EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

VMP REG (EU) 2019/6
Pharmacovigilance and the Veterinarian

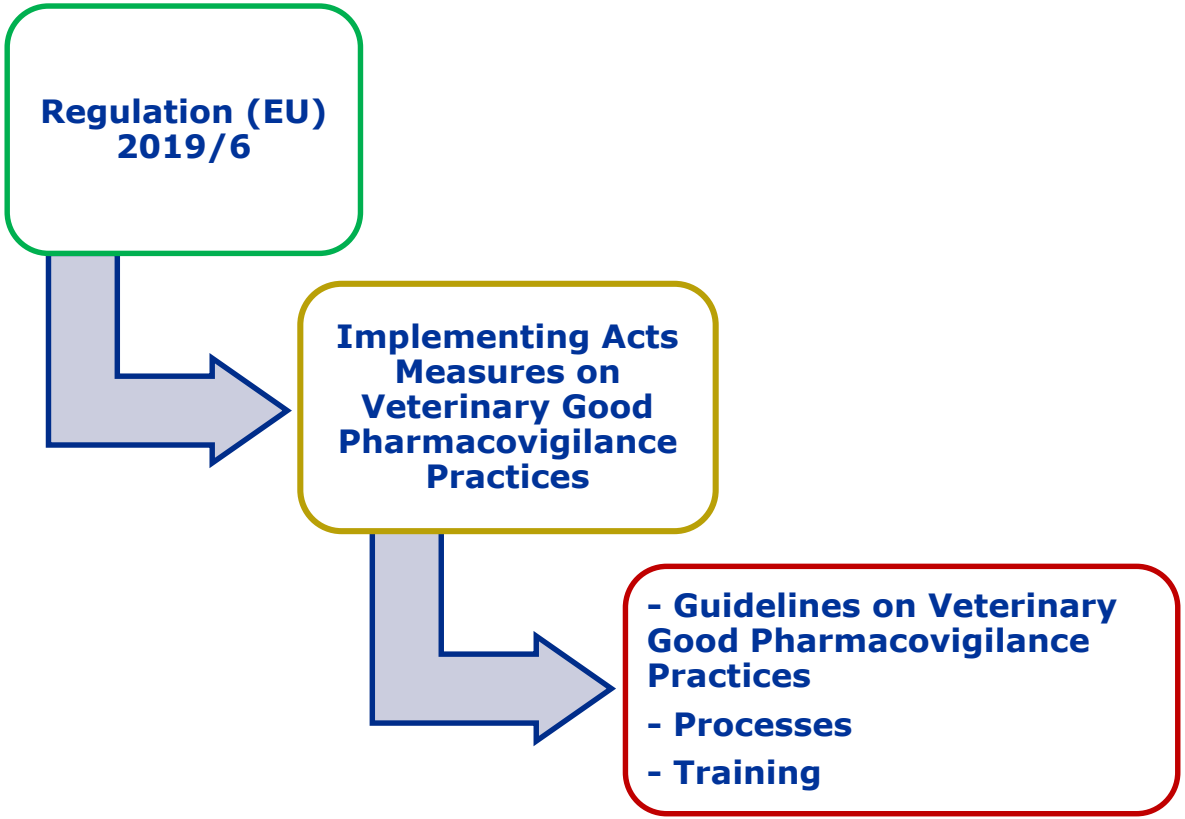
Webinar

Presented by Jos Olaerts on 30 March 2021
Veterinary Risk and Surveillance Service

An agency of the European Union

Objectives

1. Explain Pharmacovigilance in the EU under the Veterinary Medicinal Products Regulation (VMP-Reg)
    - Collecting adverse event reports
    - Signal detection
    - Communication
    - PhV Inspections – PSMF (Pharmacovigilance System Master File)
    - Personal data
2. Veterinarians' requirements and expectations
    - Reporting
    - Communication
    - …



Pharmacovigilance scope (Art. 73 (2))

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

b) Lack of efficacy (whether or not in accordance with SPC).

