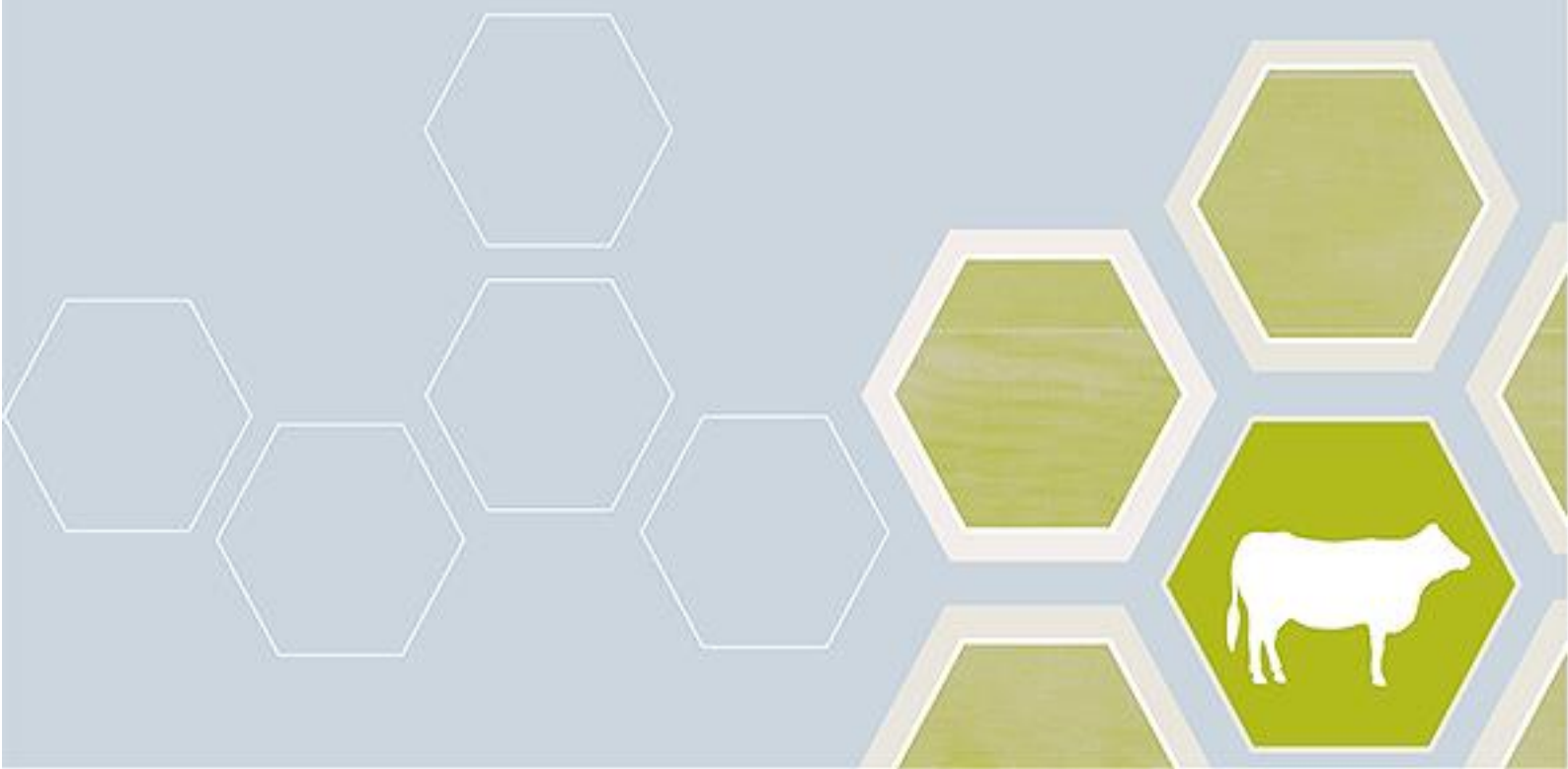




Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



REPORT OF ADVERSE EXPERIENCES

FOR VETERINARY MEDICINES AND AGRICULTURAL CHEMICALS

2012

JULY 2014

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ISSN: 1443-1343 (electronic)

ISBN: 978-1-922188-71-7 (electronic)

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The Manager, Public Affairs
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604 Australia

Telephone: +61 2 6210 4701

Email: communications@apvma.gov.au

This publication is available from the APVMA website: www.apvma.gov.au.

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EXECUTIVE SUMMARY

Adverse Experience Reporting Program (AERP)

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

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

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

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

Assessments and classification in 2012

This report summarises the findings of AERP assessments of adverse experiences reports in 2012.

The APVMA assessed and classified 2112 adverse experience reports involving registered veterinary medicines. Of these adverse experience reports, 76 per cent involved animal safety, 21 per cent involved lack of efficacy and 3 per cent involved human health issues.

The APVMA assessed and classified 60 adverse experiences involving agricultural chemical products. Of these, 52 per cent involved human health issues, 45 per cent involved effects on crops or animals, 2 per cent involved lack of efficacy, and 1 per cent involved effects on the environment.

The APVMA assessed 101 reports relating to adverse experiences from registered veterinary medicines and agricultural chemicals involving effects on human health. Of these, 26 were classified as *probable or possible*, 55 as *off-label* (used contrary to label instructions) and 20 as *unlikely or unknown*.

No adverse experience assessed and classified by the APVMA in 2012 required a major regulatory action against any registered product.

More information

For more information about the AERP, contact the APVMA:

Phone: +61 2 6210 4806

Fax: +61 2 6210 4840

Email: aerp@apvma.gov.au

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 2012 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-arthritis 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 Vet and AERP Ag is one method by which registrants can meet certain legislative obligations of Section 161 of the *Agvet Code*.

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

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

Reporting off-label adverse experiences

The scope of the AERP does not cover reports involving the off-label use of registered products and therefore these adverse experiences are not included in this report. However, the APVMA 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 agency in another 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 or warnings.
- Suspending and/or cancelling the registration of a product.
- Reviewing the active constituent of a product under the APVMA's Chemical Review Program.
- Referring for action, such as compliance action 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 sold¹.
- The APVMA may take regulatory action if, for a particular product:
 - the reporting incidence is greater than one per 10 000 in two out of three consecutive years
 - an exceptional incidence of three or more per 10 000 occurs on any one occasion, or
 - a consistent rising trend is seen over 5 years (irrespective of the reporting incidence).
- The APVMA also considers available scientific literature and information relating to trend analysis and risk assessment when determining if regulatory action is required.

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

- In addition, the APVMA considers if the noted presenting signs (adverse experiences) are listed in warning statements on the product label, in which case a higher reporting incidence may be acceptable. It also considers the severity of presenting signs (more severe signs may trigger regulatory action at a lower reporting incidence).

1.6 Assessments and classifications in 2012

In 2012, a total of 2112 adverse experience reports involving registered veterinary products were assessed and classified.

- Of these adverse experience reports, 76 per cent involved animal safety, 21 per cent involved lack of efficacy and 3 per cent involved human health issues (Figure 1).
- Of the 2112 adverse experiences reports assessed under the AERP Vet, 1286 were classified as either *probable* or *possible*.

