A veterinarian’s role in pharmacovigilance

Why adverse event reporting matters

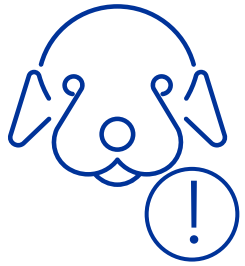
EMA/FVE information session for veterinary students: the importance of pharmacovigilance, 13 October 2026

Raquel Gopal, European Medicines Agency

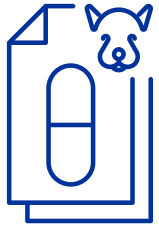


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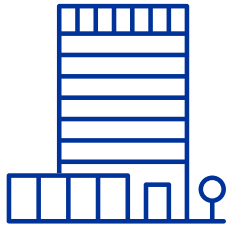
Veterinary pharmacovigilance



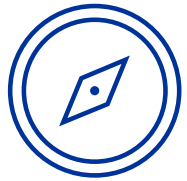
What an adverse event is



Where to report adverse events



What happens after reporting



Veterinary pharmacovigilance in practice

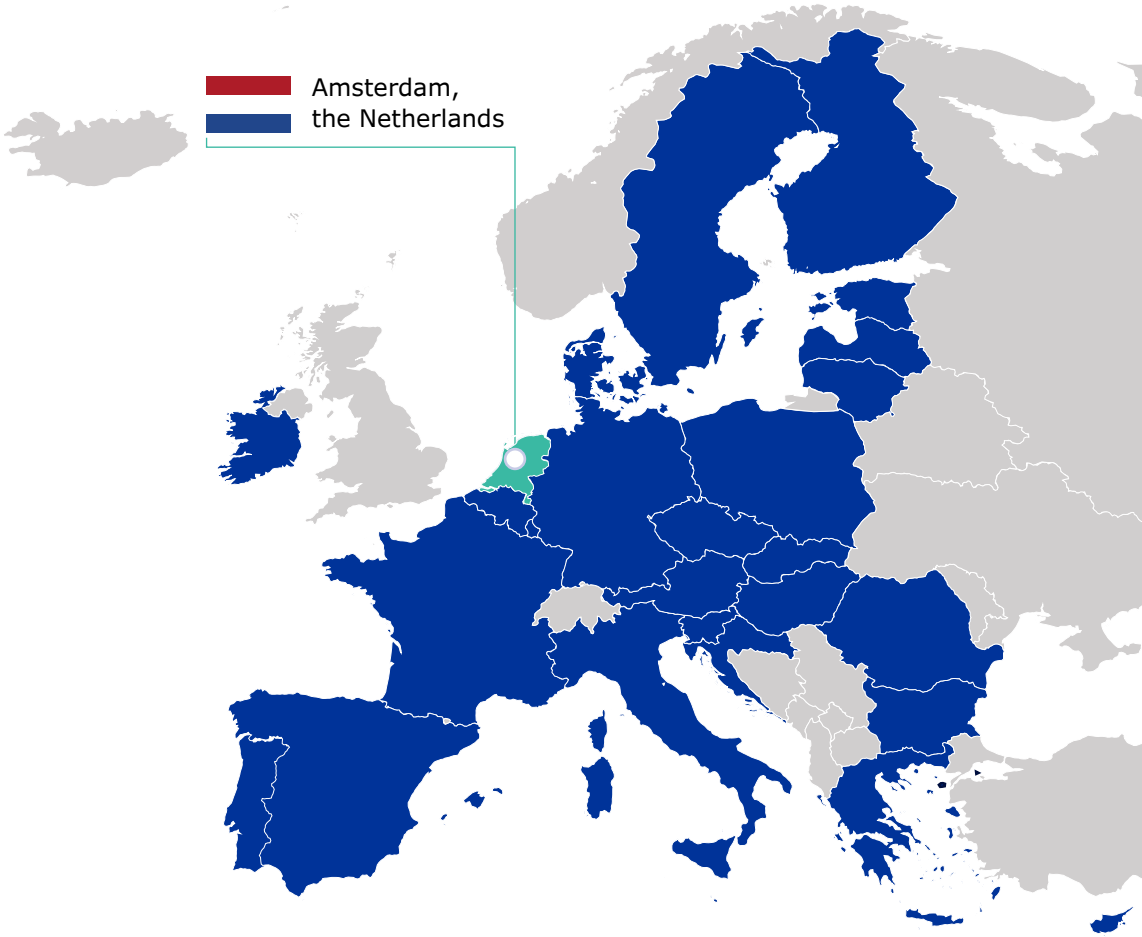


As future veterinarians, what role do you play in pharmacovigilance?

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The European Medicines Agency

- Decentralised Agency of the EU (1995)
- Responsible for the **scientific evaluation** of human and veterinary medicines in the EU; and **monitoring and supervising** the safety of medicines authorised in the EU
- Supported by scientific expert Committees (CVMP and PhVWP-V)



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Journey of a veterinary medicinal product (VMP) assessed by EMA



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The etymology of "pharmacovigilance"

Literally: "watching over medicines"

GREEK ORIGIN

pharmakon

Means a drug, medicine or medicinal substance. Historically, it could also denote a poison, a reminder that effects depend on the substance and its dose.

