Australian Government

Australian Pesticides and Veterinary Medicines Authority

REPORT OF ADVERSE EXPERIENCES

for Veterinary Medicines and Agricultural Chemicals

2010

JULY 2013

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EXECUTIVE SUMMARY

Adverse Experience Reporting Program (AERP)

As part of its work to manage veterinary medicines and agricultural chemical products throughout their lifecycle, the APVMA operates an Adverse Experience Reporting Program (AERP). The AERP aims to ensure that registered veterinary and agricultural products on the market remain safe and effective, are of acceptable quality, and that instructions and warnings on labels are appropriate.

The AERP assesses and classifies reports of adverse experiences from exposure to, the use of, or the administration of a veterinary medicine or agricultural chemical product sold in Australia. This is vital for detecting uncommon conditions not evident and therefore not assessed during clinical or field trials for the initial APVMA registration of a product. It is also used for tracking the incidence of known adverse experiences from some products (particularly veterinary medicines).

Anyone can report an adverse experience to the AERP, including farmers, pet owners, gardeners, veterinarians or the general public.

The AERP assesses each report of an adverse experience. It then classifies the relationship between the veterinary medicine or agricultural chemical product and the adverse experience. This may see the APVMA confirm the registration of a product as safe and effective, or it may request some changes to how a product is manufactured, packaged or used (and therefore require a change to label instructions and warnings). In some cases, the APVMA may cancel registration of a product and remove it from the market.

Assessments and classification in 2010

This report summarises the findings of AERP assessments of adverse experiences reports in 2010. This report is also available online on the APVMA website at www.apvma.gov.au.

The APVMA assessed and classified 1595 adverse experience reports involving registered veterinary medicines in 2010. Of these adverse experience reports, 75 per cent involved animal safety, 21 per cent involved lack of efficacy and 4 per cent involved human health issues.

One hundred and three adverse experiences involving agricultural chemical products were assessed and classified in 2010. Of the 103 adverse experience reports processed and classified, 71 per cent involved effects on crops or animals, 19 per cent involved human health issues, 8 per cent involved lack of efficacy, and 2 per cent involved effects on the environment.

The APVMA assessed 82 reports relating to adverse experiences involving effects on human health in 2010. Of these, 21 were classified as *probable or possible*, 51 as *off-label* (used contrary to label instructions) and 10 as *unlikely or unknown*.

No adverse experience assessed and classified by the APVMA in 2010 required a major regulatory action against any registered product.

Some assessments did warrant action to mitigate potential risks. These include revising label instructions and warnings, and the continued monitoring of adverse experience reports relating to particular products.

More information

For more information about the AERP, contact the APVMA:

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HOW THIS REPORT IS SET OUT

Chapter 1 introduces this report. It defines an adverse experience and explains the APVMA process for assessing and classifying a report of an adverse experience, along with any regulatory action or risk mitigation actions the APVMA may take in response.

Chapter 2 explains how to read and interpret information in this report. It is important that readers understand how to interpret data in this report correctly.

Chapter 3 sets out the results of AERP assessments in 2010 involving registered veterinary medicines and adverse experiences relating to animals.

Chapter 4 sets out the results of AERP assessments involving registered veterinary medicines and effects relating to humans.

Chapter 5 sets out the results of AERP assessments involving registered agricultural chemical products and adverse experiences not involving humans. This includes crop damage, domestic animal harm, environmental damage or lack of efficacy.

Chapter 6 sets out the results of APVMA assessments involving registered agricultural chemicals and effects relating to humans.

Note that specific chemicals could not be identified in a number of off-target spray cases. The environmental reports related to off-target spray drift are considered as part of the APVMA's Spray Drift Review program. More information about this program is at www.apvma.gov.au/use_safely/spray_drift

A Glossary of terms and **Index** of active constituents are provided at the end of this report.

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian government statutory authority that manages the National Registration Scheme for veterinary medicines and agricultural chemical products.

It ensures these products are suitable for use in Australian conditions and feature appropriate label instructions and warnings for their effective use without harming people, crops, animals or the environment.

The definitions of veterinary medicines and agricultural chemical products, as defined by the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) are:

- **Veterinary medicines** – all veterinary chemical products such as vaccines, antibiotics, parasiticides (for worms, lice, fleas and ticks), anti-inflammatory and anti-arthritic agents, nutritional supplements, therapeutic pet foods and diets for companion (pet) and production (agricultural) animals.
- **Pesticides and agricultural chemicals** – agricultural and household chemicals (such as insecticides, herbicides and fungicides) water treatment products (including swimming pool products), products for treating algae and mould, and products for preventing rot and infestation in marine structures.

The APVMA registers veterinary medicines and agricultural chemical products prior to sale, and regulates these products up to and including the point of sale.

The APVMA also operates post-registration programs to monitor the safety and performance of these products in Australia throughout their lifecycle.

1.1 Adverse Experience Reporting Program (AERP)

The APVMA Adverse Experience Reporting Program (AERP) is a post-registration program that assesses reports of adverse experiences associated with the use of a veterinary medicine or agricultural chemical product when the product is used according to label directions.

Recording, assessing and classifying adverse experiences is vital for detecting uncommon events not evident during the initial registration process of a product. The program provides a means of facilitating regulatory action that may be necessary to assure the continued safety, quality and effectiveness of registered products.

There are two components to the AERP: the ***AERP Vet*** for registered veterinary medicines, and the ***AERP Ag*** for registered agricultural chemicals.

Definitions of an adverse experience

AERP Vet adverse experience

An unintended or unexpected effect on animals, human beings or the environment, or lack of efficacy associated with the use of a registered veterinary chemical product when used according to label instructions.

AERP Ag adverse experience

An unintended or unexpected effect on plants, plant products, animals, human beings or the environment or lack of efficacy associated with the use of an agricultural chemical product when used according to label directions.

1.2 Reporting an adverse experience

Anyone can report an adverse experience to the AERP. This includes veterinarians, animal owners, farmers, gardeners, agronomists, health workers, state and territory authorities or members of the public.

Registrants of veterinary medicines and agricultural chemicals have a legal obligation to report any adverse events to the APVMA from the use of their registered product. Under Section 161 of the *Agvet Code,* registrants must provide the APVMA with any new information that comes to their attention. This new information may include adverse experience information on adverse human health effects, harm to animals, damage to plants, property or the environment, or lack of efficacy when the products are used according to label directions. The registrant reporting component of AERP *Ag* is one method by which registrants can meet certain legislative obligations of Section 161 of the *Agvet Code.*

The APVMA encourages the reporting of all adverse experiences with a veterinary medicine or agricultural chemical product. This includes ‘off-label’ incidents (where instructions for use or warnings were not correctly followed or heeded). More information about reporting off-label adverse experiences is provided below.

Even adverse experiences that are listed on a product label as a possible side effect should be reported, as this allows the APVMA to maintain records of these incidents and better understand their true incidence.

Reporting off-label adverse experiences

The scope of the AERP does not cover reports involving the off-label use of registered products and therefore these adverse experiences are not included in this report. However, the APVMA does encourage the reporting of off-label adverse experiences as these have occasionally highlighted potentially significant issues with registered products, including:

- Treatment protocols involving the administration of production animal products to companion animals, inconsistent with label directions for use, have resulted in illness or death of the treated animal.

- The use of dog products on cats can cause serious adverse effects. This action is clearly off-label and the public should be aware that certain constituents (such as high concentration permethrin) are toxic to cats.
- Spray drift can result in environmental damage or human exposure from chemical application contrary to label instructions.
- Accidental human exposure to veterinary medicines, particularly injectable products (such as vaccines) can cause unpleasant and potentially harmful adverse experiences.

1.3 Assessing an adverse experience

The APVMA assesses every adverse experience reported.

- Reports made directly to the APVMA by non-registrants (voluntary reports) are copied to the product registrant, who is then required to evaluate each report. The registrant may contact the reporting person or the attending veterinarian to help determine if any follow-up work is required.
- The product registrant must subsequently report its findings to the APVMA, which then assesses it to determine if further information is required. In some cases, additional expert opinion is sought from other government agencies such as the Office of Chemical Safety (OCS) and the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC), universities, the Australian Veterinary Association, or other appropriate authorities.
- The APVMA also considers any scientific information or information about a registered product that is published or provided by an equivalent international organisation.
- It considers if the product was used according to label instructions and warnings or if the use was off-label.
- The APVMA applies a standard methodology to classify the relationship between a reported adverse experience and exposure to or use of a product. More information on how the APVMA classifies the relationship is provided below.
- Trend analyses may be performed periodically or if a cluster of reports is submitted involving a particular product. This may see the APVMA confirm the registration of a product, or allow it to continue with changes to how the product can be used (and therefore require a change to label instructions and warnings). The APVMA may also cancel the registration of a chemical and remove a product from the market. More information on possible actions the APVMA may take is provided below.
- The APVMA advises everyone who reports an adverse experience of the outcome of its assessment and classification, including any regulatory action or ongoing monitoring activities.
- If an adverse experience is reported directly to a product registrant, the registrant must provide a report to the APVMA (Registrant report). The APVMA assesses this report to determine if any further laboratory, pathology or veterinary work is required before it classifies an adverse experience.

1.4 Classifying an adverse experience

The APVMA classifies the relationship between exposure to or use of a product and a reported adverse experience in terms of ***probable***, ***possible***, ***probable*** or ***possible off-label***, ***unlikely*** and ***unknown***.

Probable

All the following criteria are met:

- There is a reasonable association between exposure to or the use of a product and the onset and duration of the reported adverse experience.
- The description of the presenting signs is consistent with, or at least plausible, given the known pharmacology and toxicology of the product.
- There are no other equally plausible explanations (or contributing factors) for the adverse experience.

When any of these criteria cannot be satisfied (due to lack of sufficient information or conflicting data) the APVMA cannot classify the relationship as *probable*.

Possible

A *possible* classification is given when the way the suspect product was used is one of other possible and equally plausible explanations (or contributing factors) for the adverse experience (e.g. a previously existing condition).

Probable / possible off-label

As per the classification of *probable* or *possible*, but also where clear evidence of off-label use exists (including use in species not listed on the product label, over-dosing or under-dosing).

Unlikely

An *unlikely* classification is given when sufficient information exists to establish that the adverse experience was not likely to have been associated with how a product was used or if other more plausible explanations exist.

Unknown

An *unknown* classification applies when reliable data are unavailable or are insufficient to make an assessment of an adverse experience.

1.5 Responding to classifications

The APVMA may take various actions in response to its assessment and classification of an adverse experience report. These actions include but are not limited to:

- Amending the conditions of a product registration, such as requiring changes to label instructions or warnings.
- Suspending and/or cancelling the registration of a product.
- Reviewing the active constituent of a product under the APVMA's Chemical Review Program.
- Referring for action, such as compliance action, referral to state authorities for action.
- Educational and promotional activities, such as providing scientific papers or articles on issues identified with a particular product to relevant journals, magazines or newspapers. When required, education is also provided to the veterinary profession, farming community or the general public about safe and effective use of a product.

Regulatory action

The APVMA considers a broad range of issues and options when deciding what, if any, regulatory action is required to ensure registered veterinary medicines and agricultural chemical products sold in Australia are safe and effective.

