Legislative updates

Pharmacovigilance: Industry perspective

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CONTENT

- Signal management guidance updates:
  - Veterinary Union PhV DB - Best practice guide
  - VGVP module signal management
- Issues/Improvements of PhV Databases
- Review of secondary legislation with the aim to reduce administrative burden
- Global disharmonisation of PhV requirements

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GUIDANCE UPDATES

- Revised Best practice guide now includes a chapter on signal management
- It includes further elaboration of instructions provided in the VGVP module on signal management as well as practical guidance on how to use DWH queries

  -> While this guidance is much appreciated it does not fully address the concerns raised by industry regarding signal management

- The Signal Assessment Report Template is now also mandatory for refuted signals

  -> Industry is concerned that this will further increase workload without providing additional benefit for product safety

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REFLECTION ON REVISION OF VGVP MODULES

- Risk management is the main process for pharmacovigilance
- AnimalhealthEurope has proactively proposed wording for the revision of the VGVP module on risk management, and is committed to participate in the public consultation process
- It is important...
  - to ensure a harmonized process within the EU (at what point a signal becomes relevant for communication)
  - to keep in mind that risk management is based on global data - global harmonization of timelines

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EXAMPLES

- It cannot be one single approach for all products
  - Time to launch (new products vs. old products with large number of total cases that cannot be reviewed individually)
  - VMP used to treat large herds: current setup of disproportionality analysis is not adapted for low number of cases with large number of animals
- A triage step after signal detection is needed, in order to prioritize the safety observation that will undergo the validation process
- Validation is not a screening step, i.e. neither triage nor prioritization
- There should be flexibility regarding the methods used in evaluation

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PhV DATABASES

- Efforts are made by NCAs to improve quality of reports by actively reviewing cases
- Implementation of a global product dictionary would be very beneficial
- A duplicate detection system has been implemented, but its effectiveness cannot be verified by MAHs
  - The tool itself is not available to MAHs
  - Duplicates are highlighted in DWH line listings
- Issues with the transfer of data to consuming systems:
  - MAH product grouping to DWH and IRIS
  - AE reports to DWH

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PhV DATABASES - IMPROVEMENTS

- A new group has been established (EMA + NCA + MAH)
- Improve the duplicate detection system
- Improve grouping options of products for DWH analysis
- Incidence calculation in DWH
  - Not yet available to MAHs
  - Methodology of incidence calculation still under discussion

- Exchange between EMA and industry on technical topics should still be preferably take place with a broader audience (as in the former JIG meeting)

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REVIEW SECONDARY LEGISLATION

- Stakeholder meeting organised by European Commission - DG Sante last year
- High administrative burden is acknowledged and ways to reduce the burden are considered
- Maintenance of PSMF summary was highlighted by the industry as an example of disproportionate burden
  - Associated costs
  - Administrative work outside the UPD submission
- The EC signaled openness to reviewing the process for changes in the information provided in the PSMF summary
- This would not require a change to the Regulation, only to the IA and UPD

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GLOBAL DISHARMONISATION

- With VICH PSURs there is/was alignment with EU and non-EU countries
- Change from PSUR to signal management process -> several countries outside the EEA accept the new process, but not all
- Some non-EEA countries have actively switched to signal management process as well
  - E.g. UK accepted EEA due dates based on ATCvet codes
- However, if different countries/regions have different requirements for this process this further increases the burden on MAHs

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GLOBAL DISHARMONISATION (cont.)

- Complexity of risk management: challenge for MAHs is to inform countries with signals/regulatory action taken for safety reasons received from NCAs
- It is acknowledged that EMA must focus on EEA, however we ask for openess to support global harmonisation wherever possible (e.g. global product dictionary)

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CLOSING REMARKS

- Thank you to EMA and NCAs for the significant work undertaken to establish the new EU veterinary pharmacovigilance framework
- Industry appreciates the openness and many opportunities for constructive dialogue throughout the implementation
- Continued collaboration between regulators and MAHs will be key to achieving a robust and efficient EU pharmacovigilance system
- Open technical exchanges are highly valuable – forums such as the former Joint Implementation Group (JIG) were greatly appreciated and are hoped to return

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THANK YOU

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