LATIN ORIGIN

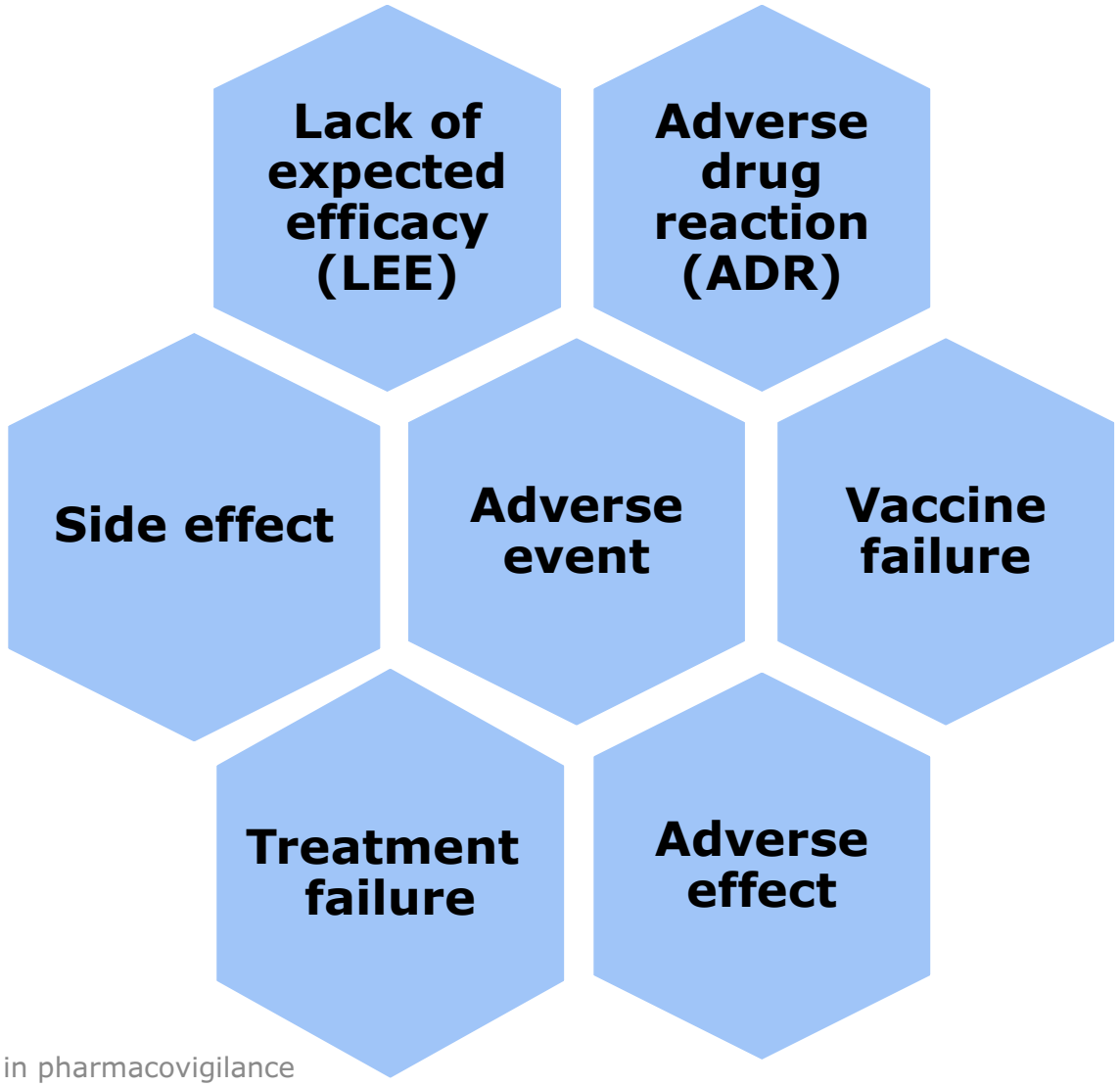
vigilantia

Means watchfulness, alertness or careful attention. It is related to *vigilare*: "to stay awake" or "to keep watch".

Science & activities relating to the detection, assessment, understanding & prevention of adverse effects or any other medicine/vaccine-related problem

