



Adverse Experience Reporting Program

Annual report of events occurring in 2014 October 2018 © Australian Pesticides and Veterinary Medicines Authority 2018

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EXECUTIVE SUMMARY 1

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How this report is set out

Chapter 1 introduces this report. It 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 2 summarises the events reported which occurred in 2014.

Chapter 3 sets out the results of AERP assessments of events occurring in 2014 involving registered Agricultural Chemicals and adverse experiences relating to Humans.

Chapter 4 sets out the results of AERP assessments of events occurring in 2014 involving registered Agricultural Chemicals and effects relating to crops, animals and environment and included lack of efficacy.

Chapter 5 sets out the results of AERP assessments of events occurring in 2014 involving registered Veterinary Medicines products and adverse experiences involving humans.

Chapter 6 sets out the results of AERP assessments of events occurring in 2014 involving registered Veterinary Medicines and effects relating to animals.

An Index of active constituents and adjuvants are provided at the end of this report.

INTRODUCTION 2

1 INTRODUCTION

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

The APVMA assesses and classifies reports of adverse experiences from the exposure to, 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 APVMA, including farmers, pet owners, gardeners, veterinarians or the general public.

We assess each report of an adverse experience, and classify the relationship between the veterinary medicine or agricultural chemical product and the adverse experience. As a result of this assessment the APVMA may confirm the registration of a product as safe and effective, or 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, we may cancel registration of a product and remove it from the market.

1.1 Classifying an adverse experience

The APVMA classifies the relationship between exposure to or use of a product and a reported adverse experience in the following terms:

- 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.

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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.

1.2 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 alphabetical order.

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.

Interpreting the data in this report

There are confounding elements with presentation of the data which should be considered when interpreting data in this report.

1. 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.

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2. 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.

3. 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 oedema
- one report also listed pain.

4. The number of reports listed under an active constituent gives no indication as to the total 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.

If a report was made for any given active, where the event occurred between 2014, and that report was classified as possible or probable. The active will be included in this report.

An active may be registered or discontinued during the period of this report. If it was discontinued it is possible that though it is no longer being sold, that there is an amount remaining in the community that has been used.

Example

ACTIVE CONSTITUENT A

Year	Total Reports	Total Probable	Total Possible
2014	3	2	1

Presenting signs (probable and possible)

Anorexia (3) Injection site reaction (3) Oedema (2)

Pain (1)

2 SUMMARY OF EVENTS REPORTED WHICH OCCUR IN 2014

2.1 Veterinary

In 2014, a total of 3515 adverse experience reports involving registered veterinary products were reported to have occurred. Of these:

- 80 per cent involved animal safety
- 1 per cent related to environmental issues
- 17 per cent involved lack of efficacy and
- 2 per cent involved human health issues (Figure 1).

Of the 3515 adverse experiences reports assessed by the APVMA, 2468 were classified as either probable or possible.

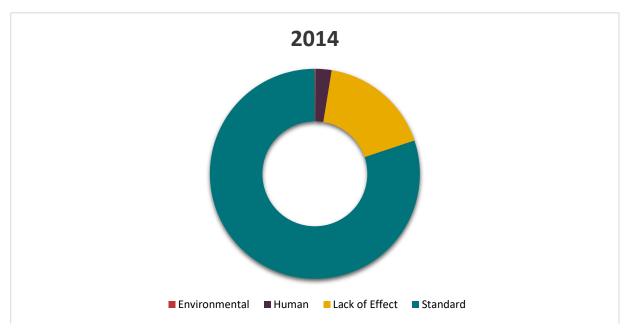


Figure 1: Adverse experience reports involving registered veterinary medicines that occurred in 2014

2.2 Agricultural

In 2014, a total of 60 adverse experience reports involving agricultural products were reported to have occurred. Of these:

- 40 per cent involved effects on crops or animals,
- 2 per cent involved Lack of effect,
- 42 per cent involved human health issues, and
- 17 per cent involved effects on the environment (Figure 2).

Of the 60 reports assessed by the APVMA, 25 were classified as probable or possible.

