EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Veterinary Medicines Info Day

14-15 March 2024
EMA, Amsterdam

The European Medicines Agency is organising the annual Veterinary Medicines Info Day to provide stakeholders with the latest updates on regulatory policy, and scientific and legislative developments in the veterinary medicines domain. This year, updates will include information on

- Veterinary pharmacovigilance
- Latest updates from VICH, the CVMP Efficacy Working Party and the CVMP Novel Therapies Working Party
- Focussed information on antiparasitic veterinary medicines and vaccines availability.

The event will also provide opportunities for participants to ask questions. Participation in person at the EMA premises in Amsterdam is encouraged to make full use of the networking breaks. A broadcast will be available on the EMA website during the event, and the video recording will be made available after the event.

EMA Veterinary Medicines Info Day 2024

Chaired by Ivo Claassen (EMA)

Day 1: 14 March 2024

13:30	**Registration**	
14:00	**Welcome and introduction**	
	Emer Cooke (EMA) and Ivo Claassen (EMA)	**10'**
14:10	**Session 1: Legislative updates**	
	Implementation of Regulation (EU) 2019/6 *Alfonso Las Heras (European Commission)*	**20'**
	Implementation of Pharmacovigilance requirements *James Mount (Chair of the CVMP Pharmacovigilance Working Party)*	**20'**
	Industry perspective on Pharmacovigilance *Andreas Werner (AccessVetMed)* *Sonja Schwab (AccessVetMed)*	**20'**
	Questions	**30'**
15:40	**Networking break**	
16:10	**Session 2: Regulatory updates**	
	CVMP workplan for 2024 and beyond *Johan Schefferlie (Chair of CVMP)*	**20'**
	VICH: latest developments and perspective *Nicholas Jarrett (EMA)*	**20'**
	Regulatory and procedural developments *Emily Drury (EMA)*	**20'**
	Questions	**30'**
17:40	**Close of Day 1**	

Day 2: 15 March 2024

09:00 Session 3: Latest scientific guidance

Update from the CVMP Efficacy Working Party *Cristina Muñoz Madero (Chair of CVMP Efficacy Working Party)*	**20'**
Overview on available guidance for antiparasitic veterinary medicines *Valentin Nicorescu (EMA)*	**20'**
Industry perspective *Klaus Hellmann (Association of Veterinary Consultants)*	**20'**
Questions	**30'**

10:30 Networking break

11:00 Session 4: Focus on innovation

Update from CVMP Novel Therapies Working Party *Jacqueline Poot (Chair of CVMP Novel Therapies Working Party)*	**20'**
Focus on vaccines availability and response to emerging diseases *Javier Pozo Gonzalez (EMA)*	**20'**
Industry perspective *Emmanuelle Royer (AnimalHealthEurope)*	**20'**
Questions	**30'**

12:30 Closing remarks

Wrap up *Ivo Claassen (EMA)*	**15'**

List of speakers

Alfonso Las Heras	European Commission
Andreas Werner	Bela-Pharm GmbH & Co KG
Cristina Muñoz Madero	Chair of the CVMP Efficacy Working Party
Emer Cooke	European Medicines Agency
Emmanuelle Royer	Boehringer Ingelheim
Emily Drury	European Medicines Agency
Ivo Claassen	European Medicines Agency
Jacqueline Poot	Chair of the CVMP Novel Therapies and Technologies Working Party
James Mount	Chair of the CVMP Pharmacovigilance Working Party
Javier Pozo Gonzalez	European Medicines Agency
Johan Schefferlie	Chair of the Committee for Veterinary Medicinal Products
Klaus Hellmann	Klifovet GmbH
Nicholas Jarrett	European Medicines Agency
Sonja Schwab	VetViva Richter GmbH
Valentin Nicorescu	European Medicines Agency

About the speakers

Dr Alfonso Las Heras

Deputy Head of Unit, DG SANTE, European Commission

Alfonso graduated in veterinary medicine at the Complutense University of Madrid in 1996 and holds a PhD in microbiology. Before joining the European Commission in 2012, he worked for the animal health industry organisation in Spain and the Spanish Technology Platform for Animal Health. Within the Commission, he was responsible for matters related to the authorisation of biocidal products in DG ENV and DG SANTE for seven years. In 2019 he became policy assistant in Directorate E of DG SANTE (Food and feed safety and innovation), where he acquired a broad experience on a number of policy areas, such as food labelling, food contact materials, GMOs, pesticides, feed and veterinary medicinal products. He also closely followed the implementation of some of the flagship initiatives under the European Green Deal, such as the Farm to Fork Strategy and the Chemicals Strategy for Sustainability. Alfonso joined Unit D4 as deputy Head of Unit in November 2022.

