EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

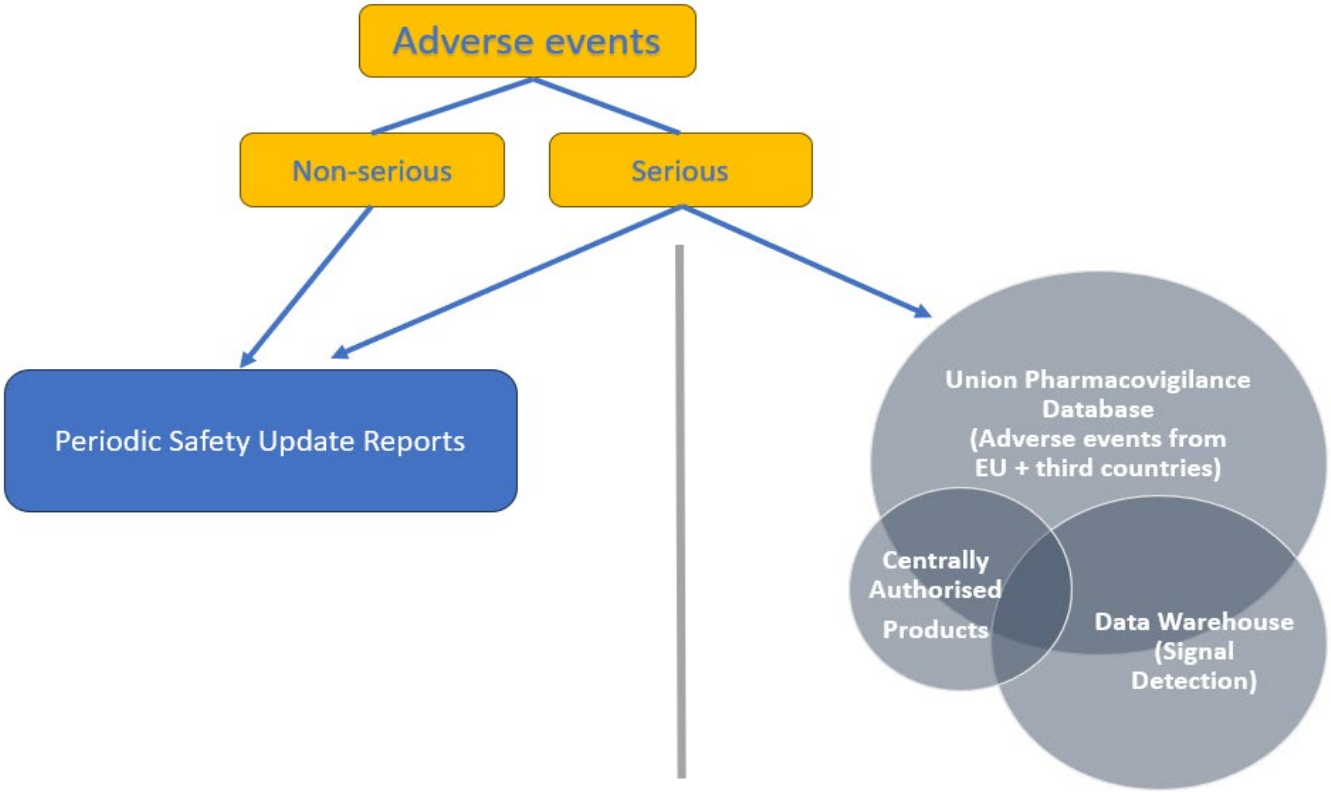
Regulatory environment: pharmacovigilance

Update

Focus group meeting for veterinarians or other healthcare professionals on facilitating pharmacovigilance reporting of medicinal products used in poultry

