Session 2: Stakeholders' insights on key business areas

Outline and survey results

Presented by
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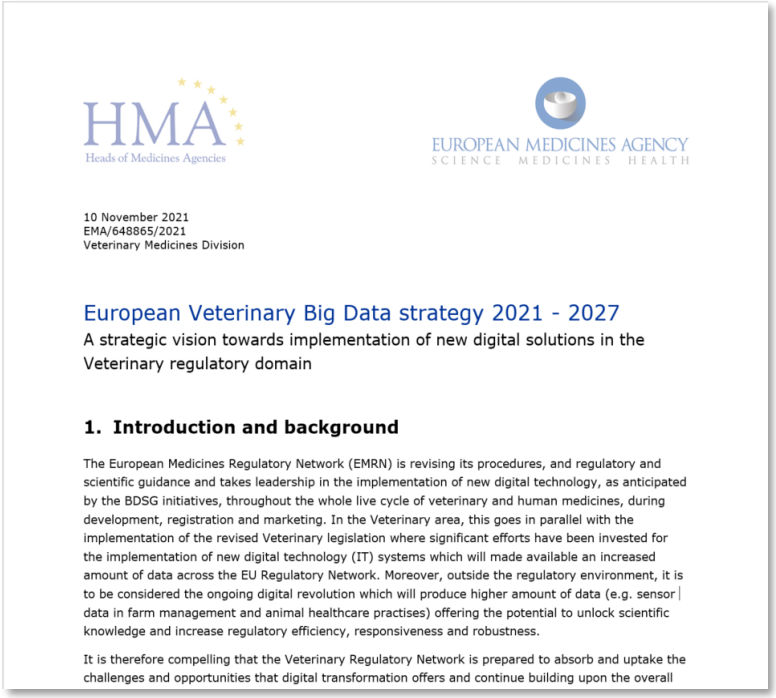
2nd Veterinary Big Data Stakeholder Forum 23 November 2022

Background



HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 November 2021
EMA/648865/2021
Veterinary Medicines Division

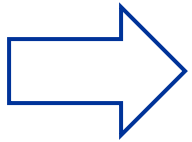
European Veterinary Big Data strategy 2021 - 2027

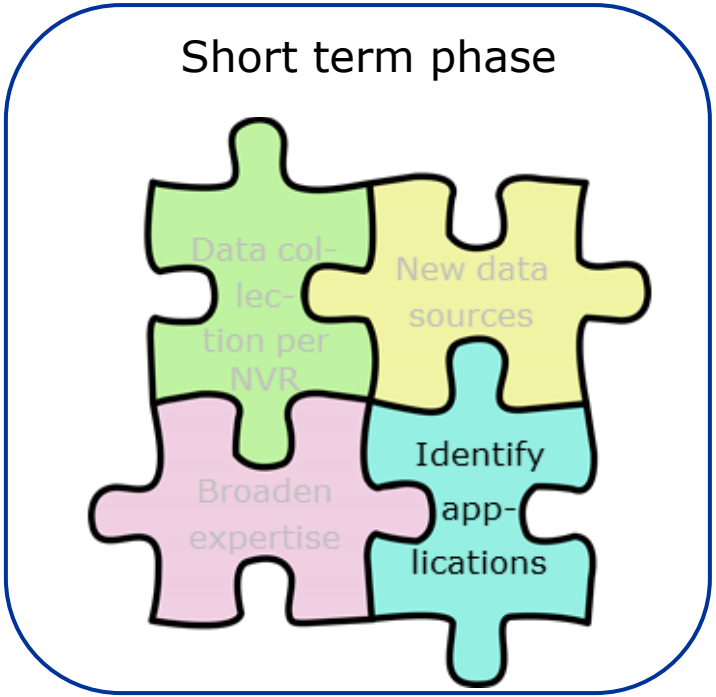
A strategic vision towards implementation of new digital solutions in the Veterinary regulatory domain

1. Introduction and background

The European Medicines Regulatory Network (EMRN) is revising its procedures, and regulatory and scientific guidance and takes leadership in the implementation of new digital technology, as anticipated by the BDSG initiatives, throughout the whole live cycle of veterinary and human medicines, during development, registration and marketing. In the Veterinary area, this goes in parallel with the implementation of the revised Veterinary legislation where significant efforts have been invested for the implementation of new digital technology (IT) systems which will made available an increased amount of data across the EU Regulatory Network. Moreover, outside the regulatory environment, it is to be considered the ongoing digital revolution which will produce higher amount of data (e.g. sensor data in farm management and animal healthcare practises) offering the potential to unlock scientific knowledge and increase regulatory efficiency, responsiveness and robustness.

