EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Veterinary Awareness Day

12-13 September 2023
European Medicines Agency, Amsterdam

Event Summary

The Veterinary Medicinal Products Regulation has been applicable for over a year now. While stakeholders such as the EU/EEA national competent authorities, marketing authorisation holders and veterinary healthcare professionals were involved in defining the new ways of working, the Agency recognises the increased interest in its activities also for other stakeholder groups. This event, the first-ever EMA Veterinary Awareness Day, aims to provide information on these activities to a wider audience.

Spread over two days, the event will focus on providing an overview of the Agency's work in veterinary medicines science and regulation in the European Union and give an insight into how this aims to benefit animal health and welfare.

It will include sessions on antimicrobial resistance, support for innovation and collaboration with academia. In addition, there will be parallel sessions on more specific topics, such as animal welfare, veterinary medicines and the environment.

EMA Veterinary Awareness Day

Day 1 – 12 September 2023

09:30 Joining and technical checks

10:00 Session 1: A new veterinary medicines regulation: one year in operation

Welcome and opening speech **10'**
Emer Cooke (EMA)

A new veterinary medicines regulation one year in operation **25'**
Eva Zamora Escribano (European Commission)

A new veterinary medicines regulation one year in operation: the Agency's perspective **25'**
Ivo Claassen (EMA)

Fostering better veterinary medicines globally through international engagement and connections **25'**
Martin Harvey Allchurch (EMA)

Questions and Answers

12:15 Lunch

13:30 Session 2: Combatting the emergence of antimicrobial resistance. Support for innovation and collaboration with Academia

Moderator: Helen Jukes, EMA

EMA's latest updates on Antimicrobial Resistance (AMR) initiatives **20'**
Zoltan Kunsagi (EMA)

Alternatives to Veterinary Antimicrobials (AVANT) **20'**
Luca Guardabassi (University of Copenhagen)

Veterinary Novel Therapies and Technologies **20'**
Jacqueline Poot (Chair of the NTWP)

Availability of veterinary medicinal products: promoting the authorisation of alternatives to antimicrobials **20'**
Noemi Garcia del Blanco (EMA)

Questions and Answers

15:30 Coffee break

16:00 Session 3: Breakout session

Room 1D **Session 3.1**	Room 1B **Session 3.2**

Room 1D

Breakout session 3.1: Veterinary Medicines and the Environment

Moderator: Ricardo Carapeto Garcia, Chair of the ERAWP

Environmental risk assessment for veterinary medicines: basic principles and current issues **20'**
Michael Telamon Empl (EMA)

Environmental safety of parasiticidal veterinary medicinal products for cats and dogs in the EU/EEA **20'**
Haru Kroneis (AGES)

Environmental Impact Assessment matters **20'**
Ivo Roessink (Wageningen University and Research)

Questions and Answers

Room 1.B

Breakout session 3.2: The impact of animals in society

Moderator: Ivo Claassen, EMA

The societal impacts of animals **20'**
Carel du Marchie Sarvaas (HealthforAnimals)

Impact of animals in society **20'**
Nancy De Briyne (FVE)

Consumer safety and Maximum residue limits **20'**
Sebastien Girault (EMA)

Questions and Answers

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Day 2 – 13 September 2023

09:00 Session 4: Breakout session

Room 1D	Room 1B
Session 4.1	**Session 4.2**

Room 1D

Breakout session 4.1: Animal Welfare

Moderator: Raffaella Corvi, Joint Research Centre, European Commission

Advancing acceptance of 3Rs testing approaches for regulatory testing of medicinal products in the EU **20'**
Sonja Beken (Chair of the 3Rs Working Party)

3RsWP Working Topics related to Veterinary Medicinal Products **20'**
Sarah Adler-Flindt (Vice-chair of the 3Rs Working Party)

Recent developments in Livestock Welfare Science **20'**
Hans Spoolder (Wageningen University)