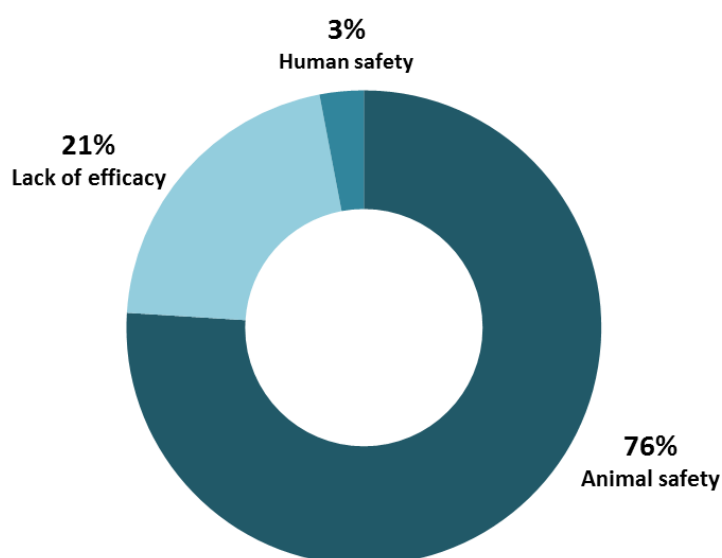


Figure 1. Adverse experience reports involving registered veterinary medicines processed and finalised in 2012.

In 2012, a total of sixty adverse experience reports involving agricultural products were assessed and classified.

- Of these adverse experience reports processed and classified, 52 per cent involved human health issues, 45 per cent involved effects on crops or animals, 2 per cent involved lack of efficacy, and 1 per cent involved effects on the environment (Figure 2).

- Of the 60 reports assessed under the AERP Ag, 20 were classified as *probable* or *possible*.

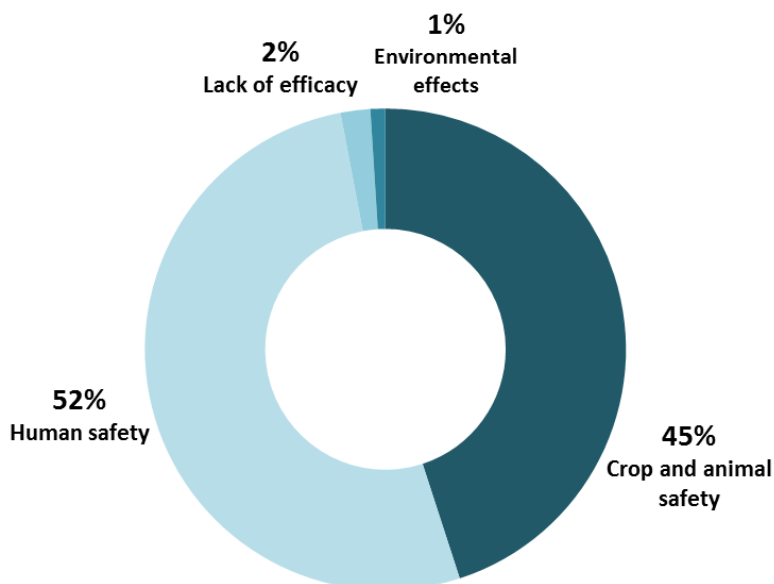


Figure 2. Adverse experience reports involving registered agriculture chemicals processed and finalised in 2012.

A total of 101 adverse experiences involving effects on humans from registered veterinary medicines and agricultural chemical products were reported in 2012. Of these, 26 were classified as *probable* or *possible*, 55 were classified as *off-label* and 20 were classified as *unlikely* or *unknown*.

No adverse experience assessed and classified by the APVMA in 2012 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 in 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 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 2012.

The APVMA assessed and classified 2112 adverse experience involving registered veterinary medicines in 2012. The largest proportion of reports involved animal safety (76%) followed by lack of efficacy (21%).

No regulatory action was required for active constituents involving veterinary medicines and animals in 2012, as the frequency of adverse experience reports received was relatively low compared with the total number of doses sold. The number of doses sold is used to estimate the size of the treated populations.

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

Abalone Powder

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	5	0

Presenting signs (probable and possible)

Vomiting (2)	Diarrhoea (1)	Urine (abnormal) (1)
Alopecia (1)	Erythema (1)	

Abamectin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Dermatitis (1)	Irritation (skin) (1)	Scabs (1)
----------------	-----------------------	-----------

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Lack of effect (2)	Scabs (1)	Wool damage (1)
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Acepromazine as Acepromazine Maleate

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)

Agelpristone

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Albendazole

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Death (1)

Malaise (1)

Alphaxalone

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Hypotension (1)

Recovery (poor) (1)

Pulmonary oedema (1)

Wheals (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Erythema (1)	Respiratory problems (1)
Oedema (1)	Wheals (1)

Aluminium hydroxide

Aluminium hydroxide is a compound commonly used as an adjuvant in vaccines. It stabilises vaccine proteins, preventing the vaccine from adhering to the glass container. It is also thought to enhance the immune response to vaccination. Because this active constituent is present in a number of vaccine products, it is reasonable to expect a larger number of reports to be associated with its use. The most commonly reported presenting signs were the occurrence of a localised lump and injection site reaction.

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

Aluminium hydroxide*Canine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
51	7	44

Presenting signs (probable and possible)

Lump (local) (23)	Collapse (1)	Swollen ears and face (1)
Injection site reaction (17)	Frothing at the mouth (1)	Tachycardia (1)
Site reaction (swelling) (4)	Pain (1)	Tachypnoea (1)
Diarrhoea (2)	Pyrexia (1)	Vomiting (1)
Facial oedema (2)	Recumbency (1)	
Lethargy (2)	Seizure (1)	

Amitraz*Canine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Lack of effect (2)

Amphotericin B

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	0	6

Presenting signs (probable and possible)

Anorexia (5)	Hypotension (1)	Vomiting (1)
Lethargy (5)	Pain (1)	
Diarrhoea (1)	Pyrexia (1)	

Benazepril hydrochloride

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Diarrhoea (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Vomiting (1)

Benzathine Penicillin

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anaphylaxis (1) Death (1)

Betamethasone valerate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Deafness (1)

Pain (1)

Bordetella bronchiseptica vaccines

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

The most commonly reported presenting signs include coughing, lethargy and injection-site reaction (inactivated, cell-free vaccine) and 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 2012 (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
78	7	71

Presenting signs (probable and possible)

Coughing (24)	Immune-mediated haemolytic anaemia (2)	Hyperaesthesia (1)
Lethargy (17)	Lymphadenopathy (2)	Inflammation (1)
Sneezing (10)	Pruritis (2)	Lack of effect (1)
Respiratory problems (7)	Urticaria (2)	Nystagmus (1)
Facial oedema (6)	Abdominal pain (1)	Ocular discharge (1)
Nasal discharge (6)	Allergy (1)	Oral (lesions) (1)
Vomiting (6)	Anaphylactoid reaction (1)	Paddling (1)
Injection site reaction (5)	Arthropathy (1)	Pain (1)
Anaphylaxis (4)	Behavioural change (1)	Pale mucous membranes (1)
Diarrhoea (4)	Cardiac arrest (1)	Panting (1)
Lump (local) (3)	Collapse (1)	Seroma (1)
Pyrexia (3)	Cyanosis (1)	Swelling (local) (1)
Anorexia (2)	Dyspnoea (1)	Syncope (1)
Death (2)	Halitosis (1)	Tachypnoea (1)
Depression (2)		Thrombocytopenia (1)

