Third Veterinary Big Data Stakeholder Forum

23 November 2023
EMA building, Amsterdam + virtual meeting

The European Medicines Agency is organising a third edition of the Veterinary Big Data Stakeholder forum to continue the discussion on Big Data in veterinary medicines regulation by presenting progress made since the last year. During this event, the use cases on veterinary medicinal product information, pharmacovigilance and antimicrobial resistance will be further analysed and complemented with additional experience from our stakeholders.

This forum aims to:

- report on the EU Veterinary Data Hub activities and the HMA/EMA Veterinary Big Data workplan.

- resume the discussion on the identified use cases, collect inputs, and learn from existing experiences from stakeholders' experts.

- pen the floor to discuss upcoming challenges and future needs of big data in the veterinary regulatory domain.

Third Veterinary Big Data Stakeholder Forum

12:50   **Joining and technical checks**

13:00   **Welcome and opening speech**

Presentation   **5'**
Ivo Claassen

13:05   **Session 1: Progress update and report at EU-level**

Chair: Laure Baduel (ANMV)

EMA/HMA Big Data Steering Group   **10'**
Jesper Kjaer (HMA/EMA Big Data Steering Group)

EMA Veterinary Big Data work plan   **10'**
Sandra Bertulat (EU Veterinary Data Hub)

The EU Veterinary data landscape analysis   **20'**
Jos Verstegen (Wageningen University & Research)

Q&A   **15'**

14:00   **Session 2: Use cases: introduction to ongoing projects**

Chair: Sandra Bertulat (BVL)

Industry's view   **25'**
Presented by Catrina Stirling (Zoetis)

Cross-Agencies cooperation view   **25'**
Presented by Dario Piselli (European Environment Agency)

14:50   **Coffee break**

15:05   **Session 2: Use cases: introduction to ongoing projects (CONT)**

Chair: Sandra Bertulat (BVL)

International regulators' view   **25'**
Presented by Michael Renaudin (Swissmedic)

Q&A   **15'**

15:45   **Session 3: Preparing for the future**

Chair: Jana Schalansky (EMA)

Panel discussion   **30'**
Thomas Heberer (representing EU Regulators' perspective)
Catrina Stirling (representing Industry's perspective)
Jobke van Hout (representing FVE's perspective)

Wrap up of the round table   **5'**

16:20   **Closing remarks and opportunity for engagements**

Wrap up   **10'**
Ivo Claassen (EMA)

List of speakers

Catrina Stirling	Zoetis
Dario Piselli	European Environment Agency
Ivo Claassen	European Medicines Agency
Jana Schalansky	European Medicines Agency
Jesper Kjær	Danish Medicines Agency
Jobke van Hout	Federation of Veterinarians of Europe
Jos Verstegen	Wageningen Economic Research
Laure Baduel	French Agency for Veterinary Medicinal Products (ANMV)
Michael Renaudin	Swissmedic
Sandra Bertulat	Federal Office of Consumer Protection and Food Safety (BVL)
Thomas Heberer	Federal Office of Consumer Protection and Food Safety (BVL)

About the speakers

Dr Catrina Stirling

Director Regulatory Affairs, 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.

Dr Dario Piselli

Expert in Environment, Health and Well-Being, EEA

Dario is an Expert in Environment, Health, and Well-Being at the European Environment Agency (EEA) in Copenhagen, Denmark, where he works on issues relating to the interface between food systems, the environment and human health. He has previously worked as an independent consultant for institutions including the Governing Pandemics initiative, the UN75 initiative and the Lancet and Financial Times Commission on Governing Health Futures. In addition, he has held research positions at the Centre for

International Environmental Studies (2018-2020) and the Global Health Centre (2016-2018) of the Graduate Institute of Geneva. He holds a PhD from the Graduate Institute of Geneva, an MSc from the London School of Economics, and a JD from the University of Siena.

Dr Ivo Claassen

Head of Veterinary Medicines, EMA

Dr Ivo Claassen is head of the Veterinary Medicines Division and Deputy Executive Director at the European Medicines Agency (EMA). 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.

Jana Schalansky

Head of Veterinary Strategic Support Office, 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.

Jesper Kjær

Head of Data Analytics, DKMA

Jesper Kjær is the Head of Data Analytics at Danish Medicines Agency (DKMA). He holds a MSc in bioinformatics and BSc (hons) in computer science. Jesper brings long experience of data handing, analyses and data visualization having worked in the academic environment and pharmaceutical industry, and he has also developed IT systems for the World Health Organization and University Hospital of Copenhagen. Jesper has also led the development of risk-based monitoring IT in Novo Nordisk and has headed activities in EU Framework Programmes, IMI2, TransCelerate Biopharma and HL7. Jesper Kjær is also co-chair of the Big Data Steering Group.

Dr Jobke van Hout

GD Animal Health

Jobke van Hout studied Veterinary Medicine at the University of Utrecht. At this university she also got her PhD Veterinary Medicine. Her fields of interest are among others: Pharmacology and Pharmacotherapy with emphasis on antimicrobial drugs, antimicrobial resistance and infectious bacterial disease. Currently, Jobke works as a veterinarian in the Pig Health of GD Animal Health.

Dr ir. Jos Verstegen

Wageningen University & Research

Jos Verstegen holds an MSc degree in Animal Sciences and executed a PhD study on the value of management information systems in livestock farming at the Animal Health Economics group of Wageningen University. Currently, he is visiting professor at two universities in Japan. His research portfolio includes projects on entrepreneurship, innovation, data-driven business models, precision agriculture, big data platforms and data warehouses. Jos is now leading the EMA project "Big Data in Veterinary Medicines Regulation: A Data Landscape Analysis".

Michael Renaudin

Head of Swissmedic 4.0

Swissmedic 4.0 is concerned with the challenges and opportunities of digital transformation. In the sense of an innovation lab, Swissmedic 4.0 is to exploit the opportunities offered by new. Michael and his team develop solutions and applications in the field of artificial intelligence and machine learning, such as automated literature search systems, triage systems or text processing applications based on large language models (LLMs). Together with his team, he creates training programmes and information material on digital transformation and supports Swissmedic in the implementation of agile frameworks such as Scrum or SAFe.

Dr Laure Baduel

French Agency for Veterinary Medicinal Products (ANMV)

Since 2020, Dr Laure Baduel has overseen 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 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.

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.

Professor Dr Thomas Heberer

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 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.