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Australian Pesticides and
Veterinary Medicines Authority

REPORT OF ADVERSE EXPERIENCES

FOR VETERINARY MEDICINES AND AGRICULTURAL CHEMICALS

2011

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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 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 2011

This report summarises the findings of AERP assessments of adverse experiences reports in 2011.

The APVMA assessed and classified 2809 adverse experience reports involving registered veterinary medicines in 2011. Of these, 82 per cent involved animal safety, 16 per cent involved lack of efficacy and 2 per cent involved human health issues.

The APVMA assessed and classified 108 adverse experience reports involving registered agricultural chemical products in 2011. Of these, 47 per cent involved effects on crops or animals, 41 per cent involved human health issues, 8 per cent involved effects on the environment and 4 per cent involved a lack of efficacy.

The APVMA assessed and classified 116 reports relating to adverse experiences from registered veterinary medicines and agricultural chemical products involving effects on human health. Of these, 25 were classified as *probable or possible*, 64 as *off-label* (used contrary to label instructions) and 27 as *unlikely or unknown*.

No adverse experience assessed and classified by the APVMA in 2011 required a major regulatory action against any registered product.

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 2011 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.

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 registered veterinary medicine or agricultural chemical product when the product is used according to label instructions.

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 instructions.

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 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 instructions. The registrant reporting component of AERP *Ag* and AERP Vet is one method by which registrants can meet certain legislative obligations under 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 encourages 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 instructions, 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 the Environment, 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 overseas country.
- It considers if the product was used according to label instructions 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*** or ***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 pre-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.
- 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 or 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 doses in two out of three consecutive years
  - an exceptional incidence of three or more per 10 000 doses 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] *Final Report to the Veterinary Products Committee*. Department for Environment, Food & Rural Affairs, United Kingdom, 2002.

1.6 Assessments and classifications in 2011

In 2011, a total of 2809 adverse experience reports involving registered veterinary products were assessed and classified.

- Of these adverse experience reports, 82 per cent involved animal safety, 16 per cent involved lack of efficacy and 2 per cent involved human health issues (Figure 1).
- Of the 2809 adverse experiences reports assessed under the AERP *Vet*, 1780 were classified as either *probable* or *possible*.

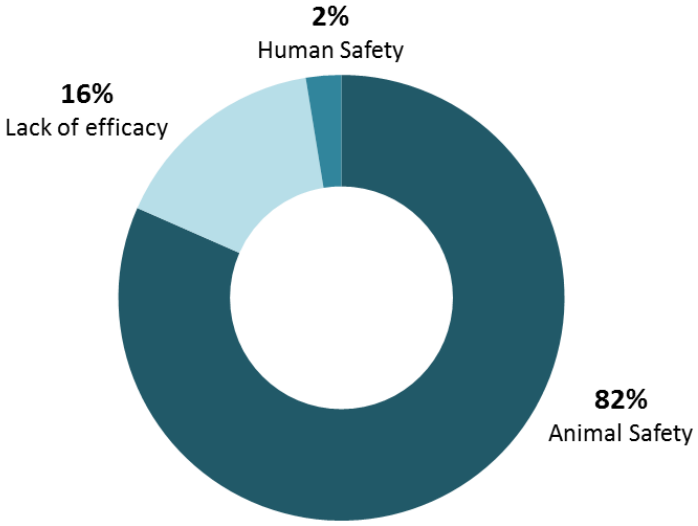

Figure 1. Adverse experience reports involving registered veterinary medicines processed and finalised in 2011.

In 2011, a total of 108 adverse experience reports involving agricultural products were assessed and classified.

- Of these adverse experience reports processed and classified, 47 per cent involved effects on crops or animals, 41 per cent involved human health issues, 8 per cent involved effects on the environment and 4 per cent involved a lack of efficacy (Figure 2).
- Of the 108 reports assessed under the AERP *Ag*, 39 were classified as *probable* or *possible.*

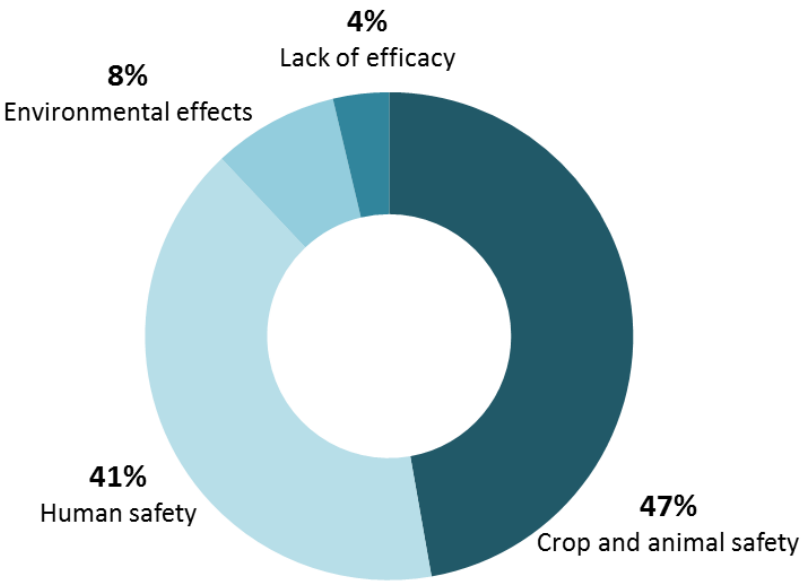

Figure 2. Adverse experience reports involving registered agriculture chemicals processed and finalised in 2011.

A total of 116 adverse experiences involving effects on humans from registered veterinary medicines and agricultural chemical products were assessed and classified in 2011. Of these, 25 were classified as *probable* or *possible*, 64 were classified as *off-label* and 27 were classified as *unlikely* or *unknown*.

No adverse experience assessed and classified by the APVMA in 2011 required a major regulatory action against any registered 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 description of the chemical is provided, along with why that number of reports may be expected, and if any 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 is a range of considerations 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	2	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 2011.

The APVMA assessed and classified 2809 adverse experience involving registered veterinary medicines in 2011. The largest proportion of reports involved animal safety (82%) followed by lack of efficacy (16%).

No regulatory action was required for active constituents involving veterinary medicines and animals in 2011, as the frequency of adverse experience reports received was relatively low compared with the total number of doses sold. The number of doses 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
2	0	2

Presenting signs (probable and possible)

Colic (1)
Hives (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	0	5

Presenting signs (probable and possible)

Lack of effect (3)
Coughing (1)
Death (1)
Diarrhoea (1)
Lethargy (1)

Acepromazine

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)

AHC-2102225 (monepantel)

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

Presenting signs (probable and possible)

Coughing (2)
Hypersalivation (1)

Albendazole

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	2	2

Presenting signs (probable and possible)

Death (3)
Bloat (1)
Lethargy (1)
Anorexia (1)
Lack of effect (1)

Alphaxalone

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	0	6

Presenting signs (probable and possible)

Recovery (prolonged) (2)
Lack of effect (1)
Recovery (poor) (1)
Bradycardia (1)
Oedema (1)
Cyanosis (1)
Paddling (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
7	0	7

Presenting signs (probable and possible)

Cardiac arrest (2)
Cyanosis (1)
Recovery (poor) (1)
Lack of effect (2)
Hypothermia (1)
Recovery (prolonged) (2)
Oedema (1)

Aluminium hydroxide

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	0	5

Presenting signs (probable and possible)