It is therefore compelling that the Veterinary Regulatory Network is prepared to absorb and uptake the challenges and opportunities that digital transformation offers and continue building upon the overall



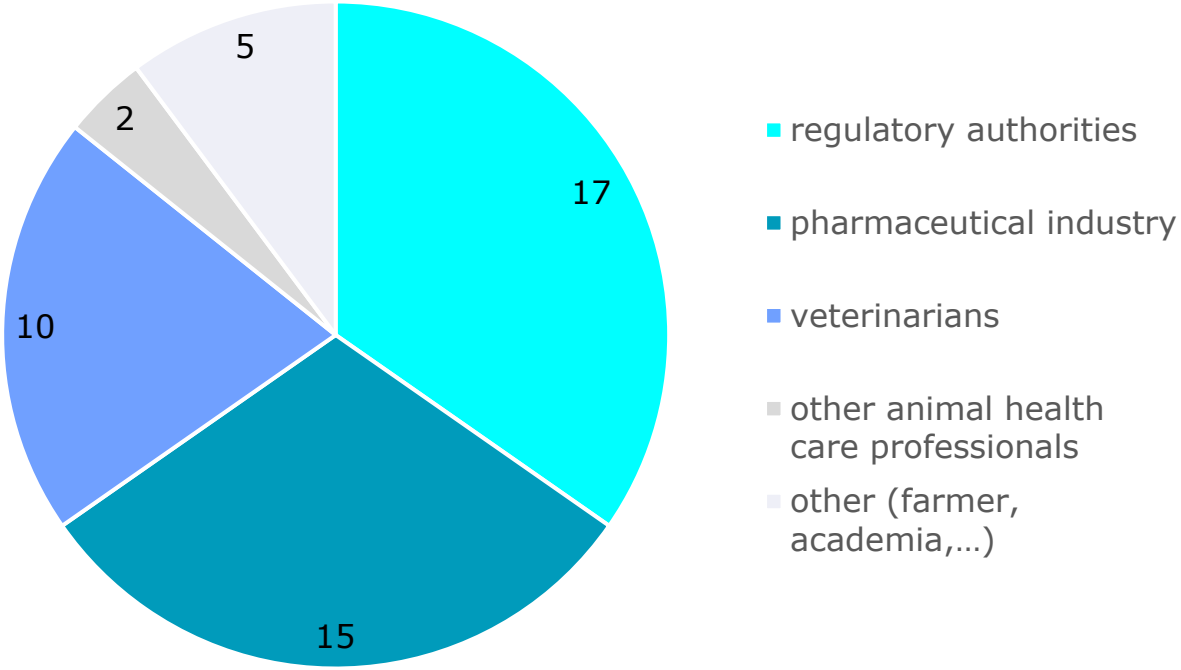


Background

- 3 key business areas identified
  - Pharmacovigilance
  - Antimicrobial Resistance
  - Veterinary Medicinal Product Information
- 4 - 5 use cases proposed per business area → need to select most relevant benefiting from application of new digital technologies
- survey launched in September 2022
  - relevance
  - maturity

Survey results

- 49 responses



Survey results – VMP use cases

1.A. To develop a solution to **monitor** the availability of **Active Pharmaceutical Ingredients** and **VMPs** in the EU and so **anticipate shortages**.

