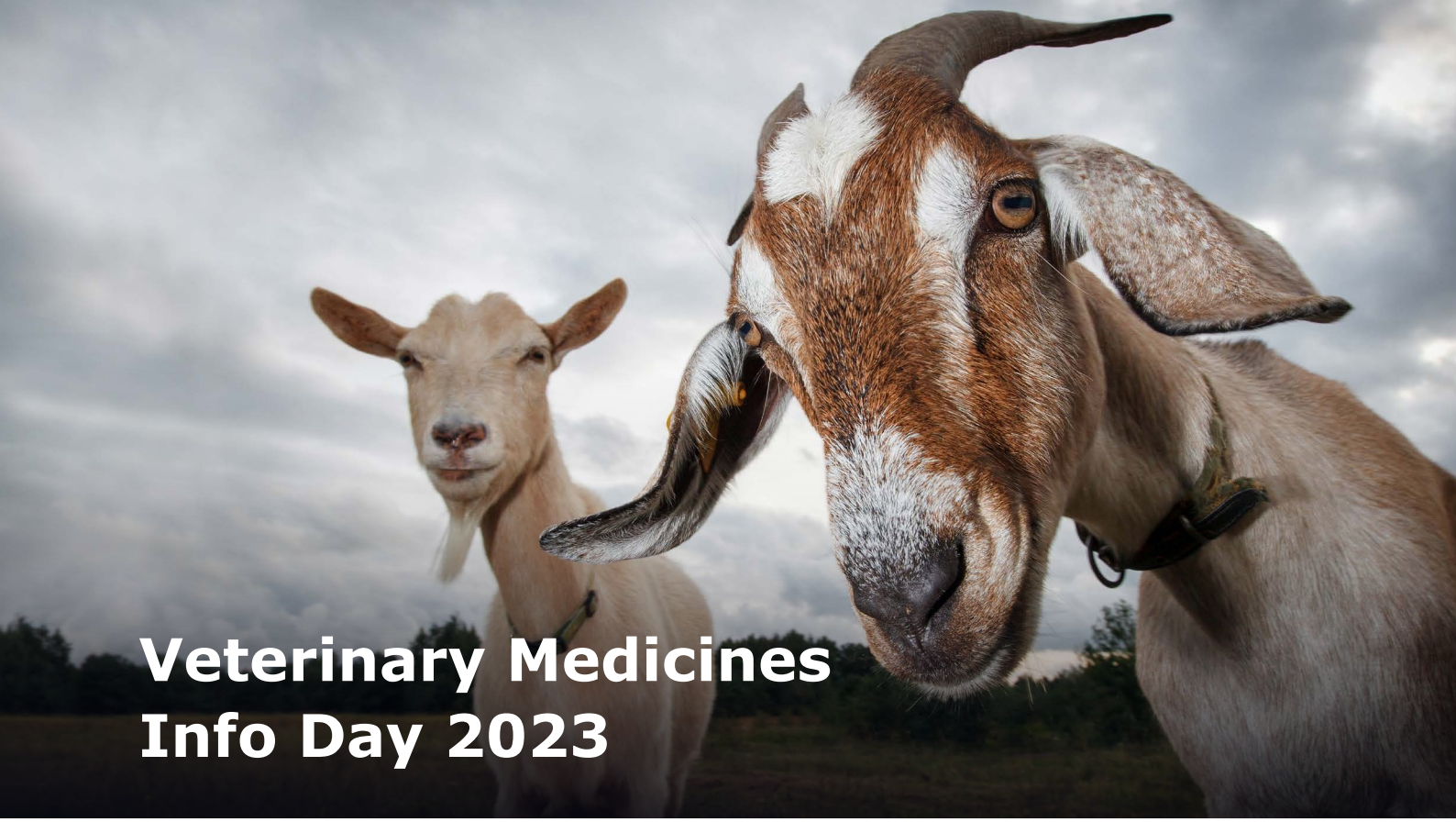

Veterinary Medicines Info Day 2023

16-17 February 2023
Virtual event (Webex)

Objectives

A year into the Veterinary Medicinal Products Regulation (EU) 2019/6, the European Medicines Agency is organising its annual edition of the Veterinary Medicines Info Day. Spread over two half-days, this event is designed to provide updates on topics such as regulatory policy, scientific and procedural developments and receive feedback from veterinary industry stakeholders. The programme will also include a session to focus on innovation. Registered participants will have the opportunity to engage and to ask questions to the panellists.