Lack of effect (2)
Lethargy (2)
Abdominal pain (1)
Anorexia (1)
Arthropathy (1)
Death (1)
Depression (1)
Pyrexia (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anorexia (1)
Behavioural change (1)

Amitraz

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Ataxia (1)
Bradycardia (1)

Amphotericin B

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	3	2

Presenting signs (probable and possible)

Lethargy (5)
Anorexia (3)
Pyrexia (3)
Pain (1)
Tremor (1)
Vomiting (1)

Anaplasma centrale

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
13	8	5

Presenting signs (probable and possible)

Lack of effect (13)

Atipamezole hydrochloride

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

Babesia bigemina

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
13	8	5

Presenting signs (probable and possible)

Lack of effect (13)

Babesia bovis

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
13	8	5

Presenting signs (probable and possible)

Lack of effect (13)

Bacitracin zinc

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Erythema (1)

Injected mucous membranes (1)

Benazepril hydrochloride

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Dermatitis (1)

Red eyes (1)

Vomiting (1)

Betacyfluthrin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
11	0	11

Presenting signs (probable and possible)

Lack of effect (11)

Bismuth subnitrate

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Abortion (1) Ataxia (1) Pyrexia (1)

Bordetella bronchiseptica vaccines

Bordetella bronchiseptica is a component of 'non-core' canine vaccine products that targets 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, sneezing and lethargy, and anaphylaxis, facial oedema and vomiting (killed vaccine). 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 *Bordetella bronchiseptica* vaccine strains is low when compared with the number of doses sold in 2011 (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.

Bordetella bronchiseptica

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
41	7	34

Presenting signs (probable and possible)

Coughing (14)
Sneezing (13)
Lethargy (10)
Pain (4)
Anorexia (3)
Injection site reaction (3)
Vomiting (3)
Immune-mediated haemolytic anaemia (2)
Nasal discharge (2)
Pyrexia (2)
Respiratory problems (2)
Site reaction (2)
Choking (1)
Depression (1)
Dyspnoea (1)
Facial oedema (1)
Lack of effect (1)
Lump (local) (1)
Malaise (1)
Recumbency (1)
Seroma (1)
Swelling (local) (1)
Thrombocytopenia (1)
URTI (1)

Bordetella bronchiseptica (inactivated cell free extract)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
25	18	7

Presenting signs (probable and possible)

Lethargy (14)
Anorexia (7)
Injection site reaction (6)
Anaphylaxis (4)
Abdominal pain (2)
Lack of effect (2)
Lame (2)
Pyrexia (2)
Urticaria (2)
Vomiting (2)
Arthropathy (1)
Ataxia (1)
Death (1)
Depression (1)
Diarrhoea (1)
Dyspnoea (1)
Erythema (1)
Facial oedema (1)
Malaise (1)
Mydriasis (1)
Pain (1)
Pale mucous membranes (1)
Pulmonary oedema (1)
Tachycardia (1)
Tremor (1)

Bordetella bronchiseptica killed vaccine

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
98	3	95

Presenting signs (probable and possible)

Facial oedema (44)
Vomiting (24)
Anaphylaxis (22)
Allergy (13)
Pruritis (12)
Lethargy (9)
Diarrhoea (6)
Erythema (5)
Injection site reaction (5)
Pale mucous membranes (4)
Tachycardia (4)
Anorexia (3)
Collapse (3)
Panting (3)
Pyrexia (3)
Urticaria (3)
Periorbital swelling (2)
Swelling (local) (2)
Abscess (1)
Ataxia (1)
Bradycardia (1)
Depression (1)
Disorientation (1)
Dyspnoea (1)
Hives (1)
Hypersalivation (1)
Immune-mediated haemolytic anaemia (1)
Lack of effect (1)
Lesions (1)
Necrosis (1)
Oedema (1)
Pain (1)
Respiratory problems (1)
Seroma (1)
Site reaction (swelling) (1)
Swollen (lips) (1)
Tremor (1)
Weakness (1)
Wheals (1)

Bovine ephemeral fever virus (BEFV)

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Lack of effect (2)
Ataxia (1)
Death (1)

Canine adenovirus type 2 vaccines

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

The most commonly reported presenting signs included a lack of effect, facial oedema, vomiting, anaphylaxis 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. 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 2011 (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
192	16	176

Presenting signs (probable and possible)

Lack of effect (49)
Facial oedema (45)
Vomiting (32)
Anaphylaxis (23)
Lethargy (23)
Allergy (13)
Sneezing (13)
Coughing (12)
Pruritis (10)
Diarrhoea (8)
Anorexia (7)
Erythema (6)
Injection site reaction (6)
Pain (6)
Pale mucous membranes (6)
Pyrexia (6)
Collapse (4)
Panting (4)
Tachycardia (4)
Depression (3)
Respiratory problems (3)
Swelling (local) (3)
Urticaria (3)
Ataxia (2)
Bradycardia (2)
Immune-mediated haemolytic anaemia (2)
Periorbital swelling (2)
Shaking (2)
Abscess (1)
Behavioural change (1)
Choking (1)
Disorientation (1)
Distress (1)
Dyspnoea (1)
Hives (1)
Hyperactivity (1)
Hypersalivation (1)
Hypotension (1)
Lesions (1)
Lump (local) (1)
Malaise (1)
Nasal discharge (1)
Necrosis (1)
Oedema (1)
Recumbency (1)
Seroma (1)
Site reaction (1)
Site reaction (swelling) (1)
Stiffness (1)
Swollen (lips) (1)
Thrombocytopenia (1)
Tremor (1)
URTI (1)
Weakness (1)
Weight loss (1)
Welts (1)
Wheals (1)
)

Canine adenovirus type 2 - live (infectious hepatitis)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
10	0	10

Presenting signs (probable and possible)

Lack of effect (6)
Abdominal pain (1)
Anorexia (1)
Arthropathy (1)
Death (1)
Lethargy (1)
Paralysis (1)
Pyrexia (1)
Thrombocytopenia (1)

Canine adenovirus type 2 live (CAV II)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lethargy (1)
Malaise (1)

Canine adenovirus type 2 strain Manhattan - live

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
15	1	14

Presenting signs (probable and possible)

Lack of effect (9)
Ataxia (1)
Bradycardia (1)
Comatose (1)
Facial oedema (1)
Immune-mediated haemolytic anaemia (1)
Injection site reaction (1)
Lethargy (1)
Unconscious (1)
Vomiting (1)
Weakness (1)

Canine coronavirus vaccine - antigen

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	0	5

Presenting signs (probable and possible)

Facial oedema (3)
Vomiting (2)
Hypersalivation (1)
Injection site reaction (1)
Lethargy (1)
Seroma (1)
Shaking (1)

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 lack of effect, facial oedema, vomiting, anaphylaxis 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 distemper virus vaccine strains is low when compared with the number of doses sold in 2011 (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
166	6	160

Presenting signs (probable and possible)