c) Any environmental incidents observed following the administration of a VMP

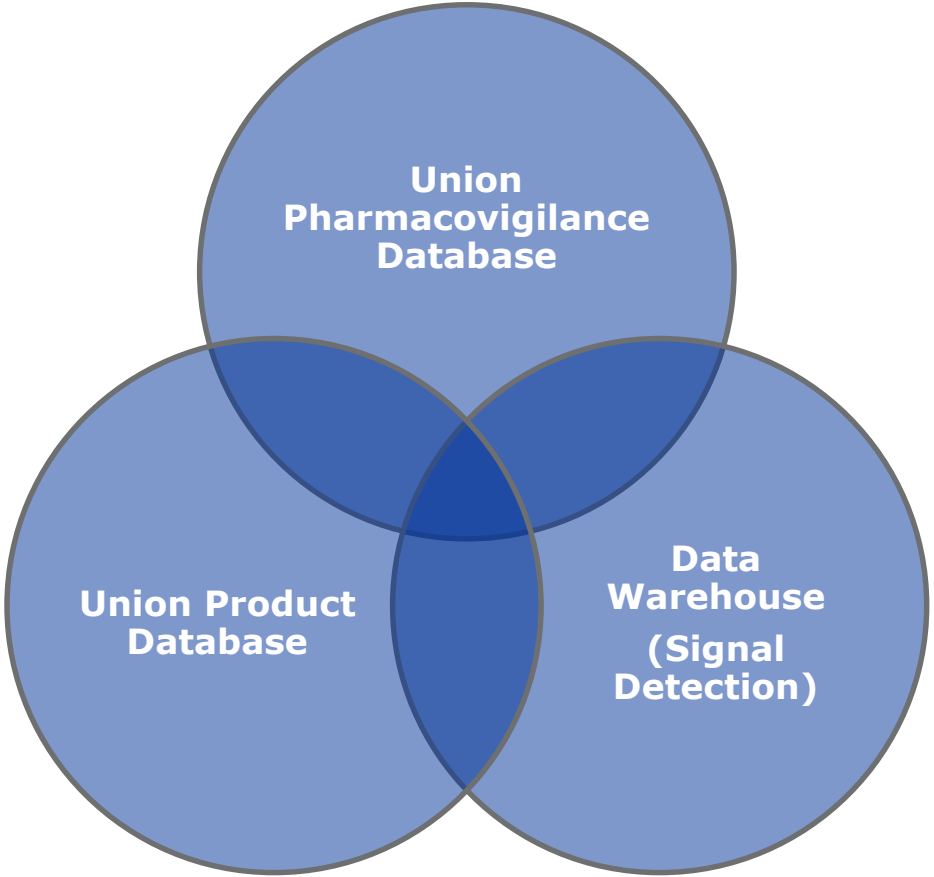
d) Any noxious reaction in humans exposed to a VMP.

e) Any residue in a product of animal origin exceeding 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 medicinal product for human use