- For each registered veterinary medicine, the APVMA conducts an analysis of all adverse experience reports received. All reports classified as *probable* or *possible* are compared with the total number of doses sold within the relevant financial year and a 'reporting incidence' is calculated (i.e. the number of adverse experience reports per number of doses sold). A control limit or 'warning line' for reporting incidence figures which indicate that further action may be required is one or more per 10 000 doses sold[1].
- The APVMA may take regulatory action if, for a particular product:
  - the reporting incidence is greater than one per 10 000 in two out of three consecutive years
  - an exceptional incidence of three or more per 10 000 occurs on any one occasion, or
  - a consistent rising trend is seen over 5 years (irrespective of the reporting incidence).
- The APVMA also considers available scientific literature and information relating to trend analysis and risk assessment when determining if regulatory action is required.
- In addition, the APVMA considers if the noted presenting signs (adverse experiences) are listed in warning statements on the product label, in which case a higher reporting incidence may be acceptable. It also considers the severity of presenting signs (more severe signs may trigger regulatory action at a lower reporting incidence).

1.6 Assessments and classifications in 2010

In 2010, a total of 1595 adverse experience reports involving registered veterinary products were assessed and classified.

[1] *Final Report to the Veterinary Products Committee*. Department for Environment, Food & Rural Affairs, United Kingdom, 2002.

- Of these adverse experience reports, 75 per cent involved animal safety, 21 per cent involved lack of efficacy and 4 per cent involved human health issues (Figure 1).
- Of the 1595 adverse experiences reports assessed under the AERP *Vet*, 1041 were classified as either *probable* or *possible*.

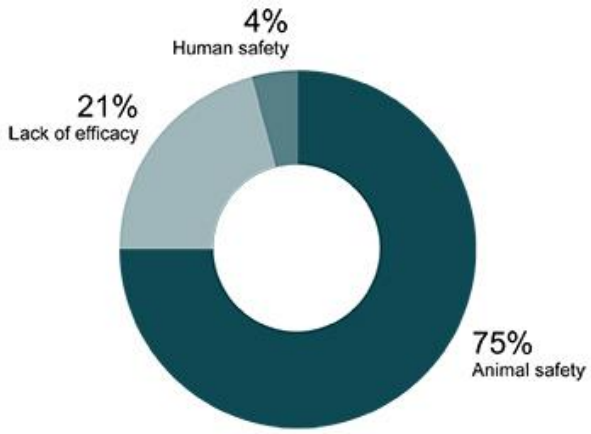

Figure 1. Adverse experience reports involving registered veterinary medicines - processed and finalised in 2010.

In 2010, a total of 103 adverse experience reports involving agricultural products were assessed and classified.

- Of these adverse experience reports processed and classified, 71 per cent involved effects on crops or animals, 19 per cent involved human health issues, 8 per cent involved lack of efficacy, and 2 per cent involved effects on the environment (Figure 2).
- Of the 103 reports assessed under the AERP *Ag*, 30 were classified as *probable* or *possible.*

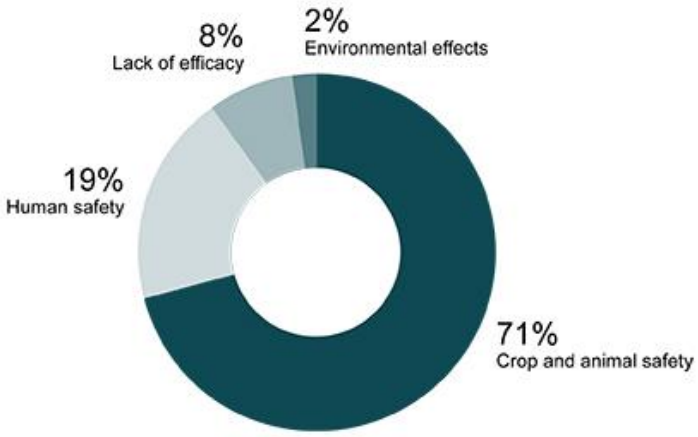

Figure 2. Adverse experience reports involving registered agriculture chemicals - processed and finalised in 2010.

A total of 82 adverse experiences involving effects on humans were reported in 2010. Of these, 21 were classified as *probable* or *possible*, 51 were classified as *off-label* and 10 were classified as *unlikely* or *unknown*.

No adverse experience assessed and classified by the APVMA in 2010 required a major regulatory action against any registered product.

Some assessments of active constituents in products did warrant APVMA action to mitigate potential risks, including the ongoing monitoring of adverse experiences reports for a product.

Under-reporting

The APVMA acknowledges there is likely under-reporting of adverse experiences. The magnitude of under-reporting is unknown and provides limitations in quantifying product risk. For this reason, the APVMA employs control limits that take into account the potential under-reporting of adverse experiences.

2 HOW TO READ THIS REPORT

This report summarises APVMA classifications of adverse experience reports in table format.

Active constituents and species affected are listed by alphabetical order.

Presenting signs are listed in order of frequency.

When active constituents have generated a notable number of reports and/or presenting signs, a brief explanation of the chemical is provided, along with why that number of reports may be expected, and if regulatory action was considered necessary.

Data in this report *should not* be used to:

- associate adverse effects with a particular registered veterinary medicine or agricultural chemical product
- assess the safety and efficacy of a product or an active constituent that it contains
- establish an acceptable frequency of occurrence of an adverse experience, or
- compare one product or active constituent with another product or active constituent.

2.1 Interpreting the data correctly

There are a range of consideration that must be taken into account when interpreting data in this report.

- **A registered product may have more than one active constituent.**

  The adverse experience reported for a particular product may be related to any one or more of its active constituents. This means the *number of reports* of an adverse experience and *presenting signs* may be listed under more than one active constituent.

  In the example below, a single *possible* report of ‘death’ associated with a product containing active constituent A, B and C would see ‘death’ listed under each active constituent. It is incorrect to conclude that three deaths were as a result of using that product. Active constituents A, B or C may also be present in other products, so the number of reports and presenting signs for an active constituent may also differ.

- **An active constituent may be present in a number of different registered products.**

  This means it will have generated a high number of adverse experience reports. This does not indicate that there is a problem with this active constituent.

- **An adverse experience report may have described multiple presenting signs.**

  This means that adding the *number* of presenting signs for an active constituent does not provide the *number of reports,* nor indicate reporting incidences. This is because an adverse experience report may have described multiple presenting signs. In the example below, the three adverse experience reports for

Active constituent A described more than one presenting sign, creating an appearance of more than three reports:

- three reports described injection site reaction
- the same three reports also described anorexia
- two of the three reports also described lethargy
- one report also listed a death.

- **The number of reports listed under an active constituent gives no indication as to the reporting incidence of adverse experiences related to that active constituent.**

  This means that data in this report is only a general reference to the types and numbers of adverse experiences reported to the APVMA or product registrants.

2.2 Example

Active constituent A

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	1

Presenting signs (probable and possible)

Injection site reaction (3)	Anorexia (3)	Lethargy (2)	Death (1)

Active constituent B

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Death (1)	Injection site reaction (1)

Active constituent C

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Anorexia (3)

Death (1)

3 VETERINARY MEDICINES—ANIMALS

This chapter summarises classifications of APVMA assessments of adverse experience reports involving registered veterinary medicines in 2010.

The APVMA assessed and classified 1595 adverse experience involving registered veterinary medicines in 2010. The largest proportion of reports involved animal safety (75%) followed by lack of efficacy (21%).

No regulatory action was required for active constituents involving veterinary medicines and animals in 2010, as the frequency of adverse experience reports received was relatively low compared with the total number of doses sold. The number of doses sold is used to estimate the size of the treated populations.

See Chapter 2: How to read this report for more information on how to interpret data in this chapter correctly, and what the data should not be used for.

Abamectin

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
8	3	5

Presenting signs (probable and possible)

Pawing at ground (2)
Behavioural change (1)
Blisters (1)
Colic (1)
Diarrhoea (1)
Illness (1)
Pain (1)
Polydipsia (1)
Shaking (1)
Swelling (local) (1)
Tachycardia (1)
Unpleasant taste (1)
Urticaria (1)
Wheals (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Death (2)
Hypersalivation (1)
Lethargy (1)
Recumbency (1)

Agelpristone

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Abscess (1)
Dehydration (1)
Lethargy (1)
Death (1)
Lack of effect (1)

Albendazole

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Death (3)
Hypersalivation (3)
Lethargy (2)
Ataxia (1)
Frothing at the mouth (1)

Alpha-cypermethrin

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

Alphaxalone

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
8	1	7

Presenting signs (probable and possible)

Anaesthesia (deep) (1)
Apnoea (1)
Bradycardia (1)
Bruising (1)
Death (1)
Erythema (1)
Haemorrhagic gastroenteritis (1)
Induction (poor) (1)
Lack of effect (1)
Nystagmus (1)
Oedema (1)
Pulmonary oedema (1)
Recovery (poor) (1)
Respiratory problems (1)
Tremor (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	0	6

Presenting signs (probable and possible)

Apnoea (2)
Anaesthesia (deep) (1)
Bradycardia (1)
Coughing (1)
Hypotension (1)
Induction (poor) (1)
Muscle twitching (1)
Recovery (poor) (1)
Recovery (prolonged) (1)

Altrenogest

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Lack of effect (2)

Aluminium hydroxide

Aluminium hydroxide is a compound commonly used as an adjuvant in vaccines. It stabilises vaccine proteins, preventing the vaccine from adhering to the glass container. It is also thought to enhance the immune response to vaccination. Because this active constituent is present in a number of vaccine products, it is reasonable to expect a larger number of reports to be associated with its use.

For more information about vaccines, go to the APVMA website at www.apvma.gov.au.

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
27	19	8

Presenting signs (probable and possible)

Injection site reaction (7)
Lethargy (7)
Pain (4)
Site reaction (swelling) (4)
Hyperaesthesia (3)
Vomiting (3)
Pyrexia (2)
Site reaction (2)
Anaphylactoid reaction (1)
Anaphylaxis (1)
Anorexia (1)
Bradycardia (1)
Bruising (1)
Death (1)
Depression (1)
Immune-mediated haemolytic anaemia (1)
Lack of effect (1)
Pulmonary oedema (1)
Swollen lips and face (1)
Tachycardia (1)
Tachypnoea (1)
Thrombocytopenia (1)
Wheals (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Anorexia (1)
Lethargy (1)
Pyrexia (1)
Sarcoma (1)

Amitraz

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Lack of effect (2)

Ammonium ferric citrate

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1)

Urticaria (1)

Amoxicillin as amoxicillin trihdyrate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Abscess (1)

Lump (local) (1)

Amphotericin B

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Anaphylactoid reaction (1)

Anorexia (1)

Ataxia (1)

Collapse (1)

Defecation (1)

Hypersalivation (1)

Pain (1)

Pyrexia (1)

Anaplasma centrale

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
12	5	7

Presenting signs (probable and possible)

Lack of effect (11)

Vaccination reaction (1)

Babesia bigemina

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
12	5	7

Presenting signs (probable and possible)

Lack of effect (11)

Vaccination reaction (1)

Babesia bovis

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
12	5	7

Presenting signs (probable and possible)

Lack of effect (11)

Vaccination reaction (1)

Bacitracin zinc

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Irritation (eye) (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Irritation (eye) (1)

Benazepril hydrochloride

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Coughing (1)

Dyspnoea (1)

Betacyfluthrin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
7	6	1

Presenting signs (probable and possible)

Lack of effect (7)

Betamethasone valerate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Deafness (1)

Biotin—vitamin H

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1) Urticaria (1)

Bordetella bronchiseptica

Bordetella bronchiseptica is a component of 'non-core' canine vaccine products that target common canine respiratory illness. Non-core vaccines are required only for animals at risk from a specific disease due to their geographical location or local environment.