Lack of effect (47)
Facial oedema (44)
Vomiting (31)
Anaphylaxis (22)
Lethargy (20)
Allergy (13)
Pruritis (10)
Diarrhoea (8)
Anorexia (6)
Erythema (6)
Pain (6)
Pyrexia (6)
Injection site reaction (5)
Pale mucous membranes (5)
Collapse (4)
Panting (4)
Tachycardia (4)
Depression (3)
Swelling (local) (3)
Urticaria (3)
Ataxia (2)
Bradycardia (2)
Immune-mediated haemolytic anaemia (2)
Periorbital swelling (2)
Respiratory problems (2)
Abscess (1)
Behavioural change (1)
Coughing (1)
Disorientation (1)
Dyspnoea (1)
Hives (1)
Hypersalivation (1)
Hypotension (1)
Lesions (1)
Lump (local) (1)
Malaise (1)
Necrosis (1)
Oedema (1)
Recumbency (1)
Seroma (1)
Shaking (1)
Site reaction (1)
Site reaction (swelling) (1)
Sneezing (1)
Stiffness (1)
Swollen (lips) (1)
Thrombocytopenia (1)
Tremor (1)
Weakness (1)
Weight loss (1)
Welts (1)
Wheals (1)

Canine distemper virus - living

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
18	4	14

Presenting signs (probable and possible)

Lack of effect (8)
Lethargy (4)
Abdominal pain (1)
Anaphylaxis (1)
Anorexia (1)
Arthropathy (1)
Death (1)
Distress (1)
Facial oedema (1)
Hyperactivity (1)
Injection site reaction (1)
Malaise (1)
Pale mucous membranes (1)
Paralysis (1)
Pyrexia (1)
Shaking (1)
Thrombocytopenia (1)
Vomiting (1)

Canine distemper virus strain Onderstepoort

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
15	1	14

Presenting signs (probable and possible)

Lack of effect (9)

Ataxia (1)

Bradycardia (1)

Comatose (1)

Facial oedema (1)

Immune-mediated haemolytic anaemia (1)

Injection site reaction (1)

Lethargy (1)

Unconscious (1)

Vomiting (1)

Weakness (1)

Canine parainfluenza vaccines

Canine parainfluenza virus and associated strains is a component of 'non-core' canine vaccine products that targets 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 facial oedema, vomiting, anaphylaxis, lack of effect, coughing, sneezing 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 parainfluenza virus vaccine strains is low when compared with the number of doses sold in 2011 (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
24	6	18

Presenting signs (probable and possible)

Sneezing (13)
Coughing (12)
Lethargy (3)
Anorexia (2)
Respiratory problems (2)
Vomiting (2)
Choking (1)
Depression (1)
Immune-mediated haemolytic anaemia (1)
Nasal discharge (1)
URTI (1)

Canine parainfluenza type 2

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
112	4	108

Presenting signs (probable and possible)

Facial oedema (42)
Vomiting (25)
Anaphylaxis (22)
Lack of effect (17)
Allergy (13)
Lethargy (10)
Pruritis (10)
Diarrhoea (8)
Erythema (5)
Anorexia (4)
Injection site reaction (4)
Pale mucous membranes (4)
Panting (4)
Pyrexia (4)
Tachycardia (4)
Collapse (3)
Urticaria (3)
Periorbital swelling (2)
Swelling (local) (2)
Abscess (1)
Ataxia (1)
Bradycardia (1)
Depression (1)
Disorientation (1)
Dyspnoea (1)
Hives (1)
Hypersalivation (1)
Immune-mediated haemolytic anaemia (1)
Lesions (1)
Malaise (1)
Necrosis (1)
Oedema (1)
Pain (1)
Respiratory problems (1)
Site reaction (swelling) (1)
Swollen (lips) (1)
Tremor (1)
Weakness (1)
Wheals (1)

Canine parainfluenza virus

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
22	5	17

Presenting signs (probable and possible)

Lethargy (9)
Injection site reaction (4)
Pain (4)
Coughing (2)
Facial oedema (2)
Lack of effect (2)
Pyrexia (2)
Site reaction (2)
Anaphylaxis (1)
Anorexia (1)
Dyspnoea (1)
Immune-mediated haemolytic anaemia (1)
Lump (local) (1)
Malaise (1)
Nasal discharge (1)
Pale mucous membranes (1)
Recumbency (1)
Seroma (1)
Swelling (local) (1)
Thrombocytopenia (1)
Vomiting (1)

Canine parainfluenza virus - inactivated

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	0	5

Presenting signs (probable and possible)

Lack of effect (2)
Lethargy (2)
Abdominal pain (1)
Anorexia (1)
Arthropathy (1)
Death (1)
Depression (1)
Pyrexia (1)

Canine parvovirus vaccines

Canine parvovirus (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 worldwide distribution.

The most commonly reported presenting signs include lack of effect, facial oedema, vomiting, anaphylaxis 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 2011 (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
166	6	160

Presenting signs (probable and possible)

Lack of effect (47)
Facial oedema (44)
Vomiting (31)
Anaphylaxis (22)
Lethargy (20)
Allergy (13)
Pruritis (10)
Diarrhoea (8)
Anorexia (6)
Erythema (6)
Pain (6)
Pyrexia (6)
Injection site reaction (5)
Pale mucous membranes (5)
Collapse (4)
Panting (4)
Tachycardia (4)
Depression (3)
Swelling (local) (3)
Urticaria (3)
Ataxia (2)
Bradycardia (2)
Immune-mediated haemolytic anaemia (2)
Periorbital swelling (2)
Respiratory problems (2)
Abscess (1)
Behavioural change (1)
Coughing (1)
Disorientation (1)
Dyspnoea (1)
Hives (1)
Hypersalivation (1)
Hypotension (1)
Lesions (1)
Lump (local) (1)
Malaise (1)
Necrosis (1)
Oedema (1)
Recumbency (1)
Seroma (1)
Shaking (1)
Site reaction (1)
Site reaction (swelling) (1)
Sneezing (1)
Stiffness (1)
Swollen (lips) (1)
Thrombocytopenia (1)
Tremor (1)
Weakness (1)
Weight loss (1)
Welts (1)
Wheals (1)

Canine parvovirus type 2

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
8	4	4

Presenting signs (probable and possible)

Lethargy (3)
Lack of effect (2)
Anaphylaxis (1)
Distress (1)
Facial oedema (1)
Hyperactivity (1)
Injection site reaction (1)
Malaise (1)
Pale mucous membranes (1)
Shaking (1)
Vomiting (1)

Canine parvovirus - live

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
10	0	10

Presenting signs (probable and possible)

Lack of effect (6)
Abdominal pain (1)
Anorexia (1)
Arthropathy (1)
Death (1)
Lethargy (1)
Paralysis (1)
Pyrexia (1)
Thrombocytopenia (1)

Canine parvovirus strain 154 - live

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
15	1	14

Presenting signs (probable and possible)

Lack of effect (9)
Ataxia (1)
Bradycardia (1)
Comatose (1)
Facial oedema (1)
Immune-mediated haemolytic anaemia (1)
Injection site reaction (1)
Lethargy (1)
Unconscious (1)
Vomiting (1)
Weakness (1)

Carprofen

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Ataxia (1)
Blepharospasm (1)
Hyperaesthesia (1)
Lump (local) (1)
Renal failure (1)
Site reaction (1)

Chlamydophila felis vaccine

Chlamydophila felis is a component of 'non-core' feline vaccine products that targets common feline respiratory illness. Non-core vaccines are required only for those animals at risk from specific disease due to their geographical location or local environment.

The most commonly reported presenting signs include lethargy, pyrexia and anorexia. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, which protects the animal from serious illness. 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 *Chlamydophila felis* vaccine strains is low when compared with the number of doses sold in 2011 (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.