Questions and Answers

Room 1.B

Breakout session 4.2: Collaboration with Academia

Moderator: Tony Humphreys, EMA

Collaboration with academia on regulatory science activities **20'**
Ralf Herold (EMA)

Regulatory Science and Research in Veterinary Medicines Regulation: an overview of activities **20'**
Ana Vidal (EMA)

Support and assistance offered by EMA to veterinary academic stakeholders **20'**
Valentin Nicorescu (EMA)

Questions and Answers

11:00 Coffee break

11:30 Session 5: Feedback from breakout sessions

Facilitators: Ivo Claassen, Ricardo Carapeto García, Tony Humphreys and Raffaella Corvi

12:30 Lunch

13:30 Session 6: Contribution of EMA and the EU network to veterinary medicines science and regulation

Chair: Johan Schefferlie (Chair of CVMP)

CVMP role and responsibilities **20'**
Frida Wikström (CVMP vice-chair and Chair of SAWP)

Perspective of the manufacturers of veterinary medicines **20'**
Frederik Schutte (AnimalhealthEurope)

Perspective of the European Medicines Agency **20'**
Jordi Torren Edo (EMA)

Questions and Answers

15:00 Closing remarks

Wrap up **15'**
Ivo Claassen and Martin Harvey Allchurch (EMA)

About the speakers

Dr Ana Vidal

Scientific Specialist, European Medicines Agency

Ana Vidal graduated as a veterinarian in 1999, holds a PhD on Infectious diseases and a master's in Epidemiology. Her area of expertise includes food safety, zoonotic diseases and other public health issues such as AMR. Ana has held different research and policy positions both in academia and government organisations. She joined the Veterinary Division at the EMA in 2020 as an AMR Scientific Senior Specialist.

Currently, she is part of the Veterinary Strategy and Support Office where she coordinates the veterinary regulatory research activities, providing support and strategic advice on One Health issues.

Carel du Marchie Sarvaas

Executive Director, HealthforAnimals

Carel du Marchie Sarvaas is Executive Director of HealthforAnimals, a global animal health association representing the top 10 animal health companies developing veterinary parasiticides, vaccines, pharmaceuticals, diagnostics, and digital products. Carel joined HealthforAnimals from EuropaBio, the EU Biotechnology Association. Prior, he worked at consultancies/think tanks in Washington DC and Brussels, advising on policies related to food, agriculture, chemicals, climate, and biotech.

He is a Dutch national and holds degrees from the University of Leiden and the Johns Hopkins University (SAIS).

Emer Cooke

Executive Director, European Medicines Agency

Emer Cooke is the Executive Director of the European Medicines Agency, based in Amsterdam. She also takes the role of Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA). She was the Director responsible for all medical product-related regulatory activities at the World Health Organization in Geneva between November 2016 and November 2020.

Ms. Cooke is a pharmacist with Masters degrees in Science and Business Administration from Trinity College Dublin.

Dr Eva Zamora Escribano

Head of Unit, DG SANTE, European Commission

Eva graduated in veterinary medicine at the University Complutense of Madrid and a holds a PhD in Swine Vesicular Disease. After working in the Animal Health Research Centre of the Spanish Ministry of Food, Fisheries and Agriculture, she joined the European Commission in 1999. From 2001, she worked in the Bilateral International Relations Unit where she was responsible for sanitary and phytosanitary issues for Latin American and Caribbean countries. She continued with her career in the international area in the Multilateral International Relations Unit, as deputy Head of Unit, where her focus was on Codex Alimentarius issues. She was appointed as Head of Unit of Animal health and welfare in 2016 and she has, since mid-2020, been working as Head of Unit Animal nutrition and veterinary medicines.

