Transcript of the presentation entitled 'The role of animal owners in monitoring the safety and effectiveness of veterinary medicines'

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Hello everyone and welcome to this presentation which will cover the topic of adverse event reporting for animal owners. Adverse events include side effects, safety concerns or if a medicine is not working as expected following the use of a veterinary medicine and are most likely to be observed by veterinarians or pet owners. The HPRA uses information on reported adverse events to monitor the safety and effectiveness of veterinary medicines available for use in Ireland.

This is one of a series of presentations we have available, so if you would like to learn more about the monitoring of the safety and effectiveness of veterinary medicines (also known as veterinary pharmacovigilance), or a better insight into the work of the Health Products Regulatory Authority (HPRA), please feel free to access any of our published presentations.

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The topics that will be covered are:

- The role of animal owners in veterinary pharmacovigilance and the monitoring of the safety and effectiveness of veterinary medicines.
- The importance of reporting adverse events.
- Types and examples of adverse events. We will provide a general overview using some common examples of types of adverse events to explain what constitutes an adverse event.
- Finally, we will explain how to report an adverse event. Here we will go through the different ways to report, where to find the online reporting form, and the information that you will need to fill in a report. If you are looking specifically for a 'how to' guide on filling in the reporting form – please see our separate presentation under 'Adverse Reaction/Event Reporting' that will explain this in more detail for you.

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Before we go any further, let me explain what the term 'pharmacovigilance' means and the role of the HPRA. The World Health Organisation definition is "The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem". This also applies to veterinary medicines.

The HPRA is responsible for monitoring the quality, safety and effectiveness of veterinary medicines that have been authorised for use in Ireland. One part of this monitoring process includes accepting reports of adverse events from animal owners, vets, vet nurses and veterinary healthcare professionals.

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So what is an adverse event? An adverse event is any observation that is unfavourable and unintended and that occurs after the use of a veterinary medicine and may relate to:

- reactions in the treated animal following recommended use of the product,
- reactions in the treated animal when a veterinary medicine has not been used as recommended,
- the product did not work as intended,
- effects in humans following exposure to a veterinary medicine,
- finding residues of a veterinary medicine in produce (e.g. meat, milk, honey) from a treated animal that exceeds permitted limits,
- impact on the environment.

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An adverse reaction is one type of an adverse event and can be described as a reaction or side effect to a veterinary medicine which is harmful and unintended and which occurs at doses normally used in animals.

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We will now discuss why veterinary pharmacovigilance is important. When a product is first authorised the information available to regulatory authorities is usually based on studies carried out in a limited population of animals. Once marketed, the product will be used in a much larger population of animals so adverse events may come to light that were not observed in the controlled studies e.g. drug interactions. Prescribers and users of veterinary medicines have an important role to play in terms of reporting adverse reactions so that the safety and efficacy of each product can be monitored once marketed.

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Adverse event reporting is important in order to ensure the safe and effective use of veterinary medicines for both the animal and the person administering the product. Unless information on adverse events is reported, the regulatory bodies (such as the HPRA) as well as companies that place veterinary medicines on the market will be unaware of such events following the placing of a product on the market. The reporting of adverse events provides valuable information to allow ongoing assessment of the safety and effectiveness for each veterinary medicine and may aid in making decisions on any regulatory action that may be required e.g. including new or updating existing warnings in the package leaflet.

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Animal owners have a very important role to play in monitoring the safety and effectiveness of veterinary medicines. Owners usally know their animals better than anyone else, and are likely to

be the first to notice when something isn't right and may be the first to notice any reaction or side effect to a veterinary medicine. Animal owners commonly adminster veterinary medicines to their animals, for example, a pet owner may administer flea/tick treatments, wormers, or long term pain-relief medication for arthritis to their pets, or farmers may administer a range of veterinary medicines to their animals.