The most commonly reported presenting signs include coughing, lethargy and pain. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, whichprotects the animal from serious illnesses. However, this immune response is also responsible for most of the presenting signs observed.

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) which could also result in a higher number of reports. In most cases it is not possible to attribute the cause of an adverse reaction to a single active constituent or to any of the products used concurrently. Hence a single report may be classified against multiple active constituents that may have a potential causal relationship with an adverse experience. To protect from serious illnesses, a very large number of pets are vaccinated every year.

The number of reports associated with *Bordetella bronchiseptica* vaccine strains is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

For more information about canine vaccines, go to the APVMA website at www.apvma.gov.au.

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
42	9	33

Presenting signs (probable and possible)

Coughing (11)
Sneezing (6)
Lethargy (5)
Vomiting (5)
Facial oedema (4)
Nasal discharge (4)
Pyrexia (4)
Death (3)
Diarrhoea (3)
Injection site reaction (3)
Lump (local) (3)
Respiratory problems (3)
Collapse (2)
Pain (2)
Site reaction (2)
Swelling (local) (2)
Swollen lips and face (2)
Tachypnoea (2)
URTI (2)
Abscess (1)
Anaemia (1)
Anaphylaxis (1)
Blepharospasm (1)
Corneal oedema (1)
Dyspnoea (1)
Fasciculation (1)
Haematemesis (1)
Hives (1)
Inflammation (1)
Irritation (eye) (1)
Lack of effect (1)
Lymphadenopathy (1)
Pale mucous membranes (1)
Panting (1)
Pruritis (1)
Recumbency (1)
Seizure (1)
Shaking (1)
Swollen feet (1)
Thrombocytopenia (1)
Uveitis (1)
Vaccination reaction (1)
Weakness (1)
Wheals (1)

Bordetella bronchiseptica (inactivated cell free extract)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
56	41	15

Presenting signs (probable and possible)

Lethargy (18)
Pain (10)
Anorexia (9)
Injection site reaction (8)
Vomiting (6)
Facial oedema (4)
Shaking (4)
Site reaction (swelling) (4)
Anaphylaxis (3)
Hyperaesthesia (3)
Pruritis (3)
Collapse (2)
Death (2)
Depression (2)
Immune-mediated haemolytic anaemia (2)
Lump (local) (2)
Oedema (2)
Pale mucous membranes (2)
Pulmonary oedema (2)
Pyrexia (2)
Site reaction (2)
Swollen lips and face (2)
Anaphylactoid reaction (1)
Ataxia (1)
Bradycardia (1)
Bruising (1)
Diarrhoea (1)
Dyspnoea (1)
Erythema (1)
Frothing at the mouth (1)
Lack of effect (1)
Tachycardia (1)
Tachypnoea (1)
Thrombocytopenia (1)
Tremor (1)
Wheals (1)

Bordetella bronchiseptica killed vaccine

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
24	14	10

Presenting signs (probable and possible)

Periorbital swelling (7)
Vomiting (5)
Facial oedema (4)
Swollen lips and face (4)
Collapse (3)
Lethargy (3)
Pale mucous membranes (3)
Pruritis (3)
Pyrexia (3)
Cyanosis (2)
Defecation (2)
Erythema (2)
Hypersensitivity reaction (2)
Panting (2)
Respiratory problems (2)
Urticaria (2)
Weakness (2)
Agitation (1)
Anaphylactoid reaction (1)
Anaphylaxis (1)
Bradycardia (1)
Capillary refill time (slow) (1)
Disorientation (1)
Hives (1)
Hypotension (1)
Injection site reaction (1)
Listless (1)
Oedema (1)
Papules (1)
Preputial swelling (1)
Restless (1)
Rubbing (1)
Shaking (1)
Shock (1)
Site reaction (swelling) (1)
Swollen (lips) (1)
Tachycardia (1)
Urination (1)
Vaccination reaction (1)
Vocalisation (1)
Wheals (1)

Butorphanol base as butorphanol tartrate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Campylobacter fetus (Vibrio fetus) venerealis biotype 1

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Injection site reaction (1) Lethargy (1) Pyrexia (1)

Campylobacter fetus venerealis biotype intermedius subt1

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Injection site reaction (1) Lethargy (1) Pyrexia (1)

3.1 Canine Adenovirus type 2 Vaccines

Canine adenovirus Type 2 is a constituent of 'core' canine vaccine products that target common canine systemic illness.Core vaccines protect animals from severe, life-threatening diseases with worldwide distribution.

The most commonly reported presenting signs include lethargy, vomiting, facial oedema and injection site reaction. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this immune response is also responsible for most of the presenting signs observed.

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) which could also result in a higher number of reports. In most cases it is not possible to attribute the cause of an adverse reaction to a single active constituent or to any of the products used concurrently. Hence a single report may be classified against multiple active constituents that may have a potential causal relationship with an adverse experience. To protect from serious illnesses, a very large number of pets are vaccinated every year.

The number of reports associated with canine adenovirus vaccine strains vaccine strains is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

For more information about canine vaccines, go to the APVMA website at www.apvma.gov.au.

Canine adenovirus type 2

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
56	23	33

Presenting signs (probable and possible)

- Lethargy (11)
- Vomiting (10)
- Facial oedema (9)
- Collapse (6)
- Lack of effect (6)
- Periorbital swelling (6)
- Respiratory problems (5)
- Swollen lips and face (5)
- Anaphylaxis (4)
- Diarrhoea (4)
- Lump (local) (4)
- Pale mucous membranes (4)
- Pyrexia (4)
- Anorexia (3)
- Death (3)
- Injection site reaction (3)
- Panting (3)
- Pruritis (3)
- Weakness (3)
- Cyanosis (2)
- Defecation (2)
- Hives (2)
- Hypersensitivity reaction (2)
- Listless (2)
- Pain (2)
- Shaking (2)
- Urticaria (2)
- Vaccination reaction (2)
- Abscess (1)
- Agitation (1)
- Anaphylactoid reaction (1)
- Bradycardia (1)
- Capillary refill time (slow) (1)
- Coughing (1)
- Disorientation (1)
- Dyspnoea (1)
- Erythema (1)
- Fatigue (1)
- Hypotension (1)
- Hypothermia (1)
- Nasal discharge (1)
- Oedema (1)
- Papules (1)
- Preputial swelling (1)
- Pulmonary oedema (1)
- Recumbency (1)
- Restless (1)
- Rubbing (1)
- Shock (1)
- Site reaction (swelling) (1)
- Swelling (local) (1)
- Swollen (lips) (1)
- Tachycardia (1)
- Tremor (1)
- Urination (1)
- Vocalisation (1)
- Wheals (1)

Canine adenovirus type 2—live (infectious hepatitis)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
31	17	14

Presenting signs (probable and possible)

- Injection site reaction (8)
- Lethargy (7)
- Pain (6)
- Hyperaesthesia (3)
- Lack of effect (3)
- Pyrexia (3)
- Site reaction (swelling) (3)
- Vomiting (3)
- Death (2)
- Lame (2)
- Abscess (1)
- Anaphylactoid reaction (1)
- Anaphylaxis (1)
- Anorexia (1)
- Bradycardia (1)
- Bruising (1)
- Depression (1)
- Dyspnoea (1)
- Haematemesis (1)
- Immune-mediated haemolytic anaemia (1)
- Pulmonary oedema (1)
- Site reaction (1)
- Swelling (local) (1)
- Swollen lips and face (1)
- Tachycardia (1)
- Tachypnoea (1)
- Thrombocytopenia (1)
- Wheals (1)

Canine adenovirus type 2—live (cav ii)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	5	1

Presenting signs (probable and possible)

Collapse (2)
Pale mucous membranes (2)
Dyspnoea (1)
Erythema (1)
Frothing at the mouth (1)
Immune-mediated haemolytic anaemia (1)
Injection site reaction (1)
Lethargy (1)
Pruritis (1)
Swollen lips and face (1)
Urticaria (1)
Vomiting (1)

Canine adenovirus type 2 strain manhattan—live

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
22	5	17

Presenting signs (probable and possible)

Lack of effect (9)
Coughing (2)
Lethargy (2)
Pain (2)
Blepharospasm (1)
Corneal oedema (1)
Fasciculation (1)
Inflammation (1)
Injection site reaction (1)
Irritation (eye) (1)
Nasal discharge (1)
Recumbency (1)
Respiratory problems (1)
Seizure (1)
Site reaction (1)
Site reaction (swelling) (1)
Sneezing (1)
Swelling (local) (1)
Swollen feet (1)
Swollen lips and face (1)
Tachypnoea (1)
Uveitis (1)
Vomiting (1)
Wheals (1)

Canine coronavirus vaccine—antigen

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anaphylaxis (1)
Collapse (1)
Death (1)
Pale mucous membranes (1)
Respiratory problems (1)
Vomiting (1)
Weakness (1)

3.2 Canine Distemper Virus Vaccines

Canine distemper virus (in various strains) is a constituent of 'core' canine vaccine products that targets common canine systemic illness. Core vaccines protect animals from severe, life-threatening diseases with which have worldwide distribution.

The most commonly reported presenting signs include lethargy, injection site reaction, facial oedema and vomiting. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this immune response is also responsible for most of the presenting signs observed.

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) which could also result in a higher number of reports. In most cases it is not possible to attribute the cause of an adverse reaction to a single active constituent or to any of the products used concurrently. Hence a single report may be classified against multiple active constituents that may have a potential causal relationship with an adverse experience.

The number of reports associated with *Canine Distemper Virus* vaccine strains is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

For more information about canine vaccines, go to the APVMA website at www.apvma.gov.au.

Canine distemper virus

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
44	17	27

Presenting signs (probable and possible)

Facial oedema (8)
Vomiting (8)
Lack of effect (6)
Lethargy (6)
Periorbital swelling (6)
Collapse (5)
Pale mucous membranes (4)
Pyrexia (4)
Swollen lips and face (4)
Diarrhoea (3)
Injection site reaction (3)
Lump (local) (3)
Panting (3)
Pruritis (3)
Respiratory problems (3)
Weakness (3)
Anaphylaxis (2)
Cyanosis (2)
Death (2)
Defecation (2)
Hives (2)
Hypersensitivity reaction (2)
Listless (2)
Shaking (2)
Urticaria (2)
Vaccination reaction (2)
Abscess (1)
Agitation (1)
Anaphylactoid reaction (1)
Bradycardia (1)
Capillary refill time (slow) (1)
Disorientation (1)
Erythema (1)
Fatigue (1)
Hypotension (1)
Hypothermia (1)
Oedema (1)
Pain (1)
Papules (1)
Preputial swelling (1)
Recumbency (1)
Restless (1)
Rubbing (1)
Shock (1)
Site reaction (swelling) (1)
Swelling (local) (1)
Swollen (lips) (1)
Tachycardia (1)
Urination (1)
Vocalisation (1)
Wheals (1)

Canine distemper virus—live

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
47	28	19

Presenting signs (probable and possible)

Lethargy (12)
Injection site reaction (9)
Pain (7)
Vomiting (5)
Anorexia (4)
Anaphylaxis (3)
Collapse (3)
Death (3)
Dyspnoea (3)
Hyperaesthesia (3)
Lack of effect (3)
Pyrexia (3)
Site reaction (swelling) (3)
Swollen lips and face (3)
Immune-mediated haemolytic anaemia (2)
Lame (2)
Pale mucous membranes (2)
Pulmonary oedema (2)
Abscess (1)
Anaphylactoid reaction (1)
Bradycardia (1)
Bruising (1)
Depression (1)
Diarrhoea (1)
Erythema (1)
Facial oedema (1)
Frothing at the mouth (1)
Haematemesis (1)
Lump (local) (1)
Pruritis (1)
Respiratory problems (1)
Site reaction (1)
Swelling (local) (1)
Tachycardia (1)
Tachypnoea (1)
Thrombocytopenia (1)
Tremor (1)
Urticaria (1)
Wheals (1)

Canine distemper virus strain onderstepoort

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
22	5	17

Presenting signs (probable and possible)

Lack of effect (9)
Coughing (2)
Lethargy (2)
Pain (2)
Blepharospasm (1)
Corneal oedema (1)
Fasciculation (1)
Inflammation (1)
Injection site reaction (1)
Irritation (eye) (1)
Nasal discharge (1)
Recumbency (1)
Respiratory problems (1)
Seizure (1
Site reaction (1)
Site reaction (swelling) (1)
Sneezing (1)
Swelling (local) (1)
Swollen feet (1)
Swollen lips and face (1)
Tachypnoea (1)
Uveitis (1)
Vomiting (1)
Wheals (1)

3.3 Canine Parainfluenza Vaccines

Canine parainfluenza virus and associated strains is a component of 'non-core' canine vaccine products that target common canine respiratory illness. Non-core vaccines are required only for those animals at risk from specific diseases due to their geographical location or local environment.

