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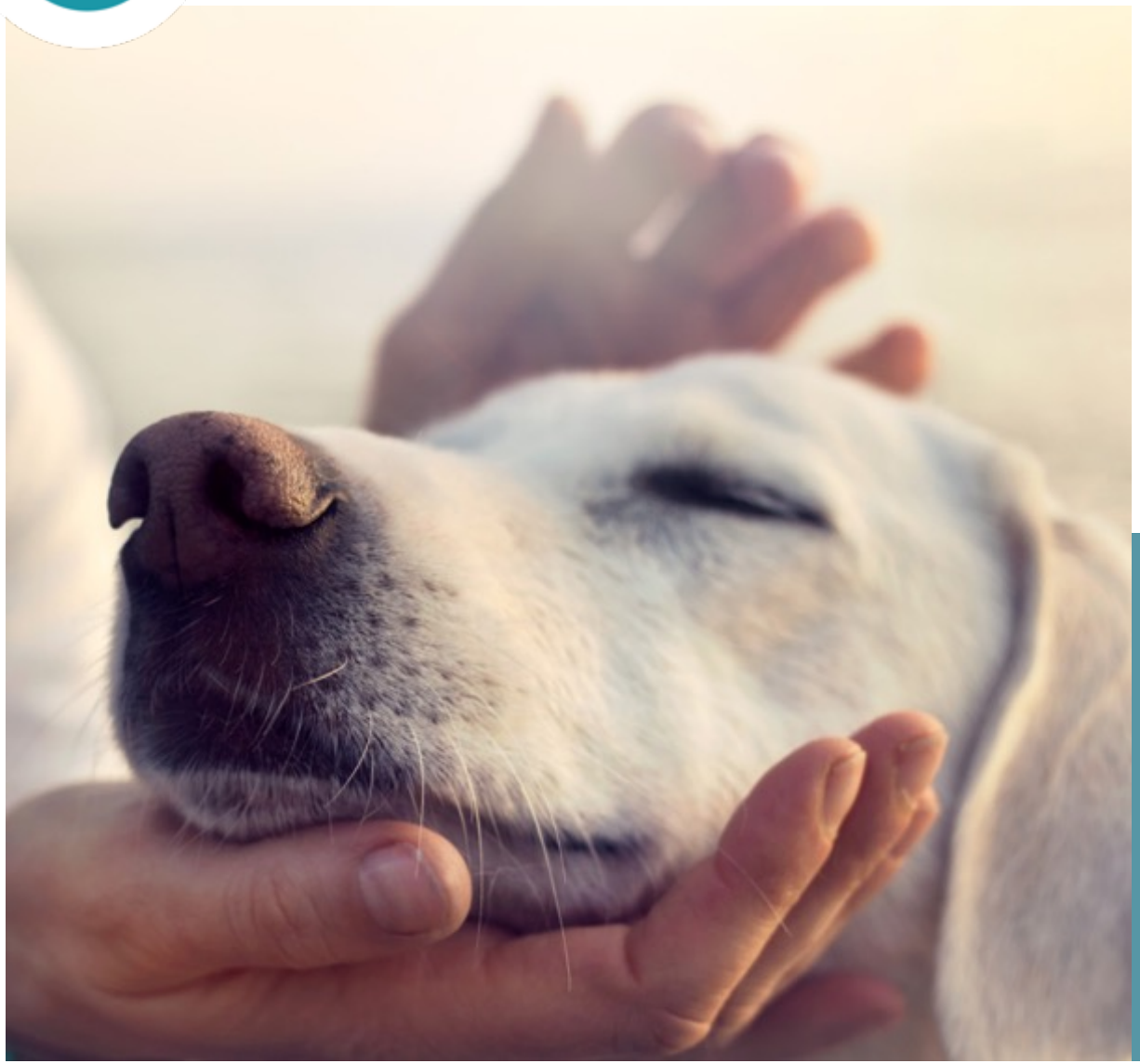

Veterinary Medicines Info day 2021

Update on pharmacovigilance, signal detection and surveillance - Industry perspective

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EU Regulation 2019/6

Pharmacovigilance relevant key changes:

- Pharmacovigilance System Master File (PSMF)
- Adverse Event Management
- Signal Management (SM)

PSMF - Most relevant changes:

