



Federal Office of
Consumer Protection
and Food Safety

Veterinary NCA Data Quality activities and uses of Adverse Event data

Presented by Kathrin Schirmann

Why is data quality important?

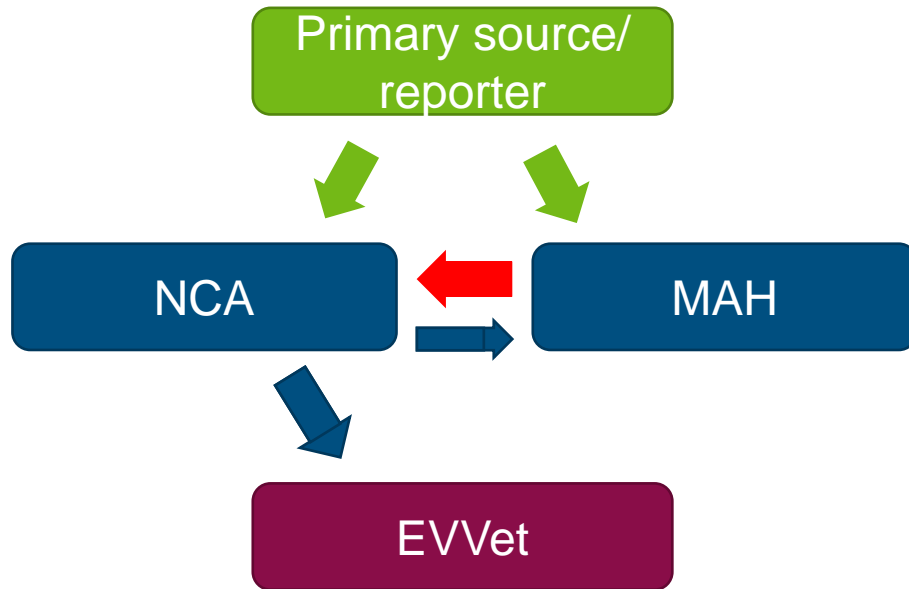
„ When data quality meets the standard for its intended use, data consumers can trust the data and leverage it to improve decision-making, leading to the development of new business strategies or optimization of existing ones.“

From IBM Website

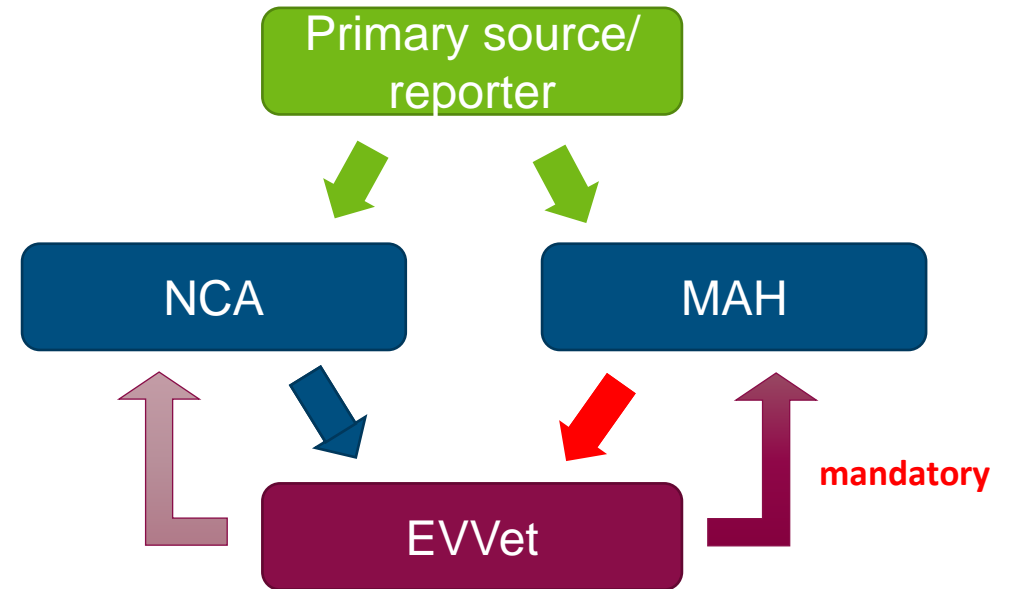
Reporting Pathways

Comparison of AE reporting between pre- and post EU Regulation 2019/6

‘Old’ legislation (up until end of January 2022)



‘New’ legislation (since end of January 2022)



NCA = national competent authority; MAH = marketing authorisation holder; EVVet = EudraVigilance Veterinary/ Union Pharmacovigilance Database

The BVLs national database

- **According to legal requirements the database**
 - Is capable of sending and receiving adverse event reports in VICH standard
 - re-routing of all DE reports from EVVET to the national database
 - Has passed the tests with the EVVET database
- **Facilitates**
 - AE entry, review and submission to EVVET (including receipt of ACK)
 - Duplicate detection
 - Surveillance
 - Archiving of AEs

Data Quality checks performed on all reports received

Examples

- **Entry of minimum criteria**
 - Only one species per report
 - Correct entry of veterinary medicinal product name or active substance in the respective fields
 - VeDDRA coding according to description in the case narrative
 - No confidential information included in the case narrative (e.g. ear tag number of a cow)
- **Case narrative**
 - Should contain all known relevant clinical and related information as provided by the primary reporter
 - Where applicable, the information in the case narrative should also be provided in structured format in the applicable fields (i.e. coded)

Common errors/ data quality issues

- **Database (in)compatibilities**
 - Incorrect mapping (?)
- **Data entry**
 - Multiple species in one AE report
 - Entry of active substance in the brandname field; use of 'unknown' and active substance
 - Wrong or non coding of VMPs other MAHs (e.g. incorrect spelling, no enquiry regarding brandname)
 - VeDDRA coding not matching the case narrative
- **Case narrative**
 - Incomplete case narrative
 - Not all information entered in provided data fields
 - Breeds mentioned but not coded

Data Quality - National level

Possible actions taken

- **Contacting the MAH**
 - Informing and liaising with the MAH on the issue detected (if applicable)
- **Entry in the internal list**
 - Internal record keeping of issues detected
 - Shared with inspectors
- **Entry in EU list**



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PhVWP-V Data Quality Subgroup

- **Subgroup initiated to**
 - discuss data quality issues that have been noticed
 - draft possible solutions
 - facilitate exchange to Inspectors

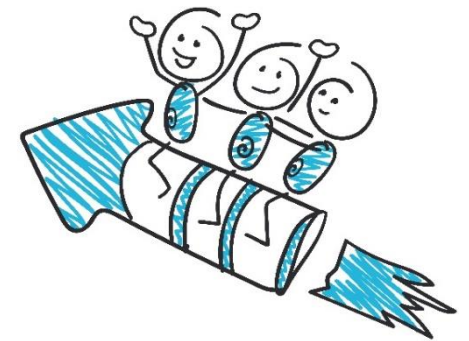


Collation of data quality issues within the EU

Use of AE data

On national level the AE data is used for

- Reporting
- Signal detection and analysis, surveillance
- Publication of data



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Thank you for your attention!





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Contact:

Dr. Kathrin Schirmann

Unit 322 Pharmacovigilance

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

kathrin.schirmann@bvl.bund.de