HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Transcript of the presentation entitled 'How to report an adverse event using the HPRA online reporting form'

SLIDE 1

Hello everyone and welcome to this presentation which will cover the topic of how to report an adverse event to the Health Products Regulatory Authority using the online reporting form available on the HPRA's website.

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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This presentation has been designed for anyone who wishes to report an adverse event using the HPRA online reporting form. We hope it will be informative and by the end you will know how to report an adverse event 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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Laboratory reports or necropsy findings can be added if applicable. New information can be sent as a 'follow-up' report.

All reports are dealt with in full compliance with the General Data Protection Regulation requirements.

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Before submitting a report you should consider:

- Whether there is an association between the timing of administration of the medicine and the occurrence of the adverse event. Perhaps the event occurred within a few minutes or hours following administration, or perhaps the animal was not seen until the following day (in which case there might be another cause for the event seen).
- Whether there are other plausible explanations for the event e.g., was the animal exposed to a poison, or could the disease being treated have led to the signs seen?
- Were there any other medicines given to the animal which could have given rise to the event e.g., other drugs given at the same time?

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We will now look at how to report an adverse event using the online reporting form available on the HPRA's website which is the preferred and quickest method of submission.

Just to note that you can also download a reporting form from the HPRA's website which can be printed, completed and posted to the HPRA by Freepost or you can report directly 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).

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This slide shows you where to find the reporting form on the HPRA website. On the home page, click on the 'VETERINARY' tab at the top and you will see a link entitled 'Report an Issue'.

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This link will open a list of online reporting forms and you should select the one entitled 'Veterinary Medicines Adverse Reaction/Event'.

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This will then open the online reporting form. The first page is the reporter information. Anything with a red asterisk is required information and completion of the report cannot be progressed until this information is included. Although the fields with a red asterisk represent only the minimum details required, it is important that the report is as comprehensive as possible in order to facilitate a full evaluation.

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There is a dropdown menu for 'Reporter type' where you select the relevant category. When you have this page filled in click the 'Next' button at the bottom right of the screen.

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On the second page the dropdown menu beside safety report will allow you to select if the adverse event occurred in animals or in humans.

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When you select the safety report 'In Animals' option, the report produces fields to fill in with information about the animal such as species, breed, age and the number of animals reacting. Please fill in as much detail as possible. The animal ID can either be a number or a name. There is also a free text box where you can add any additional information.

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When you select the safety report 'In Humans' option, the report produces fields to fill in and these include sex, age and occupation. There is a dropdown menu for occupation with the options of veterinary surgeon, farmer, pet owner and other. There is also the free text box where you can add any additional information.

When you have filled in this page click the 'Next' button at the bottom right of the screen.

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The third page requests details of the product administered.

At the top of the page under 'Drug Type' there are two headings in the dropdown menu - concomitant or suspect.

'Suspect' is a product you think was involved in the adverse event and 'concomitant' is a product that was also administered at the same time or around the same time as the suspect product and could be involved in the adverse event but you think it may not be the main cause.

You will find the authorisation number on the outer packaging of the product and it will either begin with the letters 'VPA' if it is authorised by the HPRA or 'EU' if it is authorised by the European Medicines Agency. There is also a dropdown menu for route of administration with multiple options so please select the relevant option.

There is a dropdown menu to select if the company responsible for the product has been informed. This is important information for the HPRA as it will help avoid duplicate reports being entered into the European Pharmacovigilance database. In most cases it is enough to report the adverse event once so please only report the adverse reaction to either the company responsible for placing the product on the market or to the HPRA and not both.

When you have filled in this page click the 'Next' button at the bottom right of the screen.

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The fourth page is where details of the adverse event are entered.

There is a dropdown menu beside the 'Type of report' and there are four options to pick from.

The first option is 'Environmental problem' and this should be selected if an environmental issue has occurred following use of a product e.g. contamination of a watercourse by a sheep dip.

The next option is 'Maximum Residue Limit Violation' and this should be selected if residues above the maximum residue limit have been detected after observing the authorised withdrawal period of the product.

The next option is 'Suspected Adverse Reaction' and this should be selected for a reaction to a veterinary medicinal product which is harmful and unintended and which occurs at doses normally used in animals for the prevention, diagnosis or treatment of disease or to restore, correct or modify a physiological function.

The next option is 'Lack of Expected Efficacy' and this should be selected if there was an apparent inability of an authorised product to have the recognised expected effect in an animal, according to the claims of the SPC and following use of the product in accordance with the SPC. Just a reminder at this point that the SPC stands for 'Summary of Product Characteristics' and this can be found on the HPRA's website (or the EMA website if it is a product authorised by the European Medicines Agency).

There is also the option to indicate if the animal has had previous exposure to the product and if similar clinical signs were observed.

There is a free text box to provide details of the adverse event.

When you have filled in this page click the 'Next' button at the bottom right of the screen.

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On the fifth page there is the option to upload a photo or a file e.g., laboratory results or a necropsy report and a free text box to provide information.

This is an optional step and is not required for successful submission of the report, however, any relevant additional information should be provided to facilitate review and assessment of the report.

When you have filled in this page click the 'Next' button at the bottom right of the screen.

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The sixth page is the final page and will bring up a preview of the report and will show you all the information you have entered. If you need to edit any details click the 'previous' button on the bottom left on the screen and go back to the required page. If you are happy with the report click the 'Submit' button on the bottom right of the screen.

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A 'Form Submission Confirmation' will appear on the screen with a ticket number which is your acknowledgement that a report has been submitted. There is also a link where you can download a PDF version of the report for your records. You will also receive a confirmation email to the email address you provided on the first page of the report and this will have a PDF copy of the submitted report attached.

You will also receive an acknowledgment email by a member of the HPRA veterinary pharmacovigilance team once the report has been reviewed.

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The HPRA recognises that there may be a perception amongst the veterinary profession that contacting the HPRA will adversely impact on their workload. Hopefully this presentation has shown that it is a simple, quick and straightforward process which does not take much time to complete.

You will rarely be asked to engage in discussion of the adverse event or case history.

Provided that the mandatory information is included in the report, there will normally be no need for the HPRA to consult with the reporter.

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This brings us to the end of this presentation. In conclusion I would like to reiterate the importance of reporting adverse events.

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.

Reporting benefits both the animal receiving the product and the person prescribing or administering the product.

So the take home message we would like you to remember is please do your part and report suspected adverse events.

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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.