EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ADRA project – info session for veterinary pharmaceutical industry

22 May 2025, 14:30 – 16:00 (CEST)
Virtual meeting

The ADRA (**D**osage **R**eview and **A**djustment of selected veterinary **A**ntibiotics) project builds on the related 2017 CVMP reflection paper, acknowledging that the authorised product information for some established veterinary antibiotics may not be fully aligned with current scientific knowledge.

Led by the Committee for Veterinary Medicinal Products (CVMP) and EMA, the ADRA project will focus on reviewing dosage regimens for established veterinary antibiotics through non-experimental approaches, with the goal to:

- refine the dosage regimens of those veterinary antibiotics to ensure the prudent use of antibiotics in veterinary medicine.
- evaluate the implications of any dose review on withdrawal periods, target animal safety and environmental risk assessment without necessitating the generation of new study data.

Interested participants are invited to read the discussion document (link) and submit questions in advance.

ADRA project information session agenda

Chaired by Emily Drury (EMA)

22 May 2025, 14:30 – 16:00 (CEST)

14:20 Joining and technical checks

14:30 Welcome remarks

Opening **5 min**
Emily Drury (EMA)

14:35 Introduction to the ADRA project

Dosage review and adjustment of established veterinary antibiotics **20 min**
Johan Schefferlie (Chair of the CVMP)

Regulatory considerations **10 min**
Ana Azaceta (EMA)

15:05 Open discussion and Q&A

15:50 Closing remarks

Wrap up **10 min**
Emily Drury (EMA)

About the speakers

Ana Azaceta

Scientific Specialist, European Medicines Agency

Ana Azaceta holds a degree in Pharmacy from the Faculty of Pharmacy in Madrid, Spain, with specialised training in regulatory affairs and regulation of medicines in the EU (MSc). She joined EMA in 2017 and has since held positions as a scientific officer in both the Human and Veterinary Referrals Offices. Prior to joining EMA, Ana worked for the Spanish National Competent Authority (AEMPS) supporting the marketing authorisation applications.

Ana currently works in the Veterinary Regulatory Affairs and Referrals Office, where she manages both referral procedures as well as regulatory matters.

Emily Drury

Head of Veterinary Surveillance and Regulatory Support Department, 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 Head of Department for Veterinary Surveillance and Regulatory Support.

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.