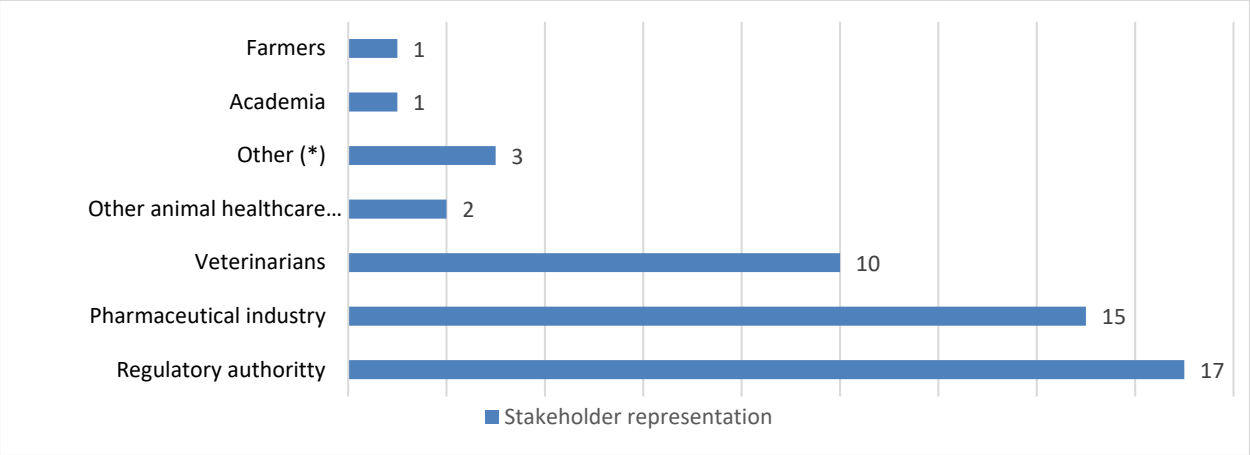
# 2nd Veterinary Big Data Stakeholder Forum

Results for EU Survey[1] on proposed use cases

## Background

- **Responses received:** 49
- **Target audience**: regulatory authorities, pharmaceutical industry, academia, veterinarians and other animal healthcare professionals (including farmers and animal management services
- **Purpose**: gather feedback on the most beneficial use cases to implement in the next 2-3 years in the areas of **Veterinary Medicinal Product Information**, **Pharmacovigilance** and **Antimicrobial Resistance**
- **Metrics**: level of priority and level of maturity

## Who responded?




(*) "Other" includes SME, private public entity, and Industry Federation

[1] Available between 16 September – 3 October 2022. For full context, see Annex.

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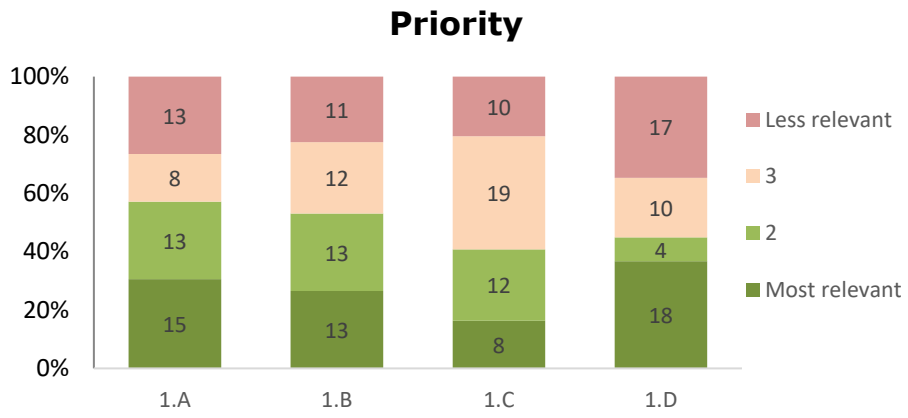
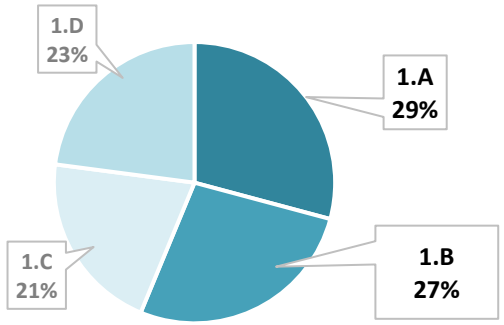
# Veterinary Medicinal Product (VMP) information use cases

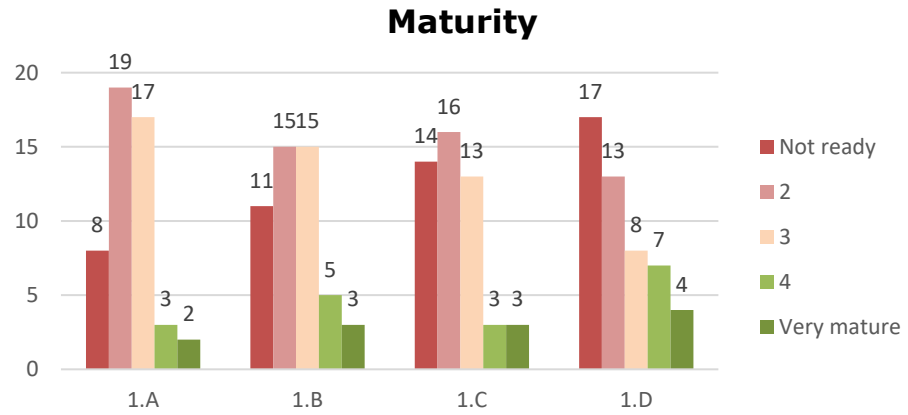
**Prioritisation level – by use case**




*The percentage represents the aggregate of priorities 1 and 2 (i.e., the cumulative green shades of the stacked column on the left).*

**Maturity level – by use case**




**VMP use cases with higher prioritisation**

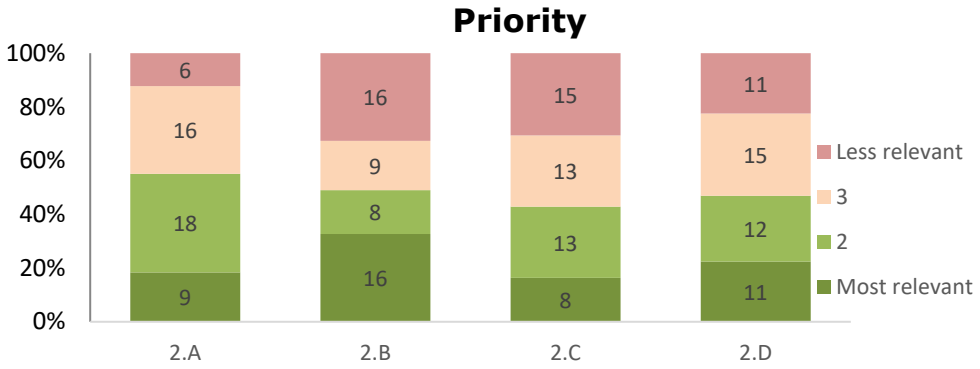
**1.A.** To develop a solution to monitor the availability of Active Pharmaceutical Ingredients and VMPs in the EU and so anticipate shortages.

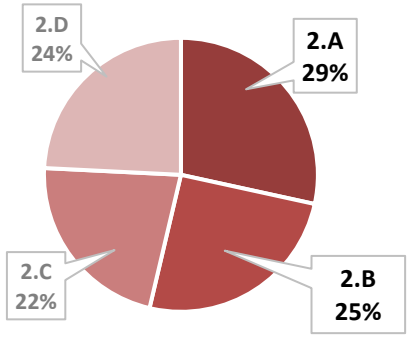
**1.B.** To develop a solution extracting clinical particulars (e.g., target species, indications, posology, pharmaceutical form, known adverse reactions) from VMPs Summary of Product Characteristics and provide:

- 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

# Pharmacovigilance (PhV) use cases

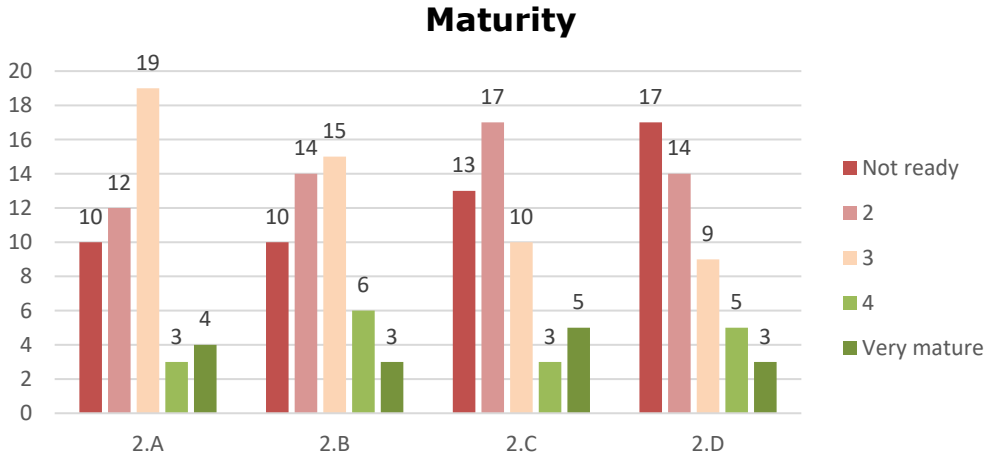
**Prioritisation level – by use case**




*The percentage represents the aggregate of priorities 1 and 2 (i.e., the cumulative green shades of the stacked column on the left).*

**Maturity level – by use case**




**PhV use cases with higher prioritisation**

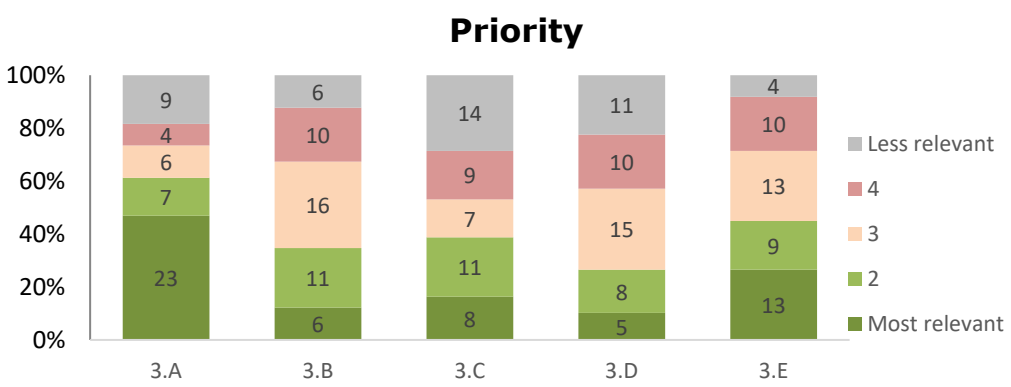
**2.A** To implement a solution which compares Signal Detection outcomes across MAHs ensuring quality control and obtaining harmonised safety outcomes.

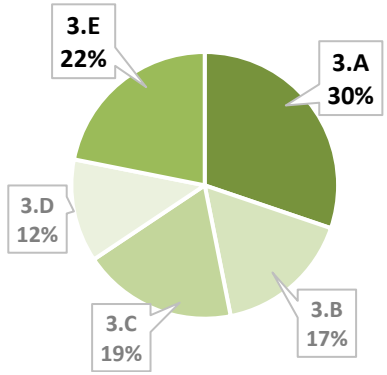
**2.B** To implement solutions to integrate VMPs submission of variations, prescription/dispensation practices and AERs reporting trends (in the Union Pharmacovigilance database) to:

- monitor compliance with PhV regulatory requirements (e.g., under reporting in UPhvD);
- 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.

# Antimicrobial Resistance (AMR) use cases

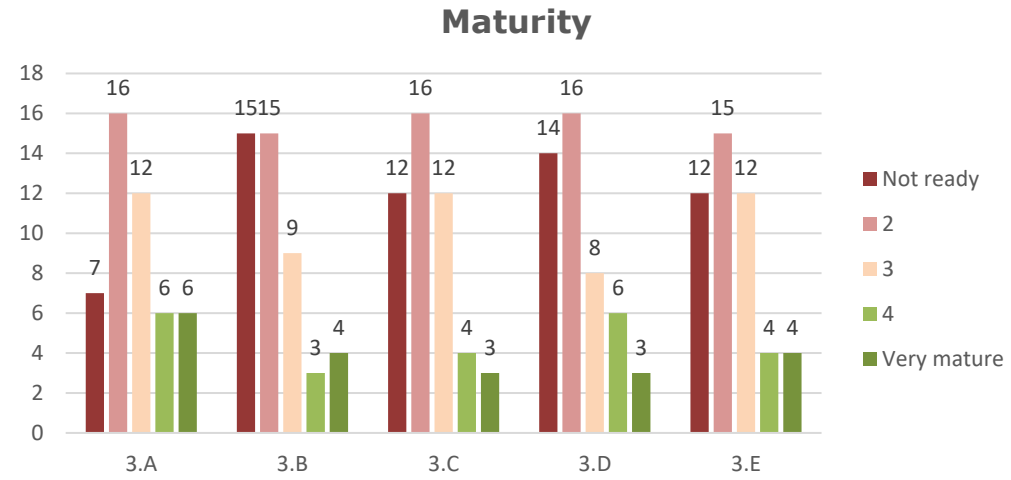
**Prioritisation level – by use case**




*The percentage represents the aggregate of priorities 1 and 2 (i.e., the cumulative green shades of the stacked column on the left).*

**Maturity level – by use case**




**AMR use cases with higher prioritisation**

**3.A.** To integrate Antimicrobial (AM) use data with a variety of other data sources and develop data analytic methods to:

- better understand the association between use of AM VMPs and the development of resistance and;
- to 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.E** To implement big data, innovative approaches and other non-observational methodologies for dose optimisation to maintain effectiveness and to limit the selection of resistant target pathogens. Application of new digital technologies to develop reliable rapid-diagnostic tests 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.

# Annex

**1. Please rank the use cases below in order of priority <u>from most to less relevant</u> in the area of Veterinary Medicinal Product (VMP) Information (select 1 for the most relevant).**
*For each case, please grade the level of maturity based on current data landscape (such as availability and accessibility of good quality data), knowledge, expertise, and resources available (with 1 being "not ready" and 5 "very mature").*

| **Uses 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:<br>• an overview of areas of unmet medical needs and therapeutic gaps;<br>• 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 regimens. |

**2. Please rank the use cases below in order of priority <u>from most to less relevant</u> in the area of Pharmacovigilance (PhV) (select 1 for the most relevant).**
*For each case, please grade the level of maturity based on current data landscape (such as availability and accessibility of good quality data), knowledge, expertise, and resources available (with 1 being "not ready" and 5 "very mature").*

| **Uses 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:<br>• monitor compliance with PhV regulatory requirements (e.g. under reporting in Union Pharmacovigilance database);<br>• drive PhV Inspections prioritisation and;<br>• provide data mining for sharing information and outcome of EU inspections across the network;<br>• 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. |

**3. Please rank the use cases below in order of priority <u>from most to less relevant</u> in the area of Antimicrobial Resistance (AMR) (select 1 for the most relevant).**
*For each case, please grade the level of maturity based on current data landscape (such as availability and accessibility of good quality data), knowledge, expertise, and resources available (with 1 being "not ready" and 5 "very mature").*

| **Uses 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:<br>• better understand the association between use of AM VMPs and the development of resistance and;<br>• to 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. |