



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Regulatory environment: pharmacovigilance

---

Update

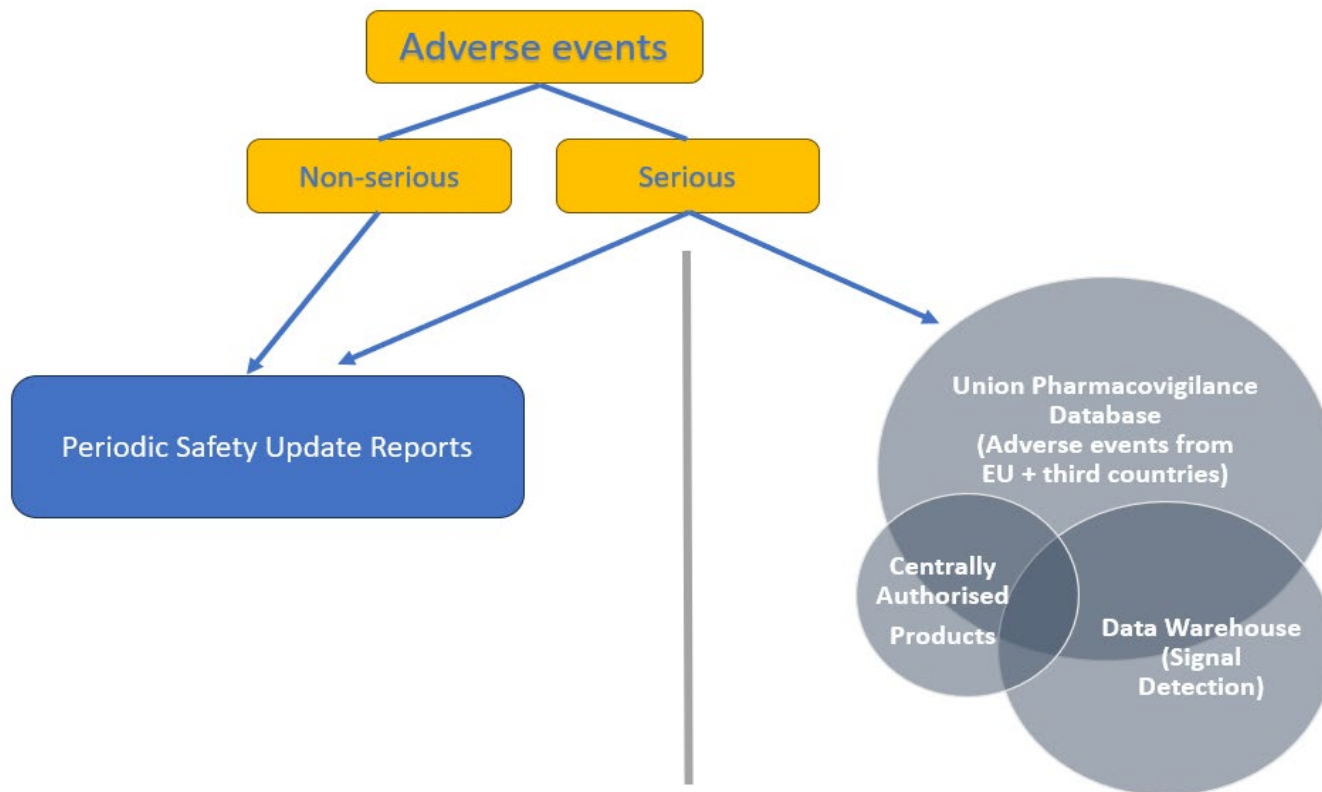
Focus group meeting for veterinarians or other healthcare professionals on facilitating pharmacovigilance reporting of medicinal products used in aquaculture

Presented by Jos Olaerts on 22 November 2023  
Head of Pharmacovigilance Veterinary