Bordetella bronchiseptica (inactivated cell free extract)*Canine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
52	7	45

Presenting signs (probable and possible)

Lump (local) (23)	Collapse (1)	Recumbency (1)
Injection site reaction (17)	Frothing at the mouth (1)	Seizure (1)
Site reaction (swelling) (4)	Immune-mediated haemolytic anaemia (1)	Swollen ears and face (1)
Diarrhoea (2)	Pain (1)	Tachycardia (1)
Facial oedema (2)	Pyrexia (1)	Tachypnoea (1)
Lethargy (2)		Vomiting (1)

Bordetella bronchiseptica* killed vaccine**Canine***

NUMBER OF REPORTS	PROBABLE	POSSIBLE
36	2	34

Presenting signs (probable and possible)

Facial oedema (18)	Pruritis (3)	Nausea (1)
Vomiting (15)	Weakness (3)	Oedema (1)
Defaecation (6)	Bradycardia (2)	Pain (1)
Lethargy (6)	Diarrhoea (2)	Pawing at face (1)
Pale mucous membranes (6)	Dyspnoea (2)	Pyrexia (1)
Hives (5)	Hypersalivation (2)	Recumbency (1)
Collapse (4)	Tachycardia (2)	Red eyes (1)
Anaphylaxis (3)	Urticaria (2)	Swelling (local) (1)
Capillary refill time (slow) (3)	Abscess (1)	Swollen lips and face (1)
Cyanosis (3)	Agitation (1)	Tachypnoea (1)
Erythema (3)	Ataxia (1)	Urination (1)

Calcium Gluconate***Feline***

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anaphylaxis (1)	Urticaria (1)	Vomiting (1)
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Calcium Lactobionate***Feline***

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anaphylaxis (1)	Urticaria (1)	Vomiting (1)
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Canine adenovirus type 2 vaccines

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

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

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

The number of reports associated with canine adenovirus vaccine strains vaccine strains is low when compared with the number of doses sold in 2012 (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
92	5	87

Presenting signs (probable and possible)

Lack of effect (27)	Diarrhoea (3)	Ocular discharge (1)
Facial oedema (20)	Erythema (3)	Pain (1)
Vomiting (17)	Bradycardia (2)	Pawing at face (1)
Lethargy (10)	Dyspnoea (2)	Periorbital swelling (1)
Coughing (8)	Hypersalivation (2)	Recumbency (1)
Pale mucous membranes (7)	Nasal discharge (2)	Red eyes (1)
Sneezing (7)	Pyrexia (2)	Seroma (1)
Defaecation (6)	Swelling (local) (2)	Swollen (lips) (1)
Anaphylaxis (5)	Abscess (1)	Swollen ears and face (1)
Collapse (5)	Agitation (1)	Swollen lips and face (1)
Hives (5)	Anaphylactoid reaction (1)	Tachycardia (1)
Pruritis (5)	Anorexia (1)	Tachypnoea (1)
Respiratory problems (4)	Ataxia (1)	Urination (1)
Weakness (4)	Haemorrhagic gastroenteritis (1)	Urticaria (1)
Capillary refill time (slow) (3)	Immune-mediated haemolytic anaemia (1)	Welts (1)
Cyanosis (3)	Lymphadenopathy (1)	
Death (3)	Nausea (1)	

Canine adenovirus type 2 - live (infectious hepatitis)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
42	0	42

Presenting signs (probable and possible)

Lump (local) (20)	Pain (1)	Tachycardia (1)
Injection site reaction (13)	Pyrexia (1)	Tachypnoea (1)
Lack of effect (4)	Recumbency (1)	Vomiting (1)
Diarrhoea (2)	Seizure (1)	
Lethargy (2)	Site reaction (swelling) (1)	

Canine adenovirus type 2 live (CAV II)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Death (1)	Immune-mediated haemolytic anaemia (1)	Tachycardia (1)
Diarrhoea (1)	Oedema (1)	Vomiting (1)

Canine adenovirus type 2 strain Manhattan - live

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
36	0	36

Presenting signs (probable and possible)

Lethargy (9)	Pyrexia (2)	Lymphadenopathy (1)
Lack of effect (8)	Urticaria (2)	Oral (lesions) (1)
Injection site reaction (5)	Anaphylaxis (1)	Panting (1)
Vomiting (5)	Anorexia (1)	Pruritis (1)
Facial oedema (4)	Arthropathy (1)	Respiratory problems (1)
Lump (local) (4)	Behavioural change (1)	Thrombocytopenia (1)
Diarrhoea (3)	Coughing (1)	
Depression (2)	Halitosis (1)	

Canine coronavirus vaccine - antigen

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

Presenting signs (probable and possible)

Anaphylaxis (3)	Death (2)	Swollen ears and face (1)
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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, lethargy, injection site reaction, facial oedema and vomiting. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this immune response is also responsible for most of the presenting signs observed.

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

The number of reports associated with canine distemper virus vaccine strains is low when compared with the number of doses sold in 2012 (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

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Facial oedema (1)

Injection site reaction (1)

Canine distemper virus

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
76	4	72

Presenting signs (probable and possible)

Lack of effect (27)	Bradycardia (2)	Pyrexia (1)
Facial oedema (20)	Death (2)	Recumbency (1)
Vomiting (17)	Dyspnoea (2)	Red eyes (1)
Lethargy (7)	Hypersalivation (2)	Seroma (1)
Pale mucous membranes (7)	Swelling (local) (2)	Sneezing (1)
Defaecation (6)	Abscess (1)	Swollen (lips) (1)
Anaphylaxis (5)	Agitation (1)	Swollen ears and face (1)
Hives (5)	Anaphylactoid reaction (1)	Swollen lips and face (1)
Pruritis (5)	Anorexia (1)	Tachycardia (1)
Collapse (4)	Ataxia (1)	Tachypnoea (1)
Weakness (4)	Immune-mediated haemolytic anaemia (1)	Urination (1)
Capillary refill time (slow) (3)	Nausea (1)	Urticaria (1)
Cyanosis (3)	Pain (1)	Welts (1)
Diarrhoea (3)	Pawing at face (1)	
Erythema (3)	Periorbital swelling (1)	

Canine distemper virus - living

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
48	0	48

Presenting signs (probable and possible)

Lump (local) (20)	Tachycardia (2)	Ocular discharge (1)
Injection site reaction (13)	Vomiting (2)	Oedema (1)
Lack of effect (4)	Collapse (1)	Pain (1)
Diarrhoea (3)	Coughing (1)	Recumbency (1)
Lethargy (3)	Haemorrhagic gastroenteritis (1)	Seizure (1)
Death (2)	Immune-mediated haemolytic anaemia (1)	Site reaction (swelling) (1)
Pyrexia (2)	Lymphadenopathy (1)	Tachypnoea (1)

Canine distemper virus strain Onderstepoort

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
36	0	36

Presenting signs (probable and possible)Lethargy (9)

Lack of effect (8)	Pyrexia (2)	Halitosis (1)
Injection site reaction (5)	Urticaria (2)	Lymphadenopathy (1)
Vomiting (5)	Anaphylaxis (1)	Oral (lesions) (1)
Facial oedema (4)	Anorexia (1)	Panting (1)
Lump (local) (4)	Arthropathy (1)	Pruritis (1)
Diarrhoea (3)	Behavioural change (1)	Respiratory problems (1)
Depression (2)	Coughing (1)	Thrombocytopenia (1)

