

What happens after I report?

When the HPRA receives a report of a suspected adverse event, we review all the details including the possible impact of the medicine. Typically, the receipt of a single report will not result in any regulatory action but it will heighten our awareness of the product/issue. However, should a pattern of adverse events for a specific product emerge, the HPRA will take action to enhance the safety of the product. The regulatory options available to us include:

- the inclusion of warnings on the product label;
- changes in the authorised use of the product;
- the suspension of the product from the market until the safety issue is resolved.

The final action we take will be based on the seriousness of the adverse events as well as the conditions under which they have appeared.

What are the benefits of an effective pharmacovigilance system?

An effective pharmacovigilance system helps to ensure the health and welfare of animals and humans.

Specific benefits include:

- The continued monitoring of the benefit/risk balance of veterinary medicines;
- Assurances on the continued safety of veterinary medicines;
- Increased knowledge of the safety profile of veterinary medicines, leading to better advice for the users of these products;
- Updated and improved label warnings leading to safer use of medicines;
- Removal from the marketplace of products (or batches of products) that have unacceptable safety profiles.

The Health Products Regulatory Authority (HPRA)

Our role is to protect and enhance public and animal health by regulating medicines, medical devices and other health products.

What does the HPRA do?

As the regulatory authority, we monitor the safety and quality of medicines available in Ireland. Our aim is to make sure that medicines are as safe as possible and do what they are intended to do.

More information

This is one in a series of information leaflets that you can get from the HPRA and from our website: www.hpra.ie. If you have any queries about the content contained in this leaflet, please e-mail: vetsafety@hpra.ie.

For further information about the regulation of veterinary medicines, please visit the Veterinary section of our website.



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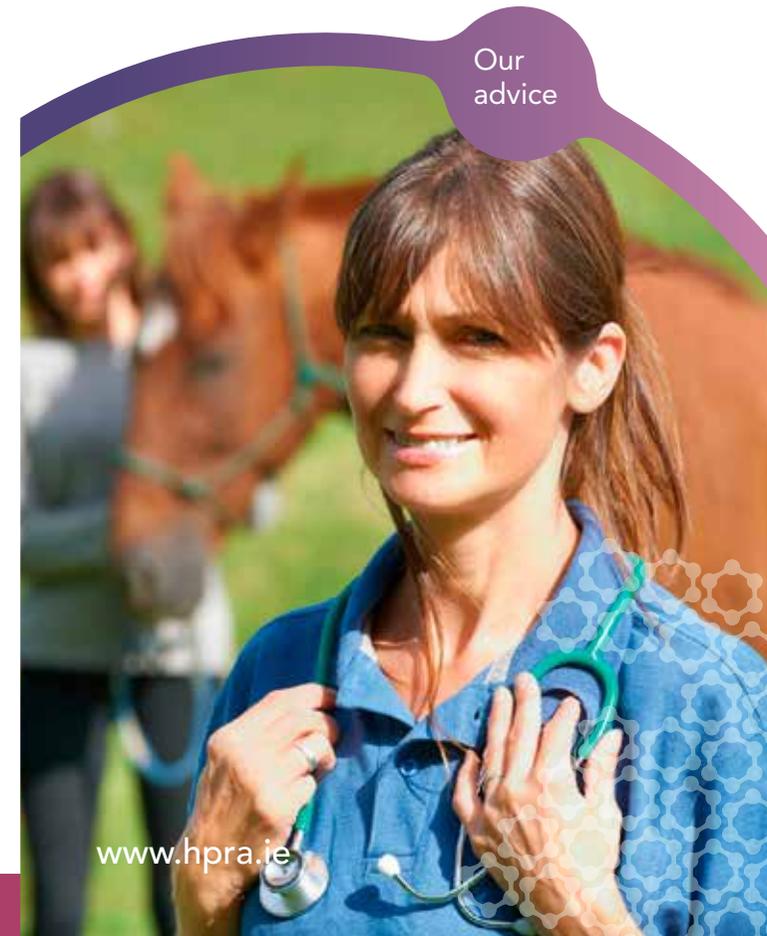


An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

VETERINARY MEDICINES

Reporting Adverse Events

Our advice



www.hpra.ie

OUR ADVICE ON

Reporting Adverse Events

The Health Products Regulatory Authority (HPRA) is responsible for monitoring the safety, quality and efficacy of authorised veterinary medicines. The ongoing monitoring of medicine safety and efficacy is referred to as pharmacovigilance.

