Industry perspective on Pharmacovigilance

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This is a joint industry presentation in collaboration with

PhV IT systems

Experience from MAHs

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EVWEB

Good progress since last year

✓ Interface generally working well, submission and retrieval of ADR reports well established by now

Data quality

- **Duplicate management**: work in progress, but effectively not working yet
- Currently, processes causing significant **extra workload** to MAHs (e.g., follow-up, VeDDRA coding…)
- MAHs operating at global level supportive of VICH wide initiative: global **harmonisation** of use of datafields required

Reports that are only **API-related** (API reported in brand name field)

- Time consuming, not very useful as usually amount of information sparse
- Hopes for improvement - at least for products where 3rd country product names are provided by MAHs

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DWH

- **Dashboards: continuous improvement**. Still, much focus on **product short name & substance queries**
- **Precalculations** for some dashboards (more to come) **improving performance significantly**
- Still, complex and time-consuming activity. **Enhanced system performance needed (stability and speed)**
- Value of some queries is questionable; MAHs only use a small subset of queries
- MAHs/NCAs collaboration to better develop **mutual understanding** on this important topic
- Enhanced **communication and training** to NCAs and MAHs would be welcome to achieve a better collaboration / understating of the process

IRIS

- **Improvements noted,** interface more user friendly i.e. authorization country visible now
- **Issues remain with selecting all concerned products**, involves administrative burden
- Not possible to follow up / update on a previously submitted signal

Product grouping

Starting to be implemented. Product grouping will enable:

- easier and faster signal detection and assessment,
- as well as easy finding and submission in IRIS - tab already visible in IRIS, but link with UPD not yet established

But not robust enough yet, functionality implemented, without the ability to use it

Plans re. full deployment and communication?

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Submission of VoS in the UPD

- 2023 submission should have been completed **29 Feb 2024**. First year to submit full dataset (**EEA + non-EEA sales**)
- **Resources required at MAHs side have been very significant**
  - ✓ Getting all sales data - more difficult when MAHs are selling via distribution partners - data requests to distributors
  - ✓ **Very high burden for small (manual creation of file) and large (development of new systems) companies**
- **Improvements noted** as compared to last year
  - ✓ **UPD data quality**. But not full accuracy yet - 100% correctness needed for the operation of MAH validated systems
  - ✓ Changes in UPD pack identifiers seems to be **more stable** now
- Guidance on how to allocate sales data in specific circumstances?

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Sales data submission

FURTHER EFFORTS NEEDED TO ENHANCE EFFICIENCY AND REDUCE UNNECESSARY ADMINISTRATIVE BURDEN

- **Duplicate reporting**: In some MSs, separate / additional national systems exist to report availability and/or sales data and/or antibiotic sales data → duplicate efforts for MAHs (with no added value)

VISION

UPD should be the **single source** of all data relating to VMPs in the EEA
No duplicate reporting into national databases / via national systems

- **Reporting "zero sales" data:** MAHs very much appreciate that technical solutions being sought by the UPD team at present (e.g. link to availability status)

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PV Guidelines

Experience from MAHs

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Dose factor guideline

Consultation Oct-Nov'23, joint set of comments from industry stakeholders

- Many **examples and specific cases** brought forward by industry

Published Dec'23

- Most industry suggestions integrated in final guidance – collaborative approach, **THANK YOU**
- Much **rework at MAHs** side during Jan/Feb 2024; **MAHs struggling to meet 29 Feb deadline** for the VoS submission

Ongoing discussions

- Species group weights were dropped in final version (e.g. cattle, swine)
- Industry concerns regarding method of displaying incidence data

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Experience with PV guidelines 2023

Experience with submission of **Annual Statements and Signal Reports**

- Due dates timetable before end of the year allowed better planning and management activities. Still, product concentrations and intense workload peaks, but possibility to manage signals within 60 days allows a good flow (even in summer)
- Products not in UPD for some countries requires more careful administrative management

Experience with **Signal Management**

- Learning process has evolved since last year. **Thanks for engagement**
- Criteria for detection, validation, rejection or inclusion of signals should be refined (when to register a validated signal in IRIS or when to reject it)

Experience with **Inspections**

- Intense PV inspection days in 2023, comprehensive evaluation of systems
- Cooperative environment and learning process for both MAHs and inspectors

Experience with **Communication → next slides**

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Experience with PV guidelines: Communication

Anaphylactic reactions in cattle following the use of injectable veterinary medicinal products (2023)

Procedure	Anaphylactic reactions in cattle following the use of injectable veterinary medicinal products
Status	Ongoing
Procedure start date	March 2023
Description	National competent authorities have identified a significant increase of adverse event reporting of anaphylactic reactions in cattle in 2020, 2021, and 2022. Reports of adverse events were related to the use of injectable veterinary medicinal products (pharmaceuticals and vaccines). Most of the reported cases occurred in France, Spain, Italy, and Belgium. The root cause has not yet been established and the objective is to allow an in-depth investigation of the adverse events focused on the potential sensitisation of animals from e.g., specific vaccinations which may explain the apparent regional occurrence.
Advice for veterinarians	Veterinarians should promptly report any adverse events observed to the relevant national competent authority or the marketing authorisation holder. They should provide the complete vaccination history and overview of the veterinary medicinal products used in the reacting animals, where possible.

EMA
First "Targeted signal management procedures"

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Hypersensitivity cattle - Communication

- This case has been a **learning curve** on working with new PV communication GL
- Principles in guideline and overarching communication plan OK, but still **a lot of uncertainty** how to manage this in practice and how to move forward?
- Moving to a centralised way of handling PV communication, but a lot still needs to rely on **actions at local level** (via local networks for effective information dissemination)
- **EU network not solid/mature enough yet**. Setting up collaboration with NCAs, other MAHs, vet organisations.... takes too much time

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Reg network & MAHs; Interactions and communication

- We appreciate the involvement of industry in **stakeholder meetings** and **JIG meetings** and the possibilities to provide ***early comments to the pharmacovigilance guidelines***, as well as ***involvement in IT developments*** as **SME experts**. Thank you for the respectful consideration to industry comments, fruitful exchanges and collaboration.
- Some points to consider, as sometimes….
  - Very short **timeframe** to adapt to the new guidelines and new provisions
  - **Communication on implementation** of new features has room for improvement
    - Decisions taken not always clear / distributed in a timely manner to all MAHs
    - Smaller MAHs, not affiliated to EU association (Access VetMed, AnimalhealthEurope), communication through EMA/NCAs
  - **EMA website search tools** not handy
- JIG: positive all MAHs now invited – also not affiliated to EU associations

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Conclusions

- PV guidelines: **experience gained, but still learning process**
- **PV workload has considerably increased** under Reg 2019/6 as compared to previous Directive. → **Very substantial rise in admin burden**, more PV staff needed, not in line with the original objectives of the regulation
- **PV practices not adapted to vet business scale.** PV teams much smaller in vet pharma industry than in human. For small-medium sized MAHs, resources dedicated to PV are very scarce. Now, these teams have many more (quantity and diversity) tasks and responsibilities (i.e. IT, contact distributors)
- Keep right and center strong **focus on risk management via signal detection**, not to move away from Reg 2019/6 objectives and original intentions

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Acronyms

- ADR – Adverse Drug Reaction
- DWH – Data Warehouse
- EVWEB - EudraVigilance Veterinary Web Interface
- MAHs – Marketing Authorisation Holder
- NCA – National Competent Authority
- PV - Pharmacovigilance
- UPD – Union Product Database
- VICH - Veterinary International Conference on Harmonization
- VMP – Veterinary Medicinal Product
- VoS – Volume of Sales

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