Canine parainfluenza vaccines

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

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

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

The number of reports associated with canine parainfluenza virus vaccine strains is low when compared with the number of doses sold in 2012 (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
17	1	16

Presenting signs (probable and possible)

Coughing (7)	Anaphylaxis (2)	Facial oedema (1)
Sneezing (6)	Death (2)	Pruritis (1)
Respiratory problems (4)	Nasal discharge (2)	Vomiting (1)
Lethargy (3)	Anorexia (1)	

Canine parainfluenza virus type 2

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
55	3	52

Presenting signs (probable and possible)

Facial oedema (18)	Erythema (3)	Recumbency (1)
Lack of effect (17)	Bradycardia (2)	Red eyes (1)
Vomiting (15)	Diarrhoea (2)	Sneezing (1)
Pale mucous membranes (7)	Dyspnoea (2)	Swelling (local) (1)
Defaecation (6)	Hypersalivation (2)	Swollen (lips) (1)
Lethargy (6)	Abscess (1)	Swollen lips and face (1)
Hives (5)	Agitation (1)	Tachycardia (1)
Collapse (4)	Ataxia (1)	Tachypnoea (1)
Pruritis (4)	Nausea (1)	Urination (1)
Weakness (4)	Pain (1)	Urticaria (1)
Anaphylaxis (3)	Pawing at face (1)	Welts (1)
Capillary refill time (slow) (3)	Periorbital swelling (1)	
Cyanosis (3)	Pyrexia (1)	

Canine parainfluenza virus

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
61	6	55

Presenting signs (probable and possible)

Coughing (16)	Allergy (1)	Ocular discharge (1)
Lethargy (14)	Anaphylactoid reaction (1)	Oedema (1)
Vomiting (6)	Anaphylaxis (1)	Oral (lesions) (1)
Diarrhoea (5)	Anorexia (1)	Paddling (1)
Facial oedema (5)	Arthropathy (1)	Pain (1)
Injection site reaction (5)	Behavioural change (1)	Pale mucous membranes (1)
Nasal discharge (4)	Cardiac arrest (1)	Panting (1)
Immune-mediated haemolytic anaemia (3)	Collapse (1)	Pruritis (1)
Lump (local) (3)	Cyanosis (1)	Seroma (1)
Pyrexia (3)	Death (1)	Swelling (local) (1)
Respiratory problems (3)	Dyspnoea (1)	Syncope (1)
Sneezing (3)	Halitosis (1)	Tachycardia (1)
Depression (2)	Hyperaesthesia (1)	Tachypnoea (1)
Lymphadenopathy (2)	Inflammation (1)	Thrombocytopenia (1)
Urticaria (2)	Lack of effect (1)	
Abdominal pain (1)	Nystagmus (1)	

Canine parainfluenza virus - inactivated

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
51	7	44

Presenting signs (probable and possible)

Lump (local) (23)	Collapse (1)	Swollen ears and face (1)
Injection site reaction (17)	Frothing at the mouth (1)	Tachycardia (1)
Site reaction (swelling) (4)	Pain (1)	Tachypnoea (1)
Diarrhoea (2)	Pyrexia (1)	Vomiting (1)
Facial oedema (2)	Recumbency (1)	
Lethargy (2)	Seizure (1)	

Canine parvovirus vaccines

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

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

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

The number of reports associated with canine parvovirus vaccine strains is low when compared with the number of doses sold in 2012 (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
77	4	73

Presenting signs (probable and possible)

Lack of effect (27)	Bradycardia (2)	Pawing at face (1)
Facial oedema (20)	Death (2)	Periorbital swelling (1)
Vomiting (17)	Dyspnoea (2)	Pyrexia (1)
Lethargy (7)	Hypersalivation (2)	Recumbency (1)
Pale mucous membranes (7)	Swelling (local) (2)	Red eyes (1)
Defaecation (6)	Tachycardia (2)	Seroma (1)
Anaphylaxis (5)	Abscess (1)	Sneezing (1)
Hives (5)	Agitation (1)	Swollen (lips) (1)
Pruritis (5)	Anaphylactoid reaction (1)	Swollen ears and face (1)
Collapse (4)	Anorexia (1)	Swollen lips and face (1)
Weakness (4)	Ataxia (1)	Tachypnoea (1)
Capillary refill time (slow) (3)	Immune-mediated haemolytic anaemia (1)	Urination (1)
Cyanosis (3)	Nausea (1)	Urticaria (1)
Diarrhoea (3)	Oedema (1)	Welts (1)
Erythema (3)	Pain (1)	

Canine parvovirus type 2

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	0	5

Presenting signs (probable and possible)

Death (2)	Haemorrhagic gastroenteritis (1)	Lymphadenopathy (1)
Collapse (1)	Immune-mediated haemolytic anaemia (1)	Ocular discharge (1)
Coughing (1)	Lethargy (1)	Pyrexia (1)
Diarrhoea (1)		Vomiting (1)

Canine parvovirus - live

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
42	0	42

Presenting signs (probable and possible)

Lump (local) (20)	Pain (1)	Tachycardia (1)
Injection site reaction (13)	Pyrexia (1)	Tachypnoea (1)
Lack of effect (4)	Recumbency (1)	Vomiting (1)
Diarrhoea (2)	Seizure (1)	
Lethargy (2)	Site reaction (swelling) (1)	

Canine parvovirus strain 154 - live

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
36	0	36

Presenting signs (probable and possible)

Lethargy (9)	Pyrexia (2)	Lymphadenopathy (1)
Lack of effect (8)	Urticaria (2)	Oral (lesions) (1)
Injection site reaction (5)	Anaphylaxis (1)	Panting (1)
Vomiting (5)	Anorexia (1)	Pruritis (1)
Facial oedema (4)	Arthropathy (1)	Respiratory problems (1)
Lump (local) (4)	Behavioural change (1)	Thrombocytopenia (1)
Diarrhoea (3)	Coughing (1)	
Depression (2)	Halitosis (1)	

Cefovecin as sodium salt

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anaphylaxis (1)	Death (1)
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Cephalexin as cephalexin monohydrate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Hypersensitivity reaction (1) Vomiting (1)

Chlamydophila felis Baker strain—live, attenuated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
15	6	9

Presenting signs (probable and possible)

Lethargy (11)	Vomiting (2)	Hypersensitivity reaction (1)
Anorexia (6)	Agitation (1)	Injection site reaction (1)
Pyrexia (4)	Alopecia (localised) (1)	Pain (1)
Facial oedema (3)	Anaphylaxis (1)	Self trauma (1)
Hyperaesthesia (3)	Diarrhoea (1)	Tachycardia (1)
Erythema (2)	Hypersalivation (1)	Tachypnoea (1)

Chlorfenvinphos

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Chlorhexidine digluconate

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Chlorhexidine gluconate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	2	2

Presenting signs (probable and possible)

Erythema (3)

Irritation (paws) (1)

Welts (1)

Agitation (1)

Pruritis (1)

Inflammation (1)

Restless (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Respiratory problems (1)

Chondroitin sulfate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Vomiting (1)

Clomipramine hydrochloride

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Anorexia (2)

