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THE VOICE OF THE ANIMAL MEDICINES INDUSTRY

Adverse Drug Reaction reporting and data quality

The view of the industry for veterinary medicinal products

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Access VETMED

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AVC

Association of Veterinary Consultants

The scene (1)

- **Animal:**
  - Multiple species with different requirements for reporting
  - In general, farm animals are considered as a group. Extreme cases with bees (bee hives), poultry and fish
  - Pets are usually one animal per case
- **Human exposure to a VMP, symptomatic or not**

- **Adverse Event:**
  - Special cases to be considered:
    - Environmental incident
    - Violation of approved maximum residue limits (MRLs)
  - Business drives the reporting, e.g., decrease in production performance (growth, milk production), increase in mortality will trigger ADR reporting

The scene (2)

- **Reporter:**
  - Source: mainly spontaneous reports, relatively little pre-marketing clinical trial experience
  - Reporting triggered by customer care activities
  - Reporter can be animal owner, vet nurse, Animal Health technician, with impact on case quality
  - Veterinarians need to ensure their business and have less time to dedicate to ADR reporting
  - Social Media cases

- **Product:** reporting at brand level

The scene (3)

- It is a challenge to have standardized rules for quality of such a diversity of reports
- Customer interactions always include commercial elements
- One of the use cases for AI in human health - form to case - does not have an exact parallel in Animal Health

The process - how vet pharmacovigilance use the collected ADRs

EU regulation 2019/6 in place since January 2022 established:

- Strong **focus on risk management via signal detection**
  - Annual confirmation of MAHs that risk management has been conducted for all products (Annual statements)
  - Submission of signal reports for validated signals
- EMA provides **one common database (EudraVigilance Veterinary - EVVet) and analysis tool (EVVet Data Warehouse)** to be used by all stakeholders
- No submission of Periodic Safety Update Reports (PSURs)

The process - working in EVVet

- **EVVet data model:**
  - Assessment of causal relationship between AEs reported and products involved: not required anymore
  - Limitations of system to capture case details, e.g., concomitant products, products used as diagnostics
  - Cases not forwarded to stakeholders concerned (NCAs, MAHs), but manual download required if own database is used for signal detection activities
  - Data over-written by each follow-up, therefore restriction for follow-up submission to the case originator only

- **EVVET process:**
  - Focus on case coding (VeDDRA) because of signal detection based on pair product-VeDDRA term
  - (re)-coding of products

The challenges identified in the current playing field

- Duplicate reports: identification, work-out and nullification
- Non-harmonized requirements for reporting of PV cases:
  - Submission of worldwide PV cases to EVVet but local regulatory requirements
  - Reporting at case level vs product level: coding of all reported signs (for all involved VMPs) vs. coding of signs related “only” to recording MAH-own VMP

- Currently, processes causing significant extra-workload to MAHs
- Tools used do create issues in terms of case quality
- Limited experience with the new process on risk management, however case quality is considered key for signal detection activities

Conclusion

- Pharmacovigilance practices need to be adapted to the vet business.
- The PV teams are much smaller than in pharmaceutical industry for human medicines.
- The requirements of multiple agencies need to be accomodated with the same report

Any initiative on data quality for ADR reporting requires a harmonization at VICH level.