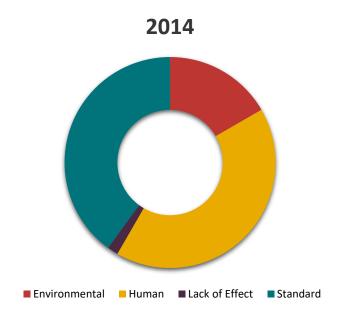


Figure 2: Adverse experience reports involving registered agriculture chemicals that occurred in 2014

2.3 Human

A total of 114 adverse experiences involving effects on humans from registered veterinary medicines and agricultural chemical products were reported to have occurred in 2014. Of these:

- 29 per cent were classified as probable or possible,
- 54 per cent were classified as off-label and
- 17 were classified as unlikely or unknown.

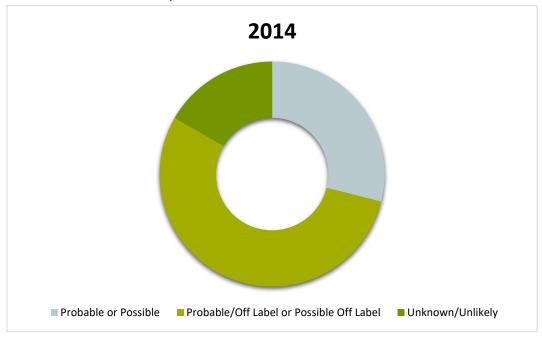


Figure 3: Classification ration of human reports of agricultural chemical and veterinary medicines

No adverse experience assessed and classified by the APVMA in 2014 required 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.

3 AGRICULTURAL—HUMAN

This chapter summarises classifications of APVMA assessments of adverse experience reports involving registered agricultural chemicals and effected humans, relating to events occurred during 2014. At the time of publication 60 reports had been received. Human health issues accounted for 47 per cent of these.

3.1 Chemical review

Chemical reviews are undertaken when there is concern relating to a chemical active. AERP data and trends provide an input to formal reviews of the safety and effectiveness of agricultural and veterinary chemicals.

In the years preceding and in 2014 the following reviews were completed:

Diuron—completed in March 2012

The APVMA commenced a review of diuron on the basis of environmental and human health concerns, specifically the potential for diuron to contaminate the marine environment through agricultural runoff, and the possible toxicity of some impurities of diuron active constituents.

In November 2011, the APVMA suspended the registration of selected diuron products while it considered additional information and submissions provided to the review. In March 2012 the APVMA finalized the review for:

- active constituent approvals (approval of suppliers of diuron to product manufacturers)
- antifouling paints (continued registration with variations to two label instructions)
- pond and aquarium products (continued registration)
- cotton defoliation products (continued registration after variations to label instructions).

The 2011 human health assessment report raised no concerns in relation to the continued approval of diuron active constituents and diuron product registrations.

Full review outcome details can be found at: https://apvma.gov.au/node/12511

Methamidophos—completed in June 2012.

APVMA undertook a review of methamidophos because of concerns about its high acute and chronic toxicity and its potential to cause delayed neurotoxicity. This action was based on advice from the Therapeutic Goods Administration that, methamidophos may pose a potential hazard to public health and should be re-evaluated using contemporary data and assessment standards.

In June 2012, the APVMA released the <u>Human health risk assessment of methamidophos</u> for information purposes only, as all approvals of the active constituent were concurrently cancelled at the request of the approval holder. The assessment concluded that there was not sufficient evidence of delayed neuropathy to prevent the ongoing registration of methamidophos. In addition, the Office of Chemical Safety revised the acceptable daily intake for methamidophos and established a new acute reference dose.

However, while the toxicological assessment supported the ongoing use of methamidophos products, further assessment would be required for any future application for registration due to concerns about possible human health impacts under conditions of use. This would ensure that appropriate maximum residue limits (MRLs) are established and that dietary exposures to methamidophos residues are acceptable.

Full review outcome details can be found at: https://apvma.gov.au/node/12601.

Sheep ectoparasiticides—completed in June 2014.

APVMA began a review in 1999, of selected sheep ectoparasiticides due to concern relating to potential environmental, occupational health and safety and trade risks from residues on treated wool.

The APVMA concluded that it was necessary to vary product labels to include:

- a sheep rehandling interval (SRI) statement indicating the interval from application to when the sheep can be safely handled without the need for protective equipment
- a safety statement advising the use of Personal Protective Equipment (PPE) if sheep are handled during the SR
- a wool harvest interval (WHI) statement which indicates the minimum interval from when the sheep are treated to when the sheep can be shorn
- a trade advisory statement

"Wool treated with this product may contain detectable residues; adequate treatment records should be kept and made available, if requested by wool buyers.

