2ⁿᵈ Veterinary Big Data Stakeholder Forum

Agenda

23 November 2022, 09:30 - 17:00 (CET)
EMA and virtual

Time	Item	Duration
09:20	**Connection to virtual room and technical checks**	
09:30	**Welcome**	
	Emer Cooke, Executive Director, EMA	**5'**
	Dr Ivo Claassen, Deputy Executive Director and Head of Veterinary Division, EMA	**5'**
	Prof. Thomas Heberer, HMA Management Group	**5'**
09:45	**Session 1: Advancements in the area of Big Data and digitalisation in the veterinary domain**	
	Moderator: Dr Ivo Claassen	
	Veterinary Big Data - Highlights of the last year	**15'**
	Dr Ricardo Carapeto, AEMPS	
	EMA/HMA Big Data Steering Group: recommendations and workplan	**15'**
	Dr Peter Arlett, Head of Data Analytics and Methods, EMA	
	Q&A	**10'**
10:25	**Coffee break**	

11:00 **Session 2: Stakeholders' insights on key business areas**

Moderator: Dr Sandra Bertulat, BVL

Outline of the session: survey results, prioritised use cases and objectives   **10'**

Dr Sandra Bertulat, BVL

Pharmaceutical Industry's view

Rick Clayton, AnimalhealthEurope   **20'**
Q&A   **5'**

Veterinarians' view

Despoina Iatridou, FVE   **20'**
Q&A   **5'**

Other animal healthcare professionals' view

Dr Jeanine Wiegel, GD Animal Health   **20'**
Q&A   **5'**

12:25 **Lunch break**

13:30 **Session 2: Stakeholders' insights on key business areas (Cont.)**

Moderator: Dr Sandra Bertulat, BVL

Academia's view

Dr Miel Hostens, Utrecht University   **20'**
Q&A   **5'**

EU Veterinary Medicines Regulators' view

Dr Laure Baduel, ANSES   **20'**
Q&A   **5'**

International Veterinary Medicines Regulators' view

Dr Hesha J. Duggirala, FDA CVM   **20'**
Q&A   **5'**

Open discussion   **20'**

Conclusions   **5'**

15:10 **Coffee break**

15:40   Session 3: Big Picture on Big Data

Moderator: Dr Catrina Stirling, Director of Regulatory Affairs, Zoetis

Current and future use of omics and other data in food/feed safety assessments   **15'**

Konstantinos Paraskevopoulos, EFSA

Dr Mirko Rossi, EFSA

WOAH: Current data analytics experience and future direction for travel   **15'**

Lina Awada, WOAH

Dr Andrés García Campos, WOAH

The DECIDE project: Data-driven control and prioritisation of endemic contagious animal diseases   **15'**

Prof. dr. ir. Gerdien van Schaik, Utrecht University

Opportunities for data-driven insights into animal health and regulation   **15'**

Prof. Alasdair Cook, University of Surrey

16:40   Round table and open discussion   **15'**

16:55   Closing remarks   **5'**

Dr Ivo Claassen

17:00   End of meeting

2nd Veterinary Big Data Stakeholder Forum

Event programme

23 November 2022, 09:30 - 17:00 (CET)

EMA and virtual

Objectives

Driven by the principles embraced by the European Medicines Regulatory Network in the European Veterinary Big Data strategy for 2021-2027, and following the successful event held in June 2021, the European Medicines Agency is organising a second annual forum on Veterinary Big Data to foster collaboration and engage stakeholders.

This second edition will continue the discussion on Big Data in veterinary medicines regulation by presenting progress made since last event and moving to a more concrete level of discussion on targeted veterinary use cases in the area of veterinary medicinal product information, pharmacovigilance and antimicrobial resistance. These use cases were selected based on a survey where over 40 veterinary stakeholders expressed their opinion on the relevance and maturity among several veterinary regulatory scenarios that could benefit from the application of new digital technologies. During this event, speakers representing the main stakeholders' groups will provide a deep dive exploring the potential offered by advanced analytical solutions into one or more of such selected use cases and giving an overview on the benefits, state of play, obstacles, and future recommendations. The forum will also provide a platform for a broader discussion on current initiatives on data analytics application to foster animal and public health at EU and international level.

The goal of this forum is to identify a prioritised list of initiatives that will inform and shape the Veterinary Big Data work plan in EU for the coming years.

Programme

The programme will include three separate sessions which will focus on:

- **Session 1: Advancements in Big Data and digitalisation in the veterinary domain:** will resume the discussion on Big Data in veterinary medicines regulation by presenting progress made since the first forum in June 2021.

- **Session 2: Stakeholders' insights on key business areas:** will include a series of presentations from stakeholders that will focus on their iews on selected veterinary use cases in the areas of Veterinary Medicinal Product Information, Pharmacovigilance and Antimicrobial Resistance, highlighting benefits, barriers, limitations and future recommendations.

- **Session 3: The Big Picture on Big Data:** will include broader insights into current projects and data analytics initiatives to foster animal and public health from other EU and international organisations. This session will include a round table discussion with main participants.

List of speakers, chairs, moderators and panellists

Alasdair Cook	*University of Surrey*
Andrés García Campos	*World Organisation Animal Health*
Catrina Stirling	*Zoetis*
Despoina Iatridou	*Federation of Veterinarians of Europe*
Emer Cooke	*European Medicines Agency*
Gerdien van Schaik	*Utrecht University*
Hesha J. Duggirala	*Food and Drug Administration (FDA) Center for Veterinary Medicine*
Ivo Claassen	*European Medicines Agency*
Jeanine Wiegel	*GD Animal Health*
Laure Baudel	*French Agency for Food, Environmental and Occupational Health & Safety*
Lina Awada	*World Organisation Animal Health*
Konstantinos Paraskevopoulos	*European Food Safety Authority*
Miel Hostens	*Utrecht University*
Mirko Rossi	*European Food Safety Authority*
Peter Arlett	*European Medicines Agency*
Ricardo Carapeto García	*Spanish Agency of Medicines and Medical Products*
Rick Clayton	*AnimalhealthEurope*
Sandra Bertulat	*Federal Office of Consumer Protection and Food Safety*
Thomas Heberer	*Heads of Medicines Agencies (HMA) Management Group*

Emer Cooke
Executive Director, European Medicines Agency (EMA)

Emer Cooke is as of 16 November 2020 the new 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. In this role, Ms Cooke was responsible for leading WHO's global work on regulation of health technologies (medicines, vaccines, diagnostics, vector control products and devices), coordinating the regulatory teams (Prequalification, Regulatory Systems Strengthening, and Safety), and working with member states and international partners to assure the quality, safety and efficacy of appropriate health technologies.

Ms. Cooke is a pharmacist with Masters degrees in Science and Business Administration from Trinity College Dublin. She has over 30 years' experience in international regulatory affairs and spent 14 years (2002 to 2016) in management positions at the European Medicines Agency as Head of Inspections and Head of International Affairs respectively. From September 1998 to July 2002, she worked in the Pharmaceuticals unit of the European Commission.

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).

Professor Dr Thomas Heberer
Heads of Medicines Agencies (HMA) Management Group

Prof. Dr. Thomas Heberer is head of department at the Federal Office of Consumer Protection and Food Safety (BVL) since 2010. His department is responsible for the authorization and registration of veterinary medicinal products (VMPs) in Germany and is also in charge of many other related issues such as antimicrobial resistance or crisis management of VMPs.

His career also includes work in environmental research at university, he was head of the section "Residues of Medicinal Products" at the Federal Institute for Risk Assessment (BfR) and head of the Food Institute Oldenburg of the Lower Saxony State Office for Consumer Protection and Food Safety (LAVES). Thomas Heberer is teaching toxicology and modern instrumental analysis as an adjunct professor at the Technical University of Berlin. In 2004, he received the research award from the German Chemical Society for his pioneering research on the occurrence and fate of pharmaceutical residues in the environment.

Session 1

Ricardo Carapeto García
Spanish Agency of Medicines and Medical Devices (AEMPS)

Ricardo Carapeto García is a veterinarian with more than 10 years of experience in the regulatory field of veterinary medicines. He combines his work as Head of Service of Environmental Risk Assessment at the Spanish Agency of Medicines and Medical Devices (AEMPS) with the participation in the CVMP as co-opted member and in the CVMP Environmental Risk Assessment Working Party, where is the current chair.

Dr Peter Arlett
European Medcicines Agency (EMA)

Dr Peter Arlett is the Head of the Data Analytics and Methods Task Force, the Co-chair of the Big Data Task Force at the European Medicines Agency, and since 2020, Honorary Professor at the London School of Hygiene and Tropical Medicine.

He has twenty-five years of experience of drug benefit risk management and of delivering programs of major change in regulation and legislation. This experience has been gained through organizations at national, European, and international level.

Session 2

Dr Sandra Bertulat
Federal Office for Consumer Protection and Food Safety (BVL)

Dr Sandra Bertulat received her degree in Veterinary Medicine. Afterwards, she worked in the field of university research for several years specializing in bovine health management as well as animal reproduction and was responsible for a multitude of studies utilizing data from farm management systems as well as advanced analytics.

In 2017 Dr Bertulat joined the Federal Office for Consumer Protection and Food Safety (BVL) as an assessor and is responsible for clinical aspects of marketing authorization procedures for veterinary medicinal products.

Since February 2020 she is one out of two veterinary members of the Big Data Steering group and also became a member of the EU Veterinary Big Data Team responsible for the development of the EU Big Data strategy for the use of advanced analytics and emerging digital technologies in the veterinary domain. In addition, in October 2020, Dr Bertulat was elected as member of the CVMP Efficacy Working Party.

Rick Clayton
AnimalhealthEurope (AhE)

Rick has worked for the European industry association since 1997 and comes from a background of product development and registration. In this role he is in regular dialogue with decision makers within the European institutions and the European medicines regulatory network with the principle aim of supporting the smooth running of regulatory systems.

He is also coordinator for the European industry representation to the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products ("VICH"). He has a degree in Applied Biology, a diploma in Marketing and he is an Honorary Life Member of TOPRA.

Despoina Iatridou
Federation of Veterinarians of Europe (FVE)

Despoina Iatridou is senior policy officer at the Federation of Veterinarians of Europe (FVE). She qualified as veterinarian by the Faculty of Veterinary Medicine of the Aristotle University of Thessaloniki and holds a PhD from the Faculty of Veterinary Medicine of Ghent University. After several years in veterinary practice, she joined the FVE team in Brussels. Her dossiers of responsibility include mainly veterinary medicines, antimicrobial resistance, One Health interprofessional collaboration and veterinary education.

She has been representing the veterinary profession in committees or working groups relevant to these areas and since June 2022, she represents the veterinarians' organisations in the Management Board of the European Medicines Agency.

Dr Jeanine Wiegel
GD Animal Health

In 2014 Jeanine completed her veterinary medicine studies at Utrecht University, with a focus on livestock and public health. Soon thereafter she started working as a poultry veterinarian at GD Animal Health.

Her work consists of giving advice to veterinarians, farmers and other professionals in the poultry industry. It concerns health and diseases, diagnosis, treatment and prevention. Responsibilities are linked to monitoring, research projects and consultancy, in the

Netherlands and abroad. Many of the research projects concern antimicrobial use and resistance in poultry.

Jeanine graduated Cum Laude from University of Georgia, USA as a Master in Avian Health and Medicine in 2019.

Dr Miel Hostens
Utrecht University

Dr Miel Hostens is an Assistant Professor at the department of Farm Animal Health in Utrecht University, focusing on Herd Health Management in relation to Precision Livestock Management and Big Data in Dairy Cows.

Dr Hostens is responsible for bachelor and master students in Veterinary Medicine, statistical training of Ph.D. students in data management in the area of dairy cows and post academic and extension services in the area of herd health management in dairy cows. His areas of expertise are Data Science, Veterinary Epidemiology, Veterinary Medicine and Information and Computing Sciences.

Combining the passion for dairy farming with data science, Dr Hostens is devoted to creating methodologies using precision livestock farming to monitor sustainable food production systems from a global perspective.

