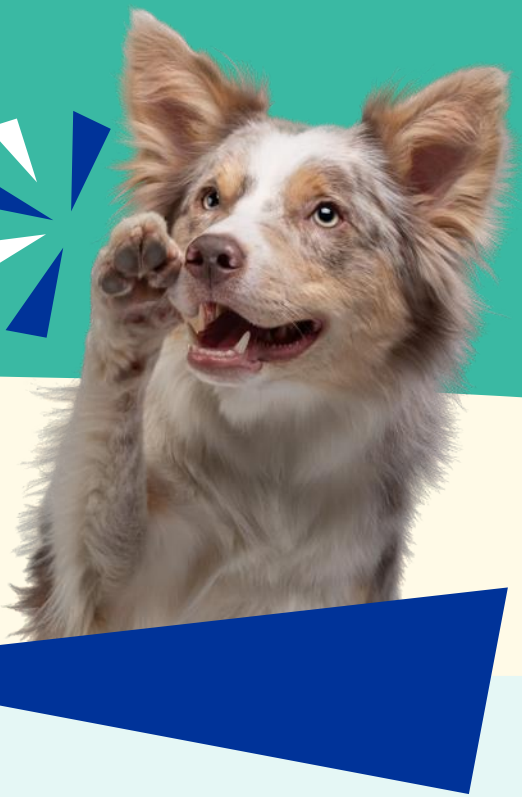
EMA
EUROPEAN MEDICINES AGENCY

FVE
Federation of Veterinarians of Europe

Adverse event reporting in the EU

Veterinary pharmacovigilance



Veterinary pharmacovigilance (aka drug safety) monitors the **safety of authorised veterinary medicines**, including vaccines, to ensure that their benefits continue to outweigh their risks.

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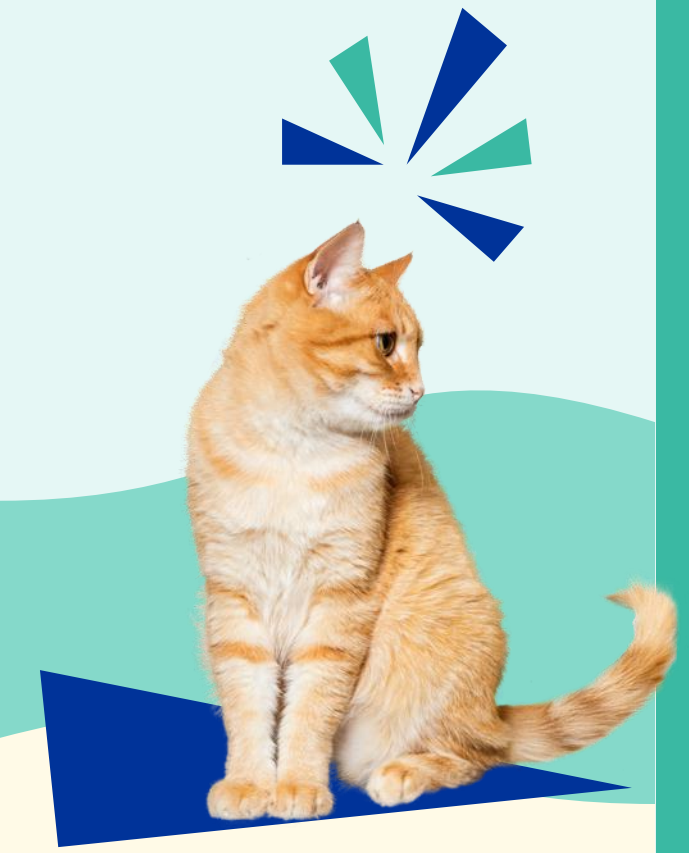


What is an adverse event?

What is an adverse event?

- An unfavourable and unintended event in an animal*, person or the environment after using:
  - a veterinary medicine or vaccine, including off-label; or
  - a human medicine to treat an animal.
- Also known as a side-effect, adverse drug reaction or vaccine/treatment failure.

* including birds and fish

What should be reported?

What should be reported?

- All suspected adverse events in animals after using veterinary medicines:
  - a) when a treatment or a vaccine has not worked.
  - b) including off-label use.
  - c) even if stated in the product information.
- Adverse events in people exposed to veterinary medicines or treated animals.
- Environmental incidents, high product residues in foods and suspected transmission of infectious agents.
- Suspected adverse events in animals after the use of human medicinal products.