The most commonly reported presenting signs include coughing, lethargy and injection site reaction. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this immune response is also responsible for most of the presenting signs observed.

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) which could also result in a higher number of reports. In most cases it is not possible to attribute the cause of an adverse reaction to a single active constituent or to any of the products used concurrently. Hence a single report may be classified against multiple active constituents that may have a potential causal relationship with an adverse experience.

The number of reports associated with *Canine parainfluenza virus* vaccine strains is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.For more information about canine vaccines, go to the APVMA website at www.apvma.gov.au.

Canine parainfluenza

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Coughing (1)

Lethargy (1)

Nasal discharge (1)

Respiratory problems (1)

Vomiting (1)

Canine parainfluenza virus type 2

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
25	13	12

Presenting signs (probable and possible)

Periorbital swelling (6)
Vomiting (5)
Collapse (4)
Facial oedema (4)
Pale mucous membranes (4)
Swollen lips and face (4)
Lethargy (3)
Pyrexia (3)
Respiratory problems (3)
Weakness (3)
Anaphylaxis (2)
Cyanosis (2)
Defecation (2)
Hypersensitivity reaction (2)
Panting (2)
Pruritis (2)
Urticaria (2)
Agitation (1)
Anaphylactoid reaction (1)
Bradycardia (1)
Capillary refill time (slow) (1)
Death (1)
Disorientation (1)
Erythema (1)
Hives (1)
Hypotension (1)
Injection site reaction (1)
Lack of effect (1)
Listless (1)
Oedema (1)
Papules (1)
Preputial swelling (1)
Restless (1)
Rubbing (1)
Shaking (1)
Shock (1)
Site reaction (swelling) (1)
Swollen (lips) (1)
Tachycardia (1)
Urination (1)
Vaccination reaction (1)
Vocalisation (1)
Wheals (1)

Canine parainfluenza virus

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
56	20	36

Presenting signs (probable and possible)

- Coughing (9)
- Lethargy (9)
- Facial oedema (6)
- Sneezing (6)
- Injection site reaction (5)
- Vomiting (5)
- Collapse (4)
- Diarrhoea (4)
- Lump (local) (4)
- Pyrexia (4)
- Swollen lips and face (4)
- Anorexia (3)
- Death (3)
- Dyspnoea (3)
- Nasal discharge (3)
- Pain (3)
- Anaphylaxis (2)
- Lack of effect (2)
- Pale mucous membranes (2)
- Pruritis (2)
- Respiratory problems (2)
- Site reaction (2)
- Swelling (local) (2)
- Tachypnoea (2)
- URTI (2)
- Abscess (1)
- Anaemia (1)
- Blepharospasm (1)
- Corneal oedema (1)
- Erythema (1)
- Fasciculation (1)
- Frothing at the mouth (1)
- Haematemesis (1)
- Hives (1)
- Immune-mediated haemolytic anaemia (1)
- Inflammation (1)
- Irritation (eye) (1)
- Lymphadenopathy (1)
- Panting (1)
- Pulmonary oedema (1)
- Recumbency (1)
- Seizure (1)
- Shaking (1)
- Swollen feet (1)
- Thrombocytopenia (1)
- Tremor (1)
- Urticaria (1)
- Uveitis (1)
- Vaccination reaction (1)
- Wheals (1)

Canine parainfluenza virus—inactivated

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
27	19	8

Presenting signs (probable and possible)

- Injection site reaction (7)
- Lethargy (7)
- Pain (4)
- Site reaction (swelling) (4)
- Hyperaesthesia (3)
- Vomiting (3)
- Pyrexia (2)
- Site reaction (2)
- Anaphylactoid reaction (1)
- Anaphylaxis (1)
- Anorexia (1)
- Bradycardia (1)
- Bruising (1)
- Death (1)
- Depression (1)
- Immune-mediated haemolytic anaemia (1)
- Lack of effect (1)
- Pulmonary oedema (1)
- Swollen lips and face (1)
- Tachycardia (1)
- Tachypnoea (1)
- Thrombocytopenia (1)
- Wheals (1)

3.4 Canine parvovirus vaccines

Canine parvovirus (in various strains) is a constituent of 'core' canine vaccine products that target common canine systemic illness. Core vaccines protect animals from severe, life-threatening diseases with worldwide distribution.

The most commonly reported presenting signs include facial oedema, vomiting injection site reaction and lethargy. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this immune response is also responsible for most of the presenting signs observed.

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) which could also result in a higher number of reports. In most cases it is not possible to attribute the cause of an adverse reaction to a single active constituent or to any of the products used concurrently. Hence a single report may be classified against multiple active constituents that may have a potential causal relationship with an adverse experience.

The number of reports associated with *Canine parvovirus* vaccine strains is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

For more information about canine vaccines, go to the APVMA website at www.apvma.gov.au.

Canine parvovirus

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
45	18	27

Presenting signs (probable and possible)

- Facial oedema (8)
- Vomiting (8)
- Lack of effect (6)
- Lethargy (6)
- Periorbital swelling (6)
- Collapse (5)
- Swollen lips and face (5)
- Pale mucous membranes (4)
- Pyrexia (4)
- Diarrhoea (3)
- Injection site reaction (3)
- Lump (local) (3)
- Panting (3)
- Pruritis (3)
- Respiratory problems (3)
- Urticaria (3)
- Weakness (3)
- Anaphylaxis (2)
- Cyanosis (2)
- Death (2)
- Defecation (2)
- Hives (2)
- Hypersensitivity reaction (2)
- Listless (2)
- Shaking (2)
- Vaccination reaction (2)
- Abscess (1)
- Agitation (1)
- Anaphylactoid reaction (1)
- Bradycardia (1)
- Capillary refill time (slow) (1)
- Disorientation (1)
- Erythema (1)
- Fatigue (1)
- Hypotension (1)
- Hypothermia (1)
- Oedema (1)
- Pain (1)
- Papules (1)
- Preputial swelling (1)
- Recumbency (1)
- Restless (1)
- Rubbing (1)
- Shock (1)
- Site reaction (swelling) (1)
- Swelling (local) (1)
- Swollen (lips) (1)
- Tachycardia (1)
- Urination (1)
- Vocalisation (1)
- Wheals (1)

Canine parvovirus type 2

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
15	10	5

Presenting signs (probable and possible)

- Lethargy (5)
- Anorexia (3)
- Collapse (3)
- Anaphylaxis (2)
- Dyspnoea (2)
- Pale mucous membranes (2)
- Vomiting (2)
- Death (1)
- Diarrhoea (1)
- Erythema (1)
- Facial oedema (1)
- Frothing at the mouth (1)
- Immune-mediated haemolytic anaemia (1)
- Injection site reaction (1)
- Lump (local) (1)
- Pain (1)
- Pruritis (1)
- Pulmonary oedema (1)
- Respiratory problems (1)
- Swollen lips and face (1)
- Tremor (1)

Canine parvovirus—live

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
31	17	14

Presenting signs (probable and possible)

Injection site reaction (8)
Lethargy (7)
Pain (6)
Hyperaesthesia (3)
Lack of effect (3)
Pyrexia (3)
Site reaction (swelling) (3)
Vomiting (3)
Death (2)
Lame (2)
Abscess (1)
Anaphylactoid reaction (1)
Anaphylaxis (1)
Anorexia (1)
Bradycardia (1)
Bruising (1)
Depression (1)
Dyspnoea (1)
Haematemesis (1)
Immune-mediated haemolytic anaemia (1)
Pulmonary oedema (1)
Site reaction (1)
Swelling (local) (1)
Swollen lips and face (1)
Tachycardia (1)
Tachypnoea (1)
Thrombocytopenia (1)
Wheals (1)

Canine parvovirus strain 154—live

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
22	5	17

Presenting signs (probable and possible)

Lack of effect (9)
Coughing (2)
Lethargy (2)
Pain (2)
Blepharospasm (1)
Corneal oedema (1)
Fasciculation (1)
Inflammation (1)
Injection site reaction (1)
Irritation (eye) (1)
Nasal discharge (1)
Recumbency (1)
Respiratory problems (1)
Seizure (1)
Site reaction (1)
Site reaction (swelling) (1)
Sneezing (1)
Swelling (local) (1)
Swollen feet (1)
Swollen lips and face (1)
Tachypnoea (1)
Uveitis (1)
Vomiting (1)
Wheals (1)

Carprofen

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Death (2)
Anaphylactoid reaction (1)
Anorexia (1)
Bradycardia (1)
Cardiac arrest (1)
Cyanosis (1)
Lethargy (1)

Cefovecin as sodium salt

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Ataxia (2)
Anorexia (1)
Colitis (1)
Lack of effect (1)
Vomiting (1)

Cephalexin as cephalexin monohydrate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Pain (2)
Lame (1)
Oedema (1)
Pyrexia (1)
Site reaction (1)
Swelling (local) (1)

Chlamydophilia felis baker strain—live, attenuated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	4	1

Presenting signs (probable and possible)

Anorexia (3)
Lethargy (3)
Ataxia (2)
Pyrexia (2)
Abdominal pain (1)
Anaphylactoid reaction (1)
Collapse (1)
Defecation (1)
Hypersalivation (1)
Injection site reaction (1)
Recumbency (1)

Chloramphenicol

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anorexia (1)
Lethargy (1)
Vomiting (1)

Chlorhexidine digluconate

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Chlorhexidine gluconate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Irritation (skin) (2)
Erythema (1)
Skin slough (1)

Choline bitartrate

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1) Urticaria (1)

Chondroitin sulfate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
11	9	2

Presenting signs (probable and possible)

Diarrhoea (6) Vomiting (4) Dehydration (1) Pruritis (1)

Citric acid monohydrate

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Colic (1) Death (1) Dyspnoea (1)

Citronella oil

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Site reaction (1)

CLA—Corynebacterium pseudotuberculosis ovis

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

Clavulanic acid as potassium clavulanate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Abscess (1)
Lump (local) (1)