Dr Frida Wikström

Vice-chair of the Committee for Veterinary Medicinal Products (CVMP)

Frida Wikström is a veterinarian by training with a PhD in infection biology and immunology. Her research focused on the interaction between Porcine Circovirus and the immune system of the pig. In 2008, Frida joined the Swedish Medical Products Agency as a clinical assessor with particular interest in immunological and novel therapy products. She has been representing Sweden as alternate member and member of the CVMP since 2013.

She is the current vice-chair of the CVMP and chair of the veterinary Scientific Advice Working Party.

Dr Hans Spoolder

Senior Scientist, Wageningen University and Research

Hans Spoolder is senior scientist and EU account manager at Wageningen Livestock Research, part of Wageningen University & Research, in The Netherlands. Hans is an applied ethologist, specializing in issues related to pig welfare, e.g. sow group housing, stereotypies, tail biting, castration and transport and slaughter. Between July 2013 and August 2019, Hans was the president of the 'Health & Welfare commission' of the European Federation of Animal Science (EAAP). He is currently EAAP Vice-President for Science. Since 2012 he is a member of the Animal Health and Welfare panel of the European Food Safety Authority (EFSA), and contributed as working group chair to many opinions of the Panel. In March 2018 the European Commission designated the first EU Reference Centre for Animal Welfare (EURCAW), of which he became the Director.

Hans is also a member of the Management Team of the EU Partnership on Animal Health and Welfare.

Haru Kroneis

Member of the CVMP Environmental Risk Assessment Working Party

Haru Kroneis graduated from the Vienna University of Technology's Technical Chemistry degree programme with a specialisation in Chemical Engineering and Environmental Technology, as well as from the Medical University of Vienna's Toxicology postgraduate programme. She is a European Registered Toxicologist.

Since 2018, she has been working for the Austrian Medicines and Medical Devices Agency, where she is currently in charge of the non-clinical safety and environmental safety of herbal and veterinary pharmaceuticals.

Dr Helen Jukes

Seconded National Expert, European Medicines Agency

Helen Jukes is a seconded national expert at the European Medicines Agency (EMA), where she joined the Antimicrobial Resistance team in the Veterinary Division in 2019. The focus of her work is on the use of antimicrobials in animals and its impacts on public and animal health. Her responsibilities include providing scientific and regulatory support to working groups advising the Committee for Veterinary Medicinal Products (CVMP) and the European Commission.

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.

He has been a member of the Committee for Medicinal Products for Veterinary Use (CVMP).

Dr ir Ivo Roessink

Senior Scientist, Wageningen Environmental Research

Dr ir Ivo Roessink is a senior scientist and project leader of the experimental group within the Environmental Risk Assessment team of Wageningen Environmental Research. He studied Environmental Sciences at Wageningen University and during his PhD, Ivo investigated the impact of contaminants on shallow freshwater ecosystems in floodplain lakes in The Netherlands.

Ivo's current work is focusing on the impact of chemical and biological stressors on the environment.

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).

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 Jordi Torren Edo

Head of Evaluation and Innovation Support Department, European Medicines Agency

Jordi Torren Edo graduated as a veterinarian in 1989, from the University Autonomous of Barcelona. He joined the Veterinary Division of the EMA in 2000, previously he worked for 7 years in the veterinary pharmaceutical industry. Since 2019 he is the Head of Evaluation and Innovation Support Department in the Veterinary Medicines Division at the EMA where he is responsible for the coordination of the assessment of applications for authorisation of veterinary medicinal products (VMPs) through the centralised procedure in the EU. Before his current position his focus was on the area of antibiotic resistance, and in particular on the use of antibiotics in animals and its impact on public health.

Prof. Luca Guardabassi

Professor MSO, University of Copenhagen

Luca Guardabassi graduated in veterinary medicine from the University of Pisa in 1994 and completed his PhD in veterinary microbiology at the University of Copenhagen in 2000, where he works as professor of One Health AMR since 2012. For over 20 years, his research has focused on evolution and epidemiology of multidrug-resistant bacteria of clinical relevance in human and veterinary medicine. Luca is vice-chair of the Scientific Advisory Board in the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR). He is a pioneer of antimicrobial stewardship in veterinary medicine and has been involved in several national and international committees for the development of practice guidelines for rational antimicrobial use in animals.