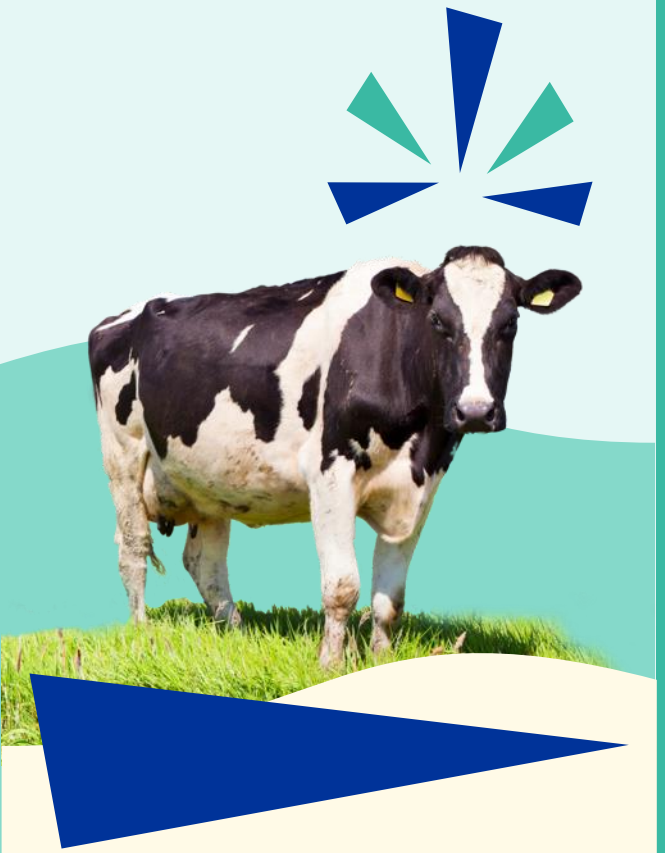
A suspicion of an adverse event should be reported.
The event does not need to be investigated or confirmed.

How to report adverse events?

How to report adverse events?

- You can report to:
  - the competent authority in your country*
  - the company responsible for the product**
- Anyone can report including members of the public, veterinarians, farmers, doctors, pharmacists, etc.
- You are encouraged to provide as much information as possible in the report.
- The association between the suspected adverse event and the veterinary medicine does not need to be confirmed before reporting.
- Animal owners/keepers should preferably report via their veterinarian.

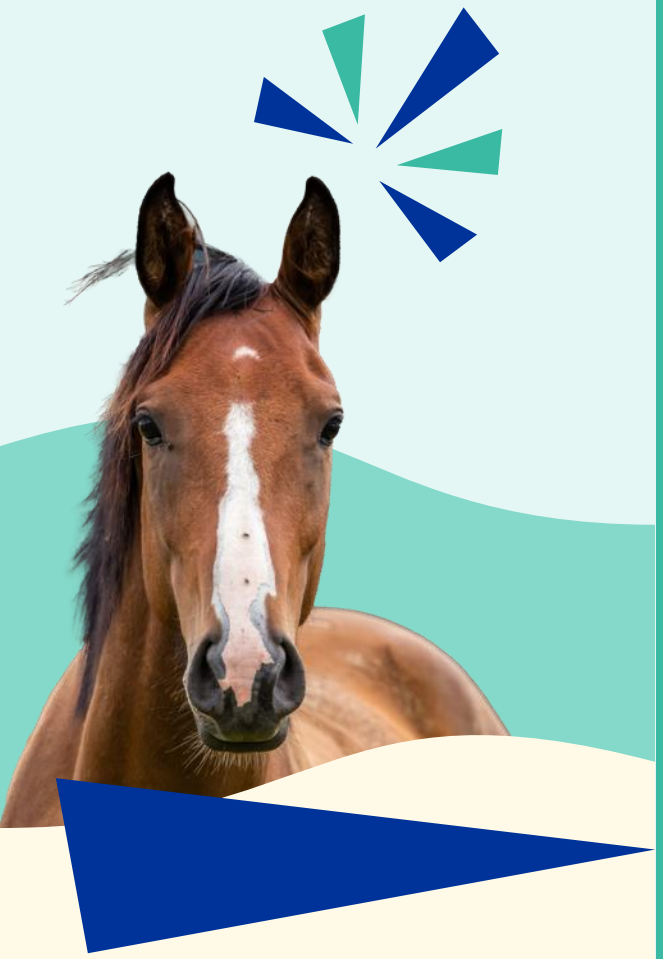
* In some countries, veterinarians have the legal obligation to report to their national authority.
** Contact details are listed on the product information.



What happens after reporting?

What happens after reporting?

- All suspected adverse event reports are collected in the EU Adverse event Database at EMA.
- Companies have a legal obligation to continuously monitor suspected adverse event reports.
- Each adverse event report contributes to the data being continuously monitored to ensure the benefits of veterinary medicines continue to outweigh their risks.
- If new risks are identified, measures can be taken, such as new warnings added to the product information.
- Very rarely veterinary medicines are suspended or withdrawn from the market until safety concerns are resolved.



Why report adverse events?

Why report adverse events?

By reporting, you directly contribute to **improving the safety of medicines**, animal health and welfare, public health and protecting the environment.

As a veterinarian you are in a **unique position** to observe and report adverse events.

Every report counts!

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Everyone should do their part and report all suspected adverse events.
Every report counts.

Safer medicines, healthy animals.

Report adverse events!

#VetMedSafetyDay

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