EU Veterinary Medicines Regulators' view

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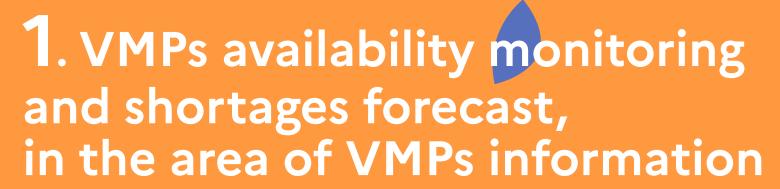
Introduction

National competent authorities' (NCAs) point of view on the benefits and challenges of Big Data on:

1. **VMPs availability monitoring and shortages forecast, in the area of VMPs information**

2. **Data integration and analytics, in the area of Antimicrobial Resistance (AMR)**

Based on the answers of 5 european NCAs to a recent survey circulated by CMDv

1. VMPs availability monitoring and shortages forecast, in the area of VMPs information

VMPs availability monitoring and shortages forecast

Benefits of Big Data

- Data collection in a European database (UPD) concerning the availability of products would be beneficial as availability problems in one country could be compensated by stock from another country if this information is available.
  Especially for the veterinarians and the supervising authorities it is important to know if and where a VMP is available in the EU. If there is no appropriate medicinal product for the treatment of the animal species available, veterinarians are allowed to get a VMP from another member state or use a medicinal product for humans according to articles 111 and 112 of the regulation (EU) 2019/6.
  It would be very useful if the **availability of a VMP would be documented in the UPD, but also the research for active ingredients, animal species and indications should be possible.**
- Better overview and possibility for **earlier information of stakeholders**
- To be able to **predict shortages and if possible ensure the availability of a product or its alternatives**
- **The Eu SPOC** already provides useful but not exhaustive information

Current initiatives of NCAs

Variable according to the MS concerned:
- In Germany MAHs are asked to **report shortages of VMPs on a voluntary basis** (a legal basis is missing). This does not work very well. The BVL hopes to get the information out of the UPD in the near future, since the MAH is obliged to report availability / non availability in the UPD for each MS, but in this respect the UPD is not yet working.
- We will download the availability data from the UPD for our products
- No current initiative for one of the responding NCAs
- In France, MAHs are asked to report **(only) critical shortages** of VMPs and those presenting a critical risk. Anses **communicates only on shortages, confirmed as critical**, according to criteria established and agreed with stakeholders (recorded in a GP guide) .
  Limited remaining disparities in the reporting of information, depending on the MAH.

Existing SPOC at the Eu level, for human & VMPs

VMPs availability monitoring and shortages forecast

Barriers faced by NCAs

- In Germany MAH act in a **free market economy**. The BVL has no insight into the production capacity, goods traffic and stock of VMPs of MAHs. Assessment of the availability of VMPs by the BVL is not possible; **these data are subject to the production secrets of the companies.**
New and unexpected situations as the corona pandemic or the war in Ukraine can result in bottlenecks in packaging materials, in large scale failures of production and transport capacities or in blackouts. This may require more management by the authorities in the future.
- **Some implementation necessary in our system, UPD not fully functional yet**
- To **get access to data** - provided they are available
- MAHs may be **reluctant to disclose VMPs availability information.**

Needs of NCAs

- Availability problems can occur at short notice and can have **various causes**. Preparation for such cases are essential and will become more important in the future.
- Information on **shortages of VMPs in UPD** (database)
- Information on **shortages of active ingredients** (or other essential materials for VMPs)
- Knowledge about demand data and/or sales volume of VMPs in UPD
- Possibility for **monthly reports from UPD, visibility of availability in all MS**
- Data on **national and European stock of VMPs from pharmacies, wholesalers, MAHs inventories, veterinarians**
- **Exhautive information (incl. alternatives), provided by MAHs,** quickly available for NCAs (e.g via UPD) **notably for defined critical VMPs.**

VMPs availability monitoring and shortages forecast

Proposed NCAs' recommendations

➢ Availability data for VMPs should be recorded in a database (UPD) in a good searchable format. Information should be not only searchable for each VMP separately, but also for active ingredients, indications, animal species etc.