Use of this product may result in wool residues that may not comply with European Union environmental quality standards."

A number of active constituents included in the sheep ectoparasiticides review (chlorfenvinphos, temephos, propetamphos and diazinon) have been or still are under review by the APVMA in their own right. This is to enable the APVMA to separately assess these active constituents, their uses and any concerns which may or may not include their use as sheep ectoparasiticides. While the active constituent reviews are being conducted separately, the outcomes of the ectoparasiticides review will be considered by the APVMA as part of those reviews.

Full review outcome details can be found at: https://apvma.gov.au/node/12711

The information presented in the following section should be considered with regard to APVMA guidance on how to read this report available at Chapter 1.2

2,4-D PRESENT AS THE DIMETHYLAMINE AND DIETHANOLAMINE SA

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Irritation (skin) (1)

Rash (1)

BETACYFLUTHRIN

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Burning sensation (1) Irritation (eye) (1) Sweating (1)

BIFENTHRIN

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Hypersensitivity reaction (1) Rash (1)

CALCIUM HYPOCHLORITE

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Burn(s) (1)

CHLORINE PRESENT AS CALCIUM HYPOCHLORITE

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Burn(s) (1)

CHLORINE PRESENT AS SODIUM DICHLOROISOCYANURATE

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Respiratory problems (1)

DICAMBA PRESENT AS THE DIMETHYLAMINE SALT

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Disorientation (1) Dizziness (1)

DIETHYLTOLUAMIDE

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Facial oedema (1)

Hypersensitivity reaction (1)

Rash (1)

IMIDACLOPRID

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Burning sensation (1)

Irritation (eye) (1)

Sweating (1)

MCPA PRESENT AS THE DIMETHYLAMINE SALT

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Disorientation (1)

Dizziness (1)

N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Facial oedema (1)

Hypersensitivity reaction (1)

Rash (1)

4 AGRICULTURAL—STANDARD

This chapter summarises classifications of APVMA assessments relating to events in 2014 of adverse experience reports involving agricultural chemicals that were classified as probable or possible.

There were 60 adverse experience events reported which occurred in 2014 involving agricultural chemical products, of which:

- 40 per cent involved effects on crops or animals,
- 42 per cent involved human health issues,
- 17 per cent involved effects on the environment, and
- 2 per cent involved a lack of effect.

The information presented in the following section should be considered with regard to APVMA guidance on how to read this report available at Chapter 1.2

BIFENTHRIN

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Agitation (2) Pawing at face (2) Vocalisation (2)

Muscle twitching (2) Shaking (2)

SODIUM FLUOROACETATE

Sodium fluoroacetate, is commonly known as 1080. The chemical is used for controlling feral animals. Its use for animal control was first pioneered in Australia as a rabbit poison in the early 1950s. It is now used to control wild dogs, feral pigs, foxes, rabbits, cats and dingoes. It is also used to control native animals in newly established timber plantations and other agricultural/horticultural crops.

The APVMA reviewed the use of 1080 because of concerns over poisoning of non-target species. The labels now contain adequate instructions for the chemical to be used safely with respect to the environment. As per the label instructions, it is mandatory for the users of 1080 to notify their neighbours of imminent baiting and to observe certain minimum distances from roads, dwellings and water sources while placing baits. On rare occasions, domestic animals are able to gain access to baits even when all precautions are followed.

Year	Total Reports	Total Probable	Total Possible	
2014	7	5	2	
Presenting signs (p	probable and possible)			
Agitation (1)	Distress (4)	Seizure (3)	
Cardiac arrhythmia	(1) Foaming	(1)	Vocalisation (3)	
Convulsions (2)	Frothing a	at the mouth (1)	Vomiting (1)	
Death (5)	Hyperacti	vity (3)		
Defaecation (1)	Regurgita	tion (1)		

5 VETERINARY—HUMAN

This chapter summarises classifications of APVMA assessments of adverse experience reports involving registered veterinary medicines and effects on humans which occurred during 2014.

There were 3515 adverse experience events reported which occurred in 2014 involving registered veterinary medicines of which:

• 3 per cent of these reports related to adverse experiences in humans, for example, needle stick injuries (approximately 100 each year).

The variety of products used in animals that are administered by injection includes biologics, vaccines, antibiotics and hormones. The procedure, pharmaceutical and species all impact on the risk to the person administering the product. Accidental injections or product exposures can result in mild to severe injuries. The frequency of needle stick injury (NSI) is not reflected in this report, as off label incidents are not presented here.

Though severe reactions are not common, reports regarding NSI, which do not receive correct initial treatment, are received every year. Any concerns regarding exposure should be referred to a health professional directly, it is valuable to present the package or insert at the time of consult, and healthcare professionals should consult the label and manufacturer for appropriate management. They hold detailed information in regard to the actives and adjuvants, they should be contacted in the first instance for information and subsequently to report adverse effects.

The information presented in the following section should be considered with regard to APVMA guidance on how to read this report available at Chapter 1.2

(S)-METHOPRENE

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Allergy (1) Hives (1)

ABAMECTIN

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Irritation (skin) (1)

BORDETELLA BRONCHISEPTICA KILLED VACCINE

Year	Total Reports	Total Probable	Total Possible
2014	2	2	0

Presenting signs (probable and possible)

QC (2)

CLOSTRIDIUM CHAUVOEI - FORMOL CULTURE

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Abscess (1)

Injection site reaction (1)

Pain (1)

CLOSTRIDIUM NOVYI TYPE B - TOXOID

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Abscess (1)

Injection site reaction (1)

Pain (1)

CLOSTRIDIUM PERFRINGENS TYPE D - TOXOID

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Abscess (1)

Injection site reaction (1)

Pain (1)

CLOSTRIDIUM SEPTICUM - TOXOID

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Abscess (1)

Injection site reaction (1)

Pain (1)

CLOSTRIDIUM TETANI - TOXOID

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Abscess (1)

Injection site reaction (1)

Pain (1)

CORYNEBACTERIUM PSEUDOTUBERCULOSIS (OVIS) - TOXOID

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Abscess (1)

Injection site reaction (1)

Pain (1)

DELTAMETHRIN

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Allergy (1)

Headache (1)

DERQUANTEL

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Irritation (skin) (1)

DICYCLANIL

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Nausea (1)

Vomiting (1)

DIMETHYL AZELATE

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Headache (1)

Irritation (eye) (1)

Sore throat (1)

DIMETHYL PIMELATE

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Headache (1)

Irritation (eye) (1)

Sore throat (1)

FIPRONIL

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Allergy (1)

Hives (1)

IMIDACLOPRID

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Irritation (skin) (1)

Periorbital swelling (1)

INDOXACARB

Year	Total Reports	Total Probable	Total Possible
2014	3	1	2

Presenting signs (probable and possible)

Erythema (2)

Headache (1)

Pruritus (1)

LACTIC ACID

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Pain (1)

Swelling (local) (1)

Ulceration (1)

METHOPRENE - RS

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1)

Respiratory problems (1)

METHYL OLEATE

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Headache (1)

Irritation (eye) (1)

Sore throat (1)

METHYL PALMITATE

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Headache (1)

Irritation (eye) (1)

Sore throat (1)

MORAXELLA BOVIS

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

MORAXELLA BOVIS STRAIN EPP63

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

MORAXELLA BOVIS STRAIN FLA 64

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

MORAXELLA BOVIS STRAIN SAH38

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1)

Respiratory problems (1)

PERMETHRIN

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Irritation (skin) (1)

Periorbital swelling (1)

PIPERONYL BUTOXIDE

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1)

Respiratory problems (1)

PYRETHRIN

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1)

Respiratory problems (1)

PYRETHRUM EXTRACT

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1)

Respiratory problems (1)

SALICYLIC ACID

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Pain (1)

Swelling (local) (1)

Ulceration (1)

SYNTHETIC ANALOGUE OF F3 FRACTION FELINE FACIAL PHEROMON

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Headache (1) Irritation (eye) (1) Sore throat (1)

SYNTHETIC ANALOGUE OF THE CANINE APPEASING PHEROMONE

Year	Total Reports	Total Probable	Total Possible
2014	3	0	3

Presenting signs (probable and possible)

Burning sensation (1) Headache (1) Pain (1)

Coughing (2) Lethargy (1)

6 VETERINARY—STANDARD

This chapter summarises classifications of APVMA assessments of adverse experience reports involving registered veterinary medicines which occurred during 2014.