Data driven



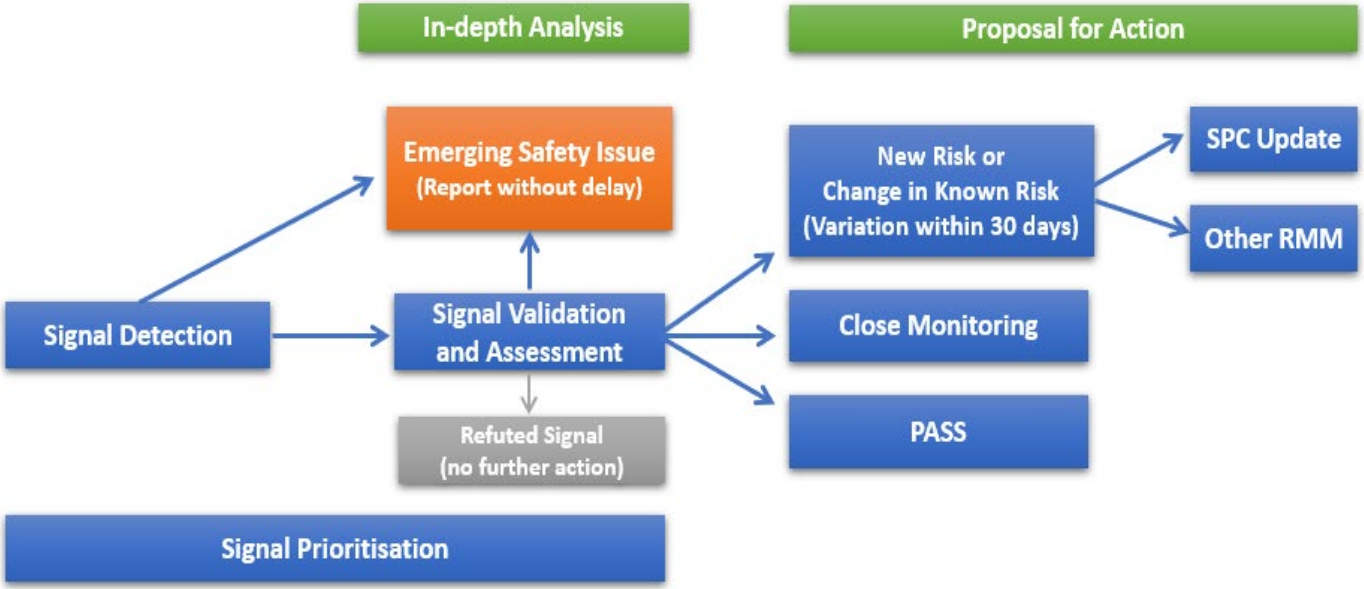
VMP-Reg PhV Pillars

- **Adverse Event reports collection and recording**
  - 30 days + non-serious cases (EU + non EU)
  - Yearly sales (+ estimation of exposed Number of target species)
- **Continuous Adverse Event analysis by MAH (signal management)**
  - Using EudraVigilance Veterinary database or own database (+ 1 yearly SD analysis on EVVET)
  - Yearly MAH statements + SM outcomes submitted to database
- **Regulator oversight through**
  - PhV Inspections
  - Risk based signal surveillance by regulators
  - Ad-hoc targeted surveillance
- **Pharmacovigilance Master File (+ Quality Management System)**

Central role Veterinarians

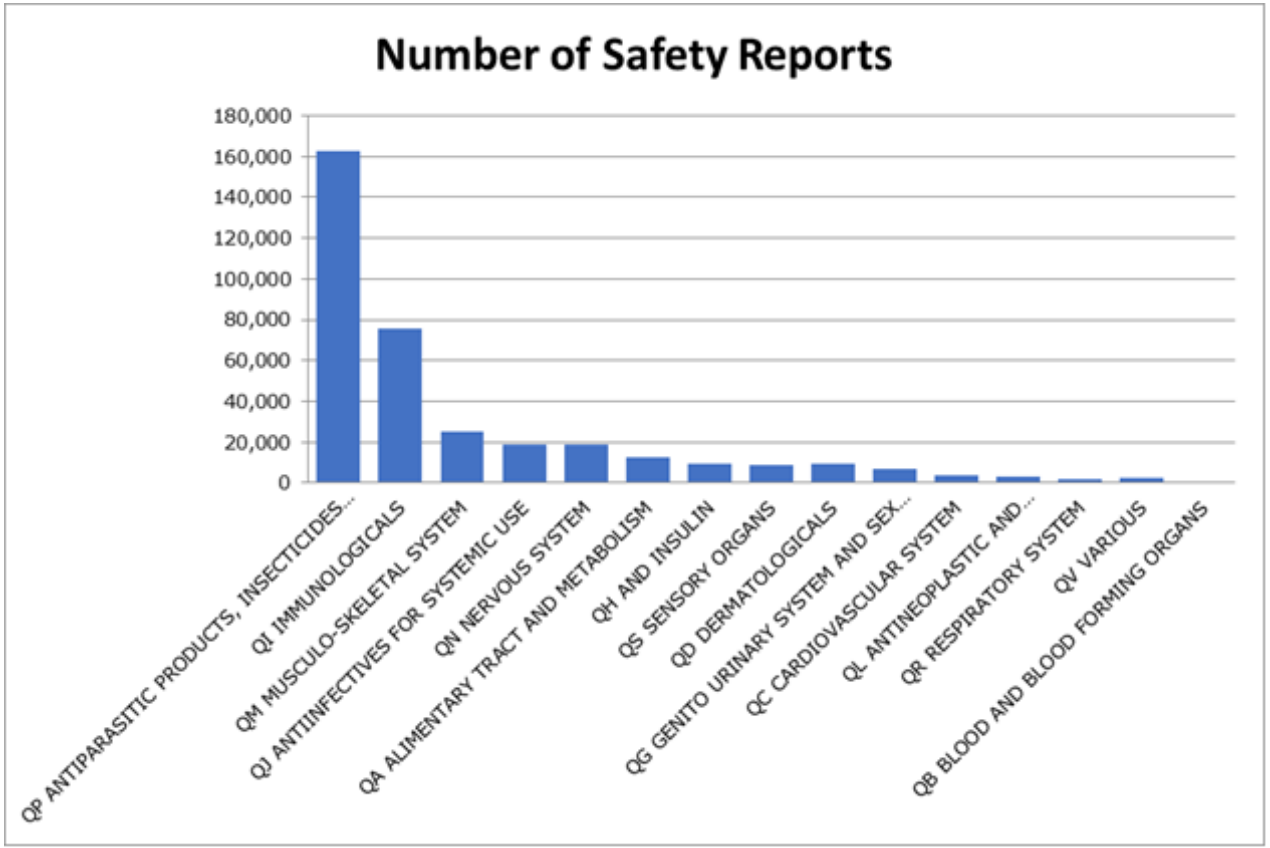
- Reporting
- Data Quality
- Link to practice management tools?
- Future – Big data?