Vomiting (2)

Hepatopathy (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

Presenting signs (probable and possible)

Urinary retention (3)

Constipation (1)

Lethargy (1)

Closantel

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

Clostridium chauvoei—killed

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lethargy (1)

Pain (1)

Stiffness (1)

Clostridium chauvoei–toxoid*Caprine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lethargy (1)

Pain (1)

Stiffness (1)

Clostridium novyi type B - killed*Caprine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lethargy (1)

Pain (1)

Stiffness (1)

Clostridium novyi type B - toxoid*Caprine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lethargy (1)

Pain (1)

Stiffness (1)

Clostridium perfringens type D toxoid*Caprine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lethargy (1)

Pain (1)

Stiffness (1)

Clostridium septicum - toxoid*Caprine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lethargy (1)

Pain (1)

Stiffness (1)

Clostridium tetani - toxoid*Caprine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lethargy (1)

Pain (1)

Stiffness (1)

Clotrimazole

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Deafness (2)

Pain (1)

Cobalt EDTA

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Collapse (1)

Fasciculation (1)

Coronavirus

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Facial oedema (1)

Injection site reaction (1)

Cupric Oxide

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Cyclosporin

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
11	6	5

Presenting signs (probable and possible)

Vomiting (10)

Diarrhoea (3)

Pruritis (1)

Cyclosporin A

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Ocular pathology (1)

Cypermethrin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Lack of effect (2)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Cyromazine

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Lack of effect (2)

Cythioate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anorexia (1)

Diarrhoea (1)

Vomiting (1)

Deltamethrin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

Presenting signs (probable and possible)

Lack of effect (4)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Deslorelin as deslorelin acetate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
7	6	1

Presenting signs (probable and possible)

Lack of effect (3)

Lethargy (1)

Recovery (prolonged) (1)

Injection site reaction (1)

Low efficacy (1)

Swelling (local) (1)

Dexamethasone Phenylpropionate

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Agitation (1)

Wheals (1)

Dexamethasone Sodium Phosphate

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Agitation (1)

Wheals (1)

Diazinon

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Death (1)

Poisoning (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
10	0	10

Presenting signs (probable and possible)

Lack of effect (8)

Alopecia (1)

Coat discoloration (1)

Dicyclanil

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Lack of effect (3)

Diflubenzuron

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

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

Diflubenzuron

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
18	0	18

Presenting signs (probable and possible)

Lack of effect (16)

Lesions (2)

Necrosis (2)

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 2012 (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
8	2	6

Presenting signs (probable and possible)

Anorexia (2)	Death (1)	Sneezing (1)
Injection site reaction (2)	Illness (1)	Stiffness (1)
Lethargy (2)	Pain (1)	Tachycardia (1)
Vomiting (2)	Pyrexia (1)	

Feline calicivirus - Inactivated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
26	12	14

Presenting signs (probable and possible)

Lethargy (14)	Pain (2)	Hypersensitivity reaction (1)
Anorexia (7)	Swollen (ears) (2)	Hypotension (1)
Pyrexia (6)	Swollen feet (2)	Injected mucous membranes (1)
Vomiting (6)	Tachycardia (2)	Muscle twitching (1)
Facial oedema (5)	Tachypnoea (2)	Oedema (1)
Diarrhoea (3)	Agitation (1)	Periorbital swelling (1)
Erythema (3)	Anaphylaxis (1)	Self trauma (1)
Hyperaesthesia (3)	Ataxia (1)	Seroma (1)
Alopecia (localised) (2)	Blood in faeces (1)	Swollen (lips) (1)
Hypersalivation (2)	Collapse (1)	
Injection site reaction (2)	Haematemesis (1)	

Feline calicivirus - live

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Dyspnoea (1)	Pyrexia (1)	Respiratory problems (1)
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Feline *chlamydia psittaci*—inactivated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Muscle twitching (1)

Feline immunodeficiency virus (Petaluma strain) inactive

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	0	6

Presenting signs (probable and possible)

Alopecia (localised) (2)

Dyspnoea (1)

Respiratory problems (1)

Erythema (2)

Haematemesis (1)

Stiffness (1)

Lethargy (2)

Hypotension (1)

Swollen (ears) (1)

Pyrexia (2)

Injection site reaction (1)

Tachycardia (1)

Blood in faeces (1)

Pain (1)

Vomiting (1)

Diarrhoea (1)

Periorbital swelling (1)

Feline leukaemia virus - inactivated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
15	6	9

Presenting signs (probable and possible)

Lethargy (11)

Facial oedema (2)

Hypotension (1)

Anorexia (7)

Hyperaesthesia (2)

Injection site reaction (1)

Pyrexia (5)

Pain (2)

Muscle twitching (1)

Vomiting (3)

Anaphylaxis (1)

Tachycardia (1)

Diarrhoea (2)

Hypersensitivity reaction (1)

Tachypnoea (1)

Feline panleukopenia virus vaccines

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

The most commonly reported presenting signs include anorexia, lethargy, 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 panleukopenia virus vaccine strains is low when compared with the number of doses sold in 2012 (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 panleukopenia

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
8	2	6

Presenting signs (probable and possible)

Anorexia (2)	Death (1)	Sneezing (1)
Injection site reaction (2)	Illness (1)	Stiffness (1)
Lethargy (2)	Pain (1)	Tachycardia (1)
Vomiting (2)	Pyrexia (1)	

Feline panleucopenia virus - inactivated

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
26	12	14

Presenting signs (probable and possible)

Lethargy (14)	Pain (2)	Hypersensitivity reaction (1)
Anorexia (7)	Swollen (ears) (2)	Hypotension (1)
Pyrexia (6)	Swollen feet (2)	Injected mucous membranes (1)
Vomiting (6)	Tachycardia (2)	Muscle twitching (1)
Facial oedema (5)	Tachypnoea (2)	Oedema (1)
Diarrhoea (3)	Agitation (1)	Periorbital swelling (1)
Erythema (3)	Anaphylaxis (1)	Self trauma (1)
Hyperaesthesia (3)	Ataxia (1)	Seroma (1)
Alopecia (localised) (2)	Blood in faeces (1)	Swollen (lips) (1)
Hypersalivation (2)	Collapse (1)	
Injection site reaction (2)	Haematemesis (1)	

Feline panleucopenia virus - live

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Dyspnoea (1)	Pyrexia (1)	Respiratory problems (1)
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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 and pyrexia. These symptoms occur occasionally with vaccines of this type. Vaccines act by stimulating an immune response, which protects the animal from serious illnesses. However, this immune response is also responsible for most of the presenting signs observed.

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

The number of reports associated with feline rhinotracheitis virus vaccine strains is low when compared with the number of doses sold in 2012 (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
26	12	14

Presenting signs (probable and possible)

Lethargy (14)	Pain (2)	Hypersensitivity reaction (1)
Anorexia (7)	Swollen (ears) (2)	Hypotension (1)
Pyrexia (6)	Swollen feet (2)	Injected mucous membranes (1)
Vomiting (6)	Tachycardia (2)	Muscle twitching (1)
Facial oedema (5)	Tachypnoea (2)	Oedema (1)
Diarrhoea (3)	Agitation (1)	Periorbital swelling (1)
Erythema (3)	Anaphylaxis (1)	Self trauma (1)
Hyperaesthesia (3)	Ataxia (1)	Seroma (1)
Alopecia (localised) (2)	Blood in faeces (1)	Swollen (lips) (1)
Hypersalivation (2)	Collapse (1)	
Injection site reaction (2)	Haematemesis (1)	

Fenbendazole

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

Fipronil

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

The most commonly reported presenting signs included pruritis, site reaction, erythema and localised alopecia.