Chlamydophila felis Baker strain - live, attenuated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
25	11	14

Presenting signs (probable and possible)

Lethargy (14)
Pyrexia (8)
Anorexia (7)
Pain (4)
Vomiting (3)
Facial oedema (2)
Incoordination (2)
Injection site reaction (2)
Lump (local) (2)
Pupillary light reflex (abnormal) (2)
Abscess (1)
Alopecia (localised) (1)
Anaphylaxis (1)
Behavioural change (1)
Collapse (1)
Death (1)
Diarrhoea (1)
Hypothermia (1)
Muscle stiffness (1)
Swelling (local) (1)
Tremor (1)

Chlorfenvinphos

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Alopecia (localised) (1)

Chlorhexidine gluconate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Blisters (1)
Irritation (skin) (1)
Rash (1)

Chlorpheniramine maleate

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Diarrhoea (1)
Lethargy (1)
Vomiting (1)

Chondroitin sulfate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Agitation (1)
Behavioural change (1)
Diarrhoea (1)
Vomiting (1)

Citronella oil

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1) Sweating (1) Swelling (local) (1)

Clomipramine hydrochloride

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Hepatopathy (1) Vomiting (1)

Clorsulon

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Behavioural change (1) Death (1) Sweating (1)

Clostridium chauvoei - formol culture

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Ataxia (1) Hypersalivation (1) Stiffness (1)

Erythema (1) Milk production decrease (1)

Clostridium novyi type B

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Ataxia (1)	Hypersalivation (1)	Stiffness (1)
Erythema (1)	Milk production decrease (1)	

Clostridium perfringens type D toxoid

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Ataxia (1)	Hypersalivation (1)	Stiffness (1)
Erythema (1)	Milk production decrease (1)	

Clostridium septicum - toxoid

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Ataxia (1)	Hypersalivation (1)	Stiffness (1)
Erythema (1)	Milk production decrease (1)	

Clostridium tetani uf toxoid

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Anorexia (1)
Behavioural change (1)
Death (1)
Injection site reaction (1)
Lethargy (1)
Pain (2)

Cobalt as cobalt disodium EDTA

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Contagious pustular dermatitis virus, living, cell culture

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Low efficacy (2)
Lesions (1)

Cyclosporin

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	5	1

Presenting signs (probable and possible)

Vomiting (4)
Gingival hyperplasia (2)
Behavioural change (1)
Diarrhoea (1)
Hyperactivity (1)
Lack of effect (1)
Pruritis (1)
Tachypnoea (1)

Cypermethrin

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lesions (1)

Cyromazine

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

Cythioate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Hyperactivity (1)

Lack of effect (1)

Deltamethrin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Agitation (1)

Epiphora (1)

Lack of effect (1)

Site reaction (1)

Diazinon

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Bradycardia (1)
Hypersalivation (1)
Pupillary light reflex (abnormal) (1)
Seizure (1)
Site reaction (1)
Vomiting (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)
Erythema (1)
Necrosis (1)

Dicyclanil

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Dipyrone

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Ataxia (1)
Facial oedema (1)
Urticaria (1)

Doramectin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Lack of effect (3)
Alopecia (1)

Emodepside

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
12	10	2

Presenting signs (probable and possible)

Alopecia (localised) (9)
Behavioural change (2)
Hypersalivation (2)
Anorexia (1)
Diarrhoea (1)
Prolapsed third eyelid (1)
Self trauma (1)
Site reaction (1)

Eprinomectin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Agitation (1)
Epiphora (1)
Site reaction (1)

Erysipelothrix rhusiopathiae

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Death (2)
Anaphylaxis (1)
Hypersalivation (1)
Recumbency (1)

Eucalyptus oil

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1)
Sweating (1)
Swelling (local) (1)

Febantel

Febantel is a systemic anthelmintic chemical primarily used to treat worm infection in domestic animals. The most commonly reported presenting sign was vomiting.

The number of reports associated with febantel is low when compared to the number of doses sold in 2011 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Febantel

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
23	11	12

Presenting signs (probable and possible)

Vomiting (11)
Lack of effect (6)
Hyperactivity (3)
Lethargy (2)
Agitation (1)
Behavioural change (1)
Diarrhoea (1)
Listless (1)
Malaise (1)
Polydipsia (1)
Shaking (1)

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 2011 (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

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lethargy (1)

Site reaction (swelling) (1)

Feline calicivirus - inactivated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
62	35	27

Presenting signs (probable and possible)

Lethargy (34)
Anorexia (22)
Pyrexia (19)
Vomiting (11)
Diarrhoea (7)
Pain (6)
Alopecia (localised) (4)
Anaphylaxis (4)
Injection site reaction (4)
Pruritis (4)
Behavioural change (3)
Facial oedema (3)
Vocalisation (3)
Collapse (2)
Incoordination (2)
Lump (local) (2)
Pupillary light reflex (abnormal) (2)
Swelling (local) (2)
Abscess (1)
Ataxia (1)
Blood in faeces (1)
Death (1)
Dehydration (1)
Distress (1)
Hyperactivity (1)
Hypothermia (1)
Malaise (1)
Muscle stiffness (1)
Panting (1)
Tachycardia (1)
Tremor (1)
Urticaria (1)

Feline *Chlamydia psittaci* - inactivated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

Presenting signs (probable and possible)

Lethargy (2)
Anorexia (1)
Malaise (1)
Pyrexia (1)

Feline immunodeficiency virus (Petaluma strain) inactive

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
14	3	11

Presenting signs (probable and possible)

Anorexia (5)
Lethargy (5)
Pyrexia (5)
Pain (3)
Alopecia (localised) (2)
Injection site reaction (2)
Behavioural change (1)
Death (1)
Diarrhoea (1)
Facial oedema (1)
Lump (local) (1)
Muscle stiffness (1)
Swelling (local) (1)

Feline leukaemia virus - inactivated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
9	4	5

Presenting signs (probable and possible)

Lethargy (7)
Pyrexia (5)
Anorexia (4)
Pain (2)
Alopecia (localised) (1)
Lump (local) (1)
Muscle stiffness (1)
Swelling (local) (1)
Tremor (1)
Vomiting (1)

Feline panleucopenia virus vaccines

Feline panleukopenia virus is a constituent of 'core' feline vaccine products that targets 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, pyrexia 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 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 2011 (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

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lethargy (1)

Site reaction (swelling) (1)

Feline panleucopenia virus - inactivated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
62	35	27

Presenting signs (probable and possible)

Lethargy (34)
Anorexia (22)
Pyrexia (19)
Vomiting (11)
Diarrhoea (7)
Pain (6)
Alopecia (localised) (4)
Anaphylaxis (4)
Injection site reaction (4)
Pruritis (4)
Behavioural change (3)
Facial oedema (3)
Vocalisation (3)
Collapse (2)
Incoordination (2)
Lump (local) (2)
Pupillary light reflex (abnormal) (2)
Swelling (local) (2)
Abscess (1)
Ataxia (1)
Blood in faeces (1)
Death (1)
Dehydration (1)
Distress (1)
Hyperactivity (1)
Hypothermia (1)
Malaise (1)
Muscle stiffness (1)
Panting (1)
Tachycardia (1)
Tremor (1)
Urticaria (1)

Feline rhinotracheitis virus vaccine

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, pyrexia 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. 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 2011 (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 rhinotracheitis virus - inactivated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
62	35	27

Presenting signs (probable and possible)

Lethargy (34)
Anorexia (22)
Pyrexia (19)
Vomiting (11)
Diarrhoea (7)
Pain (6)
Alopecia (localised) (4)
Anaphylaxis (4)
Injection site reaction (4)
Pruritis (4)
Behavioural change (3)
Facial oedema (3)
Vocalisation (3)
Collapse (2)
Incoordination (2)
Lump (local) (2)
Pupillary light reflex (abnormal) (2)
Swelling (local) (2)
Abscess (1)
Ataxia (1)
Blood in faeces (1)
Death (1)
Dehydration (1)
Distress (1)
Hyperactivity (1)
Hypothermia (1)
Malaise (1)
Muscle stiffness (1)
Panting (1)
Tachycardia (1)
Tremor (1)
Urticaria (1)

Fenvalerate

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Lack of effect (2)

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.

