# Fact Sheet: Pharmacovigilance

## Introduction

EPRUMA promotes the responsible use of medicines in animals (www.epruma.eu ) and shares information on responsible use of medicines by promoting best practices to prevent, control and treat animal diseases, supporting animal health and welfare, contributing to food safety and One Health.

This fact sheet outlines the process of pharmacovigilance, a key step in ensuring the responsible and safe use of veterinary medicine.

## What is Pharmacovigilance?

Veterinary pharmacovigilance is the practice related to monitoring, evaluating and improving the safety of veterinary medicines, with particular reference to reporting adverse events in animals and people to the use of these medicines.

A good pharmacovigilance system provides for the detection of adverse reactions and increased knowledge of known adverse effects in animals. It can also include collection of information on adverse events due to off-label use and investigations of the validity of the withdrawal period and of potential environmental problems.

## Who has to report?

For the proper functioning of a pharmacovigilance system, active participation of both health professionals and veterinarians is required. In veterinary care, it is a legal obligation that any suspected adverse event is reported by the veterinarian. Whether or not they are described in the summary of product characteristics (SPC), and whether or not they are serious events, the veterinarian must report all suspected adverse events via the pharmacovigilance system.

## What is reported?

It is important that adverse reactions are reported even if a relation to the product(s) used is only suspected, especially the following types of reaction:

- an adverse reaction, which results in death
- an adverse reaction, which results in significant, prolonged or permanent signs
- an unexpected adverse reaction, which is not mentioned on the label or package insert
- an adverse reaction to veterinary medicines, which occurs in man
- an adverse reaction, which is observed after off-label use of medicines
- lack of expected efficacy (possibly indicating development of resistance)
- problem related to withdrawal periods, possibly resulting in unsafe residues
- possible environmental problems
- a known adverse reaction (mentioned on the package insert), which is serious or which seems to increase in frequency and/or seriousness. If the suspected adverse reaction is serious, particularly if an animal has died, the incident should be reported immediately.

It is important that as much detail as possible is reported. If available, laboratory data, post-mortem reports, photographs or other relevant information should be included, and likely differential diagnoses should be considered.

Reports should at a minimum include the following information:

1) Identification of the notifier
2) Characteristics of the animal(s) or person(s) with whom the event occurred

3) Identification of the medicine(s) used
4) Description of the adverse event

## How to report?

There are two possible ways of reporting adverse events linked to the use of veterinary medicines:

1) Via the laboratory that holds the marketing authorization for the veterinary medicine (Marketing Authorization Holder) who will then report this to the authorities
2) Directly via the authorities

It is important to select only one path of reporting adverse events to avoid duplication.

## Why is it important?

Pharmacovigilance reporting contributes directly to the safety of veterinary medicines. It helps inform both manufacturers and the authorities if the benefit/risk balance of using the veterinary medicine remains favourable once the product is licensed for use and placed on the market. Observations from veterinarians and other users help form a basis for authorities to advise on the safe and efficacious use of licensed veterinary medicines.

Veterinary pharmacovigilance is important for the continued monitoring of the safety of veterinary medicines, including vaccines, in order to ensure:

- safe use of veterinary medicines in animals
- safety of animal-source food
- safety for people using or in contact with veterinary medicines
- safety for the environment

This supports veterinarians with selecting the appropriate treatment in animal health care.

## What is the outcome?

If a pattern or recurrence of adverse reactions for a specific product is reported, regulatory actions to enhance the safety will be initiated depending on the conditions under which the adverse reactions have appeared and depending on their seriousness.

Depending on the gravity of adverse events, actions can include such procedures as:

- inclusion of warnings on the product label
- changes in the authorised use of the product
- suspension of the product from the market until the safety issues are solved.

## More information about pharmacovigilance in Europe:

**European Medicines Agency:** https://www.ema.europa.eu/en/veterinary-regulatory/post-authorisation/pharmacovigilance/pharmacovigilance-guidance

**Spain:**

- VetResponsable https://www.vetresponsable.es/farmacovigilancia-reacciones-incidentes/menu-principal/farmacovigilancia_66_1_ap.html
- Spanish Agency of Medicines and Sanitary Products (AEMPS) https://www.aemps.gob.es/vigilancia_medicamentosveterinarios/