Dr Laure Baudel
French Agency for Veterinary Medicinal Products (ANMV)

Since 2020, Dr Laure Baduel has been in charge of cross-functional projects within the Regulatory Affairs and transversal projects Mission at the French Agency for Veterinary Medicinal Products (ANMV). In 2021, she also joined the EU Veterinary Big Data Team.

Before being recruited at the end of 2015 at ANMV as Head of the Pharmaceuticals Assessment Unit, Laure worked for 27 years in the veterinary pharmaceutical industry where she first managed European clinical development projects and then headed clinical and preclinical development and regulatory affairs departments within several international veterinary pharmaceutical companies.

She graduated as a vet from the French National Veterinary School of Toulouse in 1987 and also has qualifications in biostatistics for clinical research.

Dr Hesha J. Duggirala
U.S. Food and Drug Administration (FDA)

Hesha J. Duggirala, PhD, MPH is a senior epidemiologist at the Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) and chair of the FDA Data Science Council.

She received her bachelor's degree from Rutgers University, Master's in Public Health from George Washington University, and her Doctor of Philosophy with a concentration in epidemiology from the Tulane University School of Public Health and Tropical Medicine.

Dr. Duggirala joined FDA as an epidemiologist in the Office of Surveillance and Biometrics at the Center for Devices and Radiological Health. She co-founded, and continues to chair, the FDA Data Science Council (formerly Data Mining Council). This group, a part of the FDA's Scientific Computing Board, advises and provides support to data mining programs across the Agency. She was the lead author of the Council's seminal white paper on data mining at the FDA.

Dr. Duggirala currently serves as an epidemiologist in CVM's Office of Surveillance and Compliance where she provides epidemiologic support to various groups across CVM as well as developing a framework for the Center's big data analytics programs.

Session3

Dr Catrina Stirling
Zoetis

Dr Catrina (Cat) Stirling graduated from the University of Edinburgh with a degree in Virology before doing a PhD in Veterinary Immunology at the Pirbright Institute/University of Sussex. She then spent 4 years as a post-doc at Pirbright working on DNA vaccines for FMDV and ASFV immunology before joining the UK Veterinary Medicines Directorate (VMD). After 2 years at VMD she moved to Pfizer Animal Health, now Zoetis focusing on regulatory affairs, she is currently Director of Regulatory affairs focusing on companion animal vaccines and biologicals.

She is an expert on immunological and biological product development and registration as well as 3Rs aspects of vaccine release.

Konstantinos Paraskevopoulos
European Food Safety Authority (EFSA)

Konstantinos (Kostas) is currently working at EFSA's chief scientist office (CSO) as a scientific project coordinator in the SPIDO (Science Studies and Project Identification and Development Office) team which supports EFSA's preparedness for future risk assessment requirements by advancing selected scientific themes while fostering connectivity and partnerships with Member States and other EU Agencies as well as international organisations and third countries.

Prior to joining the CSO, Kostas worked in the genetically modified organisms Unit of EFSA for 6 years. Before joining EFSA in 2014, Kostas held an academic career working as researcher in molecular and cell biology and biochemistry in several research institutes (e.g. the European Molecular Biology Laboratory (EMBL) in Germany and the Medical Research Council (MRC) in the UK). Kostas obtained his bachelor's degree in biophysics followed by a Master's in cheminformatics and a Ph.D. in molecular and structural biology.

Dr Mirko Rossi
European Food Safety Authority (EFSA)

Doctor in Veterinary Medicine with a PhD in Epidemiology and control of Zoonoses from University of Bologna, he received the title of Docent in Zoonotic Bacteriology from the University of Helsinki in 2015.

From 2013 to 2018 he was appointed as associate professor at the University of Helsinki researching on genomic epidemiology of Campylobacter and other food-borne pathogens.

Currently he is scientific officer at the European Food Safety Authority, Unit Biological Hazards & Animal Health and Welfare (BIOHAW). His main task in EFSA is to support the Authority in any aspects related to the use of Whole Genome Sequencing applied to foodborne outbreak. Currently, he is managing the EFSA One Health WGS system, a data collection workflow and analytical platform for collecting WGS data from Member States with the aim of supporting European Commission in quick response to foodborne outbreaks.