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Definition* of adverse event



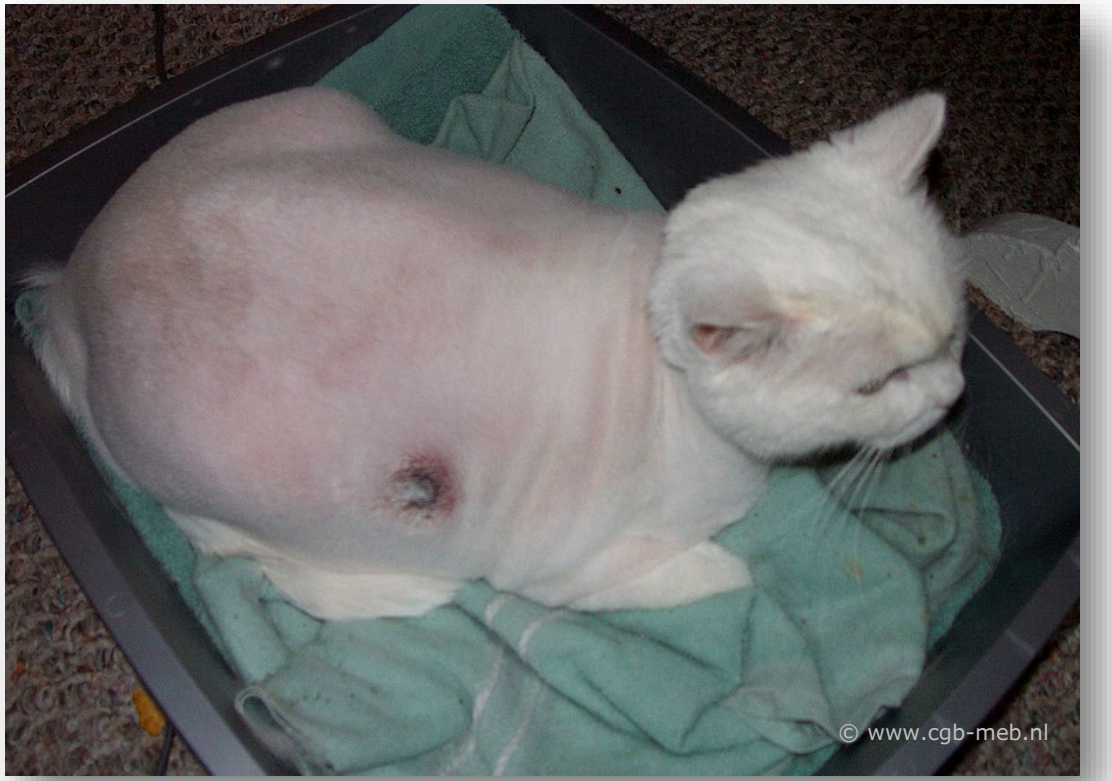
*Any **observation in animals, whether or not** considered **product-related,** that is **unfavourable** and **unintended** that occurs **after any use of VMP** (off-label and on-label uses)*