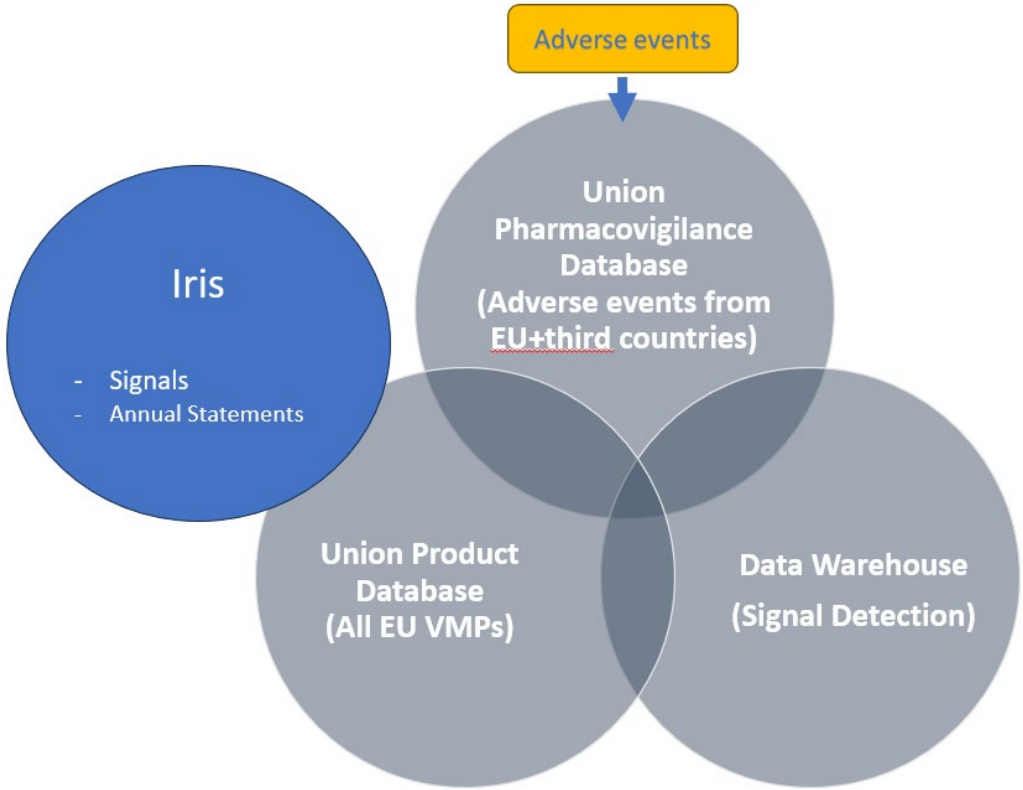
Presented by Jos Olaerts on 11 October 2023
Head of Pharmacovigilance Veterinary

Pre-2022



Regulation (EU) 201/16

- Data driven
- Continuous monitoring by MAH
- Cumulative lifecycle analysis
- Risk-based approach
- Pharmacovigilance inspections



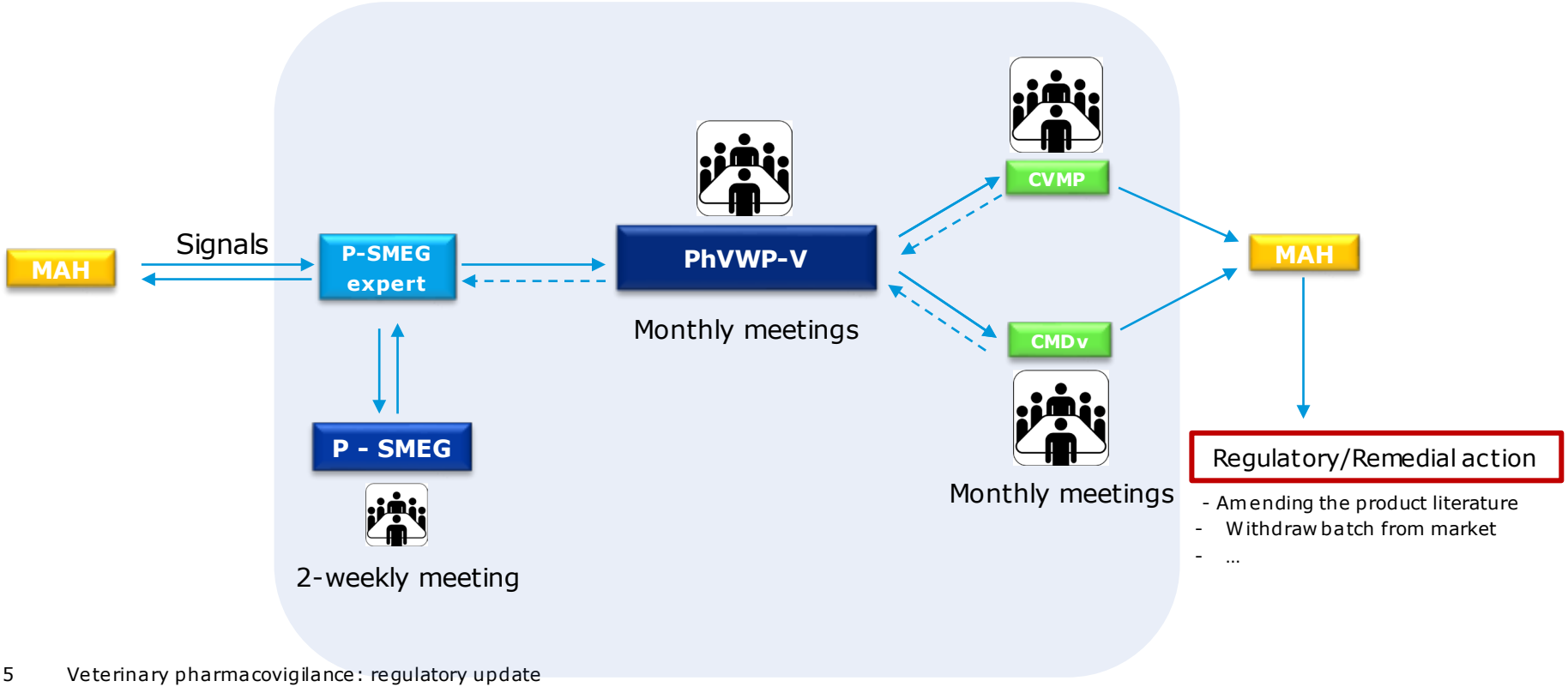
What is a signal?