Clomipramine hydrochloride

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anorexia (1)
Hepatopathy (1)
Polydipsia (1)
Sedation (marginal) (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Urinary retention (2)

Clorsulon

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Collapse (1) Death (1)

Clostridium chauvoei—formol culture

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	2	3

Presenting signs (probable and possible)

Injection site reaction (2) Anorexia (1) Death (1) Pyrexia (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Lack of effect (2) Injection site reaction (1)

Clostridium chauvoei—killed

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Collapse (1) Death (1) Injection site reaction (1)

Clostridium chauvoei—toxoid

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Injection site reaction (2)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Injection site reaction (2) Collapse (1) Death (1)

Clostridium novyi type b

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Anorexia (1) Death (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Injection site reaction (1) Lack of effect (1)

Clostridium novyi type b—killed

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Collapse (1) Death (1) Injection site reaction (1)

Clostridium novyi type b—toxoid

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Injection site reaction (2) Pyrexia (1)

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Injection site reaction (2)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	2	2

Presenting signs (probable and possible)

Injection site reaction (2)	Collapse (1)	Death (1)	Lack of effect (1)

Clostridium perfringens type d toxoid

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	2	3

Presenting signs (probable and possible)

Injection site reaction (2)	Anorexia (1)	Death (1)	Pyrexia (1)

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Injection site reaction (2)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	3	3

Presenting signs (probable and possible)

Injection site reaction (3)	Lack of effect (2)	Collapse (1)	Death (1)

Clostridium septicum—toxoid

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	2	3

Presenting signs (probable and possible)

Injection site reaction (2) Anorexia (1) Death (1) Pyrexia (1)

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Injection site reaction (2)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	3	3

Presenting signs (probable and possible)

Injection site reaction (3) Lack of effect (2) Collapse (1) Death (1)

Clostridium tetani—toxoid

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Injection site reaction (2) Pyrexia (1)

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Injection site reaction (2)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	3	2

Presenting signs (probable and possible)

Injection site reaction (3) | Collapse (1) | Death (1) | Lack of effect (1)

Clostridium tetani UF toxoid

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Diarrhoea (1) | Vomiting (1)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Injection site reaction (1) | Pyrexia (1)

Clotrimazole

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Deafness (2) | Papules (1)

Cobalt (ii) sulfate

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1) Urticaria (1)

Contagious pustular dermatitis virus—live, cell culture

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Lack of effect (2)

Copper sulfate

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1) Urticaria (1)

Corynebacterium pseudotuberculosis ovis—toxoid

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Cyclosporin

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
13	4	9

Presenting signs (probable and possible)

Vomiting (8)
Lethargy (3)
Ataxia (1)
Blurred vision (1)
Diarrhoea (1)
Disorientation (1)
Hyperactivity (1)
Lack of effect (1)
Lame (1)
Paralysis (1)
Pruritis (1)

Cyclosporin A

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Periorbital swelling (1)

Cypermethrin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Lack of effect (2)

Deltamethrin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Lack of effect (2)
Hypersalivation (1)
Irritation (skin) (1)

Deslorelin as deslorelin acetate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
7	5	2

Presenting signs (probable and possible)

Lack of effect (4) Site reaction (2) Inflammation (1) Pain (1)

Detomidine hydrochloride

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Low efficacy (1)

Diazinon

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Ataxia (1) Toxicity (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	0	5

Presenting signs (probable and possible)

Lack of effect (5)

Dicyclanil

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Low efficacy (2)

Diflubenzuron

Diflubenzuron is an insect growth-regulating compound (IGR). An IGR is a chemical that controls the lifecycle of pests such as roaches and fleas by inhibiting their maturation. Diflubenzuron achieves this by inhibiting the production of chitin which is used by an insect to build its exoskeleton.

The sheep and wool industry rely heavily on the use of the IGR group of chemicals for treating lice. There are IGR-resistant insects with reduced susceptibility to this type of chemical, which may contribute to instances of reduced efficacy. The product labels have appropriate and relevant information regarding this issue.

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
83	45	38

Presenting signs (probable and possible)

Lack of effect (80)	Low efficacy (1)	Scabs (1)	Wool damage (1)

Doramectin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	3	1

Presenting signs (probable and possible)

Lack of effect (4)

Emodepside

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
15	14	1

Presenting signs (probable and possible)

Alopecia (localised) (9)
Self trauma (3)
Hypersalivation (2)
Incoordination (2)
Lethargy (2)
Diarrhoea (1)
Lack of effect (1)
Panting (1)
Vomiting (1)

Erysipelothrix rhusiopathiae

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)
Frothing at the mouth (1)
Muscle twitching (1)
Paddling (1)

Eucalyptus oil

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Site reaction (1)

Febantel

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
12	9	3

Presenting signs (probable and possible)

Vomiting (10)
Anorexia (1)
Ataxia (1)
Colic (1)
Lack of effect (1)
Lethargy (1)
Malaise (1)
Vocalisation (1)

3.5 Feline calicivirus vaccines

Feline calicivirus is a constituent of 'core' feline vaccine products that targets common feline respiratory illness. Core vaccines protect animals from severe, life-threatening diseases with worldwide distribution.

The most commonly reported presenting signs include anorexia, lethargy and pyrexia. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this desired immune response is also responsible for most of the presenting signs observed.

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) which could also result in a higher number of reports. In most cases it is not possible to attribute the cause of an adverse reaction to a single active constituent or to any of the products used concurrently. Hence a single report may be classified against multiple active constituents that may have a potential causal relationship with an adverse experience. To protect from serious illnesses, a very large number of pets are vaccinated every year.

The number of reports associated with *Feline calicivirus* vaccine strains is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

For more information about feline vaccines, go to the APVMA website at www.apvma.gov.au.

Feline calicivirus - Inactivated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
30	17	13

Presenting signs (probable and possible)

Anorexia (15)
Lethargy (14)
Pyrexia (11)
Pain (6)
Depression (4)
Vomiting (4)
Ataxia (3)
Facial oedema (3)
Injection site reaction (3)
Alopecia (localised) (2)
Abdominal pain (1)
Agitation (1)
Anaphylactoid reaction (1)
Behavioural change (1)
Collapse (1)
Death (1)
Defecation (1)
Diarrhoea (1)
Disorientation (1)
Hyperaesthesia (1)
Hypersalivation (1)
Immune-mediated haemolytic anaemia (1)
Lump (local) (1)
Panting (1)
Pruritis (1)
Recumbency (1)
Rubbing (1)
URTI (1)

Feline calicivirus—live

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Anorexia (1)
Cardiac arrest (1)
Death (1)
Lethargy (1)
Pyrexia (1)
Recumbency (1)

Feline chlamydia psittaci—inactivated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	2	3

Presenting signs (probable and possible)

Lethargy (3)
Anorexia (2)
Pyrexia (2)
Alopecia (localised) (1)
Ataxia (1)
Disorientation (1)
Pain (1)
Vomiting (1)

Feline immunodeficiency virus (petaluma strain)—inactive

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	4	1

Presenting signs (probable and possible)

Anorexia (3)
Pyrexia (3)
Defecation (2)
Lethargy (2)
Pain (2)
Anaphylactoid reaction (1)
Ataxia (1)
Collapse (1)
Dehydration (1)
Depression (1)
Hypersalivation (1)
Injection site reaction (1)

Feline leukaemia virus—inactivated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	2	3

Presenting signs (probable and possible)

Anorexia (2)
Lethargy (2)
Pain (2)
Pyrexia (2)
Alopecia (localised) (1)
Anaphylactoid reaction (1)
Ataxia (1)
Collapse (1)
Defecation (1)
Hypersalivation (1)
Vomiting (1)

3.6 Feline panleucopenia virus vaccines

Feline panleukopenia virus is a constituent of 'core' feline vaccine products that target common feline systemic illness. Core vaccines protect animals from severe, life-threatening diseases with worldwide distribution.

The most commonly reported presenting signs include anorexia, lethargy and pyrexia. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this desired immune response is also responsible for most of the presenting signs observed.

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) which could also result in a higher number of reports. In most cases it is not possible to attribute the cause of an adverse reaction to a single active constituent or to any of the products used concurrently. Hence a single report may be classified against multiple active constituents that may have a potential causal relationship with an adverse experience. To protect from serious illnesses, a very large number of pets are vaccinated every year.

The number of reports associated with *Feline panleucopenia virus* vaccine strains is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

For more information about feline vaccines, go to the APVMA website at www.apvma.gov.au.

Feline panleucopenia virus - inactivated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
30	17	13

Presenting signs (probable and possible)

Anorexia (15)
Lethargy (14)
Pyrexia (11)
Pain (6)
Depression (4)
Vomiting (4)
Ataxia (3)
Facial oedema (3)
Injection site reaction (3)
Alopecia (localised) (2)
Abdominal pain (1)
Agitation (1)
Anaphylactoid reaction (1)
Behavioural change (1)
Collapse (1)
Death (1)
Defecation (1)
Diarrhoea (1)
Disorientation (1)
Hyperaesthesia (1)
Hypersalivation (1)
Immune-mediated haemolytic anaemia (1)
Lump (local) (1)
Panting (1)
Pruritis (1)
Recumbency (1)
Rubbing (1)
URTI (1)

Feline panleucopenia virus—live

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Anorexia (1)	Death (1)	Pyrexia (1)
Cardiac arrest (1)	Lethargy (1)	Recumbency (1)

Feline rhinotracheitis virus—inactivated

Feline rhinotracheitis virus is a constituent of 'core' feline vaccine products that targets common feline respiratory illness. Core vaccines protect animals from severe, life-threatening diseases with worldwide distribution.

The most commonly reported presenting signs include anorexia, lethargy and pyrexia. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this immune response is also responsible for most of the presenting signs observed.

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) which could also result in a higher number of reports. In most cases it is not possible to attribute the cause of an adverse reaction to a single active constituent or to any of the products used concurrently. Hence a single report may be classified against multiple active constituents that may have a potential causal relationship with an adverse experience. To protect from serious illnesses, a very large number of pets are vaccinated every year.

The number of reports associated with *Feline rhinotracheitis virus* vaccine strains is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

For more information about feline vaccines, go to the APVMA website at www.apvma.gov.au.

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
30	17	13

Presenting signs (probable and possible)

- Anorexia (15)
- Lethargy (14)
- Pyrexia (11)
- Pain (6)
- Depression (4)
- Vomiting (4)
- Ataxia (3)
- Facial oedema (3)
- Injection site reaction (3)
- Alopecia (localised) (2)
- Abdominal pain (1)
- Agitation (1)
- Anaphylactoid reaction (1)
- Behavioural change (1)
- Collapse (1)
- Death (1)
- Defecation (1)
- Diarrhoea (1)
- Disorientation (1)
- Hyperaesthesia (1)
- Hypersalivation (1)
- Immune-mediated haemolytic anaemia (1)
- Lump (local) (1)
- Panting (1)
- Pruritis (1)
- Recumbency (1)
- Rubbing (1)
- URTI (1)

Fenbendazole

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

- Dehydration (1)
- Diarrhoea (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

- Ataxia (1)
- Death (1)
- Hyperactivity (1)
- Recumbency (1)

Fipronil

Fipronil is a broad-spectrum phenyl pyrazole insecticide, which acts on the nervous system of insects following contact or ingestion. In veterinary situations, fipronil products are used as spray or concentrated spot-on formulations to control fleas, ticks and other ectoparasites that live on the skin of dogs and cats. Fipronil products are also used for the treatment and control of flea allergy dermatitis. These products have a very high volume of sales.