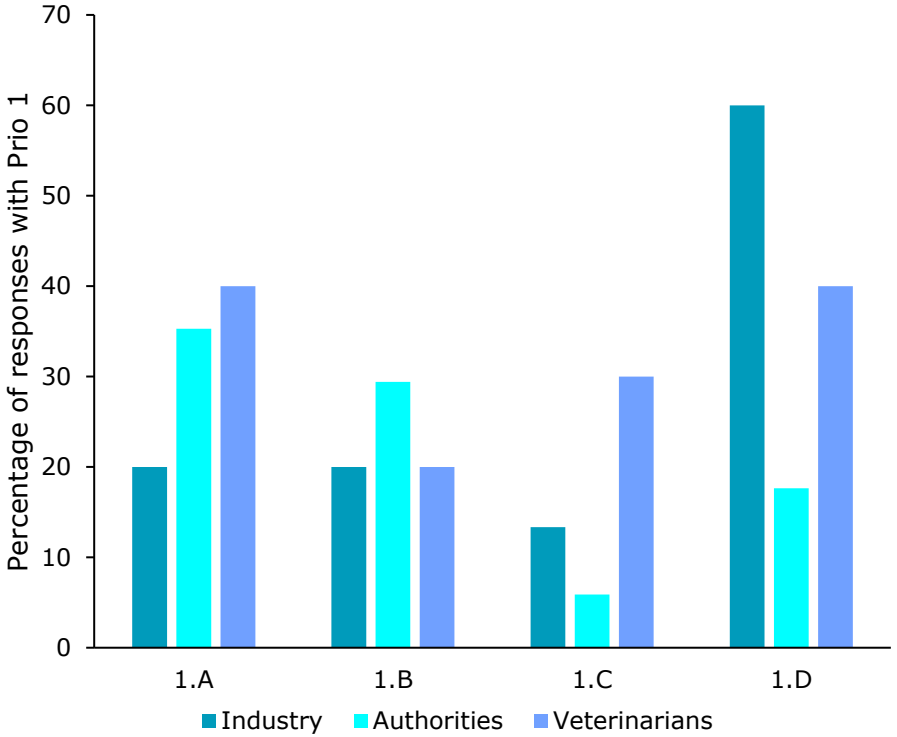
1.B. To develop a solution **extracting clinical particulars** (e.g., target species, indications, posology, pharmaceutical form, known adverse reactions) from VMPs Summary of Product Characteristics and provide:

- an overview of areas of **unmet medical needs** and therapeutic gaps;
- support to veterinary practitioners to define **alternative treatment plans**, particularly in case of unavailability of a specific product.

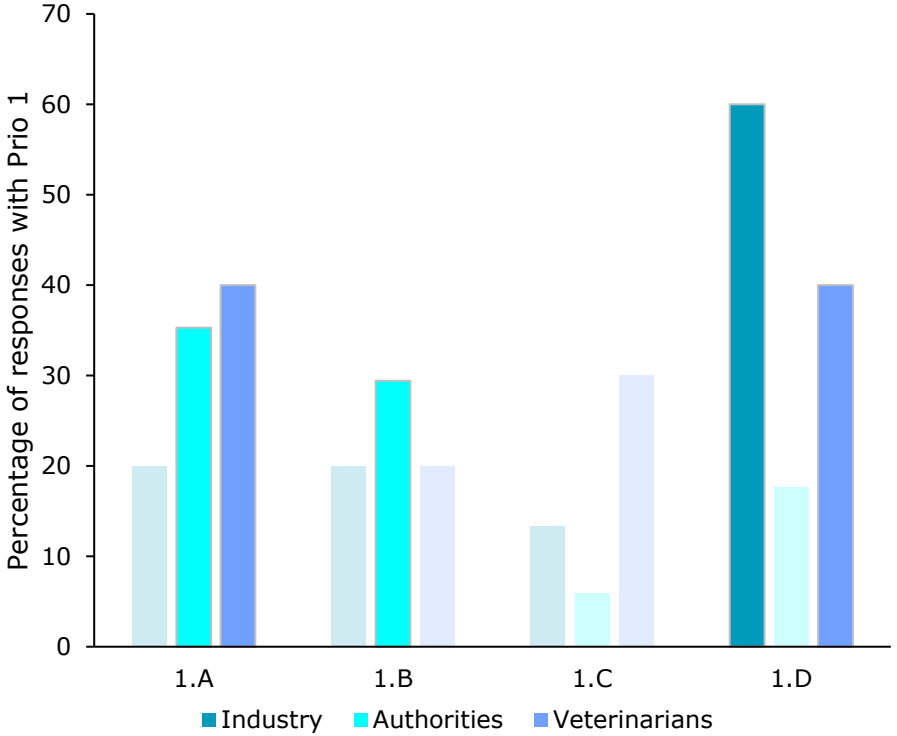
1.C. To develop a solution which integrates VMP data such as **clinical particulars** (e.g., indications, prophylactic administrations) and **emerging health threats/disease outbreak forecasts** to monitor and **anticipate** availability of treatments and identify **therapeutic gaps** and **VMP shortages**.