Part of our role at the HPRA is to operate a national pharmacovigilance system which is based on the receipt and review of reports of suspected adverse events (SAEs). An adverse event is a harmful or unintentional side effect following the use of a medicine. The operation of an effective pharmacovigilance system enables the HPRA to monitor the continued safety and efficacy of veterinary medicines under actual use conditions.

The reports that we receive mainly relate to adverse effects experienced by an animal following the use of a particular product. However, the scope of the HPRA reporting system also includes:

- reports of lack of expected efficacy (effectiveness) of a veterinary medicine when used in line with the label recommendations;
- adverse effects associated with 'off-label' use;
- adverse environmental effects resulting from contamination with a medicine;

Reporting Adverse Events

- detection of drug residues in milk, meat or produce of treated animals;
- harmful and unintended effects in humans exposed to veterinary medicines.

We receive reports from marketing authorisation holders, veterinary practitioners, pharmacists, licensed merchants and animal owners.

Why is it important that I report suspected adverse events?

Pre-authorisation safety studies are typically conducted in relatively small numbers of animals, under controlled conditions of use. Safety information resulting from the widespread use of a medicine once it is on the market is therefore very valuable. This is because certain safety issues may only come to light when the product is in the hands of the intended user and is being used on large numbers of target animals. Examples include adverse effects that occur rarely or are specific for certain breeds or groups of animals.

A well-defined safety profile for each authorised veterinary medicine is essential for selecting the right treatment in veterinary practice. For this reason, it is vitally important that suspected adverse events are reported to the HPRA so we can continue to give appropriate advice on the safe and effective use of medicines based on our assessment of the known benefits and risks.

If you are a supplier* of medicines, you are obliged to report suspected adverse events that are serious or unexpected in nature. By doing so, you will be contributing directly to the safety profile of veterinary products.

* In accordance with national legislation (European Communities (Animal Remedies) (No.2) Regulations 2007, S.I. No. 786 of 2007), persons licensed to sell or supply animal remedies are obliged to notify the HPRA or the relevant marketing authorisation holder of all serious or unexpected SAEs and all human adverse reactions associated with the use of veterinary products that come to their attention within 15 days of receipt of such information.

How can I report suspected adverse events?

Completing and submitting a report form should take you no more than five minutes. You can report an adverse event by:

- Using the online report form on www.hpra.ie.
- Downloading and printing a copy of the form from our website. You can then post the completed form to us or send it by e-mail to vetsafety@hpra.ie.
- Requesting a prepaid self-addressed copy of the form from us and submitting the completed version by post.

What should I report?

It is important that adverse events are reported even if you only suspect that it is linked to a medicine. A valid report will require at least the following core details:

- An identifiable reporter (such as a veterinary practitioner, pharmacist, licensed merchant or animal owner).
- Animal/human details: Species, age, sex.
- Suspect product: Name and authorisation number.
- Event details.

Note that these are the minimum requirements. If you possess further information about the adverse event we ask that you provide this to the HPRA so that we can carry out a full scientific evaluation. Where relevant, this may include laboratory findings and post mortem examination findings. If the suspected adverse event is serious, particularly if an animal has died, please report it immediately.

Anyone can report an adverse event. However, to ensure that the information is as accurate and complete as possible, you may find it helpful to consult a veterinary practitioner prior to submitting a report to the HPRA. It also may be necessary for us to contact the reporter in order to clarify aspects of the case.