Lina Awada
World Organisation for Animal Health (WOAH)

Lina Awada is a veterinary epidemiologist (DVM, MSc, PhD) working for the World Organisation for Animal Health (WOAH). She has 11 years of experience in international organizations related to disease surveillance, disease reporting, epi analysis of animal health data and health information systems and data management. She has contributed significantly to the management and modernization of WOAH's World Animal Health Information System (WAHIS) and is currently involved in WOAH data integration activities across the organization.

Dr Andrés García Campos
World Organisation for Animal Health (WOAH)

Andrés (DVM, MSc, PhD, DipEVPC) is a veterinarian who graduated at University of Zaragoza (Spain) in 2009 and obtained his PhD in Veterinary Parasitology in 2016. Andrés worked for 3 years at the Health Products Regulatory Authority based in Dublin (Ireland), responsible for the assessment of safety and efficacy aspects prior to granting marketing authorization of veterinary medicinal products via Centralise and DCP/MRPs. In 2021, he also became European Specialist in Veterinary Parasitology by the European Board of Veterinary Specialisations.

Andrés joined WOAH as programme manager in July 2022. His mission is to contribute to the scientific excellence and integrity of WOAH activities in alignment with WOAH Strategy on AMR and the Prudent Use of Antimicrobials, by developing projects aimed at combating substandard and falsified veterinary product circulation in WOAH Members, and defining ways to guide Members in the responsible and prudent use of antiparasitics.

Professor Dr Ir Gerdien van Schaik
Utrecht University

Gerdien van Schaik graduated in 1995 at Wageningen University in quantitative veterinary epidemiology. In 2000 she finished her PhD thesis entitled "Introduction of infectious disease into dairy farms" at the department of Farm Economics of Wageningen University. She worked as a postdoctoral fellow at the Population Medicine group of Cornell University, USA and as an associate professor at the Preventive Medicine group of Universidad Austral de Chile, Chile.

Since October 2004, she works at Royal GD till July 2021 as the head of the Epidemiology Group and then as senior epidemiologist. The focus of her chair is on, amongst others, evaluation of current surveillance activities and possibilities for improvement with innovative quantitative methods, such as risk-based surveillance and syndromic surveillance. From July 2021, she coordinates a Horizon 2020 project for the development of tools for data-driven control and prioritisation of non-EU-regulated contagious animal diseases (DECIDE). The DECIDE project with 19 partners in 11 countries has a budget of €10 million to reduce the impact of endemic infections in livestock and aquaculture.

Professor Alasdair Cook
University of Surrey

Professor Alasdair "Alex" Cook is Head of the Department of Veterinary Epidemiology & Public Health and is a member of the School's Senior Management Team. He is engaged in developing research and teaching in the areas of epidemiology and veterinary public health in the new School of Veterinary Medicine.

Alex is a veterinary epidemiologist with more than 25 years national and international experience in livestock animal health in Government, academic and development environments. He joined the new School of Veterinary Medicine in January 2013. Previously, he worked in the Animal Health and Veterinary Laboratories Agency (AHVLA) where he was a senior member of staff engaged in leading research and surveillance programmes as well as part of the senior management team formulating strategy and implementing change. Alex's research interests are primarily in the epidemiology and control of zoonotic diseases, especially foodborne zoonoses. He also has a strong interest in surveillance and the impact of endemic disease on farm animal welfare and productivity. He is a firm believer in a multi-disciplinary team approach to research, engaging with molecular biologists, microbiologists and socio-economists to name but a few. Since joining Surrey, Alex has been working with the 5G Innovation Centre and the Business School in creating innovate digital solutions to animal health issues. He has been a principal investigator/ project leader on projects funded agencies including Defra, EC, AHDB-BPEx and the Wellcome Trust. Recent awards include funding from the British Council and FAPESP for an early career researcher workshop in São Paolo State, Brazil, on the theme of One Health, and a contract from Defra to join other providers in supporting surveillance of farmed livestock health in England through post-mortem examinations.