1.D. To support the application of **new technologies** (e.g., genomics, proteomics, combination of other loggers and intelligent devices) for the discovery and design of (**novel**) **VMPs** and/or **better** define **treatment regimen**

Survey results – VMP use cases



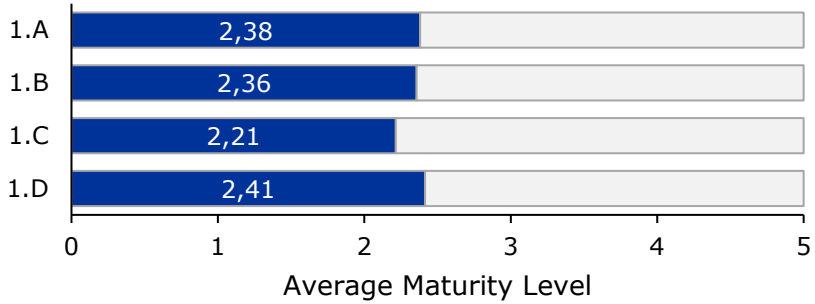
Survey results – VMP use cases



1.A. monitor availability APIs and VMPs to anticipate shortages

1.B. using clinical particulars from SPCs to identify unmet medical needs, therapeutic gaps and support to define alternative treatment plans

1.D. new technologies to discovery novel VMPs and/or improve treatment regimen



Survey results – PhV use cases

2.A. To implement a solution which **compares Signal Detection** outcomes **across MAHs** ensuring quality control and obtaining harmonised safety outcomes.

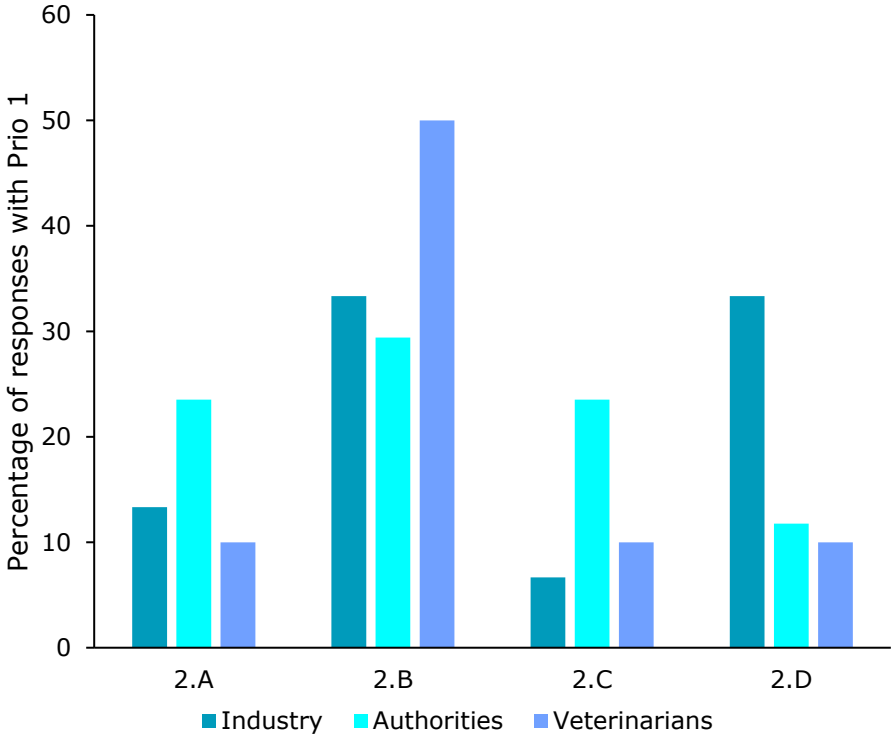
2.B. To implement solutions to **integrate** VMPs submission of **variations**, **prescription/dispensation** practices and **AERs reporting** trends (in the Union Pharmacovigilance database) to:

- **monitor compliance** with PhV regulatory requirements (e.g. under reporting in Union Pharmacovigilance database);
- drive **PhV Inspections prioritisation** and;
- provide data mining for sharing information and outcome of EU inspections across the network;
- **investigate** potential **safety risks** related to misuse of VMPs.

