Adverse Event Reporting Programme for Vertebrate Toxic Agents

ACVM guideline

1. Introduction

The adverse event reporting programme is part of the quality assurance programme developed by the Ministry for Primary Industries (MPI). It aims to ensure that all vertebrate toxic agents (VTAs) in the marketplace are efficacious, of acceptable quality, used appropriately, and that product labels provide sufficient consumer information for correct use.

All products claiming to kill or control a vertebrate are VTAs. Any substance used on vertebrates with the intended purpose of killing or limiting the viability of individual animals or populations of animals are VTAs. This includes products that have a negative effect on the reproduction of vertebrates, making them sterile, limiting their reproductive fertility, or having a negative effect on the viability of offspring.

Any VTA used in New Zealand must be registered under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

2. Definition of an *'adverse event'*

MPI defines a VTA 'adverse event' as any observation in target, or non- target animals that is unintended, and that occurs after the use of a VTA. This may include unintended effects, target animal welfare issues, residue issues, lack of efficacy or application issues (such as bait spillage from bait stations).

All unfavourable or unintended events that are recognised outcomes of product use and that may or may not be identified on the product label are classified as adverse events.

3. Risks posed by vertebrate toxic agents

The ACVM Act legislates the importation, manufacture, sale and use of VTAs.

The purpose of the ACVM Act is to prevent or manage the following risks associated with the use of VTAs:

- risks in trade in primary products;
- risks to public health;
- risks to animal welfare; and
- risks to agricultural security.

In addition, the Act is to ensure that there are no breaches in domestic food residue standards and that there is provision of sufficient consumer information about the VTA.

VTAs are reviewed and appraised by MPI and undergo a technical appraisal and risk assessment of their quality, humaneness (relating to animal welfare) and efficacy where appropriate.

However, this process will not always detect unexpected events following the use of VTAs because of:

- the relatively small number of animals used in registration trials compared to the wider animal population (especially due to sub-lethal doses, weather conditions, range of species);
- the wide range of environmental conditions; and
- the fact that it is impossible to include in registration trials all age groups, feeding habits etc that may be exposed to the product.

Therefore, even after a thorough review and appraisal prior to registration, it is possible that unforeseen problems that may affect the target animals or trade can arise. It is critical that adverse events (see definition above) are brought to the attention of the person responsible for the product (that is, the registrant or distributor) and MPI so that unusual, rare or individual conditions that were not evident in caged or field trials conducted before registration are detected and, if necessary, action can be taken.

4. The Adverse Event Reporting Programme

Objectives of the programme are to:

- ensure risks under the ACVM Act are appropriately managed;
- maintain public confidence in the registration process.

SCOPE

The programme covers adverse event reports involving:

- target animal welfare issues (EPA NZ is responsible for non-target animal welfare);
- non-target animal events (if a number of concerning non-target events are occurring, we may review how the product is used and revise label instructions/conditions of registration etc if the product is not working as intended);
- inefficacy, where applicable; and
- potential residue issues.

Off-label use (that is, contrary to mandatory label directions) is included in the programme. All VTAs have a condition of registration that states off-label uses are not allowed at any time.

SOURCE OF REPORTS

There are two complementary components of the Adverse Event Reporting Programme: registrants and others.

Registrants

The registrant component is mandatory. Registrants of VTAs must report the full details of any adverse events that they become aware of for their products.

Others

The voluntary component encourages users, veterinarians and the general public (including animal owners, farmers and other users) to report any adverse events to us and the product registrant. (**Veterinarians:** The *Code of Professional Conduct for Veterinarians* recommends that you report adverse events.)

Some adverse events are expected outcomes and are managed by registration or by label information (such as the desired effect of VTAs is to control pest animals by killing them). However, adverse events should be reported when they are observed at an increased frequency or risks to animal welfare/residues in primary produce etc are a consideration. For recently registered products where there is a limited body of knowledge surrounding a VTA, reporting of adverse events is an essential tool in ensuring the safety and efficacy of the product.

5. What to do if an adverse event occurs

If a non-target animal has been adversely affected after the use of a VTA, you should seek advice from your 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 VTA (and is not the desired effect), then you or your veterinarian should report the matter to the product registrant (refer to the contact details on the product label). When doing so, inform them that you wish to report an adverse event. As mentioned above, the registrant must report the matter to MPI.

You may also provide a report directly to us using this AER form:

Adverse event report: vertebrate toxic agents

INFORMATION REQUIRED

Please take the time to complete the form as thoroughly as possible because this allows a more robust investigation.

Veterinarians: When describing the adverse event, please describe the clinical signs observed in addition to the end diagnosis, for example:

- clinical signs: pale mucus membranes, caesuras and tachypoena etc
- diagnosis: (cause of poisoning)

This allows more accurate comparison to other reports. Include case notes, laboratory tests and post mortem reports if appropriate.

CONFIDENTIALITY, RIGHTS AND RESPONSIBILITIES

All information provided on suspected adverse events is treated as confidential. All information held by MPI is subject to the provisions in the Official Information Act 1982

and the Privacy Act 1993. Any request for information will be considered on case by case basis under the Official Information Act 1982 and the Privacy Act 1993. The consideration will take into account whether the request for information relates to information that could be considered to be commercially sensitive under section 12 or Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997.

The Adverse Event Reporting Programme is not intended to replace a person's right or responsibility to complain to the registrant or distributor about an adverse event with a VTA.

6. What happens once an adverse event report is received

Reports made directly to us are copied to the product registrant or distributor for immediate 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 us with an investigation report into the incident. We will assess this information and determine if the product was used according to label directions and whether any further investigative work is required. We also consider scientific information publicly available either on the Internet or from other international regulatory agencies (such as in Australia, UK, Canada or USA).

The person making the report of an adverse event will be advised of the outcome of the investigations. This will include an explanation of whether the observed adverse effects were considered likely to be related to the use of or exposure to the product. Note that if a causal link is not established between the adverse event and the use of or exposure to the product, or if there is insufficient information to make a definite conclusion, then no action may be taken.

If an adverse event is reported directly to the product registrant, they will investigate the matter and provide a report to MPI. We will then assess this information and determine whether any further investigative or regulatory work is required, and if any corrective actions should be taken.

7. Possible regulatory outcomes

Based on evaluation of the investigation information, and whether there have been any other similar reports for the product, we will determine if any regulatory action is required. This may take the form of:

- additional label warning statements;
- product recalls;
- formulation or manufacturing process changes;
- education of product users through the media or other appropriate forums; or
- tighter conditions of registration (such as a requirement to hold an Approved Handler certificate).

FURTHER INFORMATION

For further information about the Adverse Event Reporting Programme contact us (approvals@mpi.govt.nz).