Martin Harvey Allchurch

Head of International Affairs, European Medicines Agency

Martin Harvey is Head of International Affairs at the European Medicines Agency since October 2021. He joined the EMA legal team in 1995 after several years as a European affairs consultant in Brussels. He has headed the Office of the Executive Director, served as Head of Communication, before later moving to the Agency's International Affairs team. He took an 18-month career break with UNITAID, the WHO-hosted partnership dedicated to innovation in global health from 2019-2020.

Martin holds law degrees from the University of Dundee (UK) and the Vrije Universiteit Brussel (Belgium).

Dr Michael Telamon Empl

Scientific Specialist, European Medicines Agency

Michael graduated as a veterinarian from the University of Veterinary Medicine Hannover in 2010 and is a certified specialist for veterinary pharmacology and toxicology, as well as a European Registered Toxicologist. He holds a doctorate in veterinary medicine and a PhD in toxicology. Between 2010-2018, he worked as researcher at the Institute for Food Toxicology of the University of Veterinary Medicine Hannover.

Michael provides support to the Agency's Joint CHMP/CVMP 3Rs Working Party and to the CVMP Environmental Risk Assessment Working Party (ERAWP).

Nancy De Briyne

Executive Director, Federation of Veterinarians of Europe (FVE)

Nancy De Briyne presently serves as Executive Director at FVE, driving initiatives in key areas, including veterinary medicines, antimicrobial resistance, animal welfare, and the status of the veterinary profession. She is a diplomate for the European College of Animal Welfare and Behavioural medicine and a member of the EU Platform on Animal Welfare.

Nancy completed her studies in veterinary medicine in Ghent and after gaining experience as a veterinary practitioner in Belgium and the UK, she joined FVE where she works since 2000.

Dr Noemi Garcia Del Blanco

Head of the Biologicals and Emerging Therapies, European Medicines Agency

Noemi Garcia del Blanco is the Head of the Biologicals and Emerging Therapies Service since 2020. A highly skilled veterinarian with tensive post-graduate qualifications in the field of microbiology and infectious diseases, Noemi made significant contributions to the development and regulation of vaccines and other biological veterinary medicinal products, both in industry and regulatory bodies.

During her tenure at the Veterinary Medicines Directorate in the UK, spanning more than a decade, Noemi served as a scientific assessor and later rose to the position of Head of Biologicals.

Dr Raffaella Corvi

Scientific Project Officer, Joint Research Centre

Raffaella Corvi studied Biological Sciences at the University of Pavia (Italy) and obtained her PhD at the University of Heidelberg (Germany) working at the German Cancer Research Centre. Since 2001 she works at the Joint Research Centre of the European Commission, which hosts the European Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM). Here she established the activities in the area of genotoxicity and carcinogenicity.

Currently, she conducts activities that evaluate innovative and integrated approaches to assess chemical safety and support their regulatory implementation, while also promoting the 3Rs across multiple regulatory sectors.

Ralf Herold

Senior Scientific Officer, European Medicines Agency

Ralf is a Senior scientific officer in the Task Force Regulatory Science & Innovation of the EMA, responsible for Horizon scanning, Academia liaison and Regulatory science project involvement. Previously, he worked with stakeholders on Oncology, Haematology & Diagnostic as well as Paediatric medicines, starting 2007 at the Agency. Ralf was the Paediatric development leader of Bayer AG, Regulatory affairs from 2017 to 2018. At Humboldt University in Berlin, he obtained an experimental research PhD, board-certified in paediatric and adolescent medicine, trained in Paediatric oncology and haematology, and managed a national clinical research network.