➢ More information than "temporarily unavailable" on shortages in the UPD would be beneficial (e.g. date when it will be available again, reason for shortage, as it is communicated in some Eu MS)

➢ Because wholesalers or MAHs do not necessarily have data or want to share data on inventory and shortages, find together the best approach (define an agreed policy?) at the Eu level, to enable NCAs to be aware of the useful and necessary information and to deliver an adequate communication to the stakeholders.

2. Data integration and analytics, in the area of Antimicrobial Resistance

Data integration and analytics on AMR

Benefits of Big Data

- Recognition of **patterns and trends in connection with other medical data** as well as on e.g. genome level; understanding and **recognition of possible connections between certain events and occurrence of resistance situations**; earlier problem solutions possible, as well as a **development of more specific therapeutics and diagnostic possibilities**
- Finding **patterns between AMR and use in animals, humans -**> JIACRA
  What else influences AMR -> animals: biosecurity at farm, farm size, etc? humans, plants, environment? Interactions between all systems.
- To be able to **monitor the development over time of AMR in animal and human populations**
- Possibility of **more accurate and detailed analysis of data**

Current initiatives of NCAs

Variable according to the MS concerned:
- Involvement in various expert groups internally as well as externally; **imparting and building expert knowledge** through e.g . further training; procurement of specially trained personnel, creation of technical prerequisites such as interfaces, equipment, software, etc.; building of awareness regarding this topic
- Structured data in **database on use in animals and AMR is ready and data are available.**
  Data on animals/farms are available in a database. Publication in progress: Statistical modelling/ML AMR and use of AM in pigs.
- **No current initiative** for one of the responding NCAs
- **Structured database and analytics on AM sales, on progress on usage, for some but not all species.**

JIACRA already provides data on AM use and AMR in Eu but not on a yearly basis

Data integration and analytics on AMR

Barriers faced by NCAs

- Provision of the technical possibilities and the corresponding know-how, sensible collection of data in connection with **applicable data protection guidelines**, processing and storage of the data masses
- **Missing links between AMR, AM use data** and other possible covariates (at farm level). No/less data on plants, environment.
- To get **quality data** on AMR.
- Appropriate software to analyse collected data.
  Some issues about quality, harmonisation, representativeness and safety of data, and on interface with prescription/delivery vets' softwares.
  Some competition amongst Eu MS.

Needs of NCAs

- Quality data on AMR that are representable samples of the populations over time
- Collect and analyse more precise and detailed data according to time (season), species (+ age) and region, in order to have a more accurate analysis of the AM use and AMR occurence.

Data integration and analytics on AMR

Proposed NCAs' recommendations

- Big data will be the future for this area and a way to identify trends, improve the resistance situation and get more information about e.g. emergence, occurrence in the environment etc. Research and training should be supported to build more capacity to use Big data. Hardware and software should be expanded.
International networking and cross functional collaboration should be further developed to better understand resistance situations globally.

- Data availability of AMR and also of possible covariates.
Overview of statistical methods.

- To explore if this is a realistic and doable use case that actually answers new scientific questions that are not already adressed by surveillance programs.

3- Conclusions

Conclusions

1. Importance of :
   Quality of data
   Standardisation of data
   Relevance of data
   Stakeholders' cooperation for data collection

2. Appropriate and sustainable processes and systems
   Defined and agreed analytical methods, modelling & simulation

3. Be able to deliver accurate and reliable analysis of Big data, useful for VMPs use and prescription,
   in respect of public and animal health as well as environmental safety.
   Adequate and regular communication

Thank you for your attention

Questions ?