Pharmacovigilance, signal detection and surveillance – industry perspective

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A new era for veterinary pharmacovigilance

- Completely new model under implementation, industry is confident in meeting objectives of Reg 2019/6, namely reduction of administrative burden
- But we are not yet there:
  - MAH processes and systems need to be significantly changed
  - Increased resource requirements and administrative burden (expected transitory)
- Introductory phase, currently testing
  - Guidelines published shortly before 28 Jan, no opportunity to test before
- "Learning by doing" – all: EMA, NCAs and MAHs
- Need time to implement and test/optimise new systems

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Industry involvement during implementing phase

THANK YOU for the opportunity to contribute along the process.

- All company sizes represented (large and SMEs), trainings (EMA) and info sessions (EMA and NCAs)
- Encourage continued involvement with industry

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New IT Systems: overview

- All parties doing their best to manage the current situation with immature (not fully populated) databases. UPD limitations – impact EVVET and PhV operations.
- Industry proposals considered constructively, which shall be continued. Thanks to EMA IT for considering industry's feedback and for the solutions provided so far.
- MAHs not yet fully confident in the EVVET systems and the reliability of the data

  → Effective and rapid support from EMA service desk and NCAs.

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New IT Systems: learnings so far

Expected areas of improvement

- UPD data entry completion. Lack of product data entries impacts EVWEB and DWH functionalities
- Search functionalities in EVWEB
- Download of cases from EVWEB (manual process – resource intensive)
- Signal detection/evaluation tools
- Adaptation IRIS portal to VMP submissions

→ EMA IT is active with valuable improvements implemented or underway

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New PhV principles and requirements

- Big efforts at present, and also expected for quite some time
- Uncertainties and concerns, i.e.
  - Signal management; principles are clear, but how to implement those?
- Additional training and guidance would be much welcome, i.e
  - Practical guidance on signal management (with examples)
  - Entering the data into IRIS

Industry priorities and the way forward

- Keep in mind objectives of regulation, to not lose sight on reduction of admin burden. We need to get there (shared objective)
- Finalize registration of products in UPD, complete and quality data as this has an impact on the cases in EVVET and signal management
- Continue good dialogue and communication, joint effort
- Additional guidance & training sessions would also be very useful
- Patience and flexibility during +/- 1 year needed from all involved to adapt businesses processes and get practice

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