*A **signal** is defined as information that arises from one or multiple sources, including observations and experiments, which **suggests** a potentially **new** causal association, or a new aspect of a known causal association between an intervention and an **adverse event** or a set of related adverse events, that is judged likely to justify further **investigation** of possible causality*

Pilot signal Management Expert Group (P-SMEG)

- 12 members
- Until end of 2024
- Goals:
  - set-up and **test new processes** through close cooperation of a group of MS experts
  - build an overall sustainable regulatory operational framework to support provisions of Regulation (EU) 2019/6 related to signal management

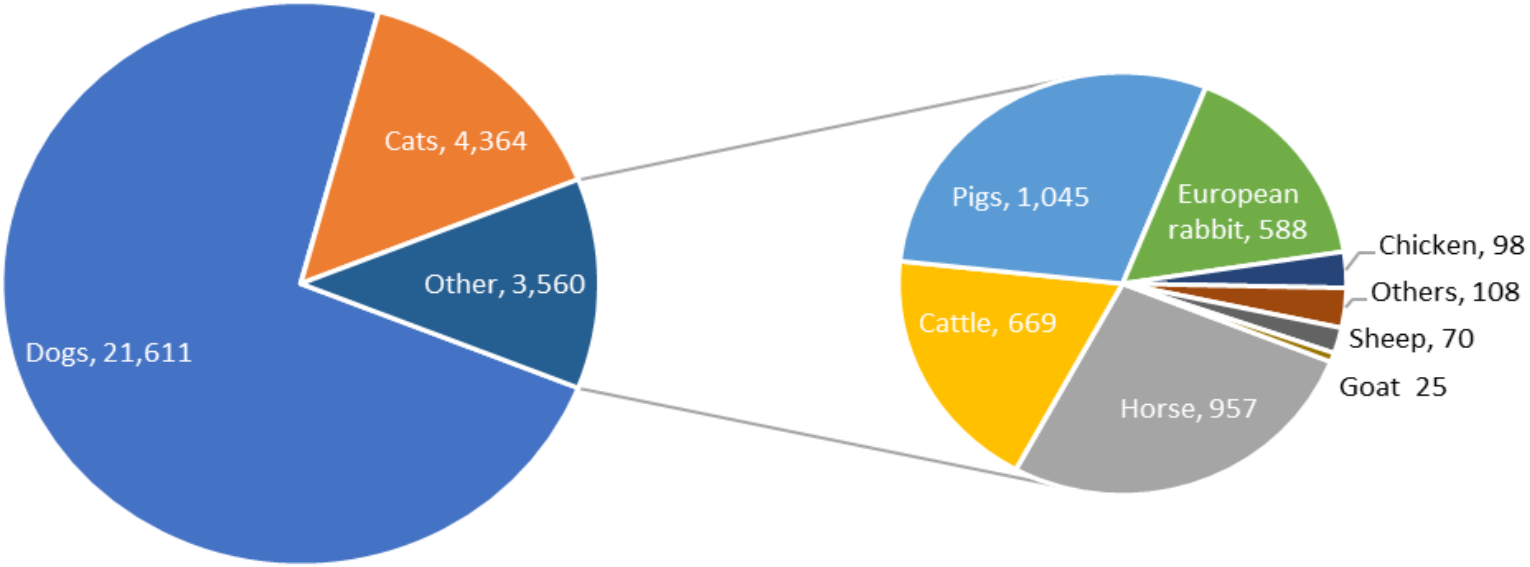
Signal management



Signal management

- Data from voluntary reporting
  - Underreporting
  - Rare events
  - By definition often difficult to conclude definitively regarding causality
- **Sound clinical judgement** should always be applied. Aim is to provide a high quality assessment of all evidence available and make decisions on a case by case basis.
- Focus on **medical important (MI) terms** rather than just disproportionality methods

Adverse event reporting by species (2020) for centrally authorised products



Adverse events – new scope

a) any unfavourable and unintended reaction in any animal to a VMP

b) any observation of a lack of efficacy of a VMP following its administration to an animal, whether or not in accordance with the summary of product characteristics

c) any environmental incidents observed following the administration of a VMP to an animal

d) any noxious reaction in humans exposed to a VMP

e) any finding of a pharmacologically active substance or marker residue in a product of animal origin exceeding the maximum levels of residues established in accordance with Regulation (EC) No 470/2009 after the set withdrawal period has been respected

f) any suspected transmission of an infectious agent via a VMP

g) any unfavourable and unintended reaction in an animal to a human medicinal product

Pharmacovigilance: detecting, consolidating and publishing relevant findings

Art. 79 (2) of Regulation 2019/6: "*The Agency may organise meetings or a network for groups of veterinarians or other healthcare professionals...*"

Specialised veterinary practices

EU regulators

Direct exchange of know-how




Any questions?

Further information

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