Dr Ricardo Carapeto García

Chair of the CVMP Environmental Risk Assessment Working Party

Ricardo Carapeto García is a veterinarian working in the regulatory framework of Veterinary medicines since the last 13 years. Currently he is Head of the Area of Environmental Risk Assessment within the Veterinary Department of the Spanish Medicines Agency (AEMPS).

He is also co-opted member of the CVMP and current Chair of the Environmental Risk Assessment Working Party (ERAWP).

Frederik Schutte

FIDIN Director and board member of AnimalhealthEurope

Frederik Schutte has a degree in Dutch and International Law from the University of Amsterdam and completed an LLM at Duke University in USA. He is partner of an independent consultancy firm (Brabers) that serves the interests of sector organisations operating in regulated markets. As a consultant, Frederik acts as director of the Dutch trade association of the veterinary pharmaceutical industry (FIDIN), but also advises in other sectors such as human medicines and medical devices.

As FIDIN director, Frederik also serves as board member of AnimahealthEurope.

Dr Sarah Adler-Flindt

Vice-Chair of the CVMP/CHMP Joint 3Rs Working Party

Sarah Adler-Flindt holds a PhD in cell biology and is European Registered Toxicologist. Sarah is a scientific officer at the department of veterinary drugs at the German federal office of consumer protection and food safety (BVL) and since 2022 Vice-Chair of the CVMP/CHMP Joint 3Rs Working Party (3RsWP) at the European Medicines Agency (EMA).

Her main areas of expertise relate to stem cell biology, alternative methods to animal experiments (3Rs) and regulatory risk assessment of plant protection products, biocides and veterinary medicinal products.

Dr Sonja Beken

Chair of the CVMP/CHMP Joint 3Rs Working Party

Sonja Beken holds a Master in Biological Sciences and PhD in Pharmaceutical Sciences from the Vrije Universiteit Brussel (VUB), Belgium and a Master in Applied Toxicology from the University of Surrey, UK. Sonja is the Coordinator of the Unit of non-clinical evaluators at the Belgian Federal Agency for Medicines and Health Products (FAMHP).

Her main areas of expertise relate to regulatory science, non-clinical drug development, (in vitro) toxicology and metabolism as well as alternative models to animal experiments (3Rs, NAMs).

Dr Sebastien Girault

Scientific Specialist, European Medicines Agency

Sebastien Girault became a doctor in veterinary medicine (DVM) in 1994 and is certified in toxicology and biological and medical sciences. Sebastien Girault joined the EMA in 2014. He deals mainly with safety issues of veterinary medicines to human beings: 'consumers' potentially exposed to residues through foodstuff of animal origin, 'users' in contact with the medicine or with the treated animals. He acts as secretariat of the CVMP Safety Working Party and other EMA or cross-agencies expert groups.

Previously, he has worked in pharmaceutical industry for 17 years as toxicologist and manager in the research and development of new active substances for human use.

Valentin Nicorescu

Senior 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).

Tony Humphreys

Head Regulatory Science and Innovation Taskforce, European Medicines Agency

He is the Head of the Regulatory Science and Innovation Task Force (TRS). He is responsible for providing leadership in the Task Force and the Agency to enable its continuous future proofing through operation of a regulatory science observatory, addressing key scientific and technological trends and their translation through the development of regulatory science strategy, planning and governance.

Zoltan Kunsagi

Scientific Officer for AMR, European Medicines Agency

Zoltan graduated as a veterinarian in Budapest, Hungary, and holds additional master's degrees as a specialist in toxicology and as an analytical chemist specialised in chromatography techniques. Between 1999 and 2014, he worked as a laboratory analyst, a researcher, and a consultant in Hungary (Central Agricultural Office), Belgium (European Commission, DG JRC), and Saudi Arabia (SFDA). In 2014, Zoltan joined EMA, and since then he has been working in the Veterinary Division and leads the antimicrobial resistance team. He provides support to the CVMP's Antimicrobials Working Party and is the main contributor from EMA to the Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA).