



# INFORMATION SHEET

Australian Pesticides & Veterinary Medicines Authority

## Adverse Experience Reporting Program for Veterinary Chemicals

In Australia, all veterinary chemical products, which are used in the prevention and 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.

In the majority of cases, veterinary chemical products serve us well; however, 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 (AERP).

### What is the Adverse Experience Reporting Program?

The AERP is a quality assurance initiative established by the APVMA to facilitate responsible management of veterinary chemical products throughout their lifecycle.

### Why the Adverse Experience Reporting Program?

Recording and investigating reports of adverse experiences from people who use veterinary chemical products is an important step in detecting unusual and rare conditions that were not evident in clinical or field trials and as a result, could not be assessed during the product registration process. The results of these investigations ensure that veterinary chemical products in the marketplace:

- remain safe and effective;

- are used in the best possible way; and
- have appropriate instructions for use on the product label.

### What you Should 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.
- Keep any remaining product in a safe place in case a sample is required.
- Contact the APVMA.

If you or anyone you know has had an adverse experience from the use of a veterinary product, 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:

- product formulation;
- manufacturing processes;
- use practices; or
- product labelling.

The assessment will take into account any published material available from similar reports as well as any relevant scientific literature published by regulatory

## Adverse Experience Reporting continued...

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agencies worldwide. The APVMA will then notify you of the findings and proposed course of action.

Where the experience is definitely product-related, the APVMA may require the registrant to change the product label or its formulation.

In extreme cases, the APVMA may enforce product recall or revoke product registration, effectively removing it from the market.

### **How do we Know if an Adverse Experience Report has been Made?**

The APVMA publishes an annual report summarising all adverse experiences. The report outlines all incidents of adverse experience, outcomes of investigations and the course of action taken. The reports are available by contacting the APVMA or on our website at [www.apvma.gov.au](http://www.apvma.gov.au)

### **How Do I Make a Report?**

If you have had an adverse experience which may be associated with the use of a veterinary chemical product, report it to us.

To make a report contact the AERP Coordinator on (02) 6272 3651

Reporting forms are also available on the APVMA website at [www.apvma.gov.au](http://www.apvma.gov.au)

## Contacting the APVMA

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### **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 E240  
Kingston ACT 2604

#### **Phone:**

02 6272 5158

#### **Fax:**

02 6272 4753

#### **Website:**

**[www.apvma.gov.au](http://www.apvma.gov.au)**



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