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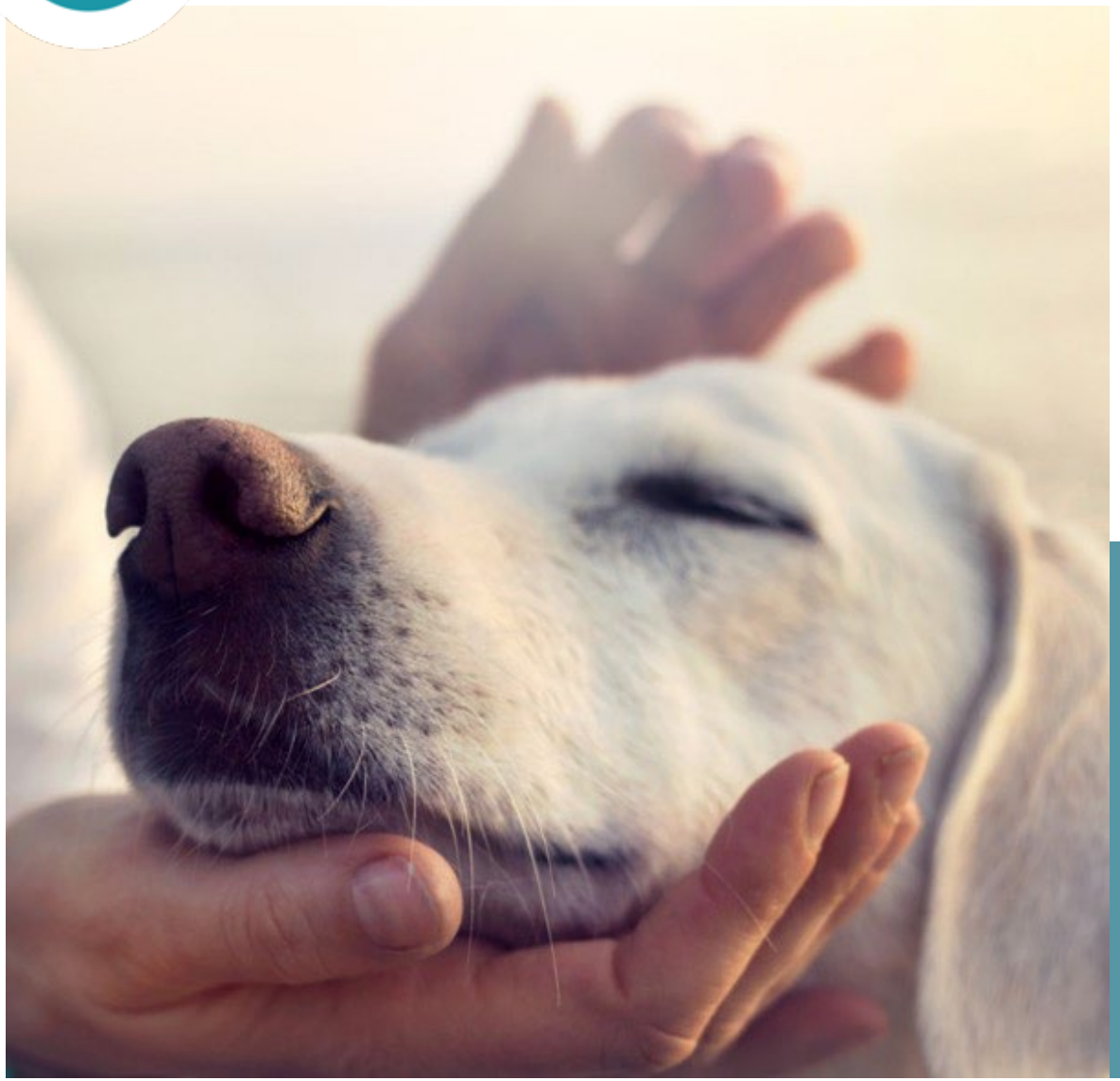

Pharmacovigilance Industry perspective:

achievements, main issues and priorities for 2023

Veterinary Information Day, 16-17 February 2023

Tony Simon, Zoetis Global Pharmacovigilance

on behalf of Magali Quetin, Head EU GPV, QPPV,

Boehringer-Ingelheim Vetmedica GmbH

Joint industry presentation with

Access VETMED

Committed to animal well-being in Europe

AVC

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Contents

Achievements in 2022

1) **Industry is very grateful for the numerous webinars organized in 2022 by EMA and the reactivated meetings in JIG format.**