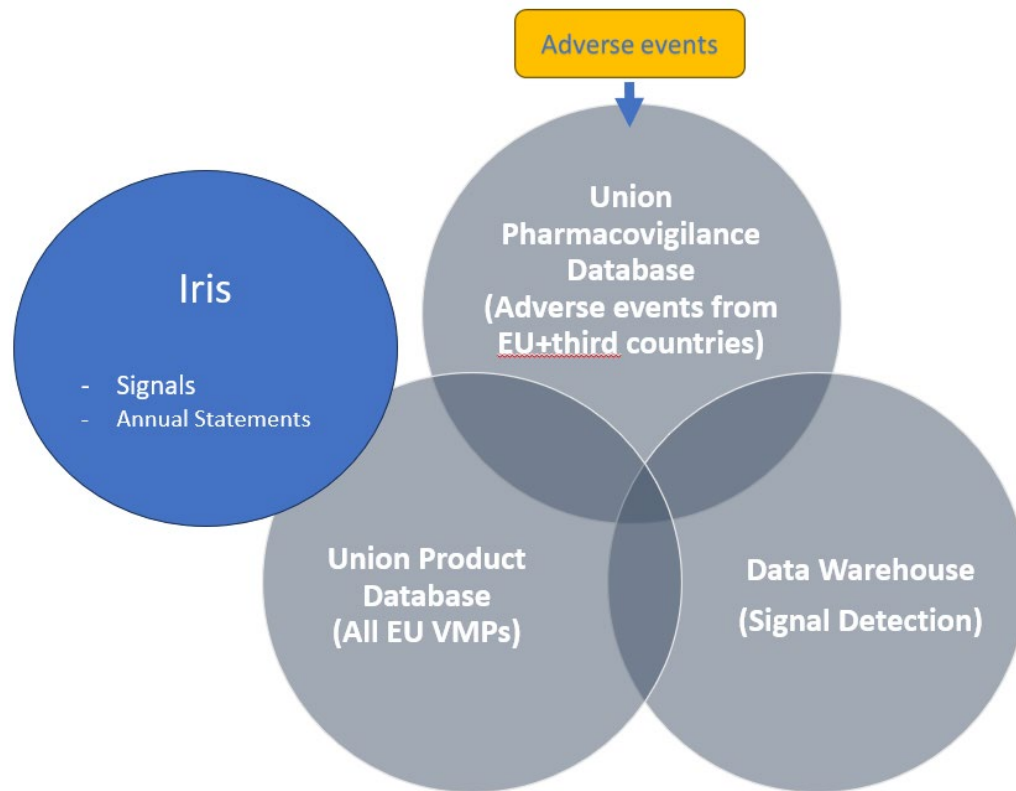
# Pre-2022





## 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*

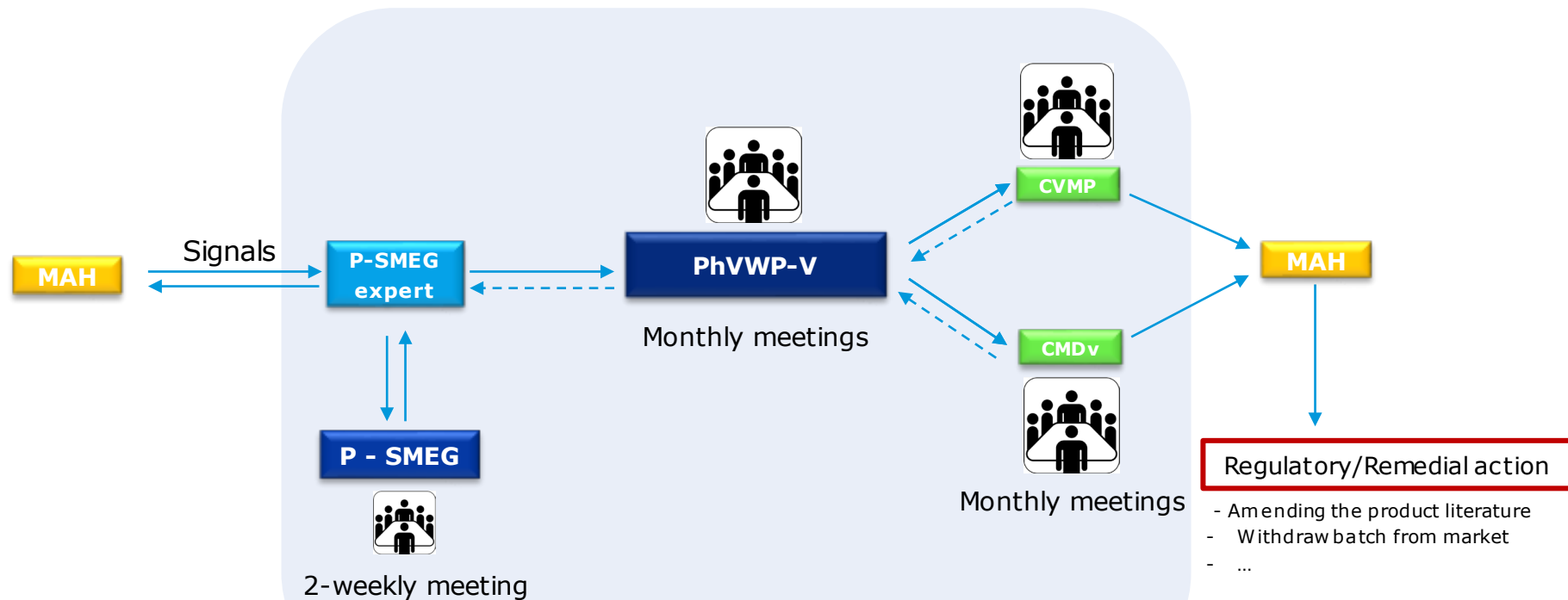


## Pilot signal Management Expert Group (P-SMEG)

- 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



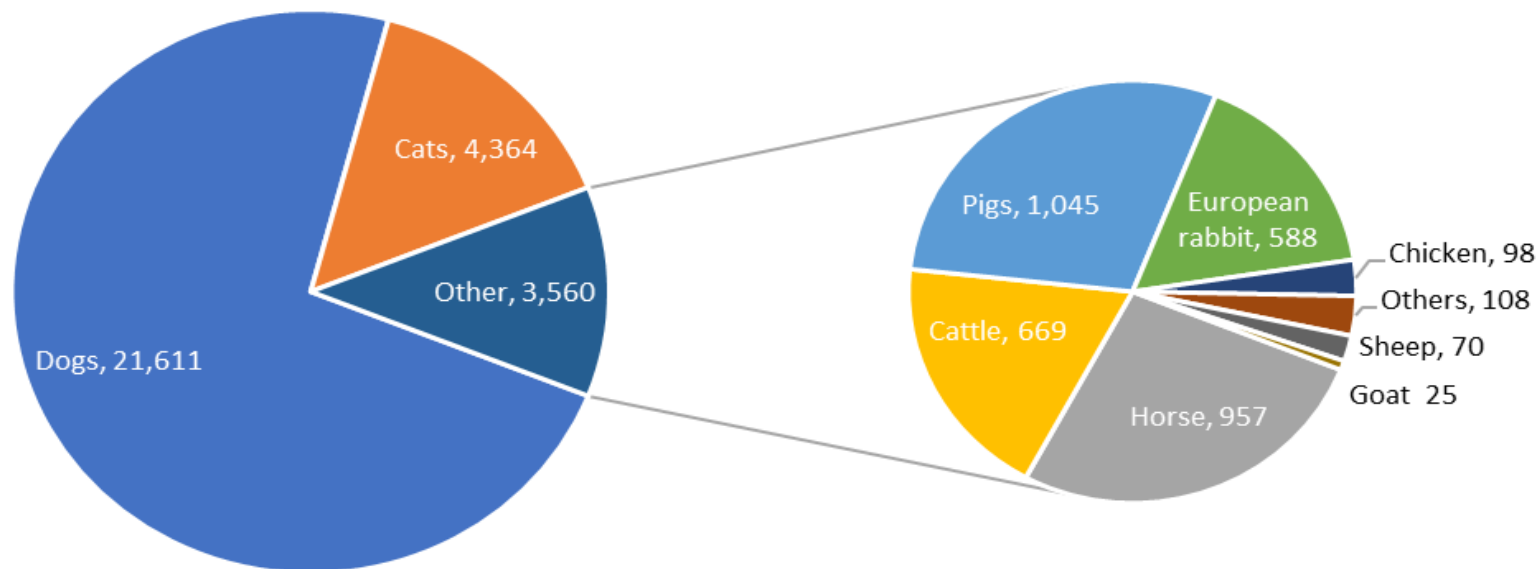


# Signal management

- 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...”*





# Any questions?

## Further information

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Telephone** +31 (0)88 781 6000

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

Follow us on  **@EMA\_News**