



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

**ADVERSE EXPERIENCE REPORTING PROGRAM
FOR VETERINARY MEDICINES**

**GUIDELINES FOR VETERINARIANS,
ANIMAL OWNERS AND CHEMICAL USERS**

KP81_G02	Approved by: Position: Program Manager, QA & C	Version: 5 Issue Date: 12/09/2007	Page 1 of 5
----------	---	--------------------------------------	-------------

ADVERSE EXPERIENCE REPORTING PROGRAM FOR VETERINARY MEDICINES

GUIDELINES FOR VETERINARIANS, ANIMAL OWNERS AND CHEMICAL USERS

The APVMA's Adverse Experience Reporting Program for veterinary medicines (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 are used in the best possible way, and that instructions and warnings on labels are appropriate.

Introduction

The Australian Pesticides and Veterinary Medicines Authority (APVMA) evaluates, registers and regulates pesticides and veterinary medicines in Australia. 'Pesticides' include agricultural and household products such as insecticides, herbicides and fungicides. 'Veterinary medicines' include all veterinary products such as vaccines, antibiotics, worming treatments, and flea and tick washes.

Before a pesticide or veterinary medicine can enter the Australian market, it must go through the APVMA's rigorous assessment process to ensure that it meets high standards of safety and effectiveness.

The APVMA is committed to ensuring that pesticides and veterinary medicines sold in Australia:

- are of a high quality,
- do not pose a threat to people, domestic or native animals, crops, plants, or the environment,
- will not pose any unacceptable risk to trade with other nations, and
- continue to work effectively.

Why do we have the AERP Vet?

In Australia, all veterinary medicines that are used to prevent and treat animal diseases must be registered by the APVMA. Prior to registration veterinary medicines are subjected to a rigorous assessment of their safety, quality and efficacy. However, that assessment cannot always determine the full potential for unexpected effects of the chemicals because of:

- the relatively small number of animals used in field trials compared to the wider population,
- the wide range of environmental conditions encountered under practical farming conditions, and
- the fact that it is impossible to include in clinical trials all breeds of animals and age groups, or all types of pests and diseases that may be exposed to the product.

Therefore a product with a potentially wide range of uses may not be tested on all groups of animals or under the conditions that fully reflect its ultimate market.

While in the main veterinary medicines serve us well, occasionally unforeseen problems can arise that may affect people, animals, the environment or trade. The APVMA seeks to identify and act promptly on such '*adverse experiences*' through the AERP *Vet*. It is therefore important that adverse experiences are brought to the attention of the person responsible for the product (ie the 'registrant') and the APVMA so that unusual, rare or idiosyncratic conditions that were not evident in clinical or field trials conducted before registration, are detected and necessary action can be taken.

Scope of the AERP *Vet*

The Scope of the AERP *Vet* covers adverse experience reports involving:

- animal health issues, including both domestic and native birds and animals,
- human health issues, where people are exposed to veterinary medicines,
- lack of efficacy,
- residue issues, and
- environmental damage.

The scope does not include:

- registered agricultural chemicals (these are dealt with as part of the AERP *Ag*),
- trade issues as these do not fall within the definition of an '*adverse experience*' (see below),
- packaging design faults, which also do not fall within the definition of an '*adverse experience*',
- illegal off-label uses (ie contrary to label directions without veterinary advice, which include instances where products are used on resistant or suspect resistant pest populations if the label specifically warns against such use), or
- products not registered by the APVMA.

The AERP *Vet* may decide not to investigate a report because it falls outside the scope of the program as outlined above.

Source of reports

The three complementary components of the AERP *Vet*:

1. The '*voluntary*' component that encourages veterinarians and the general public (including animal owners, farmers and other chemical users) to report any adverse experiences to both the APVMA and the product registrant.
2. The '*state*' component through which state agencies are encouraged to report to the APVMA any adverse experience reports that they receive that are within APVMA jurisdiction. It also provides a mechanism for the APVMA to inform the relevant state authority of any information that it becomes aware of that falls within state jurisdiction (such as state control of use issues etc).
3. The '*registrant*' component that provides a mechanism for registrants of veterinary medicines to report to the APVMA any adverse experiences that they become aware of for their products.

Definition of an ‘adverse experience’

The APVMA defines an ‘adverse experience’ as ‘*an unintended or unexpected effect on animals, human beings or the environment, including injury, sensitivity reactions or lack of efficacy associated with the clinical use of a veterinary medicine.*’

What to do if an adverse experience occurs

If the person treating the animal with a veterinary medicine has been adversely affected then medical advice should be sought.

If your animal has been adversely affected after the use of a veterinary medicine you should seek veterinary advice from your usual veterinarian. Your veterinarian can assess the situation and determine the appropriate treatment. If the adverse reaction is considered to have been associated with the use of a veterinary medicine, then you or your veterinarian should report the matter to the registrant of the product (refer to the contact details on the product label). When doing so, inform them that you wish to report an adverse experience with one of their products and ask to speak to a technical services veterinarian (if available).

Under the *Agricultural and Veterinary Chemicals Codes*, the registrant has an obligation to report the matter to the APVMA and provide full details of the incident.

You may also provide a report directly to the APVMA using the *Adverse Experience Reporting Form for Veterinary Medicines (KP81F3)* or you can obtain a copy of the form by contacting the APVMA AERP Coordinator or your veterinarian.

What happens once an adverse experience report is received?

Reports made directly to the APVMA are copied to the product registrant for investigation. The registrant may then contact either you or your veterinarian and discuss the matter to determine if any follow up laboratory, pathology or other veterinary work is required.

The product registrant will subsequently provide the APVMA with an investigation report into the incident. The APVMA assesses this information and determines whether any further investigative work is required. In some cases, additional expert opinion may be sought from the Australian Veterinary Association, relevant State/Territory government agencies, universities or other appropriate authorities. The APVMA also considers scientific information publicly available either on the Internet or from an international agency (such as in the UK, Canada or US).

In all cases, a standard method of assessment is used to determine whether the adverse experience may have been related to the use of a veterinary medicine (ie the ‘*causality assessment*’). The APVMA also considers whether the product was used according to the label directions.

The person making the report of an adverse experience will be advised of the outcome of the investigations as soon as possible.

If a report of an adverse experience is made directly to the product registrant, they will investigate the matter and provide a report to the APVMA. The APVMA will then assess this information and determine whether any further investigative or regulatory work is required.

Possible regulatory outcomes

Based on evaluation of the investigation information, the causality assessment and whether there have been any other similar reports for the product, the APVMA then determines if any regulatory action is required. This may take the form of:

- additional label warning statements,
- product recalls,
- formulation or manufacturing process changes, or
- education of product users through the media.

AERP Vet publications

The APVMA has previously published *Annual Reports of Adverse Experiences* and will continue to publish periodic reports as appropriate. As the information in these reports is arranged according to the active constituent of the products therefore individual products are not identified. A summary of the regulatory actions taken by the APVMA is also included in these reports.

Further Information

For further information about the AERP *Vet* contact:

AERP Coordinator
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Telephone (02) 6210 4806
Facsimile (02) 6210 4813
E-mail AERPCoordinator@apvma.gov.au