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

Updates on the progress of the review are available on the APVMA website:

www.apvma.gov.au/products/review/current/fipronil.php

Fipronil

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
97	37	60

Presenting signs (probable and possible)

Pruritis (23)	Pyoderma (4)	Diarrhoea (1)
Site reaction (22)	Vomiting (4)	Hypersalivation (1)
Erythema (19)	Coat discoloration (3)	Hypersensitivity reaction (1)
Alopecia (localised) (15)	Pain (3)	Listless (1)
Scabs (8)	Rubbing (3)	Lump (local) (1)
Alopecia (7)	Self trauma (3)	Mydriasis (1)
Behavioural change (7)	Dermatitis (2)	Odour (1)
Lack of effect (7)	Panting (2)	Restless (1)
Inflammation (6)	Papules (2)	Swollen (lips) (1)
Anorexia (5)	Site reaction (swelling) (2)	Unknown (1)
Irritation (skin) (5)	Ulceration (2)	Welts (1)
Lethargy (5)	Agitation (1)	Wheals (1)
Coat colour change (4)	Allergy (1)	
Lesions (4)	Crusting skin (1)	

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
44	31	13

Presenting signs (probable and possible)

Alopecia (localised) (28)	Papules (2)	Pain (1)
Erythema (18)	Rash (2)	Pyoderma (1)
Alopecia (8)	Site reaction (2)	Scabs (1)
Pruritis (6)	Dermatitis (1)	Swelling (local) (1)
Behavioural change (5)	Hypersalivation (1)	Ulceration (1)
Inflammation (3)	Irritation (skin) (1)	Vomiting (1)
Anorexia (2)	Lesions (1)	
Lack of effect (2)	Lethargy (1)	

Firocoxib*Canine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
7	2	5

Presenting signs (probable and possible)

Vomiting (3)	Lethargy (1)	Papules (1)
Blood in faeces (2)	Melaena (1)	Pruritis (1)
Diarrhoea (2)	Pancreatitis (1)	

Fluoxetine Hydrochloride*Canine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
13	5	8

Presenting signs (probable and possible)

Anorexia (4)	Aggression (1)	Lack of effect (1)
Incontinence (3)	Ataxia (1)	Sedation (1)
Lethargy (3)	Behavioural change (1)	Seizure (1)
Vomiting (3)	Diarrhoea (1)	

Gentamicin

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Deafness (1)

Papules (1)

Gentamicin sulfate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Deafness (1)

Glucosamine hydrochloride

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Vomiting (1)

GNRF - protein conjugate

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Anaphylactoid reaction (1)

Death (1)

Hepatitis Canine = Canine adenovirus

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Facial oedema (1)

Injection site reaction (1)

Imidacloprid

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	3	1

Presenting signs (probable and possible)

Paraesthesia (3)

Behavioural change (1)

Self trauma (1)

Anorexia (1)

Diarrhoea (1)

Site reaction (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Irritation (skin) (1)

Self trauma (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Burn(s) (1)

Lack of effect (1)

Necrosis (1)

Inactivated bovine herpes virus type 1.2B

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anorexia (1)

Injection site reaction (1)

Pyrexia (1)

Depression (1)

Lymphadenopathy (1)

Inactivated bovine pestivirus - Bega strain

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Inactivated bovine pestivirus - Trangie strain

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Inactivated *Mannheimia haemolytica* strain X387*Bovine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anorexia (1)

Injection site reaction (1)

Pyrexia (1)

Depression (1)

Lymphadenopathy (1)

Insulin

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Ivermectin

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Lack of effect (2)

Blisters (1)

Alopecia (localised) (1)

Papules (1)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Collapse (1)

Diarrhoea (1)

Vomiting (1)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Swelling (local) (1)

Swollen lips and face (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Lack of effect (2)

Collapse (1)

Fasciculation (1)

Lactic acid*Feline*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Deafness (1)

Prolapsed third eyelid (1)

Leptospira icterohaemorrhagiae antigen*Canine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

Presenting signs (probable and possible)

Anaphylaxis (3)

Death (2)

Swollen ears and face (1)

Leptospirosis - Dog- *Leptospira Icterohaemorrhagiae*

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Facial oedema (1) Injection site reaction (1)

Levamisole hydrochloride

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Abdominal pain (1) Rolling (1)
Milk production decrease (1) Scouring (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Collapse (1) Fasciculation (1)

Lignocaine hydrochloride

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1)

Live feline herpes virus

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
9	2	7

Presenting signs (probable and possible)

Anorexia (2)	Death (1)	Sneezing (1)
Injection site reaction (2)	Dyspnoea (1)	Stiffness (1)
Lethargy (2)	Illness (1)	Tachycardia (1)
Pyrexia (2)	Pain (1)	
Vomiting (2)	Respiratory problems (1)	

Lufenuron

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
13	4	9

Presenting signs (probable and possible)

Vomiting (7)	Diarrhoea (2)	Facial oedema (1)
Lethargy (5)	Pruritis (2)	Lack of effect (1)
Anorexia (2)	Blood in faeces (1)	

Mavacoxib

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	1	3

Presenting signs (probable and possible)

Vomiting (3)	Renal failure (2)	Melaena (1)
Anorexia (2)	Death (1)	Seizure (1)
Lethargy (2)	Diarrhoea (1)	Ulceration (stomach) (1)

Melarsomine dihydrochloride

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lump (local) (1)

Site reaction (swelling) (1)

Meloxicam

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

Presenting signs (probable and possible)

Vomiting (2)

Pruritis (1)

Diarrhoea (1)

Ulceration (stomach) (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anaphylaxis (1)

Death (1)

Miconazole nitrate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	2	3

Presenting signs (probable and possible)

Erythema (3)

Inflammation (1)

Restless (1)

Agitation (1)

Irritation (paws) (1)

Welts (1)

Deafness (1)

Pruritis (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Respiratory problems (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 2012 (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
73	50	23

Presenting signs (probable and possible)

Vomiting (55)

Ataxia (1)

Hypersalivation (1)

Lethargy (14)

Behavioural change (1)

Lack of effect (1)

Diarrhoea (8)

Blood in faeces (1)

Nasal discharge (1)

Anorexia (7)

CNS dysfunction (1)

Nausea (1)

Pruritis (3)

Death (1)

Panting (1)

Depression (2)

Facial oedema (1)

Respiratory problems (1)

Shaking (2)

Hyperaesthesia (1)

Vocalisation (1)

Mometasone furoate monohydrate*Canine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Deafness (1)

Monensin as monensin sodium*Bovine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
27	13	14

Presenting signs (probable and possible)

Lack of effect (12)

Choking (3)

Illness (1)

Regurgitation (11)

Death (2)

Moraxella bovis*Bovine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
15	5	10

Presenting signs (probable and possible)

Lack of effect (10)

Lump (local) (3)

Injection site reaction (5)

Anaphylactoid reaction (1)

Moxidectin*Bovine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Death (1)

Recumbency (1)

Tremor (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Irritation (skin) (1)

Self trauma (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (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, vomiting and lethargy.

