



THE ADVERSE EXPERIENCE REPORTING PROGRAM FOR VETERINARY MEDICINES

In Australia, all veterinary medicines that are used in the prevention and/or treatment of animal diseases, must be registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA). This registration process ensures that products in the market have been rigorously assessed and meet high standards for safety, quality and efficacy.

Occasionally unforeseen problems arise from the use of these products that may affect people, animals, the environment or trade. The APVMA seeks to identify and act promptly on such 'adverse experiences' through the Adverse Experience Reporting Program for veterinary medicines (AERP Vet).

What is the AERP Vet?

The AERP Vet is a quality assurance program established by the APVMA to facilitate responsible management of veterinary medicines throughout their lifecycle. The aim of the AERP Vet is to ensure that products on the market remain safe, effective, are of acceptable quality and that instructions and warnings on labels are appropriate.

Why have the AERP Vet?

Recording and investigating reports of adverse experiences from people who use or are exposed to veterinary medicines is important in detecting unusual and rare conditions that were not evident in clinical or field trials prior to registration.

The purpose of the program is to provide the APVMA with feedback about the performance of veterinary medicines in real use situations to ensure that registration decisions being made by the APVMA are appropriate and effective, and to promote and maintain public confidence in the APVMA and the National Registration Scheme.

Who can report an Adverse Experience?

Anyone. Veterinarians, members of the public, farmers and health workers, for example, are encouraged to report any adverse experiences that have occurred after the use of or exposure to veterinary medicines that have been used according to label or APVMA Permit directions to both the APVMA and the product registrant. Such reporting is voluntary.

What should you do?

- If you have been affected - seek immediate medical advice.
- If your animal has been affected - seek immediate veterinary advice.
- Ring the contact number on the product label and report your adverse experience to the registrant.
- Keep any remaining product in a safe place in case a sample is required.
- Contact the APVMA.

If you, your pet or anyone you know has had an adverse experience from the use of a veterinary medicine, we encourage you to report it to us.

What does the APVMA do when it receives a Report?

Reports received by the APVMA are assessed to determine whether the adverse experience is related to the use of or exposure to the product or not. The APVMA may rely on advice from other Australian government agencies (such as the Department of Health and Ageing), and relevant State or Territory agencies when assessing adverse experience reports. The APVMA will also take into account any published material available from similar reports, as well as any relevant scientific literature published worldwide.

Based on the assessment of adverse experience reports, certain risk mitigation strategies or corrective actions may be required. These may include, but are not restricted to, the following:

- registration amendments, such as label changes
- referral for action, such as compliance action, investigation by the Good Manufacturing Program, or nomination of products or active constituents for formal chemical review by the APVMA; and/or
- education and publicity, such as providing scientific papers or articles on issues identified for relevant journals, magazines or newspapers.

The conclusions drawn by the APVMA following investigation and evaluation of each adverse experience report will be provided to the reporting person who submitted the initial adverse experience report. This will include an explanation of whether the APVMA considers that the observed adverse effects (including health symptoms) were related to the use of or exposure to the product. The APVMA will explain what these conclusions are and what corrective action, if any, will be taken in response to the information.

How do I find out about other adverse experiences?

The information in Annual Reports of Adverse Experiences is arranged according to the active constituent name. Individual products are not identified. Only reports classified as 'probable' or 'possible' (ie where there is an association between the use of the product and the adverse experience) are included. A summary of regulatory actions taken by the APVMA is also included in these reports.

How do I make a report

Reports should preferably be submitted using the reporting form found on the APVMA Website at:

www.apvma.gov.au/qa/vetaerp.shtml

Alternatively, to make a report, contact the AERP Coordinator on:

FreeCall: 1800 700 583

T: +61 2 6210 4806

F: +61 2 6210 4813

E: aerpcoordinator@apvma.gov.au

CONTACTING THE APVMA

Want more information?

If you would like to know more about the APVMA or any of its services please contact us.

Postal address:

PO Box 6182

KINGSTON ACT 2604 AUSTRALIA

T: +61 2 6210 4700

F: +61 2 6210 4813

W: www.apvma.gov.au

