Canary Wharf conveniently connected by a shuttle boat. The landing stage is in walking distance of the European Medicines Agency (2 min). A three day ferry ticket is included in the room rate. Please make sure you receive it when checking in. For further information, please go to: http://www1.hilton.com/en_US/hi/hotel/LONNDHI-Hilton-London-Docklands-hotel/index.do

De Vere Venue Devonport House

King William Walk - Greenwich - SE10 9JW London - United Kingdom

Tel: +44 (0)20 8269 5400 - Fax: +44 (0)20 8269 5422

www.deverevenues.co.uk

at the rate of:

£ 149.00 per room inclusive of breakfast, exclusive of VAT

To book a room at the Devonport House, please contact Eileen Murnane directly via email EMurnane@deverevenues.co.uk or by phone +44 (0)20 8269 5443. Rooms are available on a first-come first-serve basis. The Devonport House is situated on the World Heritage Site in Greenwich and Greenwich station is only a short walk away with easy access to London city by tubes and trains. Travel time is approximately 20 minutes.

Important: Please complete your reservations by 21 February 2011 at the latest. Reservations received after this date will be subject to hotel availability and room rate may vary.

REGISTRATION FORM

Global Animal Health Conference

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

ID # 11106



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 <input type="checkbox"/>
Government/academia/non profit (full-time)	€ 475.00 <input type="checkbox"/>
Conference Dinner, Wednesday night, 23 March 2011 at 19:00 at the EMA	€ 55.00 <input type="checkbox"/>

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**

11106DIA

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.

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

REGISTRANT

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

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Please indicate your professional category: Academia Government
 Industry Contract Service Organisation

PAYMENT METHODS - Credit cards are the preferred payment method.

Please charge my credit card - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

VISA MC AMEX

Card Number

Exp. Date

Cardholder's Name

Date

Cardholder's Signature

Cheques should be made payable to: DIA and mailed together with a copy of the registration form to facilitate identification to: DIA, Elisabethen Anlage 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.

Online www.diahome.org

Fax +41 61 225 51 52

Email diaeurope@diaeurope.org

Mail DIA Europe
Postfach, 4002 Basel, Switzerland