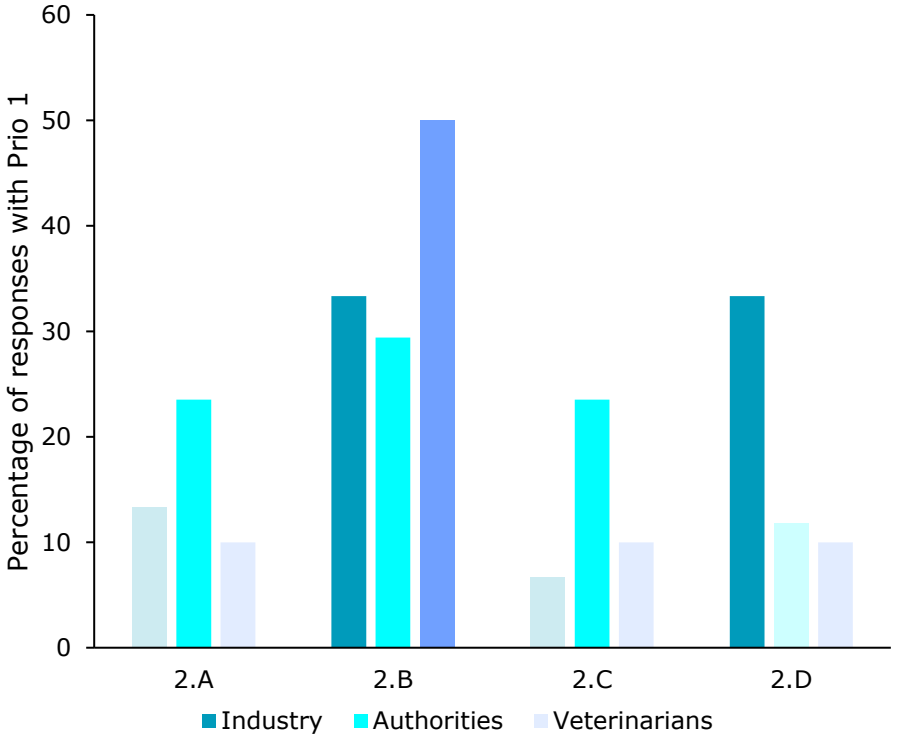
2.C. To develop a solution to harvest **safety data** on VMPs from a variety of **data sources** (e.g., regulatory outcomes, regulatory documents, literature, epidemiological studies, social media) to improve transparency and accessibility on safety information for stakeholders.

2.D. To perform a process analysis and identify areas where **digital technologies** could be implemented to **automate safety risk assessments** by pharmaceutical industry and provide a 'single routine surveillance tool' to enable efficient safety outcomes elaboration and robust decision-making by regulators

Survey results – PhV use cases



Survey results – PhV use cases

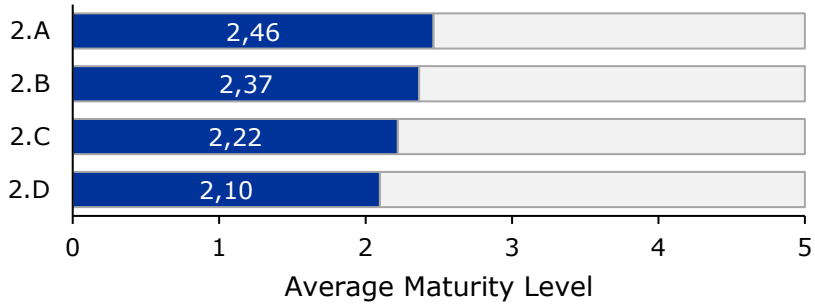


2.A. compare Signal Detection across MAHs

2.B. integrate variations, prescription/dispensation and AERs to monitor reporting compliance, prioritise Inspections, investigate safety risks due to misuse

2.C. harvest safety data from a various data sources

2.D. single routine surveillance tool to automate safety risk assessments



Survey results – AMR use cases

3.A. To **integrate** Antimicrobial (AM) **use data** with a variety of **other data sources** (e.g. prescription data, treatment outcomes, animal health records, AMR and resistance determinants across the one health spectrum - animals, humans and the environment) and develop data analytic methods to:

- better understand the **association** between **use** of AM VMPs and the **development** of **resistance** and;
- facilitate the interpretation of trends, inform risk assessment, setting risk management priorities, identify emerging use, and evaluate the impact of reduction of antimicrobial use on AMR development.