Fipronil is currently under review by the APVMA's Chemical Review Program. Fipronil was nominated for review following the reporting of adverse experiences in humans and animals. The initial review considered concerns over toxicity primarily relating to skin irritation and induction of skin sensitisation, as well as concerns about the potential for fipronil to form toxic photodegradation products, its occupational health and safety issues, animal safety issues, and the adequacy of label instructions and warnings.

Updates on the progress of the review are available on the APVMA website: www.apvma.gov.au/products/review/current/fipronil.php

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
56	5	51

Presenting signs (probable and possible)

Pruritis (19)
Erythema (18)
Lack of effect (14)
Irritation (skin) (8)
Alopecia (localised) (5)
Vomiting (5)
Lethargy (4)
Pyoderma (4)
Cellulitis (3)
Papules (3)
Site reaction (3)
Anorexia (2)
Hypersalivation (2)
Rash (2)
Restless (2)
Scabs (2)
Urticaria (2)
Wheals (2)
Alopecia (1)
Coat colour change (1)
Coat discoloration (1)
Dermatitis (1)
Diarrhoea (1)
Distress (1)
Dyspnoea (1)
Hyperpigmentation (1)
Hypersensitivity reaction (1)
Listless (1)
Pain (1)
Panting (1)
Ulceration (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
29	0	29

Presenting signs (probable and possible)

Alopecia (localised) (15)
Erythema (6)
Irritation (skin) (6)
Site reaction (6)
Scabs (5)
Lack of effect (3)
Wheals (1)
Pruritis (3)
Agitation (2)
Ataxia (2)
Cellulitis (2)
Lethargy (2)
Mydriasis (2)
Self-trauma (2)
Blindness (1)
Coat colour change (1)
Distress (1)
Hypersalivation (1)
Nystagmus (1)
Rash (1)
Swelling (local) (1)
Vomiting (1)

Firocoxib

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

Presenting signs (probable and possible)

Vomiting (3)
Anorexia (2)
Diarrhoea (2)
Blood in faeces (1)
Lethargy (1)
Restless (1)

Fluazuron

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Lack of effect (2)

Flugestone acetate

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Flumethrin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	4	0

Presenting signs (probable and possible)

Lack of effect (4)

Formalin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Injection site reaction (1)

Lethargy (1)

Pyrexia (1)

Gentamicin

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Deafness (1)

Papules (1)

Gentamicin sulfate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Deafness (1)

Glucosamine hydrochloride

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
11	9	2

Presenting signs (probable and possible)

Diarrhoea (6) Vomiting (4) Dehydration (1) Pruritis (1)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Behavioural change (1)

Glucose

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Colic (1) Death (1) Dyspnoea (1)

Glycine

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Colic (1) Death (1) Dyspnoea (1)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1) Urticaria (1)

Hydrocortisone aceponate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Hyperaesthesia (1)

Imidacloprid

Imidacloprid is an insecticidal chemical that disrupts the insect's nervous system.

The number of reports associated with imidacloprid is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
174	156	18

Presenting signs (probable and possible)

Paraesthesia (116)
Behavioural change (45)
Pruritis (29)
Self-trauma (27)
Lack of effect (20)
Agitation (19)
Vomiting (16)
Site reaction (14)
Lethargy (7)
Anorexia (6)
Alopecia (localised) (5)
Ataxia (3)
Coat discoloration (3)
Tremor (3)
Distress (2)
Erythema (2)
Facial oedema (2)
Panting (2)
Pyrexia (2)
Rash (2)
Rolling (2)
Vocalisation (2)
Adipsia (1)
Diarrhoea (1)
Hives (1)
Hyperexcitable (1)
Insomnia (1)
Irritation (skin) (1)
Muscle twitching (1)
Pyoderma (1)
Scabs (1)
Seizure (1)
Stiffness (1)
Swelling (local) (1)
Tachycardia (1)
Walking (difficult) (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
55	50	5

Presenting signs (probable and possible)

Alopecia (localised) (25)
Self-trauma (18)
Hypersalivation (7)
Anorexia (3)
Behavioural change (3)
Lethargy (3)
Site reaction (3)
Vomiting (3)
Ataxia (2)
Diarrhoea (2)
Panting (2)
Alopecia (1)
Coughing (1)
Illness (1)
Lack of effect (1)
Nil (1)
Shaking (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Burn(s) (1)

Inactivated bovine pestivirus—bega strain

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Anorexia (1)
Pyrexia (1)

Inactivated bovine pestivirus—trangie strain

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Anorexia (1)
Pyrexia (1)

Inactivated rabbit calicivirus disease virus

Rabbit

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	3	1

Presenting signs (probable and possible)

Alopecia (localised) (1)
Anorexia (1)
Bruising (1)
Crusting skin (1)
Death (1)
Diarrhoea (1)
Illness (1)
Lesions (1)
Lethargy (1)
Pruritis (1)
Pyoderma (1)
Site reaction (swelling) (1)
Swelling (local) (1)

Inositol

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1)
Urticaria (1)

Insulin

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Hives (1)

Iron as ammonium ferric citrate

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Anaphylactoid reaction (1)

Ivermectin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	2	2

Presenting signs (probable and possible)

Lack of effect (3)
Collapse (1)
Death (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Death (1)
Lack of effect (1)
Lethargy (1)
Recumbency (1)
Tremor (1)
Vocalisation (1)

Ketamine as ketamine hydrochloride

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Leptospira borgpetersenii serovar hardjo

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Injection site reaction (2)
Pyrexia (1)

Leptospira icterohaemorrhagiae antigen

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anaphylaxis (1)
Collapse (1)
Death (1)
Pale mucous membranes (1)
Respiratory problems (1)
Vomiting (1)
Weakness (1)

Leptospira interrogans serovar pomona

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Injection site reaction (2)
Pyrexia (1)

Levamisole hydrochloride

Avian

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Death (2)
Illness (1)

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Seizure (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Ataxia (1)
Death (1)
Hyperactivity (1)
Recumbency (1)

Lignocaine hydrochloride

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Live feline herpes virus

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Anorexia (1)
Cardiac arrest (1)
Death (1)
Lethargy (1)
Pyrexia (1)
Recumbency (1)

Lufenuron

Lefenuron is a benzoylurea pesticide that inhibits the production of chitin in fleas. In veterinary situations it is used as a parasiticide to control fleas in cats and dogs, sometimes in combination with milbemycin oxime.

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
34	22	12

Presenting signs (probable and possible)

Vomiting (17)
Diarrhoea (10)
Lethargy (8)
Pruritis (4)
Anorexia (3)
Tremor (3)
Ataxia (2)
Lack of effect (2)
Abdominal pain (1)
Adipsia (1)
Distress (1)
Epiphora (1)
Hypersalivation (1)
Red eyes (1)
Seizure (1)
Urticaria (1)

Lysine-l hydrochloride

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1)
Urticaria (1)

Maropitant as maropitant citrate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	1	3

Presenting signs (probable and possible)

Cardiac arrest (1)
Collapse (1)
Lack of effect (1)
Urticaria (1)
Vomiting (1)

Metomidine hydrochloride

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

Presenting signs (probable and possible)

Lack of effect (2)
Death (1)
Defecation (1)
Lethargy (1)
Low efficacy (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Low efficacy (2)

Melaleuca alternifolia oil

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Site reaction (1)

Meloxicam

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

Presenting signs (probable and possible)

Vomiting (3)
Diarrhoea (2)
Abdominal pain (1)
Blood in faeces (1)
Collapse (1)
Cyanosis (1)
Death (1)
Haemorrhagic gastroenteritis (1)
Pancreatitis (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	0	5

Presenting signs (probable and possible)

Renal failure (4)
Anorexia (3)
Dehydration (3)
Vomiting (3)
Azotaemia (1)

Methionine-dl

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1)
Urticaria (1)

Methoprene-rs

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Tremor (1)

Miconazole nitrate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Erythema (1)
Irritation (skin) (1)
Lack of effect (1)

Milbemycin oxime

Milbemycin Oxime is a widely used broad spectrum parasiticide that disrupts the invertebrate nervous system. Milbemycin Oxime is present in a number of registered veterinary chemical products in combination with other active constituents and so has a higher number of reports associated with it.

The number of reports associated with milbemycin oxime is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
48	32	16

Presenting signs (probable and possible)

Vomiting (28)
Lethargy (11)
Diarrhoea (10)
Pruritis (7)
Anorexia (4)
Hypersalivation (3)
Tremor (3)
Ataxia (2)
Erythema (2)
Lack of effect (2)
Urticaria (2)
Abdominal pain (1)
Adipsia (1)
Distress (1)
Epiphora (1)
Haemorrhagic gastroenteritis (1)
Irritation (skin) (1)
Rash (1)
Red eyes (1)
Seizure (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Lethargy (2)
Ataxia (1)
Collapse (1)
Death (1)
Frothing at the mouth (1)
Somnolence (1)
Tremor (1)

Mometasone furoate monohydrate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Deafness (1)
Papules (1)

Monensin as monensin sodium

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Anorexia (1)
Hypersalivation (1)
Lack of effect (1)

Morantel tartrate

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
8	3	5

Presenting signs (probable and possible)

Pawing at ground (2)
Behavioural change (1)
Blisters (1)
Colic (1)
Diarrhoea (1)
Illness (1)
Pain (1)
Polydipsia (1)
Shaking (1)
Swelling (local) (1)
Tachycardia (1)
Unpleasant taste (1)
Urticaria (1)
Wheals (1)

Moraxella bovis

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
17	6	11

Presenting signs (probable and possible)

Lack of effect (15)
Injection site reaction (1)
Stiffness (1)

Moxidectin

Moxidectin is a broad spectrum parasiticidal chemical that disrupts the parasitic nervous system. Moxidectin is present in a number of registered veterinary medicines in combination with other active constituents and so has a higher number of reports associated with it.

The number of reports associated with moxidectin is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

Presenting signs (probable and possible)

Lack of effect (2)
Circling (1)
Muscle twitching (1)
Recumbency (1)
Ataxia (1)
Death (1)
Paddling (1)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
16	9	7

Presenting signs (probable and possible)

Lack of effect (5)
Self-trauma (2)
Coat discoloration (1)
Pyrexia (1)
Anorexia (2)
Tremor (2)
Diarrhoea (1)
Site reaction (1)
Behavioural change (2)
Vomiting (2)
Facial oedema (1)
Stiffness (1)
Ataxia (1)
Pruritis (1)
Lethargy (2)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
39	34	5

Presenting signs (probable and possible)

Alopecia (localised) (15)
Self-trauma (12)
Hypersalivation (5)
Anorexia (3)
Behavioural change (3)
Lethargy (3)
Site reaction (3)
Vomiting (3)
Ataxia (2)
Diarrhoea (2)
Panting (2)
Alopecia (1)
Illness (1)
Lack of effect (1)
Nil (1)
Shaking (1)

Moxidectin concentrate

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)
Dehydration (1)
Distress (1)

Moxidectin microspheres

Moxidectin microspheres act as a broad spectrum parasiticide that disrupts the parasitic nervous system. The types of reactions observed and listed here are expected to occur in rare instances.

The APVMA notes that products containing this active constituent are often used in conjunction with other products (including vaccines) resulting in a higher number of reports. In most cases it is impossible to attribute the cause of an adverse reaction to a single active constituent. Hence a single report may be classified against multiple active constituents that may have a potential relationship to an adverse experience.