The most commonly reported presenting signs included site reaction, localised alopecia and skin irritation.

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.

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

Fipronil

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
90	20	70

Presenting signs (probable and possible)

Site reaction (25)	Lethargy (5)	Alopecia (1)
Alopecia (localised) (14)	Pyoderma (5)	Ataxia (1)
Irritation (skin) (10)	Vomiting (5)	Head tilt (1)
Lack of effect (10)	Dermatitis (4)	Odour (1)
Behavioural change (7)	Lesions (4)	Rash (1)
Pruritis (6)	Diarrhoea (3)	Restless (1)
Coat discoloration (5)	Agitation (2)	Scabs (1)
Erythema (5)	Inflammation (2)	Tachycardia (1)
Hypersensitivity reaction (5)	Allergy (1)	Tremor (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
55	21	34

Presenting signs (probable and possible)

Alopecia (localised) (44)	Scabs (2)	Lack of effect (1)
Site reaction (12)	Agitation (1)	Lesions (1)
Erythema (8)	Alopecia (1)	Vomiting (1)
Pruritis (6)	Diarrhoea (1)	
Behavioural change (3)	Incoordination (1)	

Firocoxib

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
9	1	8

Presenting signs (probable and possible)

Ulceration (4)
Vomiting (4)
Abdominal pain (3)
Death (3)
Anorexia (1)
Bloat (1)
Blood in faeces (1)
Diarrhoea (1)
Hypersalivation (1)
Incoordination (1)
Irritation (skin) (1)
Renal failure (1)
Urticaria (1)

Flunixin as flunixin meglumine

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Facial oedema (1)
Urticaria (1)

Fluoxetine hydrochloride

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Diarrhoea (1)
Sedation (marginal) (1)

Glucosamine hydrochloride

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Agitation (1)
Behavioural change (1)
Diarrhoea (1)
Vomiting (1)

GNRF - protein conjugate

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Behavioural change (1)
Collapse (1)
Incontinence (1)
Lack of effect (1)
Pruritis (1)
Pulmonary oedema (1)
Pyrexia (1)

Hyoscine-n-butylbromide

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Ataxia (1)
Facial oedema (1)
Urticaria (1)

Imidacloprid

Imidacloprid is an insecticidal chemical that disrupts the insect's nervous system. The most commonly reported presenting signs included paraesthesia, behavioural change and self-trauma.

The number of reports associated with imidacloprid is low when compared with the number of doses sold in 2011 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Imidacloprid

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
284	221	63

Presenting signs (probable and possible)

Paraesthesia (163)
Behavioural change (90)
Self trauma (62)
Lack of effect (16)
Vomiting (14)
Lethargy (13)
Alopecia (localised) (11)
Erythema (11)
Diarrhoea (7)
Site reaction (7)
Pruritis (5)
Urticaria (4)
Hypersalivation (3)
Lesions (3)
Rolling (3)
Rubbing (3)
Agitation (2)
Anorexia (2)
Coat discoloration (2)
Coat colour change (1)
Facial oedema (1)
Irritation (skin) (1)
Rash (1)
Seizure (1)
Shaking (1)
Welts (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
71	51	20

Presenting signs (probable and possible)

Alopecia (localised) (28)
Self trauma (16)
Hypersalivation (15)
Behavioural change (14)
Site reaction (5)
Lethargy (4)
Vomiting (3)
Lesions (2)
Oral (ulcers) (2)
Pruritis (2)
Tremor (2)
Alopecia (1)
Ataxia (1)
Depression (1)
Diarrhoea (1)
Erythema (1)
Hyperexcitable (1)
Lump (local) (1)
Scabs (1)
Unpleasant taste (1)

Rabbit

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Agitation (1)
Anorexia (1)
Lethargy (1)

Inactivated bovine pestivirus - Bega strain

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Anorexia (1)
Lack of effect (1)
Lethargy (1)
Pyrexia (1)

Inactivated bovine pestivirus - Trangie strain

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Anorexia (1)
Lack of effect (1)
Lethargy (1)
Pyrexia (1)

Inactivated rabbit calicivirus disease virus

Rabbit

NUMBER OF REPORTS	PROBABLE	POSSIBLE
9	6	3

Presenting signs (probable and possible)

Anorexia (3)
Alopecia (localised) (1)
Site reaction (swelling) (1)
Death (3)
Lethargy (1)
Tachycardia (1)
Injection site reaction (3)
Panting (1)

Ivermectin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	1	4

Presenting signs (probable and possible)

Behavioural change (2)
Injection site reaction (1)
Sweating (1)
Anorexia (1)
Lethargy (1)
Toxicity (1)
Death (1)
Oedema (1)
Erythema (1)
Photosensitization (1)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Vomiting (3)
Lethargy (1)
Diarrhoea (1)
Tachycardia (1)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Swollen (lips) (2)
Blisters (1)
Oral (ulcers) (1)

Ketamine as ketamine hydrochloride

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Lack of effect (3)

Leptospira icterohaemorrhagiae antigen

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	0	5

Presenting signs (probable and possible)

Facial oedema (3)
Injection site reaction (1)
Shaking (1)
Vomiting (2)
Lethargy (1)
Hypersalivation (1)
Seroma (1)

Levamisole hydrochloride

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Ataxia (1)
Collapse (1)
Death (1)

Live feline herpes virus

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lethargy (1)
Site reaction (swelling) (1)

Lufenuron

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
14	8	6

Presenting signs (probable and possible)

Vomiting (8)
Anorexia (2)
Inflammation (1)
Diarrhoea (4)
Dermatitis (1)
Irritation (ear) (1)
Lethargy (3)
Erythema (1)
Rash (1)
Pruritis (3)
Hives (1)

Maropitant as maropitant citrate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

Presenting signs (probable and possible)

Anaphylaxis (1)
Urticaria (1)
Facial oedema (1)
Vomiting (1)

Melaleuca alternifolia oil

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pruritis (1)
Sweating (1)
Swelling (local) (1)

Meloxicam

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

Presenting signs (probable and possible)

Vomiting (3)
Death (1)
Renal failure (1)
Blood in faeces (1)
Lethargy (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Renal failure (2)
Ataxia (1)
Electrolyte changes (1)
Anorexia (1)
Azotaemia (1)
Urinalysis (abnormal) (1)

Methoprene - rs

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	5	0

Presenting signs (probable and possible)

Hypersalivation (5)

Miconazole nitrate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Hypersensitivity reaction (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 most commonly reported presenting signs included vomiting and lethargy.