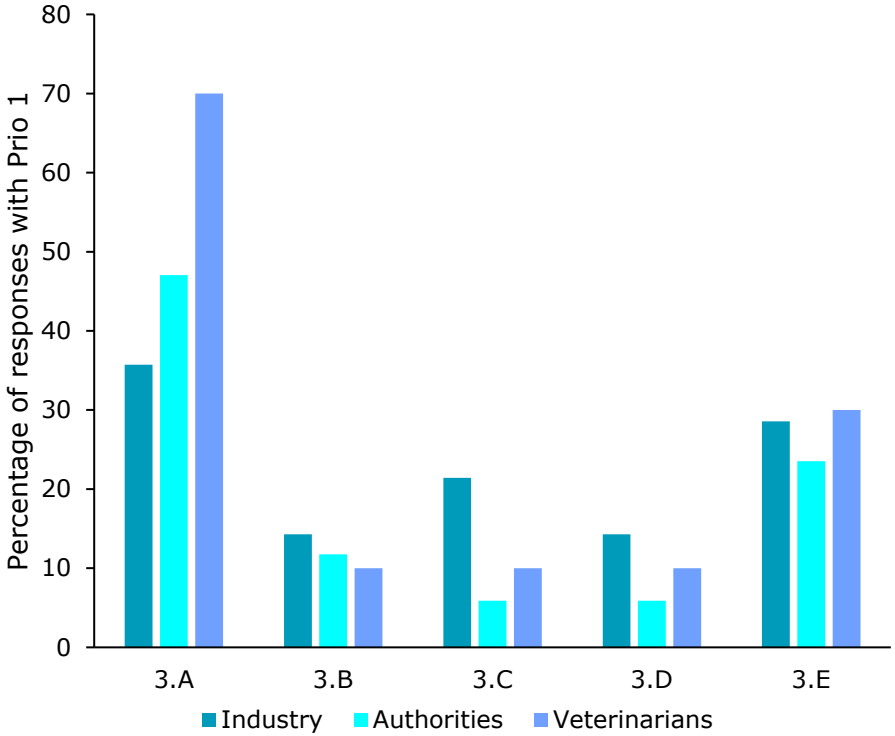
3.B. To perform a process analysis and identify areas where **big data** and other **digital technologies** (e.g., Artificial Intelligence, Machine Learning and underlying algorithms) could facilitate the **automation** of **criteria** that can be used to inform the **risk assessment of antimicrobials** (e.g., predict resistance genes or gene transfer).

3.C. To apply **novel** digital **technologies** to **generate** animal **population data across** different animal **species** and stages of **production** to support a precise spatial-temporal analysis of AM use (and resistance) according to different animal species, stages of production and geographic areas.