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 2012 (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
26	1	25

Presenting signs (probable and possible)

Facial oedema (9)	Pale mucous membranes (2)	Hyperaesthesia (1)
Vomiting (5)	Pruritis (2)	Pain (1)
Lethargy (4)	Abdominal pain (1)	Periorbital swelling (1)
Collapse (3)	Abscess (1)	Pyrexia (1)
Defaecation (3)	Anorexia (1)	Rash (1)
Injection site reaction (3)	Behavioural change (1)	Recumbency (1)
Anaphylactoid reaction (2)	Capillary refill time (slow) (1)	Seizure (1)
Anaphylaxis (2)	Death (1)	Site reaction (1)
Cyanosis (2)	Diarrhoea (1)	Swollen ears and face (1)
Dyspnoea (2)	Frothing at the mouth (1)	Weakness (1)
Erythema (2)	Gastroenteritis (1)	
Hypersalivation (2)	Hives (1)	

Mycobacterium cell wall fraction

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anaphylaxis (1)	Death (1)
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*Mycobacterium paratuberculosis**Ovine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Ataxia (1)

Death (1)

Incoordination (1)

Neomycin*Feline*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	0	6

Presenting signs (probable and possible)

Anorexia (5)

Hypotension (1)

Vomiting (1)

Lethargy (5)

Pain (1)

Diarrhoea (1)

Pyrexia (1)

Neomycin as the sulfate*Canine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Alopecia (localised) (1)

Neomycin sulfate*Feline*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1)

Nitenpyram

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	1	3

Presenting signs (probable and possible)

Vomiting (2)

Inflammation (1)

Rash (1)

Erythema (1)

Pruritis (1)

Scabs (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Hyperactivity (1)

Tachycardia (1)

Tachypnoea (1)

Nitrofurazone

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1)

Nystatin

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Alopecia (localised) (1)

Oatmeal extract

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Rash (1)

Oxantel embonate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	1	3

Presenting signs (probable and possible)

Lethargy (3)

Pruritis (1)

Vomiting (3)

Restless (1)

Oxfendazole

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anorexia (1)

Diarrhoea (1)

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Collapse (1)

Fasciculation (1)

Oxyclozanide

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Abdominal pain (1)

Rolling (1)

Milk production decrease (1)

Scouring (1)

Oxytetracycline hydrochloride

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anaphylactoid reaction (1)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Welts (1)

Parvovirus - live

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Facial oedema (1)

Injection site reaction (1)

Pentosan polysulfate sodium

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
7	4	3

Presenting signs (probable and possible)

Vomiting (2)

Epistaxis (1)

Rash (1)

Ataxia (1)

Injection site reaction (1)

Diarrhoea (1)

Pruritis (1)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

Swelling (local) (1)

Permethrin

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 (25:75:cis:trans)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Shaking (1)

Vomiting (1)

Stiffness (1)

Weakness (1)

Permethrin (40:60: cis:trans)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

Presenting signs (probable and possible)

Paraesthesia (3)

Behavioural change (1)

Self trauma (1)

Phenylpropanolamine hydrochloride

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Incontinence (1)

Pimobendan

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Ataxia (1)

Elevated ALP (1)

Vomiting (1)

Blood in faeces (1)

Haematology (abnormal) (1)

Diarrhoea (1)

Lethargy (1)

Polymyxin b

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	0	6

Presenting signs (probable and possible)

Anorexia (5)

Lethargy (5)

Vomiting (1)

Diarrhoea (1)

Pain (1)

Hypotension (1)

Pyrexia (1)

Polymyxin b sulfate

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Deafness (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Anaphylaxis (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 2012 (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
23	8	15

Presenting sign (number of incidents)

Vomiting (15)

Diarrhoea (4)

Facial oedema (1)

Lethargy (11)

Pruritis (3)

Lack of effect (1)

Anorexia (3)

Blood in faeces (1)

Restless (1)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

Presenting signs (probable and possible)

Swelling (local) (1)

Swollen lips and face (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Ataxia (1)

Vomiting (1)

Prednisolone*Canine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Vomiting (1)

Procaine penicillin*Bovine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Anaphylactoid reaction (1)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anaphylaxis (1)

Death (1)

Propentofylline*Canine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	2	2

Presenting signs (probable and possible)

Behavioural change (2)

Respiratory problems (1)

Vomiting (1)

Lethargy (1)

Vocalisation (1)

Pyraclofos*Ovine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Death (1)

Malaise (1)

Pyrantel as pyrantel embonate*Canine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Collapse (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Vomiting (1)

Pyrantel embonate*Canine*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	1	3

Presenting signs (probable and possible)

Lethargy (3)

Pruritis (1)

Vomiting (3)

Restless (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Ataxia (1)

Pyrethrins*Feline*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1)

Pyriproxyfen

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Agitation (1)

Shaking (1)

Tremor (1)

Erythema (1)

Site reaction (1)

Robenacoxib

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Anorexia (1)

Hepatopathy (1)

Vomiting (1)

Diarrhoea (1)

Lethargy (1)

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Renal failure (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, pruritis, erythema and localised alopecia.

The number of reports associated with (s)-methoprene is low when compared with the number of doses sold in 2012 (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
90	35	55

Presenting signs (probable and possible)

Site reaction (22)	Pyoderma (4)	Allergy (1)
Pruritis (19)	Vomiting (4)	Crusting skin (1)
Erythema (17)	Coat colour change (3)	Diarrhoea (1)
Alopecia (localised) (15)	Coat discoloration (3)	Hypersalivation (1)
Lack of effect (7)	Pain (3)	Hypersensitivity reaction (1)
Scabs (7)	Rubbing (3)	Listless (1)
Alopecia (6)	Self trauma (3)	Odour (1)
Behavioural change (6)	Dermatitis (2)	Restless (1)
Inflammation (6)	Panting (2)	Swollen (lips) (1)
Irritation (skin) (5)	Papules (2)	Welts (1)
Lethargy (5)	Site reaction (swelling) (2)	Wheals (1)
Anorexia (4)	Ulceration (2)	
Lesions (4)	Agitation (1)	

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
42	31	11

Presenting signs (probable and possible)

Alopecia (localised) (28)	Papules (2)	Lethargy (1)
Erythema (18)	Rash (2)	Pain (1)
Alopecia (8)	Site reaction (2)	Pyoderma (1)
Pruritis (6)	Dermatitis (1)	Scabs (1)
Behavioural change (5)	Hypersalivation (1)	Swelling (local) (1)
Inflammation (3)	Irritation (skin) (1)	Ulceration (1)
Anorexia (2)	Lesions (1)	Vomiting (1)

Salicylic acid

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Deafness (1)

Prolapsed third eyelid (1)

Selenium

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

Selenium as sodium selenate

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Injection site reaction (1)

Shark cartilage

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	5	0

Presenting signs (probable and possible)

Vomiting (2)

Diarrhoea (1)

Urine (abnormal) (1)

Alopecia (1)

Erythema (1)

Sodium selenate

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Collapse (1)

Fasciculation (1)

Spinosad

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

The most commonly reported presenting signs included vomiting, lethargy, anorexia, diarrhoea and behavioural change

The number of reports associated with spinosad has remained consistently high in the past three years. This matter was referred to the Veterinary Medicines Program for advice. It was considered in the majority of cases that the presenting sign accounting for most reports (ie vomiting) involved only a single instance from which the animal recovered very quickly. In light of this and the fact that the product label(s) contain warnings regarding expected reactions, no further action was considered necessary other than ongoing monitoring.