Ref. VICH GL 24

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Adverse event examples

Injection site reaction



Transient allergic reaction



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What should you report?

All suspected adverse events (AEs)

Animals

- When a VMP treatment or a vaccine has not worked
- After off-label or recommended use

Even if listed!

- After use of a human medicine

Humans

- After exposed to VMP or treated animal

Environmental incidents

- High product residues in foods
- Suspected transmission infectious agents

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Where to report suspected AEs?

Suspicion of AEs is sufficient to report

National authority*

To the national competent authority (NCA) in your country of practice

Company

To the marketing authorisation holder responsible for the product (see package leaflet)

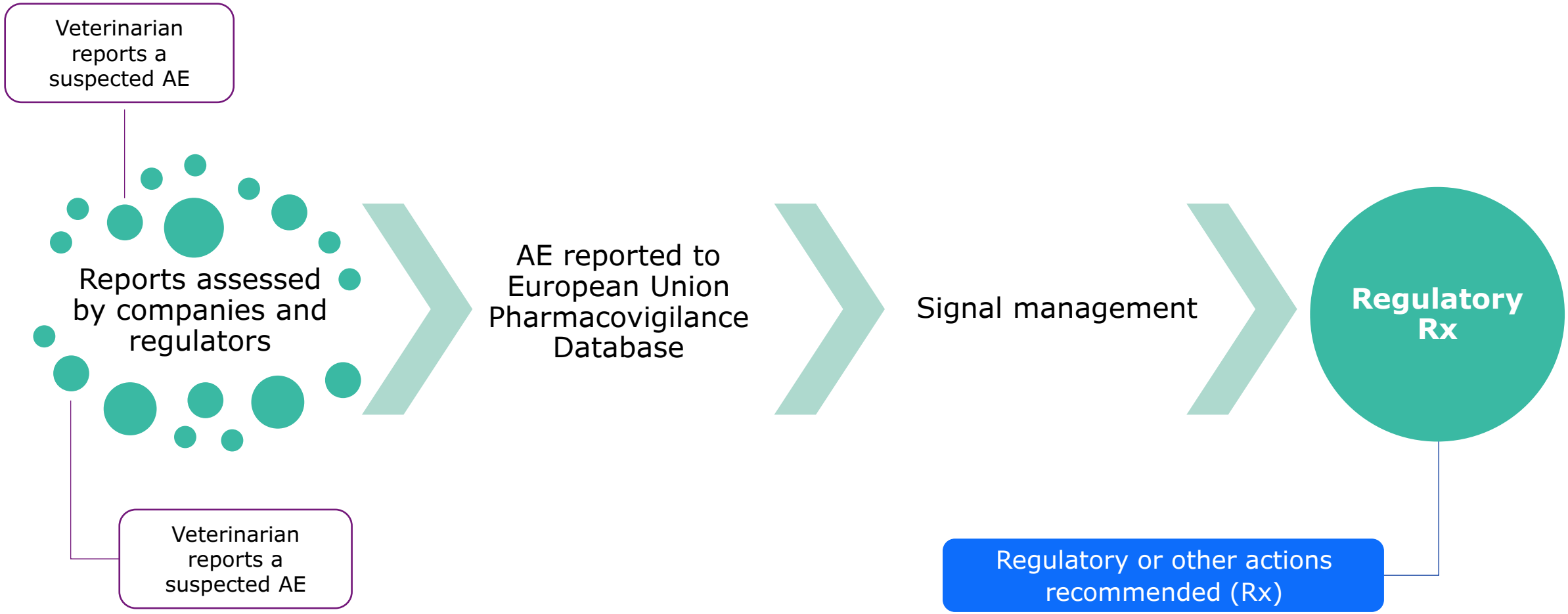
Adverse events do not need to be investigated/confirmed VMPs caused them