Dr Andreas Werner

QPPV and Senior regulatory affairs at Bela-Pharm GmbH & Co KG

Andreas Werner graduated as a veterinarian from the Justus Liebig University in Gießen in 1987, where he completed his doctorate in anatomy in 1990. Since 1990 he has been working in veterinary pharmaceutical industry as Regulatory Affairs Manager, Information Officer, Qualified Person and Qualified Person for Pharmacovigilance.

He is currently Chair of the Pharmacovigilance Working Group of Access VetMed, representing industry at the PhVMP-V interested parties meetings and Pharmacovigilance Joint Implementation Group (JIG) meetings.

Dr Cristina Muñoz Madero

Chair of the CVMP Efficacy Working Party

Cristina Muñoz Madero graduated in Veterinary Medicine at the Complutense University of Madrid, and holds a degree in Business Administration and Management, from the Business Confederation of Madrid. Working at Spanish Agency for Medicines and Health Products (AEMPS) since 1990, she is the Head of the efficacy service and preclinical/clinical area and centralised procedures.

Coordinator for the "National Action Plan to reduce risks of antibiotic resistance in Human/Veterinary Medicine" since 2014 and CVMP member for Spain since 2005, she is also the chair of the CVMP Efficacy Working Party since 2017.

Emily Drury

Head of Veterinary Regulatory Affairs and Referrals, European Medicines Agency

Emily holds a master's degree in Biological Sciences from the University of Oxford. She has over twenty years of experience in veterinary regulatory affairs. After 9 years working for a regulatory consultancy, she joined the EMA's Veterinary Medicines Division in 2009 and has since held several regulatory expert and management roles covering diverse activities. Emily has recently been appointed *ad interim* Head of Department for Veterinary Surveillance and Regulatory Support (V-SR).

Emmanuelle Royer

Head of Regulatory Affairs Biologicals Veterinary Public Health & Emerging Diseases, Boehringer Ingelheim

Emmanuelle Royer is a veterinarian with a master's degree in pharmacokinetics pharmacology and industry management. Emmanuelle has a long experience in the veterinary pharmaceutical industry, both in bio and pharma, where she was R&D Project Leader, Head of Preclinical and Regulatory Affairs. Since 2018, she holds the position of Head of Regulatory affairs Biologicals Veterinary Public Health and emerging diseases.

Dr Ivo Claassen

Head of Veterinary Medicines, European Medicines Agency

Dr Ivo Claassen is head of the Veterinary Medicines Division and Deputy Executive Director at the European Medicines Agency. Since he joined the Agency in 2018, he has been responsible for the implementation of Veterinary medicinal products regulation. Furthermore, he was involved in the development of the Veterinary Regulatory Science Strategy and the EMA Veterinary Big Data strategy. He has also over 30 years of experience in vaccine production, QC/QA, R&D and regulatory affairs, both for human and veterinary vaccines.

Dr Jacqueline Poot

Chair of the Novel Therapies and Technologies Working Party

Jacqueline graduated as a farm animal vet from Utrecht University and has worked in farm animal and companion animal practice. Her PhD work was focused on Canine Leishmaniasis disease models and vaccination. Jacqueline was a project leader in the biological R&D of a large pharmaceutical company for 12 years. In 2013 Jacqueline joined the veterinary department of the Dutch regulatory authority as an assessor and in 2017, a member of the CVMP Scientific Advice Working Party.

Since 2020 she is CVMP member for The Netherlands, and since 2021 the chair of the Novel Therapies & technologies Working Party (NTWP).