Spinosad

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
568	473	95

Presenting signs (probable and possible)

Vomiting (472)	Mydriasis (3)	Frothing at the mouth (1)
Lethargy (87)	Weakness (3)	Hyperactivity (1)
Anorexia (39)	Allergy (2)	Hyperaesthesia (1)
Diarrhoea (21)	Coughing (2)	Hypersensitivity reaction (1)
Behavioural change (18)	Depression (2)	Hypothermia (1)
Ataxia (11)	Distress (2)	Lesions (1)
Tremor (10)	Hives (2)	Nasal discharge (1)
Pruritis (9)	Irritation (skin) (2)	Panting (1)
Seizure (9)	Pain (2)	Polyuria (1)
Lack of effect (7)	Pyrexia (2)	Proprioception deficit (1)
Vocalisation (7)	Shaking (2)	Pupillary light reflex (abnormal) (1)
Erythema (6)	Stiffness (2)	Recumbency (1)
Hypersalivation (5)	Tachycardia (2)	Respiratory problems (1)
Agitation (4)	Blindness (1)	Restless (1)
Nausea (4)	Blood in faeces (1)	Tachypnoea (1)
Polydipsia (4)	Bradycardia (1)	Urticaria (1)
Somnolence (4)	CNS dysfunction (1)	Weight loss (1)
Disorientation (3)	Death (1)	
Muscle twitching (3)	Dysphagia (1)	

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
47	16	31

Presenting signs (probable and possible)

Lack of effect (42)	Lesions (1)	Scabs (1)
Alopecia (1)	Photosensitization (1)	Site reaction (1)
Crusting skin (1)	QC (1)	Wool damage (1)

Stabilised green-lipped mussel powder

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	6	0

Presenting signs (probable and possible)

Vomiting (3)

Diarrhoea (1)

Urine (abnormal) (1)

Alopecia (1)

Erythema (1)

Stilboestrol

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Incontinence (1)

Sulfadiazine

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pancreatitis (1)

Temephos

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Lack of effect (2)

Thiostrepton

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Alopecia (localised) (1)

Toceranib

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Anorexia (1)

Death (1)

Vomiting (1)

Blood in faeces (1)

Lethargy (1)

Triamcinolone acetonide

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Alopecia (localised) (1)

Trimethoprim

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Pancreatitis (1)

Vitamin B₁₂—cyanocobalamin***Bovine***

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Injection site reaction (1)

Vitamin B_{12a}—hydroxocobalamin***Bovine***

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Injection site reaction (1)

Zinc EDTA***Ovine***

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Collapse (1)

Fasciculation (1)

4 VETERINARY MEDICINES—HUMAN ADVERSE EXPERIENCES

This chapter summarises classifications of APVMA assessments of adverse experience reports involving registered veterinary medicines and effects on humans in 2012.

The APVMA assessed and classified 2112 adverse experiences involving registered veterinary medicines in 2012. Adverse experiences in humans, for example, needle stick injuries, comprised 3% of these.

No regulatory action was required for active constituents involving veterinary medicines and human health in 2012.

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.

Chlorhexidine diglucoante

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Irritation (skin) (1)

Urticaria (1)

CLA = *Corynebacterium pseudotuberculosis ovis*

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Needle stick injury (1)

Clostridium perfringens type D - Antisera/Antigen

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Needle stick injury (1)

Deltamethrin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Pain (1)

Pruritis (1)

Erysipelothrix rhusiopathiae

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

Presenting signs (probable and possible)

Needle stick injury (2)

Fipronil

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Erythema (1)

Lethargy (1)

Malaise (1)

Imidacloprid

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
8	3	5

Presenting signs (probable and possible)

Rash (3)

Irritation (skin) (1)

Paraesthesia (1)

Allergy (1)

Malaise (1)

Pruritis (1)

Dizziness (1)

Numbness (1)

Hypertension (1)

Pain (1)

Moxidectin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Dizziness (1)

Permethrin (40:60:CIS:TRANS)

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

Presenting signs (probable and possible)

Hypertension (1)

Pain (1)

Rash (1)

Numbness (1)

Paraesthesia (1)

Spinosad*Human*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Irritation (skin) (1)

Nausea (1)

Urticaria (1)

Tetanus = *Clostridium tetani**Human*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Needle stick injury (1)

Vitamin B12A = Hydroxocobalamin*Human*

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Needle stick injury (1)

5 AGRICULTURAL CHEMICALS—ANIMAL, PLANTS AND ENVIRONMENTAL SAFETY

This chapter summarises classifications of APVMA assessments in 2012 of adverse experience reports involving agricultural chemicals that were classified as ‘probable’ or ‘possible’.

Sixty adverse experience reports involving agricultural chemical products were assessed and classified as either ‘probable’ or ‘possible’ in 2012. Of these 60 adverse experience reports processed and classified, 52 per cent involved human health issues, 45 per cent involved effects on crops or animals, 2 per cent involved lack of efficacy, and 1 per cent involved effects on the environment.

No regulatory action was required for active constituents involving agricultural chemicals in 2012.

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.

Clomazone

Broad Acre Cropping

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Crop damage (1)

Copper (Cu) present as Copper naphthenate

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Skin slough (1)

Fluroxypyr as the methyl heptyl ester

Broad Acre Cropping

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Glyphosate present as the Isopropylamine salt

Other

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Property damage (minor) (1)

Picloram present as the Hexyloxypropylamine salt

Other

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Environmental damage (1)

Sodium fluoroacetate (1080)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

Presenting signs (probable and possible)

Death (3)

Convulsions (1)

Hyperactivity (1)

Anorexia (1)

Frothing at the mouth (1)

Vocalisation (1)

Triclopyr present as the Butoxyethyl ester

Other

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Environmental damage (1)

6 AGRICULTURAL CHEMICALS—HUMAN ADVERSE EXPERIENCES

This chapter summarises classifications of APVMA assessments in 2012 of adverse experience reports involving agricultural chemicals and effects on humans.

The APVMA assessed and classified 60 adverse experience reports involving agricultural chemical products in 2012. Human health issues comprised 52% of these.

No regulatory action was required for active constituents involving agricultural chemical products and human health in 2012.

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.

Diethyltoluamide

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Irritation (skin) (1)

Rash (1)

Fenoxycarb

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Headache (1)

Incoordination (1)

Shaking (1)

Glyphosate present as the Isopropylamine and Mono-ammonium salts

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Irritation (skin) (1)

Mancozeb

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Rash (1)

N-octyl bicycloheptene dicarboximide

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting signs (probable and possible)

Irritation (skin) (1)

Rash (1)

Permethrin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Headache (1)

Incoordination (1)

Shaking (1)

Picaridin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

Presenting signs (probable and possible)

Allergy (1)

Trifluralin

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

Presenting signs (probable and possible)

Headache (2)

Nausea (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
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
Epistaxis	Bleeding from the nose
Erythema	Abnormal redness of the skin due to local congestion, as in inflammation
Fasciculation	Involuntary contractions or twitching of groups of muscle fibres
Haematemesis	Vomiting of blood
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
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

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