Pharmacovigilance data analysis – Signal management

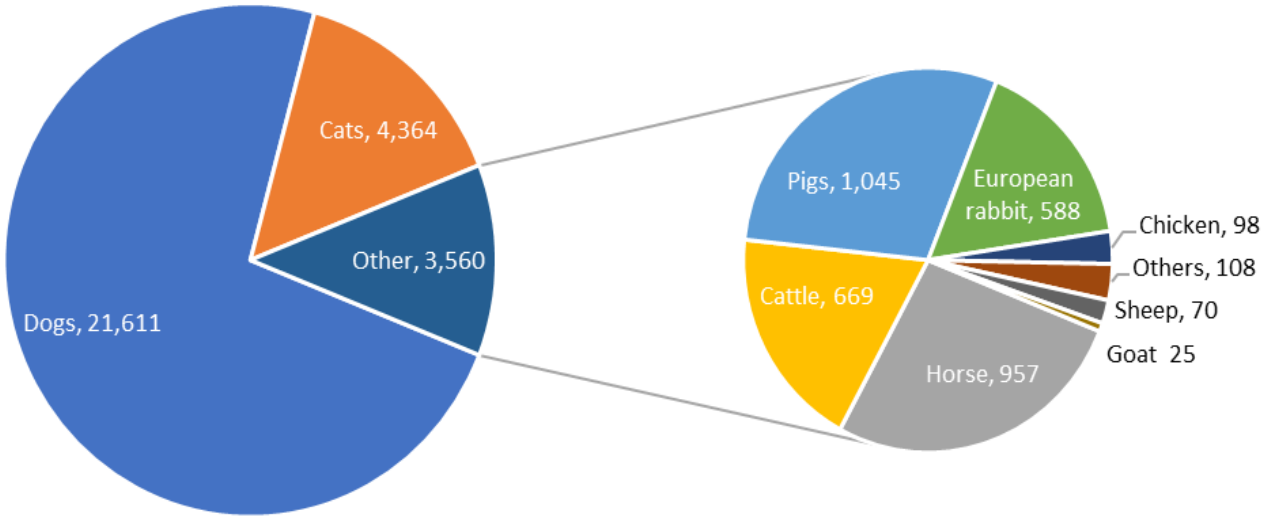


Medically Important Events (MIE) list

MIE PTs	Species association #	Excluded LLTs ¤
Abdominal pain	Horse	Abdominal cramp, Abdominal discomfort, Praying position, Stomach cramp, Tense abdomen
Abomasitis	Ruminant, Camelid	
Abortion	All	
Acute mastitis	Ruminant, Camelid, Horse	
Anaphylaxis	All	
Anorexia	Horse	
Apnoea	All	
Birth defect	All	
Blindness	All	
Bone marrow hypoplasia	All	
Cardiac arrest	All	
Cardiac insufficiency	All	
Circulatory shock	All	
Collapse NOS	All	
Coma	All	
Convulsion	All	
Deafness	All	
Death	All	Unexplained death, Unrelated death
Diabetes mellitus	All	
Dyspnoea	All	
Epileptic seizure	All	
Fish asphyxia	Fish	
Fish body deformity	Fish	
Haemolytic anaemia	All	
Haemorrhagic gastroenteritis	All	
Heart block	All	
Hepatic failure	All	
Hypersensitivity reaction	All	Allergic pruritus, Allergic reaction, Allergic skin reaction, Allergy NOS
Hypocalcaemic condition	Ruminant, Camelid	
Hypomagnesaemic condition	Ruminant, Camelid	
Impaired hearing	All	
Impaired vision	All	
Ketosis	Ruminant, Camelid	
Laminitis	Horse	
Loss of consciousness	All	
Lying down	Horse, Ruminant, Pig, Camelid	
Metastatic neoplasia	All	
Metritis	Horse, Ruminant, Camelid	
Moribund	All	
Multi-organ failure NOS	All	
Myoglobinuria (Horses only)	Horse	
Paralysis	All	
Paresis	All	
Perinatal mortality	All	
Recumbency	Horse, Ruminant, Pig, Camelid	
Renal insufficiency	All	
Reticulitis	Ruminant, Camelid	
Stillbirth	All	
Suspected infectious agent transmission	All	



Adverse event reports by species received during 2020 following the use of centrally authorised products.



“EMA to organise meetings or network for groups of veterinarians..” (Art. 79)

EUROPEAN MEDICINES AGENCY

Specialised Veterinary Practices

EU regulators

Direct exchange of know-how




- **Clinical judgment:**

  - Injection site reaction, anaphylactic type reaction.
  - Rare events, long-term effects, confounding factors concomitant products, underlying disease, possible interaction
  - Lack of efficacy
  - Human reactions
  - Abortion, mutagenicity, embryotoxicity
  - Observational data versus prospective study