

VETERINARY PHARMACOVIGILANCE IN THE EU

WHAT IS PHARMACOVIGILANCE?

Veterinary pharmacovigilance monitors the safety of veterinary medicines, including vaccines, used for prophylaxis, diagnosis or treatment of disease in animals once they reach the market after authorization.

The task of veterinary pharmacovigilance is to ensure

- safe use of veterinary medicines in animals
- safety of animal-derived foodsafety for people who get into contact with veterinary medicines
- safety for the environment.

WHY IT IS IMPORTANT TO REPORT SUSPECTED ADVERSE REACTIONS?

As a practising veterinarian or other health care professional you are in a unique position to observe adverse reactions when they occur, and your key role in reporting them will directly contribute to the safety of these medicines.

Your observations are the basis on which the Competent Authority can give appropriate advice on safe and efficacious use of authorized veterinary medicines to you and your colleagues.

A well-defined benefit to risk profile of authorized veterinary products is essential for selecting the right treatment in veterinary practice. To ensure that veterinary medicines are safe and effective, their authorization is preceded by thorough pharmacological and toxicological investigations. However, only limited number of animals can be treated in the studies that lead to the approval. Adverse reactions, which occur rarely or are specific for certain breeds or groups of animals, may come to light only when the medicines are widely used in clinical veterinary therapy. It therefore is essential that all suspected adverse reactions are brought to the attention of the Competent Authority to enable it to continuously assess the benefits of a product in view of its risks.

WHAT SHOULD BE 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 manan adverse reaction, which is observed after off-label use of medicines
- lack of expected efficacy (possibly indicating development of resistance)
- a 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.

LEGISLATIVE FRAMEWORK

Legislation for the Competent Authority and the Marketing Authorization Holders:

There is a legal obligation for the Competent Authority (National Food Chain Safety Office Directorate of Veterinary Medicinal Products – NFCSO DVMP) and for the Marketing Authorization Holders (the pharmaceutical companies) to collect and evaluate the reports of suspected adverse reactions. It is required that the obtained information is shared between the Competent Authority and the concerned Marketing Authorization Holder. This is done at intervals stated in the legislation.

Legislation for veterinary practitioners and other health care professionals:

According to the the Decree No. 128/2009. (X.6.) MARD on veterinary medicinal products the practising veterinarian is obliged to report to the NFCSO DVMP the serious, unexpected, human adverse reaction, possibly caused by veterinary medicinal products which were used in accordance with the approved package insert.

HOW ARE SUSPECTED ADVERSE REACTIONS REPORTED?

Reporting should be done preferably on the reporting form for veterinarians and health professionals.

It is important that the form is completed with as much detail as possible. Available laboratory data, post-mortem reports, photographs and other relevant information should be attached to the form.

The forms are available from the National Food Chain Safety Office Directorate of Veterinary Medicinal Products (1475 Budapest POB 318), or may be downloaded from the NFCSO DVMP website (<http://www.nebih.gov.hu>). Reports should be sent to the same address, or may be announced by the 24-hour-service ((1)-260-32-69).

WHAT HAPPENS AFTER A SUSPECTED ADVERSE REACTION WAS REPORTED?

Given the available information an assessment of casual relationship between the administration of the medicine and the reported reaction is made by the NFCSO DVMP. Should a pattern of adverse reactions for a specific product emerge, regulatory actions to enhance the safety will be initiated depending on the conditions under which the adverse reactions have appeared and on their seriousness. Examples are:

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

A good pharmacovigilance system provides for the detection of adverse reactions and increased knowledge of known adverse effects in animals. The reporting of adverse reactions provides for continuous monitoring of the benefits and risks of veterinary medicines once they are marketed and thus contributes to their safe use.

By participating in the reporting system you will contribute to better knowledge of animal medicines, with benefit for animals, the public and your colleagues in veterinary health care.

National Food Chain Safety Office
Directorate of Veterinary Medicinal Products
Inspectorate
1107 Budapest, Szállás u. 8.
1475 Budapest, 10. Pf. 318.
Phone/Fax/Answering machine: 260-3269
Fax: 262-2839