The number of reports associated with milbemycin oxime is low when compared with the number of doses sold in 2011 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Milbemycin oxime

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
22	12	10

Presenting signs (probable and possible)

- Vomiting (10)
- Lethargy (6)
- Diarrhoea (4)
- Pruritis (4)
- Anorexia (3)
- Lack of effect (3)
- Ataxia (2)
- Coughing (1)
- Dermatitis (1)
- Erythema (1)
- Hives (1)
- Hypersalivation (1)
- Inflammation (1)
- Irritation (ear) (1)
- Lesions (1)
- Mydriasis (1)
- Rash (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

- Lethargy (2)
- Anorexia (1)
- Ataxia (1)
- Somnolence (1)

Monensin as monensin sodium

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	1	4

Presenting signs (probable and possible)

Lack of effect (4)
Toxicity (1)

Morantel tartrate

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Hives (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 most commonly reported presenting signs included localised alopecia and hypersalivation (cats) and behavioural change.

The number of reports associated with moxidectin is low when compared with the number of doses sold in 2011 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Moxidectin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

CNS dysfunction (2)
Ataxia (1)
Death (1)
Fasciculation (1)
Hypersalivation (1)
Paddling (1)
Recumbency (1)
Spasm (1)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
44	15	29

Presenting signs (probable and possible)

Behavioural change (12)
Lack of effect (7)
Lethargy (6)
Pruritis (5)
Site reaction (5)
Diarrhoea (4)
Self trauma (4)
Alopecia (localised) (3)
Rolling (3)
Rubbing (3)
Hypersalivation (2)
Lesions (2)
Vomiting (2)
Agitation (1)
Facial oedema (1)
Irritation (skin) (1)
Rash (1)
Urticaria (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
42	26	16

Presenting signs (probable and possible)

Alopecia (localised) (16)
Hypersalivation (12)
Behavioural change (6)
Self trauma (6)
Site reaction (5)
Lethargy (3)
Pruritis (2)
Tremor (2)
Vomiting (2)
Alopecia (1)
Ataxia (1)
Depression (1)
Diarrhoea (1)
Erythema (1)
Hyperexcitable (1)
Oral (ulcers) (1)
Scabs (1)
Unpleasant taste (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Lack of effect (1)
Low efficacy (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 most commonly reported presenting signs included facial oedema, injection site reaction and vomiting.

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 2011 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Moxidectin microspheres

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
48	12	36

Presenting signs (probable and possible)

Facial oedema (12)
Vomiting (10)
Injection site reaction (9)
Lethargy (9)
Anaphylaxis (6)
Urticaria (5)
Erythema (4)
Allergy (3)
Pyrexia (3)
Anorexia (2)
Diarrhoea (2)
Oedema (2)
Panting (2)
Site reaction (2)
Tachycardia (2)
Thrombocytopenia (2)
Abscess (1)
Alopecia (1)
Alopecia (localised) (1)
Anaphylactoid reaction (1)
Ataxia (1)
Bradycardia (1)
Coat colour change (1)
Death (1)
Dehydration (1)
Depression (1)
Head tilt (1)
Hypersalivation (1)
Lesions (1)
Lump (local) (1)
Malaise (1)
Melaena (1)
Pain (1)
Pale mucous membranes (1)
Pruritis (1)
Recumbency (1)
Respiratory problems (1)
Swelling (local) (1)
Tremor (1)
Wheals (1)

Naphthalophos

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Death (2)
Collapse (1)

Neomycin

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	3	2

Presenting signs (probable and possible)

Lethargy (5)
Anorexia (3)
Pyrexia (3)
Pain (1)
Tremor (1)
Vomiting (1)

Neomycin sulfate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

Presenting signs (probable and possible)

Allergy (1)
Erythema (1)
Hypersensitivity reaction (1)
Injected mucous membranes (1)
Irritation (skin) (1)

Nicergoline freeze dried

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Bradycardia (1)

Nitenpyram

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Vomiting (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Hyperactivity (3)
Hyperaesthesia (1)
Panting (1)
Tachypnoea (2)
Hypersalivation (1)
Tachycardia (1)

N-octyl bicycloheptene dicarboximide

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	5	1

Presenting signs (probable and possible)

Hypersalivation (6)

Oatmeal extract

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	3	1

Presenting signs (probable and possible)

Pruritis (4)

Oestradiol benzoate

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

Presenting signs (probable and possible)

Preputial prolapse (2) Prolapse (rectal) (1)

Oxantel embonate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Lack of effect (2)

Oxfendazole

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Colic (1)

Oxytetracycline hydrochloride

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Collapse (1) Death (1) Paralysis (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
14	4	10

Presenting signs (probable and possible)

Paralysis (13)
Lame (8)
Pain (3)
Abscess (1)
Anaphylaxis (1)
Death (1)
Injection site reaction (1)
Necrosis (1)
Swelling (local) (1)

Pentosan polysulfate sodium

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
15	6	9

Presenting signs (probable and possible)

Vomiting (7)
Lethargy (6)
Anorexia (4)
Diarrhoea (4)
Abscess (2)
Blood in faeces (2)
Lump (local) (2)
Abdominal pain (1)
Lack of effect (1)
Site reaction (1)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)
Vomiting (1)

Permethrin

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 most commonly reported presenting signs included paraesthesia, behavioural change and self-trauma.

The number of reports associated with permethrin products is low when compared with the number of doses sold in 2011 (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 http://archive.apvma.gov.au/archive/community/2011-01_permethrin_cats.php

Permethrin

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
19	19	0

Presenting signs (probable and possible)

Paraesthesia (15)	Behavioural change (5)
Self trauma (6)	Vomiting (1)

Permethrin (25:75::cis:trans)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Ataxia (1)	Frothing at the mouth (1)	Lethargy (1)
Disorientation (1)	Hypersalivation (1)	Muscle twitching (1)

Permethrin (40:60::cis:trans)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
208	175	33

Presenting signs (probable and possible)

Paraesthesia (148)	Alopecia (localised) (5)	Coat colour change (1)
Behavioural change (67)	Lethargy (5)	Hypersalivation (1)
Self trauma (49)	Site reaction (4)	Lesions (1)
Erythema (11)	Urticaria (3)	Seizure (1)
Vomiting (10)	Coat discoloration (2)	Shaking (1)
Lack of effect (9)	Diarrhoea (2)	Welts (1)

Phenobarbitone

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Haematology (abnormal) (1)	Leucopenia (1)	Thrombocytopenia (1)

Pimobendan

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Red eyes (1)	Vomiting (1)

Piperazine citrate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lethargy (1)
Pain (1)
Pale mucous membranes (1)

Piperonyl butoxide

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
13	0	13

Presenting signs (probable and possible)

Lack of effect (13)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Ataxia (1)
Disorientation (1)
Frothing at the mouth (1)
Hypersalivation (1)
Lethargy (1)
Muscle twitching (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
7	5	2

Presenting signs (probable and possible)

Hypersalivation (6)
Ataxia (1)
Behavioural change (1)
Seizure (1)
Tremor (1)

Polymixin B

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	3	2

Presenting signs (probable and possible)

Lethargy (5)
Anorexia (3)
Pyrexia (3)
Pain (1)
Tremor (1)
Vomiting (1)

Polymyxin B sulfate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	3	1

Presenting signs (probable and possible)

Hypersensitivity reaction (2)
Allergy (1)
Erythema (1)
Injected mucous membranes (1)
Irritation (skin) (1)

Praziquantel

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

The most commonly reported presenting signs included vomiting and lethargy.