Dr James Mount

Chair of the CVMP Pharmacovigilance Working Party

James Mount is the chair of the CVMP Pharmacovigilance Working Party (PhVWP-V) since November 2023. He is an expert in the HMA/EMA Veterinary Data Hub, a member of the informal PhVWP-V-Inspectors Working Group Data Quality subgroup and an expert in the Pilot-Signal Management Expert Group. James qualified as a veterinarian from the University of Liverpool (UK) in 2008 and holds a PhD from the Royal Veterinary College (London, UK).

He started as a rural mixed practice veterinarian in the UK and progressed to roles such as Veterinary Pathologist at the Swedish Veterinary Agency and Laboratory Animal Veterinarian at the Karolinska Institute (Sweden). In 2018, he became a Pharmacovigilance assessor at the Swedish Medical Products Agency.

Dr Javier Pozo Gonzalez

Scientific Specialist, European Medicines Agency

Javier Pozo Gonzalez graduated as a veterinarian in 1995 and holds a PhD on animal infectious diseases and epidemiology. His area of expertise is veterinary vaccinology, having worked in research, development, and authorisation of veterinary vaccines for more than 20 years. He held different positions in academia, industry, and regulatory agencies. Javier worked at the Veterinary Medicines Directorate in the UK as a scientific assessor where he became Head of the Biologicals Assessment Team, He joined the European Medicines Agency in 2018 as a Senior Scientific Specialist in the Biologicals and Emerging Therapies service of the Veterinary Division. He also acts as scientific secretary to the CVMP Immunologicals Working Party and represents the Agency in the Vaccines, sera for veterinary use of the European Pharmacopoeia.

Johan Schefferlie

Chair of the Committee for Veterinary Medicinal Products (CVMP)

Johan Schefferlie is the chair of the CVMP. Biologist by training, Johan has been a Senior Regulatory Project Leader at the Dutch Medicines Evaluation Board since 2007. With extensive experience in toxicological and consumer risk assessment of residues of veterinary drugs in food of animal origin, he has collaborated as an expert for the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), the European Food Safety Authority and the Joint WHO/FAO Expert Committee on Food Additives (JECFA), co-authoring several reports.

Dr Nicholas Jarrett

Head of Veterinary Pharmaceuticals, European Medicines

Nick has worked in the Veterinary Medicines Division of the European Medicines Agency (EMA) since 2007. He has a background in pharmacology and toxicology and has spent much of his time at EMA working on consumer and user safety topics. Since 2017 he has been Head of Pharmaceuticals Service within the Evaluation and Innovation Support Department of the Veterinary Medicines Division where, in addition to having responsibility for oversight of applications for pharmaceutical VMPs and MRLs, he coordinates EMA's contributions to the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) and VICH. Before joining the EMA he worked as a nonclinical assessor at the UK Medicines and Healthcare Products Regulatory Agency and before that he held a number of short term laboratory-based positions in academia and industry and dabbled in medical writing.

Sonja Schwab

Deputy QPPV and Team leader clinical development, VetViva Richter GmbH

Sonja Schwab graduated as veterinarian from the University of Veterinary Medicine in Vienna. She has been working in the sector of viral vector therapy for the treatment of cancer at the Institute of Virology at the University of Veterinary Medicine Vienna for 6 years.

In 2010, she joined the veterinary pharmaceutical industry, focusing on product development and pharmacovigilance. By 2013, she became Deputy QPPV at Richter Pharma AG, later leading the clinical development group from 2018. She currently holds these positions at VetViva Richter GmbH. In 2021 and 2022, she joined the EVVET3 Product Owners group and VSIAG, respectively. Nominated as an Industry Subject Matter Expert for the Veterinary Union Pharmacovigilance Database in 2022, she represents the industry in developing and improving new veterinary IT systems.

Valentin Nicorescu

Scientific Specialist, European Medicines Agency

Valentin Nicorescu is a veterinarian by training who joined the Veterinary Medicines Division of the EMA in 2017. His work is mainly focused on efficacy aspects of pharmaceutical veterinary medicinal products and his current tasks and responsibilities include acting as scientific lead and subject matter expert for procedures and topics relating to marketing authorisation applications.

Valentin also acts as scientific secretary to the CVMP Efficacy Working Party (EWP-V).