Every report counts!

* In some countries, veterinarians may have a legal obligation to report to the NCA

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What happens after reporting suspected AEs?



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Outcomes



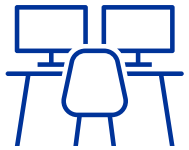
Close monitoring



New AEs or warnings product information (PI)



Direct animal healthcare professional communication (DaHPC)



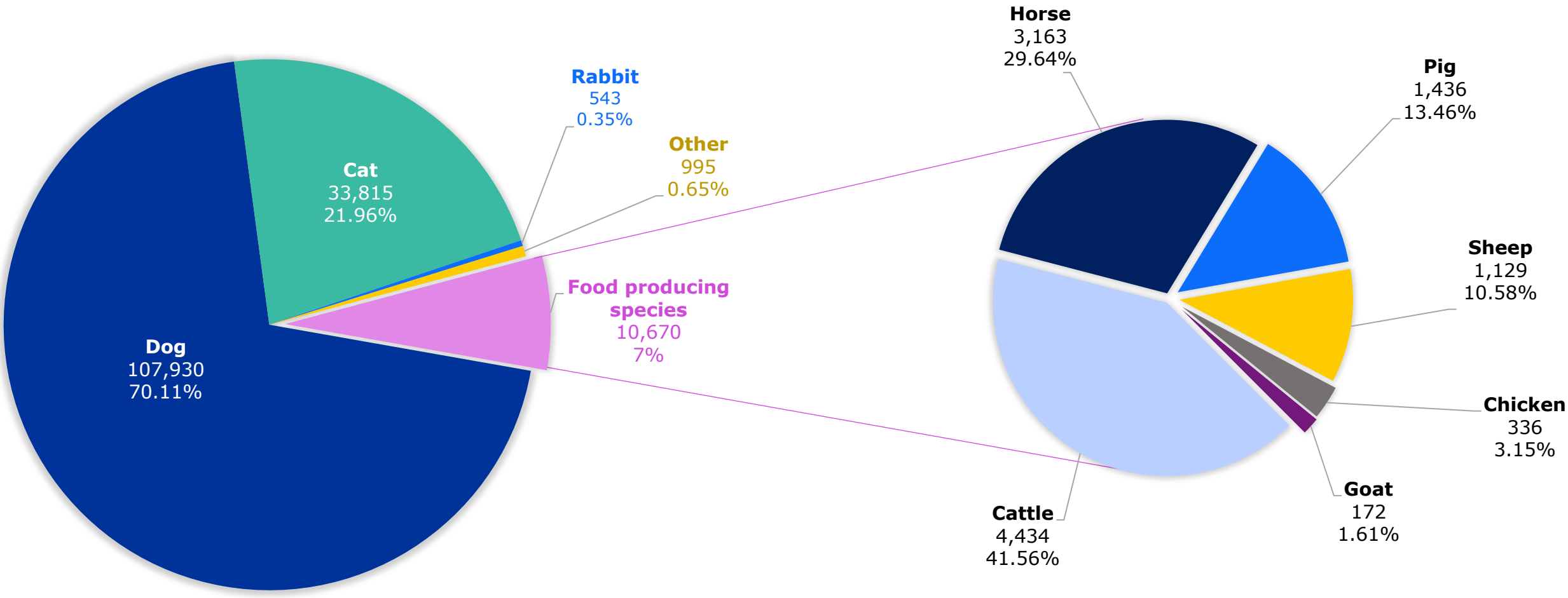
Post-marketing surveillance study



Very rarely, suspension or withdrawal of the product from the market

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Adverse events by species (2025)*