The number of reports associated with praziquantel is low when compared with the number of doses sold in 2011 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Praziquantel

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
45	23	22

Presenting signs (probable and possible)

Vomiting (21)
Lack of effect (9)
Lethargy (8)
Diarrhoea (5)
Pruritis (4)
Anorexia (3)
Hyperactivity (3)
Ataxia (2)
Agitation (1)
Behavioural change (1)
Coughing (1)
Dermatitis (1)
Erythema (1)
Hives (1)
Hypersalivation (1)
Inflammation (1)
Irritation (ear) (1)
Lesions (1)
Listless (1)
Malaise (1)
Mydriasis (1)
Polydipsia (1)
Rash (1)
Shaking (1)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Swollen (lips) (2)
Blisters (1)
Colic (1)
Oral (ulcers) (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
17	11	6

Presenting signs (probable and possible)

Alopecia (localised) (9)
Anorexia (4)
Behavioural change (4)
Ataxia (3)
Hypersalivation (2)
Lethargy (2)
Diarrhoea (1)
Prolapsed third eyelid (1)
Self trauma (1)
Site reaction (1)
Somnolence (1)

Prednisolone

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Allergy (1)
Hypersensitivity reaction (1)
Irritation (skin) (1)

Prednisolone acetate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Hypersensitivity reaction (1)

Progesterone

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

Presenting signs (probable and possible)

Preputial prolapse (2)
Prolapse (rectal) (1)

Pyraclofos

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Death (3)
Bloat (1)
Anorexia (1)
Lethargy (1)

Pyrantel as pyrantel embonate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
23	11	12

Presenting signs (probable and possible)

Vomiting (13)
Diarrhoea (2)
Malaise (1)
Lack of effect (4)
Agitation (1)
Polydipsia (1)
Hyperactivity (3)
Behavioural change (1)
Shaking (1)
Lethargy (3)
Listless (1)
Tachycardia (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Anorexia (2)
Ataxia (2)
Behavioural change (2)

Pyrantel embonate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

Presenting signs (probable and possible)

Lack of effect (4)

Pyrethrins

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
7	5	2

Presenting signs (probable and possible)

Hypersalivation (6)
Behavioural change (1)
Tremor (1)
Ataxia (1)
Seizure (1)

Pyriproxyfen

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Site reaction (2) Behavioural change (1) Self trauma (1)

Quil

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anorexia (1) Behavioural change (1)

Recombinant GP70 sub-type A

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anorexia (1) Behavioural change (1)

Robenacoxib

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
8	5	3

Presenting signs (probable and possible)

Hepatopathy (2)
Vomiting (2)
Anaphylaxis (1)
Diarrhoea (1)
Elevated ALP (1)
Hypersalivation (1)
Lack of effect (1)
Pyrexia (1)
Tachycardia (1)
Tachypnoea (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Muscle twitching (1)
Vomiting (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 most commonly reported presenting signs included site reaction and localised alopecia.

The number of reports associated with (s)-methoprene is low when compared with the number of doses sold in 2011 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

(S)-methoprene

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
87	20	67

Presenting signs (probable and possible)

Site reaction (25)	Lethargy (5)	Alopecia (1)
Alopecia (localised) (14)	Pyoderma (5)	Ataxia (1)
Irritation (skin) (10)	Dermatitis (4)	Head tilt (1)
Lack of effect (9)	Lesions (4)	Odour (1)
Behavioural change (7)	Vomiting (3)	Rash (1)
Pruritis (6)	Agitation (2)	Restless (1)
Coat discoloration (5)	Diarrhoea (2)	Scabs (1)
Erythema (5)	Inflammation (2)	Tachycardia (1)
Hypersensitivity reaction (5)	Allergy (1)	Tremor (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
53	21	32

Presenting signs (probable and possible)

Alopecia (localised) (44)	Behavioural change (2)	Lack of effect (1)
Site reaction (12)	Scabs (2)	Lesions (1)
Erythema (8)	Alopecia (1)	Vomiting (1)
Pruritis (5)	Diarrhoea (1)	

Sea minerals

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Depression (1)
Erythema (1)
Swelling (local) (1)

Selamectin

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	3	3

Presenting signs (probable and possible)

Pruritis (3)
Alopecia (1)
Behavioural change (1)
Coat colour change (1)
Lethargy (1)
Site reaction (1)
Vocalisation (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
36	35	1

Presenting signs (probable and possible)

Alopecia (localised) (31)
Alopecia (2)
Coat colour change (2)
Behavioural change (1)
Irritation (skin) (1)
Lesions (1)
Pruritis (1)
Pyoderma (1)
Scabs (1)
Self trauma (1)
Ulceration (1)
Vomiting (1)

Selenium (as selenium sodium EDTA)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Selenium as barium selenate

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Injection site reaction (1)

Selenium as sodium selenate

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	0	5

Presenting signs (probable and possible)

Lack of effect (2)
Coughing (1)
Death (1)
Diarrhoea (1)
Lethargy (1)
Low efficacy (1)

Spinosad

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

In 2011, the APVMA had received a large number of reports associated with spinosad. The most commonly reported presenting sign, by far, was vomiting in dogs. However, the APVMA notes that most of these dogs recover spontaneously without intervention. Despite the high reporting incidence involving the active constituent, the APVMA considered that the clinical signs were relatively mild in nature in the majority of the cases and adequate warning statements already appeared on product labels to indicate to the end user of the potential for vomiting. Therefore, no regulatory action was required other than to continue careful and ongoing monitoring of the adverse experience reporting.

Spinosad

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
478	367	111

Presenting signs (probable and possible)

Vomiting (394)
Lethargy (70)
Diarrhoea (15)
Pruritis (15)
Anorexia (14)
Ataxia (12)
Erythema (12)
Tremor (11)
Seizure (10)
Lack of effect (9)
Disorientation (6)
Shaking (6)
Hyperaesthesia (5)
Wheals (5)
Abdominal pain (4)
Depression (4)
Stiffness (4)
Behavioural change (3)
Mydriasis (3)
Panting (3)
Alopecia (2)
Hypersalivation (2)
Listless (2)
Muscle twitching (2)
Rash (2)
Restless (2)
Coughing (1)
Death (1)
Distress (1)
Dysphagia (1)
Excitation (1)
Flatulence (1)
Frothing at the mouth (1)
Halitosis (1)
Hyperactivity (1)
Hyperpigmentation (1)
Hypersensitive to stimuli (1)
Incontinence (1)
Incoordination (1)
Irritation (skin) (1)
Nausea (1)
Opisthotonos (1)
Pain (1)
Pale mucous membranes (1)
Photophobia (1)
Polydipsia (1)
Pyrexia (1)
Rolling (1)
Self trauma (1)
Somnolence (1)
Weakness (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
44	24	20

Presenting signs (probable and possible)

Lack of effect (44)

Stabilised green-lipped mussel powder

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Agitation (1)
Behavioural change (1)
Diarrhoea (1)
Vomiting (1)

Streptococcus equi as cell free extract

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Pain (2)
Anorexia (1)
Behavioural change (1)
Death (1)
Injection site reaction (1)
Lethargy (1)

Sulfacetamide sodium

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Allergy (1)
Hypersensitivity reaction (1)
Irritation (skin) (1)

Sulfadiazine

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Hepatopathy (1)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Anaphylactoid reaction (1)
Ataxia (1)
Collapse (1)

Temephos

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)
Hypersalivation (1)
Pneumonia (1)

Tetanus = clostridium tetani

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Ataxia (1)
Hypersalivation (1)
Stiffness (1)
Erythema (1)
Milk production decrease (1)

Triclabendazole

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Erythema (1)
Oedema (1)
Photosensitization (1)

Triflumuron

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Lack of effect (2)

Trimethoprim

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Hepatopathy (1)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Anaphylactoid reaction (1) Ataxia (1) Collapse (1)

Vitamin B1 hydrochloride = thiamine hydrochloride

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Abscess (1) Site reaction (1) Site reaction (swelling) (1)

Zeta-cypermethrin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Lack of effect (2)

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 2011.