Day 1

16 February 2023, 14:00 - 17:10 (CET)

Virtual event (Webex)

14:00	**Introduction and welcome** *Ivo Claassen, EMA*	**10'**
14:10	**Session 1: Regulatory policy** *Chair: Emily Drury, EMA*	
	Update from the Commission on the VMP-Reg and secondary legislation *Alfonso Las Heras, European Commission*	**20'**
	EMA retrospective: A year into the VMP-Reg *Ivo Claassen, EMA*	**30'**
	CVMP workplan for 2023 and beyond *Johan Schefferlie, Chair of CVMP*	**30'**
15:30	**Coffee break**	
16:00	Industry perspective *Aafke Huizenga, Access VetMed* *Heidi Schwer, AVC*	**30'**
	Questions and answers session	**40'**

Day 2

17 February 2023, 09:00 - 12:30 (CET)

Virtual event (Webex)

09:00	**Session 2: Procedural developments** *Chair: Noemi Garcia del Blanco, EMA*	
	Clarifications on actions for industry in 2023 and beyond *Jana Schalansky, EMA*	**20'**
	Pharmacovigilance: signal management *Daniel Zondag, EMA*	**30'**
	Industry perspective *Tony Simon, AnimalhealthEurope*	**15'**
	Questions and answers	**30'**
10:35	**Coffee break**	**25'**
11:00	Innovation in Europe *Raffaele Bruno, AnimalhealthEurope*	**30'**
	Open discussion	**45'**
12:15	**Close of the meeting** *Ivo Claassen, EMA*	**15'**

List of speakers, co-chairs and panellists

Aafke Huizenga	*Access VetMed*
Alfonso Las Heras	*European Commission*
Daniel Zondag	*European Medicines Agency (EMA)*
Emily Drury	*European Medicines Agency (EMA)*
Heidi Schwer	*Association of Veterinary Consultants (AVC)*
Ivo Claassen	*European Medicines Agency (EMA)*
Jana Schalansky	*European Medicines Agency (EMA)*
Johan Schefferlie	*EMA Committee for Medicinal Products for Veterinary Use (CVMP)*
Noemi Garcia del Blanco	*European Medicines Agency (EMA)*
Raffaele Bruno	*AnimalhealthEurope*
Tony Simon	*AnimalhealthEurope*

Aafke Huizenga

Senior Regulatory Affairs Manager, Dechra

Aafke Huizenga graduated in 2004 in Molecular Biology in Leiden. She has worked in the sector of gene therapy for 4 years on a treatment against head and neck cancer at the VUmc in Amsterdam. In 2008, she started working as a CRA at AstraZeneca and later moved on to Genzyme as lead-CRA on a European clinical trial for Gaucher's disease. She joined the Animal Health pharmaceutical industry in 2011 focusing in regulatory affairs. She has developed strong expertise in regulatory processes and is the chair of the variations working group in Access Vetmed.

Alfonso Las Heras

Deputy of Unit, DG SANTE, European Commission

Alfonso graduated in veterinary medicine at the University Complutense of Madrid in 1996 and a 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.

Daniel Zondag

Scientific Administrator, European Medicines Agency (EMA)

Daniel graduated as a Pharmacist at the University Complutense of Madrid in 2012 and holds a masters in Pharmacoepidemiology from Utrecht University. In 2014, Daniel joined the Dutch Medicines Evaluation Board (MEB) as a Pharmacovigilance Assessor. In 2018, he joined the European Medicines Agency (EMA) as Seconded National Expert for the Surveillance & Epidemiology

and the Pharmacovigilance teams in the Human Medicines Division. In 2020, he started as Signal Management Lead in the Pharmacovigilance department at EMA. By the end of 2020, he moved to the Veterinary Medicines Division as Pharmacovigilance Officer, where in the last years he has been responsible for the coordination of the implementation of Regulation (EU) 2019/6 with regards to pharmacovigilance, signal management and post-authorisation surveillance activities.

Emily Drury

Head of Veterinary Regulatory Affairs and Referrals, European Medicines Agency (EMA)

Emily holds a MSc Degree in Biological Sciences from the University of Oxford. She has over twenty years' experience in European veterinary regulatory affairs. For the first nine years of her career, Emily worked within the regulatory consultancy, Cyton Biosciences, across several areas for veterinary medicines and feed additives before heading up their regulatory projects team. In 2009, Emily joined the European Medicines Agency, initially as CMDv Secretary and project manager for post-authorisation procedures, and subsequently as head of the Veterinary Regulatory and Organisational Support Service. Since December 2022, she now leads the newly formed Regulatory Affairs and Referrals Service within the Veterinary Division. Emily also has specialist knowledge of product information and labelling.