The number of reports associated with moxidectin microspheres is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
28	8	20

Presenting signs (probable and possible)

- Vomiting (8)
- Facial oedema (7)
- Anaphylaxis (4)
- Collapse (4)
- Death (3)
- Diarrhoea (3)
- Erythema (3)
- Abscess (2)
- Anorexia (2)
- Hives (2)
- Injection site reaction (2)
- Lethargy (2)
- Lump (local) (2)
- Pale mucous membranes (2)
- Periorbital swelling (2)
- Pruritis (2)
- Pyrexia (2)
- Shaking (2)
- Swollen lips and face (2)
- Agitation (1)
- Ataxia (1)
- Haemorrhagic gastroenteritis (1)
- Hypersalivation (1)
- Hypersensitivity reaction (1)
- Inflammation (1)
- Pain (1)
- Respiratory problems (1)
- Restless (1)
- Rubbing (1)
- Self-trauma (1)
- Shock (1)
- Site reaction (1)
- Swollen (lips) (1)
- Tachycardia (1)
- Tachypnoea (1)
- Weakness (1)

Mycobacterium paratuberculosis

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Neomycin

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

- Anaphylactoid reaction (1)
- Anorexia (1)
- Ataxia (1)
- Collapse (1)
- Defecation (1)
- Hypersalivation (1)
- Pain (1)
- Pyrexia (1)

Neomycin as the sulfate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Deafness (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Diabetes (1)

Hepatopathy (1)

Neomycin base as the sulfate

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	6	0

Presenting signs (probable and possible)

Injection site reaction (5)

Recumbency (2)

Pain (1)

Pawing at ground (1)

Pyrexia (1)

Stiffness (1)

Neomycin sulfate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Irritation (eye) (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Irritation (eye) (2)

Nitenpyram

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Vomiting (2) Anorexia (1) Diarrhoea (1) Nausea (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	2	2

Presenting signs (probable and possible)

Hyperactivity (3) Pruritis (2) Agitation (1)
Panting (2) Tachypnoea (2) Pyrexia (1)

N-octyl bicycloheptene dicarboximide

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Dehydration (1) Lethargy (1) Vomiting (1)
Diarrhoea (1) Tremor (1)

Nystatin

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Deafness (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Diabetes (1)

Hepatopathy (1)

Oatmeal extract

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

Presenting signs (probable and possible)

Irritation (skin) (2)

Corneal ulcer (1)

Oestradiol 17 beta

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Prolapse (2)

Oxantel embonate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Lack of effect (3)

Oxfendazole

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Colic (1)

Pantothenol-d (panthenol-d)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1) Urticaria (1)

Pentobarbitone sodium

Camelid

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Pentosan polysulfate sodium

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
8	2	6

Presenting signs (probable and possible)

Vomiting (5)
Lethargy (2)
Ataxia (1)
Dehydration (1)
Depression (1)
Haemorrhage (1)
Head tilt (1)
Hives (1)
Pyrexia (1)
Shaking (1)
Tachycardia (1)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	3	2

Presenting signs (probable and possible)

Anaphylaxis (1)
Anorexia (1)
Coat discoloration (1)
Colic (1)
Death (1)
Lethargy (1)
Oedema (1)
Respiratory problems (1)
Site reaction (swelling) (1)

Permethrin

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
16	15	1

Presenting signs (probable and possible)

Paraesthesia (13)
Behavioural change (6)
Self-trauma (3)
Lack of effect (2)
Vomiting (2)
Agitation (1)
Distress (1)
Seizure (1)

Permethrin (25:75:cis:trans)

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

Permethrin (40:60: cis:trans)

Permethrin is a synthetic chemical, widely used as an insecticide, acaricide and insect repellent. Permethrin is often used in conjunction with other active constituents, which may explain the relatively high number of reports.

The term paraesthesia used in the table here is usually used by humans to describe an unpleasant tingling 'pins and needles' type sensation. In this context, this term describes symptoms which (based on human exposure to this active constituent) could be attributed to this sensation.

The number of reports associated with permethrin products is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Permethrin in high concentrations (such as in topical flea 'spot-on ' products) is highly toxic to cats. A product-wide label change was implemented in 2011 to address off-label use of dog spot-on products on cats, with the aim of reducing the number of reports relating to exposure of cats to permethrin.

Further information on how the APVMA is addressing permethrin toxicity in cats can be found on the APVMA website at www.apvma.gov.au/news_media/community/2011-01_permethrin_cats.php

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
140	130	10

Presenting signs (probable and possible)

Paraesthesia (103)
Behavioural change (36)
Pruritis (28)
Self-trauma (22)
Agitation (18)
Site reaction (14)
Lack of effect (13)
Vomiting (12)
Lethargy (5)
Alopecia (localised) (4)
Anorexia (4)
Ataxia (2)
Coat discoloration (2)
Erythema (2)
Panting (2)
Rash (2)
Rolling (2)
Vocalisation (2)
Adipsia (1)
Distress (1)
Facial oedema (1)
Hives (1)
Hyperexcitable (1)
Insomnia (1)
Irritation (skin) (1)
Muscle twitching (1)
Pyoderma (1)
Pyrexia (1)
Scabs (1)
Swelling (local) (1)
Tachycardia (1)
Tremor (1)
Walking (difficult) (1)

Piperonyl butoxide

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
9	6	3

Presenting signs (probable and possible)

Lack of effect (9)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Dehydration (1)
Diarrhoea (1)
Lethargy (1)
Tremor (1)
Vomiting (1)

Polyoxyethylene (dimethyliminio) ethylene

Other

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Death (1)
Jaundice (1)
Seizure (1)

Polymyxin b

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Anaphylactoid reaction (1)
Anorexia (1)
Ataxia (1)
Collapse (1)
Defecation (1)
Hypersalivation (1)
Pain (1)
Pyrexia (1)

Polymyxin b sulfate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Anorexia (1)
Irritation (eye) (1)
Lack of effect (1)
Lethargy (1)
Vomiting (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Irritation (eye) (2)

Potassium citrate

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Colic (1)
Death (1)
Dyspnoea (1)

Potassium phosphate monobasic

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Colic (1)
Death (1)
Dyspnoea (1)

Praziquantel

Praziquantel is a systemic anthelmintic chemical primarily used to treat worm infections in domestic animals.

The number of reports associated with praziquantel is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Avian

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting sign (number of incidents)

Death (2)

Illness (1)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
63	41	22

Presenting signs (probable and possible)

Vomiting (38)
Lethargy (12)
Diarrhoea (10)
Pruritis (7)
Lack of effect (6)
Anorexia (5)
Ataxia (3)
Hypersalivation (3)
Tremor (3)
Erythema (2)
Urticaria (2)
Abdominal pain (1)
Adipsia (1)
Colic (1)
Distress (1)
Epiphora (1)
Haemorrhagic gastroenteritis (1)
Irritation (skin) (1)
Malaise (1)
Rash (1)
Red eyes (1)
Seizure (1)
Vocalisation (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
21	16	5

Presenting signs (probable and possible)

Alopecia (localised) (9)
Lethargy (4)
Ataxia (3)
Self-trauma (3)
Hypersalivation (2)
Incoordination (2)
Tremor (2)
Vomiting (2)
Behavioural change (1)
Collapse (1)
Death (1)
Diarrhoea (1)
Frothing at the mouth (1)
Lack of effect (1)
Panting (1)
Prolapsed third eyelid (1)
Rash (1)
Somnolence (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)

Lethargy (1)

Prednisolone

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Irritation (eye) (1)

Prednisolone acetate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Prilocaine hydrochloride

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Site reaction (1)

Procaine penicillin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anaphylactoid reaction (1)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	6	0

Presenting signs (probable and possible)

Injection site reaction (5)
Pain (1)
Pyrexia (1)
Recumbency (2)
Pawing at ground (1)
Stiffness (1)

Propofol

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Erythema (1)
Facial oedema (1)
Periorbital swelling (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Erythema (1)
Urticaria (1)

Propoxur

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	4	0

Presenting signs (probable and possible)

Lack of effect (4)

Pyraclofos

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Death (3)
Hypersalivation (3)
Lethargy (2)
Ataxia (1)
Frothing at the mouth (1)

Pyrantel as pyrantel embonate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
12	9	3

Presenting signs (probable and possible)

Vomiting (10)
Anorexia (1)
Ataxia (1)
Colic (1)
Lack of effect (1)
Lethargy (1)
Malaise (1)
Vocalisation (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Ataxia (2)
Behavioural change (1)
Prolapsed third eyelid (1)
Rash (1)
Tremor (1)
Vomiting (1)

Pyrantel embonate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Lack of effect (3)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Colic (1)

Pyrethrins

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Dehydration (1)
Diarrhoea (1)
Lethargy (1)
Tremor (1)
Vomiting (1)

Pyriproxyfen

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Self-trauma (1)
Site reaction (1)

Pyriproxyfen (10%)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Muscle twitching (1) Tremor (1)

Quil

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anorexia (1) Lethargy (1) Pyrexia (1)

Quil-a

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Sarcoma (1)

Recombinant gp70 sub-type a

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Anorexia (1) Lethargy (1) Pyrexia (1) Sarcoma (1)

(S)-methoprene

(S)-methoprene is a pesticide that acts as a juvenile hormone mimic, disrupting the development of insects and preventing the larvae from emerging as adults. (S)-methoprene is used in conjunction with other active constituents.

The number of reports associated with (s)-methoprene is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
52	4	48

Presenting signs (probable and possible)

- Erythema (16)
- Pruritis (16)
- Lack of effect (14)
- Irritation (skin) (8)
- Alopecia (localised) (5)
- Lethargy (4)
- Vomiting (4)
- Cellulitis (3)
- Papules (3)
- Pyoderma (3)
- Site reaction (3)
- Anorexia (2)
- Hypersalivation (2)
- Scabs (2)
- Urticaria (2)
- Wheals (2)
- Alopecia (1)
- Coat colour change (1)
- Coat discoloration (1)
- Dermatitis (1)
- Diarrhoea (1)
- Dyspnoea (1)
- Hyperpigmentation (1)
- Hypersensitivity reaction (1)
- Listless (1)
- Pain (1)
- Rash (1)
- Ulceration (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
27	0	27

Presenting signs (probable and possible)

- Alopecia (localised) (15)
- Erythema (6)
- Irritation (skin) (6)
- Site reaction (6)
- Scabs (5)
- Pruritis (3)
- Agitation (2)
- Cellulitis (2)
- Lack of effect (2)
- Lethargy (2)
- Self-trauma (2)
- Ataxia (1)
- Coat colour change (1)
- Distress (1)
- Hypersalivation (1)
- Mydriasis (1)
- Nystagmus (1)
- Rash (1)
- Swelling (local) (1)
- Vomiting (1)
- Wheals (1)

Salicylic acid

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pyrexia (1)	Tachycardia (1)	Tremor (1)
Somnolence (1)	Tachypnoea (1)	

Selamectin

Selamectin is a broad spectrum anthelmintic and parasiticidal chemical.

The number of reports associated with selamectin is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	2	3

Presenting signs (probable and possible)

Alopecia (localised) (1)	Lack of effect (1)	Pruritis (1)	Vomiting (1)
Erythema (1)	Lethargy (1)	Urticaria (1)	

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
37	36	1

Presenting signs (probable and possible)

Alopecia (localised) (33)	Site reaction (11)	Behavioural change (3)	Pyoderma (2)
			Erythema (1)

Selenium

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

Selenium as sodium selenate

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Death (2)
Hypersalivation (1)
Lethargy (1)
Vocalisation (1)
Recumbency (2)
Injection site reaction (1)
Tremor (1)

Sodium chloride

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Colic (1)
Death (1)
Dyspnoea (1)

Sodium chondroitin sulfate

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Behavioural change (1)

Spinosad

Spinosad is an insecticidal chemical that disrupts the insect nervous system.