*European Union pharmacovigilance database (EudraVigilance Veterinary)

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Pharmacovigilance in practice

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Example (1): Senvelgo

- **Active substance:** velagliflozin
- **Authorised**: November 2023
- **Therapeutic use:** ↓ hyperglycemia in cats with non-insulin-dependent diabetes mellitus
- **Adverse event:** ↑ reports diabetic ketoacidosis (DKA)
  (if product recommendations not followed correctly)

Outcome: a DaHPC highlighting the correct use of the product to minimise serious consequences



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Example (2): PregSure BVD

- **Active substance:** inactivated Bovine Viral Diarrhoea (BVD) type 1 virus
- **Authorised:** May 2004
- **Therapeutic use:** immunisation of cattle to prevent transplacental infection & persistently infected calves
- **Adverse event:** 'Bleeding calf syndrome'
- **Regulatory & other actions**:
  - Referral triggered
  - Observational/case-control studies to identify risk factors
  - Multi-factorial syndrome, aetiology unknown NB association with vaccination


Photo from APHA, UK

Outcome: marketing authorisation suspended and product recalled

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What does this symbol mean on a veterinary medicine package?

Answer: ***The product must not be used in cats***



Permethrin-containing solutions for topical use

- Products authorised for use against ticks and fleas in dogs
- Neurologic disorders and fatalities in cats

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What type of adverse event could occur after administration of this VMP?

Answer: *Any/all of the below*

- *Skin irritation in the treated dog*
- *Accidental exposure of handler during application*
- *Lack of expected efficacy against parasites*

Antiparasitic spot-on solutions, e.g. Bravecto

- Avoid contact with the product & wear gloves
- Hypersensitivity and skin reactions

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Take home messages



Veterinarians are key to good pharmacovigilance practice, directly contributing to the improvement of the **safety of medicines, animal health and welfare**, **public health** and the protection of the **environment**.

The association between the suspected AE and the veterinary medicine **doesn't need to be confirmed before reporting**.

EVERY report counts!

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Report all adverse events!

- … to the national **competent authority** (NCA) in your country of practice* or the **MAH** for the VMP (see details on package leaflet)

In some countries, veterinarians have a legal obligation to report to their NCA.

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Useful links for your future daily practice



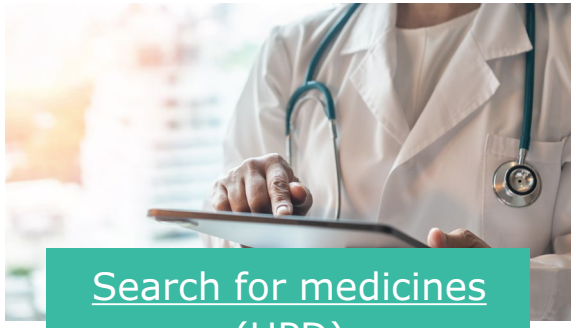
PI changes following PhV-related recommendations



Animal health practitioners' webpage



European database of suspected adverse drug reaction reports



Search for medicines (UPD)



How to report adverse events



DaHPC

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Thank you for your attention!

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Acronyms used

- ADR – adverse drug reaction
- AE – adverse event
- DaHPC - Direct animal healthcare professional communication
- LEE – lack of expected efficacy
- MAH – marketing authorisation holder
- NCA – national competent authority
- PI – product information
- PhV – pharmacovigilance
- UPD – Union Product Database
- VMP – veterinary medicinal product

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