Heidi Schwer

VetMediCo

Heidi Schwer is a veterinary surgeon by training. After starting her career as a veterinary practitioner for mainly companion animals she joined the Belgian Federal Agency of Medicines and Health Products in 2003, first as a veterinary assessor and later in the pharmacovigilance department. In 2008 she left the Agency to start up her own Consultancy company, specializing in regulatory affairs and pharmacovigilance activities for the pharmaceutical industry, a company which she still runs today with a dedicated team. Heidi became a member of AVC, the Association of Veterinary Consultants, in 2013 and is involved in a few working groups as an active member.

Dr Ivo Claassen

Head of Veterinary Medicines Division, European Medicines Agency (EMA)

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 EU 2019/6 which has as one of its objectives to reduce the risk of veterinary antimicrobial use. Furthermore, he was involved in the development of the Veterinary Regulatory Science Strategy and the EMA Veterinary Big Data strategy. He is the co-chair of the EMA-HMA Task Force that coordinates the implementation of the veterinary medicinal products regulation and with his team has delivered the three pivotal IT systems that support the functioning of the regulation and the required business changes. He has also over 30 years of experience in vaccine production, QC/QA, R&D and regulatory affairs, both for human and veterinary vaccines. He has been a member of the Committee for Medicinal Products for Veterinary Use (CVMP).

Jana Schalansky

Head of Veterinary Strategic Support Office, European Medicines Agency (EMA)

Jana holds a Bachelor of Arts in Business Administration and Psychology. She joined the European Medicines Agency as an assistant in the Veterinary Medicines Division in 2003, subsequently working in various roles in the Division. As of 2016 she held the Programme Manager position for the Veterinary Change programme preparing for and implementing the VMP-Regulation. In 2021 she was appointed ad interim Head of the newly created Veterinary Strategic Support office in the Veterinary Medicines Division, providing strategic advice to all levels of the Division’s management, currently with a special focus on the implementation of the Veterinary Medicines Regulation.

G. Johan Schefferlie

EMA Committee for Medicinal Products for Veterinary Use (CVMP)

Johan Schefferlie is the chair of the CVMP since June 2022 and has been a member of the Committee since 2007 and its Vice-chair since July 2019. He is a biologist by training and 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 (EFSA) and the Joint WHO/FAO Expert Committee on Food Additives (JECFA), co-authoring several reports.

Noemi Garcia del Blanco

Veterinary Biologicals and Emerging Therapies, European Medicines Agency (EMA)

A veterinarian with post graduate qualifications in the field of microbiology and infectious diseases. Worked for more than fifteen years within the area of animal health, including development and regulation of vaccines and other biological veterinary medicinal products, both in industry and regulatory bodies. Noemi worked at the Veterinary Medicines Directorate in the UK for more than 10 years, first as scientific assessor and eventually becoming Head of Biologicals, overseeing the authorisation of biological products, batch release of vaccines, ensuring consistency and adequate quality and providing advice to industry and other stakeholders. Noemi was UK alternate member at the CVMP for more than two years and member of the SAWP. She joined the European Medicines Agency in 2019 and is the head of the Biologicals and Emerging Therapies service within the Veterinary Division.

Raffaele Bruno

Associate Director Regulatory Affairs, Zoetis

Since 2019 Raffaele Bruno is the Head of the European R&D Regulatory Affairs team (pharmaceuticals) at Zoetis. He holds a DVM degree from the University of Bologna (Italy) and a master's degree in Drug Innovation and Regulatory Science from the University of Utrecht (The Netherlands). After mixed experience within the veterinary and human health industry, Raffaele joined

Pfizer Animal Health in 2011 (now Zoetis) where he worked at the development and initial registration of various veterinary medicinal products for both companion animals and livestock. He is currently a member of the Animal Health Europe Regulatory Procedure Working group.

Tony Simon

Director, European Scientific Affairs and Pharmacovigilance, Zoetis

Tony Simon spent a number of years in general veterinary practice and has seen spent over 30 years in Pfizer Animal Health, now Zoetis, in a wide range of different roles (many of which had a pharmacovigilance component). He is now joint head of Zoetis Global Pharmacovigilance, a member of the AnimalhealthEurope and HealthforAnimals Pharmacovigilance working groups, the VeDDRA committee and also the VICH Pharmacovigilance Expert Working Group.