2) **Developed and performed new processes**

   - e.g. submission of Annual Statements and Signal Reports

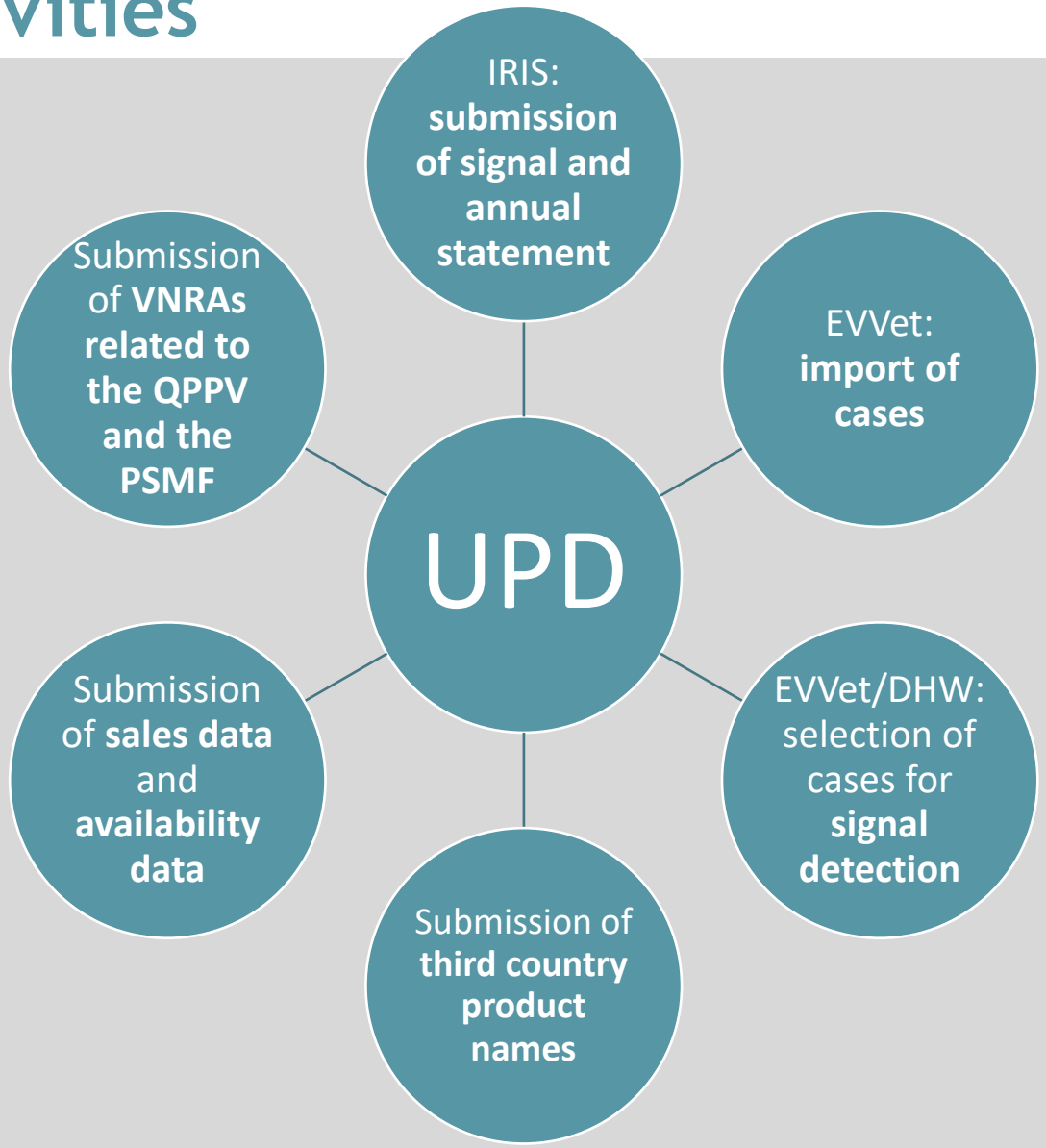
3) **Gained experience with new tools**

   - e.g. EVVet Data Warehouse, IRIS) and adapted MAH‘s internal systems to new format and requirements (e.g. VICH HL7)

…but

there is still more efforts required to achieve the main goals of the Regulation (EU) 2019/6,
a.o. a reduction of the disproportionate administrative burden

Incompleteness and inaccuracy of UPD: impact of PV activities



Must Have:

- **data completeness**: all products are in, with the correct MAH
- **data quality**: all registered presentations/ pack sizes have a specific Pack ID and are correctly described

Impact of UPD on Signal detection (SD) activities

Despite progress made, products still not available in UPD

- Products not recoded in EVVet, i.e. cases not retrievable for the SD activities, nor been imported
- Products not selectable for SD activities in EVVet DWH
- Products not selectable for submission activities in IRIS at the due date

