

## Advanced analytics to support animal and public health

Report from the 2nd Veterinary Big Data Stakeholder Forum

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EMA/HMA Big Data Stakeholder Forum - 1<sup>st</sup> December 2022



## Summary of the event

- Event run for 1 day on 23<sup>rd</sup> November 2022
- Organised in 3 sessions with 14 speakers
- Audience: regulatory authorities, marketing authorisation holders, academia and animal health practitioners
- Average turnout of 300 attendees (via Webex and broadcast)
  - Presentations and recordings will be available in due course on [EMA website](#)



## Outlines and goal

- **Overall Goal: to identify and prioritize a list of initiatives to feed into the Veterinary Big Data work plan for the coming years**
- Session 1: Advancements in the area of Big Data and digitalisation in the veterinary domain
  - focused on advancements since first Vet Big Data Forum in June 2021
- Session 2: Stakeholders' insights on key business areas
  - views on concrete use cases in the area of Veterinary Medicinal Product information, Pharmacovigilance and Antimicrobial Resistance
- Session 3: Big Picture on Big Data
  - shared ongoing applications of digital technologies in cross-domain fields such as food safety and public health, falsified products, antimicrobial resistance and disease control

## “Advancements in the area of Big Data and digitalisation in the veterinary domain”

1. Report of the EU Veterinary Big Data achievements since the last meeting in 2021 and next steps (AEMPS)
2. Outlines of the HMA/EMA Big Data Steering Group activities (EMA)

### Key conclusions

- Experiences from human domain useful to define best practise for veterinary domain
- Need to identify relevant animal health data sources
- Build network skills in collaboration with the regulatory network and industry
- European Health Data Space principles currently not available for the Veterinary Domain
- Implementation of data solutions must be related to key benefits for all stakeholders in order to increase acceptance

## “Stakeholders’ insights on key business areas”

1. Survey results on priority and maturity of proposed use cases (BVL)
2. Pharmaceutical Industry’s view (Animal health Europe)
3. Veterinarians’ view (FVE)
4. Animal healthcare professionals other than veterinarians’ view (Royal GD)
5. Academia’s view (Utrecht University)
6. EU Veterinary Medicines Regulators’ view (ANSES)
7. International Veterinary Medicines Regulators view (FDA CVM)



## VMPs availability

1.A: solution to monitor vet medicines availability and anticipate shortages

1.B: Data integration to inform areas of unmet medical needs and alternative treatment plans

View from:

Veterinarians (1A & 1B)  
EU Regulators (1A)

## Pharmacovigilance

2.A: Signal detection comparison to improve quality control and harmonise safety outcomes

2.B: Data integration to support and enhance pharmacovigilance regulatory activities (risk safety and compliance monitoring)

View from:

Pharma Industry (2A), Academia (2B)  
FDA (2A)

## Antimicrobial Resistance

3.A. data integration and develop data analytic methods to: understand association VMPs use and resistance development; inform risk management, identify emerging use, and evaluate the impact of reduction of antimicrobial use on AMR development.

View from:

Animal healthcare professional, Academia, EU Regulators, FDA



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### Report on:

- Benefits
- Ongoing initiatives
- Obstacles
- Recommendations

**VMPs availability**

**Pharmacovigilance**

**Antimicrobial  
Resistance**

**Benefits and drivers:**

- Real time monitoring of shortages and identify treatment alternatives (especially for vaccines, antibiotics & limited markets)
- Facilitate Pharmacovigilance activities: increase reporting, increase efficiency in detecting important signals with least admin burden (risk-based approach)
- Reduction of administrative burden and workload
- Improve data quality and interoperability of systems implemented in VMP Regulation
- Harmonised regulatory documents and framework

**VMPs availability**

**Pharmacovigilance**

**Antimicrobial  
Resistance**

**Obstacles:**

- Resources & timing
- Data ownership and accessibility
- Lack of standardisation
- Data quality and metadata
- Variability & heterogeneity of knowledge, data and technologies

## VMPs availability

## Pharmacovigilance

## Antimicrobial Resistance

### Recommendations:

- Build sustainable capability & capacity within the network
- Ensure Ethics and Security
- Re-use existing data and technologies
- Identify and integrate suitable data sources (e.g. a harmonised compulsory e-prescription practice in EU would support PhV and AMR)
- Access to valuable data/ heterogeneous data through federated definition and ontology mapping
- Mobilise stakeholders and expertise (i.e. combine veterinary expertise with IT specialists/ Data analysts)

## “Big Picture on Big Data”

1. Current and future use of omics and other data in food/feed safety assessments (EFSA)
2. WOAHA: Current data analytics experience and future direction for travel (World Organisation on Animal Health - WOAHA)
3. The DECIDE project: Data-driven control and prioritisation of endemic contagious animal diseases (Utrecht University)
4. Opportunities for data-driven insights into animal health and regulation (University of Surrey)

## Session 3 – Key discussion and conclusions

Interventions from EFSA, WOAHA and Academia provided insights on how data collection, integration, analysis and dissemination could support public health.

### Key conclusions

- Data-driven solutions are already a reality in animal health
- Sister agencies recognize need for further development and seek cooperation
- WOAHA already has a wealth of experience in data gathering and analytics and is now expanding to new fields like AMR and falsified products as part of his strategic plan
- The DECIDE and vHIVE projects showed the application of data-driven solutions in animal health management and highlight advantages of cooperation and partnerships between academia and industry provided that necessary funds are accessible

## Resulting proposed actions

- Continue focusing on enriching and increase data quality in veterinary systems established under VMP-Reg
- Data discoverability: further identification of data sources and metadata
- Derive an EU Vet Workplan to prioritise and implement the selected use cases considering needs of all stakeholders
- Set up an agile multidisciplinary platform to drive implementation of the workplan and advice on independent analytic methodologies integrating One Health collaboration
- Explore the potential for an Animal Health Data Space interoperable and embracing ONE Health principles (e.g. agriculture data space)
- 3<sup>rd</sup> Veterinary Big Data Stakeholder forum should be organised at the end of 2023



## Take home message

*"Since last year, awareness on Big Data in the Veterinary domain has increased and coalition of willing has been established.*

*We need to keep the momentum and consolidate cooperation with our stakeholders to establish data-driven and evidence-based decision-making practices underpinning innovation in the Veterinary Medicines Regulation domain for animal and public health"*



# Any questions?

## Further information

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