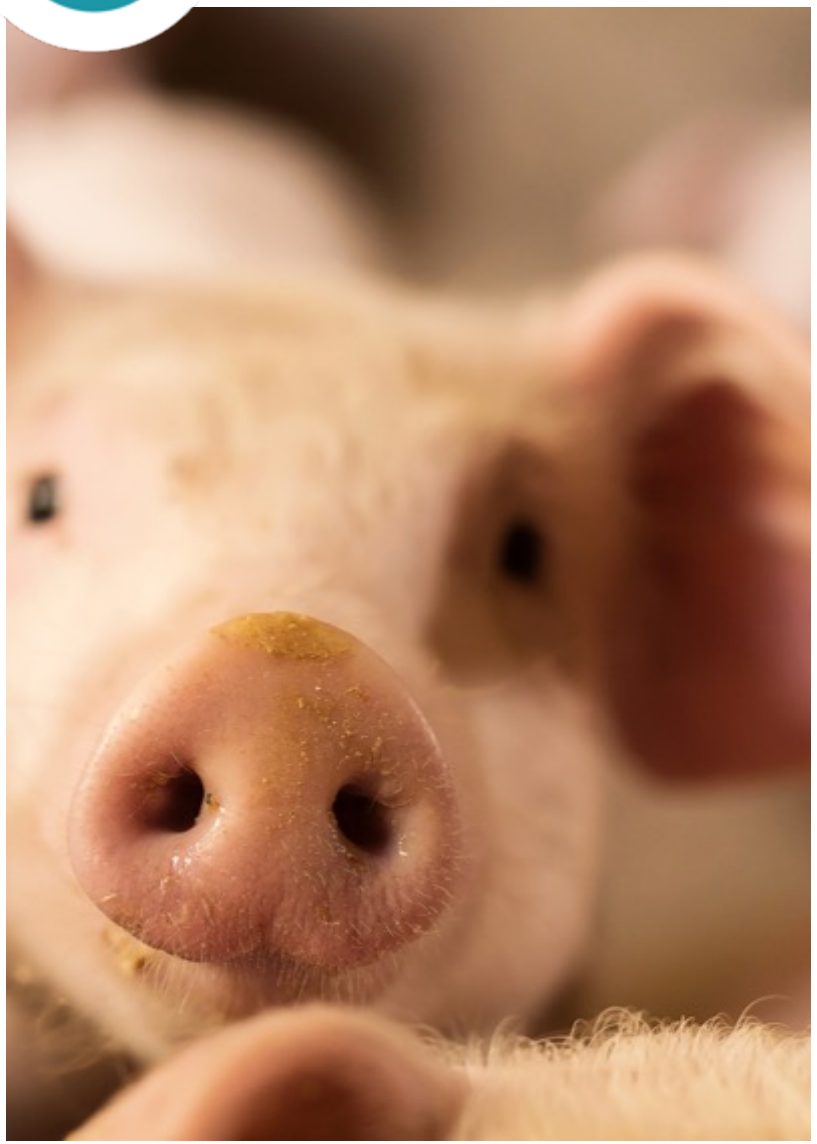
- Not part of Marketing Authorisation dossier
- Maintained by Marketing Authorisation Holder (MAH) at the MAH
- Detailed description of the MAH PV system
- Electronic format possible
- PSMF replaces DDPS

PSMF - Industry Concerns:

- PSMF Summary
- Duplication of information/effort
- Logbook
- Risk Management Plan
- Transition from DDPS to PSMF

Adverse Event Management – Most relevant changes:

- 30-day reporting for all adverse events
- Submission to Union PV Database only
- Lack of efficacy definition
- No causality assessments



Adverse Event Management – Industry Concerns:

- Readiness of Union PhV Database
- Active case forwarding from Union PhV Database
- Product Group Identifier

Signal Management – Most relevant changes:

- Replaces the need for Periodic Safety Update Reports
- 30-day reporting for Benefit Risk change (incl new risk)
- Annual recording of Signal Management process outcome
- Incidences calculated within Union Database
- Possibility to use MAH database for Signal Management
- Risk based approach to Signal Management

Signal Management - Industry concerns:

- Requirement for annual Signal Detection (SD) analysis in Union PhV Database
- Use of predefined queries
- Some outstanding questions:
  - Sales data in Union Databases
  - Data Lock Points (DLPs) for Signal Management
  - Same/Similar product definition
  - Product Group ID
  - PSUR transition
  - Process for Annual recording of SM process outcome

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Thank you!