Agency expectations following a signal submission

- Process followed unclear – MAH did not receive yet feedback for each submitted signal report
- Timelines of 2 weeks to respond to agency's question not sufficient – recommend 4 weeks as a standard (unless ESI)

Impact of UPD on the submission of sales and availability data

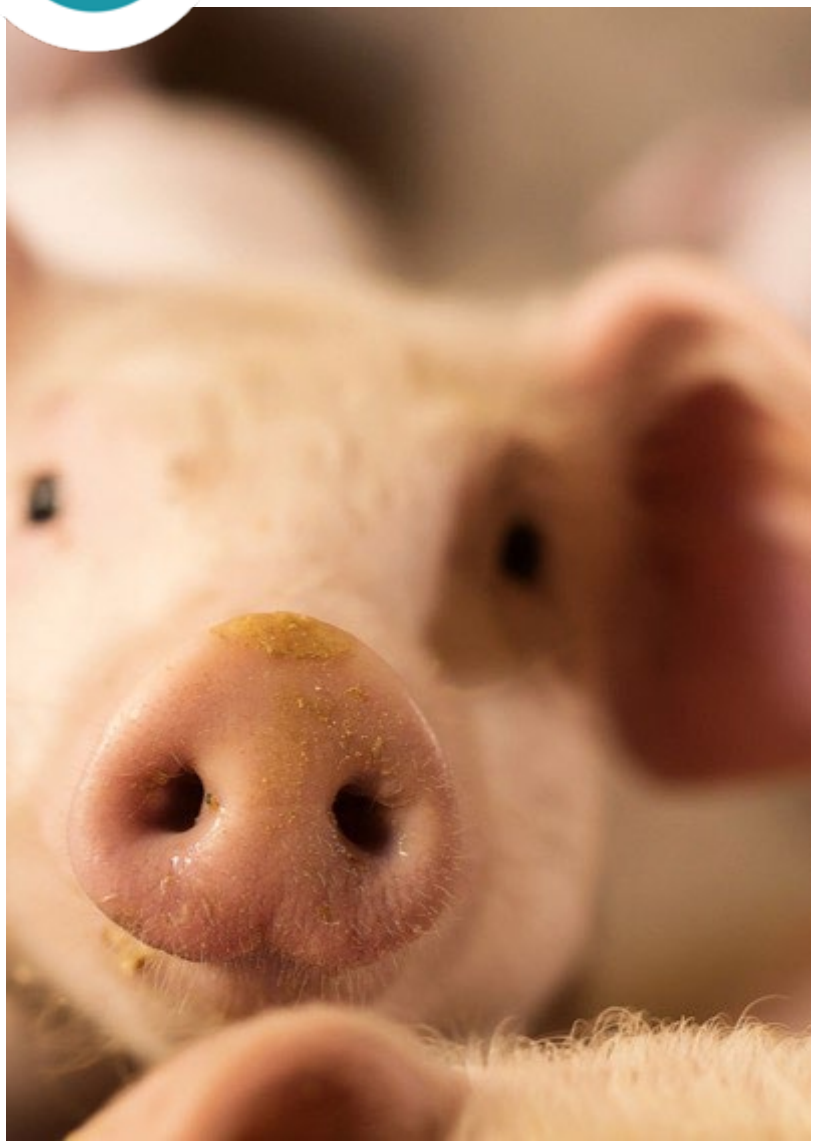
Mapping of the MAH's data with UPD

- Mapping exercise requests good coordination among several departments (PV, RA, Finance, Supply)
- Development of manual process for submission, requiring significant resources, until system interfaces can ensure automation of the submission (IT department)

Deadline of June 2023

- Deadline of June is nearly impossible for industry as internal systems need to match the requirements and data in UPD
- 6-9 months are required after UPD is completed and clean for industry to complete the mapping exercise

EVVet and case processing



Submission of follow-up

- Process impracticable for all users: exchange of information outside of the database is against quality system management principles
- Process conflicts with batch reporting via gateway

Data quality

- Important aspect and to apply to all stakeholders in EVVet
- Contradictory expectations from agencies in and outside EU on how cases should be presented

Duplicates

- Contradictory expectations from agencies in and outside EU on which cases should be kept or nullified

Priorities for 2023

- UPD complete and cleaned, before the next steps are required
  - i.e. submission of sales and availability data
- Pro-active and timely communication of
  - Due dates for Annual Statements for 2023 asap, any future changes/additions 4 months in advance as a minimum
  - Known technical issues, postponed timelines to the business users of the respective tools: User-friendly Release Notes
- Reduce the administrative burden: further develop the technical solutions for:
  - Product grouping in UPD, DWH and IRIS
  - Case follow-up in EVVet: Master Data Concept, identification of duplicate cases

2023 to be another year of transition

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Thank you!