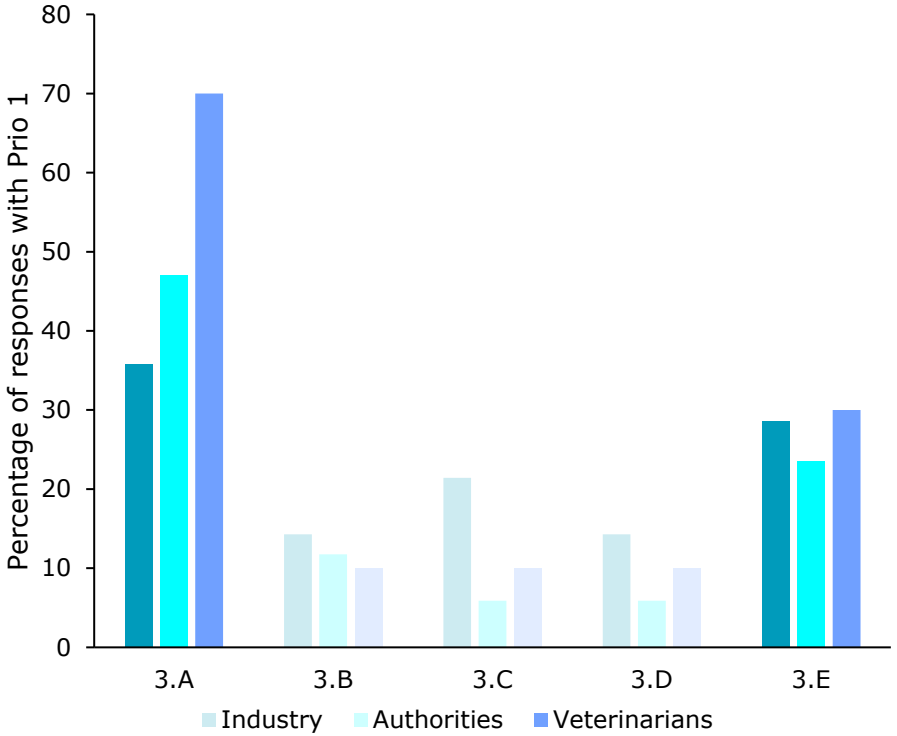
3.D To implement big data, innovative approaches and other non-observational methodologies for **dose optimisation** in order to maintain effectiveness and to limit the selection of resistant target pathogens.

3.E. Application of **new digital technologies** to develop reliable **rapid-diagnostic tests** (e.g., point care diagnostic) to detect and/or measure resistance, support responsible use, inform better targeted therapy, and improve the responsible use of antimicrobials in animals. Apply novel approaches to support **harmonisation** and **standardisation** of **methodologies** including development of clinical breakpoints to facilitate interpretation of results

Survey results – AMR use cases

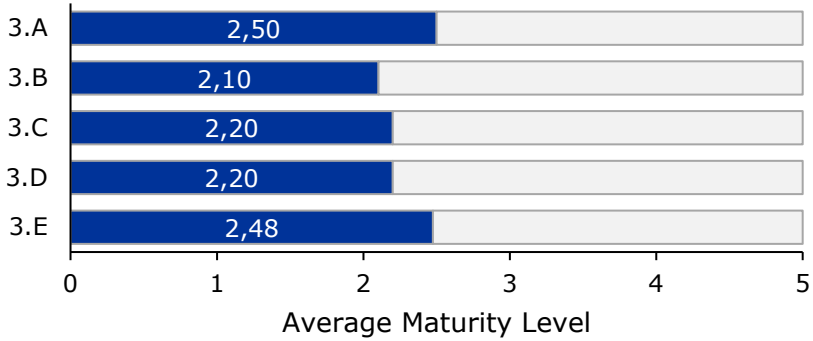


Survey results – AMR use cases



3.A. integrate use data with other data sources to understand development of AMR and implement risk surveillance/ control

3.E. advanced rapid-diagnostic tests to detect AMR, support responsible use, better targeted therapy and harmonisation/ standardisation of methodologies including determination of CBP



Conclusion

Use cases with the highest overall priority

- VMPs: to monitor availability APIs and VMPs to anticipate shortages
- PhV: to integrate variations, prescription/dispensation and AERs to monitor reporting compliance, prioritise Inspections, investigate safety risks due to misuse
- AMR: to integrate use data with other data sources to understand development of AMR and implement risk surveillance/ control

- Priority for VMP and PhV use cases divergent
- Priority for AMR use cases independed from stakeholder
- Maturity for all use cases mediocre (between 2 and 3 out of 5)
- no relationship between maturity and priority

Outline of the following Session

View of different stakeholders (20´+5´):

- *Pharmaceutical Industry* - Rick Clayton (AnimalhealthEurope)
- *Veterinarians* - Despoina Iatridou (FVE)
- *Animal healthcare professionals other than veterinarians* - Dr Jeanine Wiegel (GD Animal Health)
- *Academia* - Dr Miel Hostens (Utrecht University)
- *EU Veterinary Medicines Regulators* - Laure Baduel (ANSES)
- *International Veterinary Medicines Regulators* - Dr Hesha J. Duggirala (FDA CVM)

Any questions?

Further information

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