The number of reports associated with spinosad is low when compared with the number of doses sold in 2010 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
29	9	20

Presenting signs (probable and possible)

Vomiting (18)
Lethargy (11)
Ataxia (10)
Diarrhoea (6)
Hypersalivation (6)
Seizure (6)
Anorexia (3)
Disorientation (3)
Abdominal pain (2)
Collapse (2)
Dehydration (2)
Mydriasis (2)
Nystagmus (2)
Recumbency (2)
Tremor (2)
Blindness (1)
Bradycardia (1)
Confusion (1)
Death (1)
Depression (1)
Flatulence (1)
Hyperaesthesia (1)
Immune-mediated haemolytic anaemia (1)
Incontinence (1)
Incoordination (1)
Jaundice (1)
Muscle twitching (1)
Paddling (1)
Photophobia (1)
Proprioception deficit (1)
Pyrexia (1)
Restless (1)
Shaking (1)
Urine (abnormal) (1)
Wheals (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Stabilised green-lipped mussel powder

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Diarrhoea (3)

Streptococcus equi as cell free extract

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

Pyrexia (1)

Sulfacetamide sodium

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Irritation (eye) (1)

Sulfadiazine

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Circling (1)

Collapse (1)

Hyperaesthesia (1)

Hypersensitivity reaction (1)

Tetanus (Clostridium tetani)

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Anorexia (1)

Death (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Thiomersal

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

Thiostrepton

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Deafness (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Diabetes (1)

Hepatopathy (1)

Tiletamine as the hydrochloride

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Cyanosis (1)

Death (1)

Triamcinolone acetonide

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Deafness (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Diabetes (1)

Hepatopathy (1)

Triclabendazole

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Photosensitization (1)

Triclosan

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pyrexia (1)
Somnolence (1)
Tachycardia (1)
Tachypnoea (1)
Tremor (1)

Triflumuron

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Lack of effect (1)
Site reaction (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Lack of effect (1)
Low efficacy (1)

Trilostane—micronised

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Behavioural change (1)

Trimethoprim

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Circling (1)
Collapse (1)
Hyperaesthesia (1)
Hypersensitivity reaction (1)

Tylosin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Vitamin B_{12}—cyanocobalamin

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1)
Urticaria (1)

Vitamin B_{12a}—hydroxocobalamin

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

Vitamin B_2—riboflavin

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1)

Urticaria (1)

Vitamin B_3—nicotinamide

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1)

Urticaria (1)

Vitamin B_6 hydrochloride—pyridoxine hydrochloride

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1)

Urticaria (1)

Vitamin K_1—phytomenadione

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting sign (number of incidents)

Anaphylactoid reaction (1)
Circulatory collapse (1)
Erythema (1)
Hypotension (1)

Zeta-cypermethrin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Lack of effect (3)

Zolazepam as the hydrochloride

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Cyanosis (1)
Death (1)

4 VETERINARY MEDICINES—HUMAN ADVERSE EXPERIENCES

This chapter summarises classifications of APVMA assessments of adverse experience reports involving registered veterinary medicines and effects on humans in 2010.

The APVMA assessed and classified 1595 adverse experiences involving registered veterinary medicines in 2010. Adverse experiences in humans, for example, needle stick injuries, comprised 4% of these.

No regulatory action was required for active constituents involving veterinary medicines and human health in 2010.

See Chapter 2: *How to read this report* for more information on how to interpret data in this chapter correctly, and what data should *not* be used for.

Campylobacter fetus (Vibrio fetus) *venerealis biotype 1*

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

Campylobacter fetus venerealis *biotype intermedius subt1*

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

Diazinon

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Burning sensation (1)
Headache (1)
Nausea (1)

Fipronil

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Injection site reaction (1)

Imidacloprid

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	2	3

Presenting signs (probable and possible)

Allergy (1)
Blisters (1)
Disorientation (1)
Facial oedema (1)
Paraesthesia (1)
Swelling (local) (1)
Swollen (lips) (1)
Tachycardia (1)
Unpleasant taste (2)

Moxidectin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Facial oedema (1)
Swelling (local) (1)

Permethrin (40:60::cis:trans)

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Allergy (1)
Blisters (1)
Paraesthesia (1)
Unpleasant taste (1)

(S)—methoprene

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Blisters (1)
Rash (1)

Spinosad

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Irritation (eye) (1)
Irritation (skin) (1)

5 AGRICULTURAL CHEMICALS—ANIMAL, PLANTS AND ENVIRONMENTAL SAFETY

This chapter summarises classifications of APVMA assessments in 2010 of adverse experience reports involving agricultural chemicals and crop damage, domestic animal harm, environment damage or lack of efficacy (‘standard adverse assessment reports) that were classified as ‘probable or ‘possible ‘

One hundred and three adverse experience reports involving agricultural chemical products were assessed and classified as either ‘probable ‘ or ‘possible ‘ in 2010. Of these 103 adverse experience reports processed and classified, 71 per cent involved effects on crops or animals, 19 per cent involved human health issues, 8 per cent involved lack of efficacy, and 2 per cent involved effects on the environment.

No regulatory action was required for active constituents involving agricultural chemicals in 2010.

See Chapter 2: *How to read this report* for more information on how to interpret data in this chapter correctly, and what data should *not* be used for.

2,4-D

Lawn grass

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)

2,4-D present as the dimethylamine and diethanolamine salt

Fallow

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Low efficacy (1)

Acetamiprid

Garden

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Burn(s) (1)

Bromadiolone

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Nil (1)

Carfentrazone-ethyl

Wheat

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

Dicamba

Lawn grass

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)

Fipronil

Banana

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Glyphosate present as the potassium salt

Fallow

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Lack of effect (2)

Unknown

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

Imazapic as the ammonium salt

Fallow

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Low efficacy (1)

Mecoprop

Lawn grass

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)

Metaldehyde

Avian

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Ataxia (1)

Hypersalivation (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)

Possum

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)

Piperonyl butoxide

Capsicum

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Burn(s) (1)

Garden

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Burn(s) (2)

Crop damage (1)

Vegetables

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Burn(s) (1)

Pyrethrins

Capsicum

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Burn(s) (1)

Garden

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Burn(s) (2)

Crop damage (1)

Vegetables

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Burn(s) (1)

Sodium fluoroacetate (1080)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
7	6	1

Presenting signs (probable and possible)

Death (2)

Foaming (1)

Frothing at the mouth (1)

Hyperactivity (1)

Toxicity (1)

Tremor (1)

6 AGRICULTURAL CHEMICALS – HUMAN ADVERSE EXPERIENCES

This chapter summarises classifications of APVMA assessments in 2010 of adverse experience reports involving agricultural chemicals and effects on humans.

The APVMA assessed and classified 103 adverse experience reports involving agricultural chemical products in 2010. Human health issues comprised 19% of these.

No regulatory action was required for active constituents involving agricultural chemical products and human health in 2010.

See Chapter 2: *How to read this report* for more information on how to interpret data in this chapter correctly, and what data should *not* be used for.

Alcohol alkoxylate

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

Presenting signs (probable and possible)

Blurred vision (1)
Irritation (eye) (1)
Red eyes (1)

Alpha-cypermethrin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	3	1

Presenting signs (probable and possible)

Burning sensation (2)
Irritation (skin) (1)
Swelling (local) (1)

Bifenthrin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Blisters (1)

Cyanamide

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Blisters (1) Burn(s) (1)

Glyphosate present as the isopropylamine salt

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

Presenting signs (probable and possible)

Irritation (eye) (1) Ocular discharge (1) Red eyes (1)

Metaldehyde

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Odour (1)

Polyether modified polysiloxane

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Blurred vision (1)

Red eyes (1)

7 GLOSSARY

Abscess	A collection of pus that has accumulated within a tissue
Adipsia	Absence of thirst or abnormal avoidance of drinking
Alopecia	Absence of hair from areas where it is normally present
Analgesic	Pain relieving treatment
Anaphylactoid reaction	An anaphylactic-type reaction
Anaphylaxis/anaphylactic	An exaggerated allergic reaction of an animal to a foreign protein or other substances
Anorexia	Lack or loss of appetite
Anthelmintic	An agent destructive to worms
Antimicrobial	An agent that kills micro-organisms or suppresses their multiplication or growth
Ataxia	Unsteady walking action due to muscular incoordination
Bradycardia	Excessive slowness in the action of the heart
Coagulopathy	Any disorder of blood coagulation
Colic	A general term for abdominal pain
Conjunctivitis	Conjunctivitis is the inflammation of the conjunctiva, a thin, delicate membrane that covers the eyeball and lines the eyelid
Cyanosis	Cyanosis is a physical sign causing bluish discoloration of the skin and mucous membranes due to a lack of oxygen in the blood
Defecation	The voiding of waste from the bowels
Dermatitis	Inflammation of the skin
Dyspnoea	Laboured breathing
Epiphora	Diseases of the lacrimal apparatus
Epistaxis	Bleeding from the nose
Erythema	Abnormal redness of the skin due to local congestion, as in inflammation
Fasciculation	Involuntary contractions or twitching of groups of muscle fibres
Folliculitis	Inflammation of the follicles
Haematemesis	Vomiting of blood
Haemorrhage	Bleeding
Hepatopathy	Disease or disorder of the liver

Hypersalivation	Excessive salivation
Hypersensitivity	An excessive reaction to an allergen
Intramammary	Within or into the mammary gland
Jaundice	Yellowish staining of the skin and mucous membranes
Melaena	The passage of dark faeces due to haemorrhage in the stomach or small intestine
Mydriasis	Unusual state of dilatation of pupil of the eye
Nausea	Unpleasant sensation in the stomach with a tendency to vomit
Necrosis	Pathological process associated with severe cellular trauma
Oedematous	Abnormal accumulation of fluid in body cavities and under the skin
Paraesthesia	An abnormal sensation characterised by an unpleasant tingling sensation
Parasiticide	An agent that is destructive to parasites
Periorbital	Surrounding the eyes
Petechiae	Purplish or brownish red discoloration, caused by hemorrhage into the tissues
Preputial	Of or pertaining to the prepuce
Prolapse	To fall or slip out of place
Pruritis	Irritation and intense itching
Pyrexia	High fever
Rales	Abnormal respiratory sound heard on auscultation, indicating some pathologic condition
Registrant	The commercial party that is responsible for the marketing of the product
Seizure	A sudden attack, as of disease or epilepsy
Seroma	A collection of serum in the body, producing a tumor-like mass
Somnolence	State of sleepiness or unnatural drowsiness
Tachycardia	Excessive rapidity in the action of the heart
Tachypnoea	Rapid shallow breaths
Tenesmus	Ineffectual and painful straining in an attempt to urinate or defecate
Thrombocytopenia	Decrease in the number of blood platelets
Urticaria	Vascular reaction of the skin as a result of contact with a chemical or due to an immunological response

Wheals	A small swelling on the skin, as from an insect bite, that usually itches or burns
Withholding period	The time interval after the withdrawal of a drug or chemical use, to either the time of re-entry, harvesting or use of an animal or animal product for human consumption

8 INDEX OF ACTIVE CONSTITUENTS