There were 3515 adverse experience events reported, which occurred in 2014 involving registered veterinary medicines of which:

- 80 per cent involved animal safety,
- 17 per cent involved lack of efficacy and
- 3 per cent involved human health issues
- 0.2 per cent involved environment

The information presented in the following section should be considered with regard to APVMA guidance on how to read this report available at Chapter 1.2

(S)-METHOPRENE

Canine

Total Reports	Total Probable	Total Possible			
23	1	22			
Presenting signs (probable and possible)					
Irritation (eye) ((1)	Rash (1)			
Lack of effect (8)	Seizure (1)			
Lethargy (3)		Site reaction (4)			
Muscle twitchin	ng (1)	Weakness (1)			
Pruritus (5)					
	e and possible) Irritation (eye) (Lack of effect (a Lethargy (3) Muscle twitching	23 1 e and possible) Irritation (eye) (1) Lack of effect (8) Lethargy (3) Muscle twitching (1)			

Feline

Year	Total Reports	Total Probable	Total Possible
2014	8	1	7

Presenting signs (probable and possible)

Alopecia (localised) (5)	Crusting skin (1)	Hypersalivation (1)
CNS dysfunction (1)	Erythema (3)	Pruritus (2)

ABAMECTIN

Equine

Year	Total Reports	Total Probable	Total Possible
2014	3	0	3

Presenting signs (probable and possible)

Anorexia (1) Lethargy (1) Oral (irritation) (1)

Lack of effect (1)

Malaise (1)

Unpleasant taste (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	3	0	3

Presenting signs (probable and possible)

Death (3)

ACETYL GLUCOSAMINE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	7	3	4

Presenting signs (probable and possible)

Ataxia (1) Incontinence (1) Vomiting (2)

Collapse (2) Lethargy (2)

Diarrhoea (2)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Hypersalivation (1) Retching (1) Vomiting (1)

AFOXOLANER

Canine

2014 10 2 7	Year	Total Reports	Total Probable	Total Possible
2014 10 3 7	2014	10	3	7

Presenting signs (probable and possible)

Anorexia (1)

Behavioural change (1)

Diarrhoea (3)

Haematemesis (1)

Pustules (1)

Pyrexia (1)

Seizure (1)

Tremor (1)

Vocalisation (1)

Vomiting (2)

AGLEPRISTONE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	15	3	12

Presenting signs (probable and possible)

Anaphylactoid reaction (1) Lack of effect (13) Swelling (local) (1)

ALBENDAZOLE

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Death (2)

ALBUMIN - BOVINE SERUM

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	7	0	7

Presenting signs (probable and possible)

Lack of effect (7)

ALPHA-CYPERMETHRIN

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

ALPHAXALONE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	3	0	3

Presenting signs (probable and possible)

Apnoea (1) Facial oedema (1) Sedation (1)

Bradycardia (1) Miosis (1)

Erythema (1) Recovery (poor) (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	8	0	8

Presenting signs (probable and possible)

Facial oedema (1) Laryngospasm (1) Blindness (1) Hyperaesthesia (1) Mydriasis (1) Bradycardia (2) Hypersalivation (1) Pulmonary oedema (2) Bronchial secretion (1) Hypotension (1) Respiratory problems (1) Cardiac arrest (1) Hypothermia (1) CNS dysfunction (1) Hypoxia (1) Cyanosis (1)

ALTERNATE FORMULATION

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Alopecia (localised) (1)

Skin slough (1)

ALTRENOGEST

Equine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (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 sign was the occurrence of an injection site reaction.

Canine

Year	Total Reports	Total Probable	Total Possible
2014	24	0	24
Presenting signs (probabl			
Allergy (1)	Immune-media anaemia (1)	ated haemolytic	Panting (1)
Anaphylaxis (3)	Incontinence ((1)	Pyrexia (1)
Anorexia (1)	Injection site r	eaction (2)	Restless (1)
Ataxia (1)	Lethargy (2)		Shaking (1)
Circling (1)	Lump (local) (6)	Tachycardia (1)
Diarrhoea (1)	Malaise (1)		Thrombocytopenia (1)
Erythema (1)	Oedema (1)		Urticaria (2)
Facial oedema (4)	Pain (1)		Vomiting (6)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	4	0	4

Presenting signs (probable and possible)

Anorexia (1)	Lump (local) (2)	Weight loss (1)
Injection site reaction (1)	Pain (1)	
Lethargy (1)	Pyrexia (1)	