The APVMA assessed and classified 2809 adverse experiences involving registered veterinary medicines in 2011. Adverse experiences in humans, for example, needle stick injuries, comprised 2% of these.

No regulatory action was required for active constituents involving veterinary medicines and human health in 2011.

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.

(S)-methoprene

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Dermatitis (1)

Benzalkonium chloride

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Respiratory problems (1)

Unpleasant taste (1)

Canine adeno virus type 2

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Haemorrhage (1)

Needle stick injury (1)

Canine distemper virus - living

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Haemorrhage (1)

Needle stick injury (1)

Canine parvovirus type 2

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Haemorrhage (1)

Needle stick injury (1)

Coumaphos

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Unpleasant smell (1)

Diazinon

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Unpleasant smell (1)

Fipronil

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Dermatitis (1)

Imidacloprid

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	4	1

Presenting signs (probable and possible)

Burning sensation (1)
Irritation (skin) (1)
Numbness (1)
Paraesthesia (1)
Rash (1)
Swelling (local) (1)
Tremor (1)
Welts (1)

Naphthalophos

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Blurred vision (1)
Dizziness (1)

Permethrin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Tremor (1)

Permethrin (40:60::cis:trans)

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Numbness (1)

Paraesthesia (1)

Poly(hexamethylene biguanide) hydrochloride

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Respiratory problems (1)

Unpleasant taste (1)

Zeta-cypermethrin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Headache (1)

5 AGRICULTURAL CHEMICALS—ANIMAL, PLANTS AND ENVIRONMENTAL SAFETY

This chapter summarises classifications of APVMA assessments in 2011 of adverse experience reports involving agricultural chemicals that were classified as 'probable' or 'possible'.

One hundred and eight adverse experience reports involving agricultural chemical products were assessed and classified as either 'probable' or 'possible' in 2011. Of these, 47 per cent involved effects on crops or animals, 41 per cent involved human health issues, 8 per cent involved effects on the environment and 4 per cent involved a lack of efficacy.

No regulatory action was required for active constituents involving agricultural chemicals in 2011.

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
4	0	4

Presenting signs (probable and possible)

Burn(s) (3)

Death (2)

2,4-D ethyl hexyl ester

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Vomiting (1)

Chlorpyrifos

Guava

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Residue violation (1)

Lychee

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Residue violation (2)

Dicamba

Lawn Grass

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

Presenting signs (probable and possible)

Burn(s) (3)

Death (2)

Dicamba present as the dimethylamine salt

Lawn Grass

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

Fenthion

Avian

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	4	0

Presenting signs (probable and possible)

Death (3) Distress (1) Weakness (1)

Mango

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

Glyphosate present as the potassium salt

Fallow

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

Haloxyfop present as the haloxyfop-r methyl ester

Canola

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Residue violation (1)

MCPA present as the dimethylamine salt

Lawn Grass

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

Mecoprop

Lawn Grass

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

Presenting signs (probable and possible)

Burn(s) (3) Death (2)

Piperonyl butoxide

Garden

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	3	1

Presenting signs (probable and possible)

Death (3) Burn(s) (1) Crop damage (1)

Succulents

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Crop damage (1)

Vegetable

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Death (2) Burn(s) (1)

Pyrethrins

Garden

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	3	1

Presenting signs (probable and possible)

Death (3) Burn(s) (1) Crop damage (1)

Succulents

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Crop damage (1)

Vegetable

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Death (2) Burn(s) (1)

6 AGRICULTURAL CHEMICALS—HUMAN ADVERSE EXPERIENCES

This chapter summarises classifications of APVMA assessments in 2011 of adverse experience reports involving agricultural chemicals and effects on humans.

The APVMA assessed and classified 108 adverse experience reports involving agricultural chemical products in 2011. Adverse experiences relating to humans comprised 41% of these.

No regulatory action was required for active constituents involving agricultural chemical products and human health in 2011.

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 ethoxylate

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Headache (1)
Irritation (eye) (1)
Lethargy (1)
Nausea (1)
Respiratory problems (1)
Swelling (local) (1)

Alpha-cypermethrin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	1	4

Presenting signs (probable and possible)

Headache (3)
Lethargy (3)
Nausea (2)
Confusion (1)
Dizziness (1)
Irritation (eye) (1)
Irritation (skin) (1)
Listless (1)
Respiratory problems (1)
Swelling (local) (1)

Betacyfluthrin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Burning sensation (1) Headache (1) Odour (1)

Bioallethrin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Paraesthesia (1) Respiratory problems (1) Swollen (lips) (1)

Bioresmethrin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Paraesthesia (1) Respiratory problems (1) Swollen (lips) (1)

Deltamethrin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Coughing (1) Respiratory problems (1) Swelling (local) (1)

D-tetramethrin 20:80

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Coughing (1)
Respiratory problems (1)
Swelling (local) (1)

Fluazifop-p present as the butyl ester

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Headache (2)
Irritation (skin) (2)
Coughing (1)
Irritation (eye) (2)
Respiratory problems (2)

Nonyl phenol ethylene oxide condensate non-ionic organic

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Burning sensation (1)
Headache (1)
Odour (1)

Oryzalin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Nausea (1)

Oxyfluorfen

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Nausea (1)

Piperonyl butoxide

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Coughing (1)
Respiratory problems (1)
Swelling (local) (1)

Synthetic latex

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Headache (1)
Irritation (eye) (1)
Lethargy (1)
Nausea (1)
Respiratory problems (1)
Swelling (local) (1)

Tetramethrin 20:80

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Paraesthesia (1)
Respiratory problems (1)
Swollen (lips) (1)

7 GLOSSARY

Abscess	A collection of pus that has accumulated within a tissue
Alopecia	Absence of hair from areas where it is normally present
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
Ataxia	Unsteady walking action due to muscular incoordination
Bradycardia	Excessive slowness in the action of the heart
Colic	A general term for abdominal pain
Cyanosis	Cyanosis is a physical sign causing bluish discoloration of the skin and mucous membranes due to a lack of oxygen in the blood
Dermatitis	Inflammation of the skin
Dyspnoea	Laboured breathing
Epiphora	Diseases of the lacrimal apparatus
Erythema	Abnormal redness of the skin due to local congestion, as in inflammation
Fasciculation	Involuntary contractions or twitching of groups of muscle fibres
Haemorrhage	Bleeding
Hepatopathy	Disease or disorder of the liver
Hypersalivation	Excessive salivation
Hypersensitivity	An excessive reaction to an allergen
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
Oedema	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
Preputial	Of or pertaining to the prepuce
Prolapse	To fall or slip out of place
Pruritis	Irritation and intense itching
Pyrexia	High fever
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
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

8 INDEX OF ACTIVE CONSTITUENTS