Most importantly, animal owners play a key role in communcations with veterinary staff. They are in prime position to ask questions, raise concerns and report back to vets/nurses with any issues or concerns including possible adverse events.

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Adverse reactions can be classified as either serious or non-serious. A serious reaction may result in death or be life-threatening, or result in a persistent or significant disability, incapacity, a congenital anomaly, or birth defects.

Reports may relate to:

- adverse reactions in the treated animal following recommended use of the product – e.g. an anaphylactic reaction following a routine vaccination in a puppy;
- adverse reactions in the treated animal when a veterinary medicine has not been used as recommended – e.g., an overdose of a product;
- the product did not work as intended;
- finding residues of a veterinary medicine in produce (e.g., meat, milk, honey) from a treated animal that exceeds permitted limits;
- effects in humans following accidental exposure to a veterinary medicine – e.g., accidental self-injection or spilling a product onto skin;
- impact on the environment – use of sheep dips near watercourses and safe disposal of spent sheep dip.

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Some common examples of adverse event reports include:

- application site reaction (e.g. hair loss, inflammation, swelling, itching) after using a spot-on treatment;
- your pet developing vomiting/diarrhoea while on long-term treatment for arthritis;
- your animal being diagnosed with a disease against which it has previously been vaccinated to protect against (did not work as intended).

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So to whom should you report an adverse event? We would encourage you to discuss any adverse event with your veterinary practice in the first instance as they will have full clinical records and may be best placed to report the adverse event on your behalf.

If you intend to report the adverse event yourself, you may do so either to the company responsible for placing the veterinary medicine on the market (contact details of the marketing authorisation holder is printed on the labelling/package leaflet of the product), or directly to the HPRA.

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If reporting an adverse event to the HPRA, the easiest and quickest way is to fill in the online form available on the HPRA's website. This form can also be downloaded to be filled in manually, and sent via email or Freepost to the HPRA.

Please see our separate presentation under 'Adverse reaction/event reporting' which gives a stpe-by-step guide on how to complete the online form and submit it to the HPRA.

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The following information is needed to make sure an adverse event report is valid:

- Identifiable reporter.
- Human/Animal details (e.g. species, age, breed, weight).
- Name of product and authorisation number (this can be found on the product information and will look like: VPA 12345/678/000 or EU/1/23/456/789.

Details of the adverse event – as much relevant information as you can provide. We will let you know when we have received your report. If any of the key details we need are missing, we may need to contact you first.

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On this slide we show a snapshot of the homepage of the HPRA's website page where you will be able to download the form. Under the tab 'VETERINARY' at the top there is an option to 'Report an issue' as is marked in the red box here – then click on 'report an issue'.

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You will then be directed to another page that lists the available online report forms where you should click on 'Veterinary Medicines Adverse Reaction/Event'. As mentioned, a separate presentation is available under 'Adverse reaction/event reporting' which provides a step-by-step approach on how to complete and submit this online reporting form.

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The main take home message from this presentation is to please report any suspected adverse events either through your veterinary practice (preferably) or directly yourself. In doing so you will be contributing to the ongoing monitoring of the safety and effectiveness of the product and keeping us informed of any issues relating to individual products and any concerns encountered in their use.

Always seek advice from your veterinary practice (or alternatively your pharmacist or licensed retailer if they dispensed the product to you). They are best placed to answer any questions or concerns that you may have with any veterinary medicines that are to be administered to your animal. If you are unsure how to administer a product correctly, please always ask for advice.

Most importantly, always take the time to read the full package leaflet before using a veterinary medicine as full information on the safe and effective use of each product is provided in the package leaflet.

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And finally, please refer to other information sections and presentations available on our website for further guidance and instruction on adverse events, pharmacovigilance and the work of the HPRA. If you have any questions regarding the reporting of adverse events or product safety, please contact us here at the HPRA using this email address: **vetsafety@hpra.ie**.

Thank you for listening and we hope this presentation has been of interest. Goodbye.