HMA
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EUROPEAN MEDICINES AGENCY
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Veterinary ADR data quality

Presented by James Mount on 1 March 2024
Chair of Pharmacovigilance Working Party – Veterinary (PhVWP-V)

Importance of data quality reflected in veterinary medicines regulations

- **REGULATION (EU) 2019/6 on veterinary medicinal products**

Article 77 - Pharmacovigilance responsibilities of the marketing authorisation holder.

5. The marketing authorisation holder shall comply with good pharmacovigilance practice for veterinary medicinal products.

- **IMPLEMENTING REGULATION (EU) 2021/1281**

Article 4 - Quality management system for pharmacovigilance.

4. Marketing authorisation holders shall ensure that the quality management system includes detailed policies, processes and procedures for the record management system and data collection in accordance with Articles 10 to 15, for the following pharmacovigilance activities:

(a) initial recording of any suspected adverse event; (b) collection of additional data; (c) collation of reports of suspected adverse events and additional data;

Impact of poor data quality in adverse event reports (AERs)

- Impaired detection of new risks - VMPs in Eudravigilance Veterinary (EVV).
- Negative effect on statistical methods and analysis.
- Impacts the implementation of new techniques (data mining/AI) – need for improved data stewardship.

- Impact on **all** Stakeholders.
  - MAHs shall perform signal detection at least once a year in EVV (Article 17(7) of the Implementing Regulation).
  - PSURs now replaced now with signal management.
- General public: Data is published in public portal of ADRs for transparency - https://www.adrreports.eu/vet/.

Common data quality issues in AERs

Top 5 data quality issues that have been observed by NCAs:

1. Missing / Incorrect coding of Species/Breed.
2. Missing / Incorrect VeDDRA code(s) - e.g., use of different versions of VeDDRA list.
3. Error with product coding - e.g., active substance entered in brand name data element field.
4. Case narratives – lack of information, non-chronological, diversity structure etc.
5. Inconsistent entry of AERs from literature.

Source: Survey of PhVWP-V members undertaken in 2022.

Strategies to monitor and prevent data quality issues

- A collaborative and collective effort – NCAs and MAHs.
- Multifaceted approach of NCAs:

1. NCA quality control efforts of AERs (resource limitations).
2. Algorithms in PhV databases (Business rules / Duplicate detection).
3. Regular dialogue with Stakeholders and need for training e.g., VeDDRA coding.
   - Occasional update of coding instructions and relevant guidance (Data stewardship).
   - Following up of identified data quality issues.
4. Pharmacovigilance inspection and liaison with PhV experts.
   - Establishment of an Informal PhVWP-V / PhV IWG Data Quality subgroup.

Any questions?

Further information

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