VETERINARY PHARMACOVIGILANCE IN THE EUROPEAN UNION

WHAT IS PHARMACOVIGILANCE?

Pharmacovigilance means the science and activities related to the detection, assessment, understanding and prevention of suspected adverse events or any other problem attributed to a medicinal product.

WHAT IS THE PURPOSE OF PHARMACOVIGILANCE?

Pharmacovigilance rules are necessary for the protection of public and animal health and of the environment. The collection of information on suspected adverse events should contribute to the good use of veterinary medicinal products.

WHICH SUSPECTED ADVERSE EVENTS SHOULD BE REPORTED?

- **any unfavourable and unintended reaction in any animal to a veterinary medicinal product;**
- **any observation of a lack of efficacy of a veterinary medicinal product following its administration to an animal, whether or not in accordance with the summary of product characteristics;**
- **any environmental incidents observed following the administration of a veterinary medicinal product to an animal;**
- **any noxious reaction in humans exposed to a veterinary medicinal product;**
- **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;**
- **any suspected transmission of an infectious agent via a veterinary medicinal product;**
- **any unfavourable and unintended reaction in an animal to a medicinal product for human use.**

WHO REPORTS ON SUSPECTED ADVERSE EVENTS?

Relevant stakeholders in the Union, including veterinarians, other healthcare professionals, customers, and the general public, including monitoring of the results of scientific research by marketing authorisation holders.

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TO WHOM THE OCCURRENCE OF SUSPECTED ADVERSE EVENTS IS REPORTED?

- Reporters - to marketing authorisation holders or their representatives in the Member State
- Marketing authorisation holders or their representatives in the Member State- to the relevant local body in case of:
  - emerging safety issue-within 3 days;
  - in cases of a detection of new risk or change of the benefit-risk balance-within 30 days;
  - marketing authorisation holders shall record at least annually a conclusion on the risk-benefit balance for each of their products in the Union Pharmacovigilance Database and confirm that the signal management process has been conducted.
- The relevant local body-to the Union Pharmacovigilance Database-within 30 days of receipt of the suspected adverse event report.

ROLES AND RESPONSIBILITIES IN THE PHARMACOVIGILANCE PROCESS

Marketing authorisation holders are responsible for the continuous monitoring of pharmacovigilance data and the assessment of the benefit-risk balance of their veterinary medicinal products. A qualified person responsible for the pharmacovigilance system shall be designated.

The relevant local body must examine the summary of the master file on the pharmacovigilance system when evaluating the marketing authorization application.

- The relevant local bodies shall lay down the necessary procedures to evaluate the results and outcomes of the signal management process recorded in the pharmacovigilance database;
- may impose specific requirements on veterinarians and other healthcare professionals in respect of the reporting of suspected adverse events;
- shall record in the pharmacovigilance database all suspected adverse events which were reported to them and occurred on the territory of their Member State, within 30 days of receipt of the suspected adverse event report;
- shall make publicly available all important information on adverse events relating to the use of a veterinary medicinal product;
- shall carry out special inspections of the pharmacovigilance system on a regular basis.

The European Medicines Agency (EMA) has a coordinating role within the EU veterinary pharmacovigilance system and provides scientific and technical recommendations as and when requested by the European Commission, and leads the implementation of the Information technology (IT) systems required by the Regulation 2019/6/EU.