AMITRAZ

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Lethargy (1)

Sedation (1)

Canine

Year	Total Reports	Total Probable	Total Possible
2014	17	1	16

Presenting signs (probable and possible)

Adipsia (1) Irritation (skin) (2) Restless (2)

Behavioural change (2) Lack of effect (13) Vomiting (1)

Irritation (eye) (1) Listless (1) Xerostomia (1)

AMOXYCILLIN TRIHYDRATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Periorbital swelling (1)

AMPHOTERICIN B

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Anorexia (1)

Lethargy (1)

ANAPLASMA CENTRALE

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	9	0	9

Presenting signs (probable and possible)

Lack of effect (9)

ATIPAMEZOLE HYDROCHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1) Defaecation (1)

Cyanosis (1) Unconscious (1)

AZELAIC ACID

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Allergy (1) Sneezing (1)

BABESIA BIGEMINA

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	9	0	9

Presenting signs (probable and possible)

Lack of effect (9)

BABESIA BOVIS

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	9	0	9

Presenting signs (probable and possible)

Lack of effect (9)

BACITRACIN ZINC

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Irritation (eye) (1)

BENAZEPRIL HYDROCHLORIDE

Canine

Anorexia (2)

	Year	Total Reports	Total Probable	Total Possible
	2014	7	2	5
Presenting signs (probable and possible)				

Tremor (1)

Diarrhoea (4) Melaena (1) Vomiting (4)

Lethargy (2)

Erythema (1) Pruritus (1)

BETAMETHASONE VALERATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Deafness (1) Inflammation (1) Pain (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Facial oedema (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 included 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 below the action level of 1 reaction in 10,000 doses sold in 2014. At this time no regulatory action is required, however vaccine products are continually monitored for unexpected or severe reactions.

BORDETELLA BRONCHISEPTICA

Canine

Year	Total Reports	Total Probable	Total Possible
2014	189	9	180

Presenting signs (probable and possible)

Abscess (1)	Anorexia (13)	Circling (1)
Aggression (1)	Ataxia (2)	Circulatory collapse (1)
Allergy (2)	Behavioural change (1)	Coughing (44)
Alopecia (1)	Capillary refill time (slow) (1)	Death (1)
Anaphylactoid reaction (3)	Cardiac arrhythmia (1)	Depression (1)
Anaphylaxis (9)	Cellulitis (1)	Diarrhoea (3)

Erythema (5)	Lethargy (39)	Pyrexia (11)
Facial oedema (36)	Listless (1)	Respiratory problems (16)
Gagging (1)	Lump (local) (19)	Restless (2)
Haemorrhagic gastroenteritis	Malaise (3)	Seizure (1)
(1)	Nasal discharge (17)	Shaking (5)
Hives (2)	Nausea (1)	Site reaction (1)
Hyperactivity (1)	Necrosis (1)	Sneezing (20)
Hypersalivation (1)	Ocular discharge (1)	Tachycardia (3)
Hypersensitive to stimuli (1)	Oedema (2)	Tachypnoea (1)
Hypersensitivity reaction (1)	Pain (14)	Thrombocytopenia (1)
Immune-mediated haemolytic anaemia (1)	Pale mucous membranes (3)	Urticaria (5)
Incontinence (2)	Panting (1)	Uveitis (1)
Inflammation (1)	Periorbital swelling (1)	Vocalisation (1)
Injection site reaction (10)	Pneumonia (1)	Vomiting (17)
Irritation (eye) (1)	Polyuria (1)	
Lack of effect (3)	Pruritus (6)	

BORDETELLA BRONCHISEPTICA KILLED VACCINE

Canine

	Year	Total Reports	Total Probabl	e Total Possible			
	2014	84	1	83			
F	Presenting signs (probable and possible)						
	Agitation (2)	Cou	ughing (1)	Facial oedema (41)			
	Anaphylactoid reaction (2)	Dea	ath (1)	Haematemesis (1)			
	Anaphylaxis (13)	Def	aecation (2)	Hives (1)			
	Anorexia (2)	Dep	pression (1)	Hypersalivation (1)			
	Circulatory collapse (1)	Dia	rrhoea (3)	Hypersensitivity reaction (1)			
	Collapse (3)	Dist	tress (2)	Hypotension (1)			
		Ery	thema (5)	Incontinence (1)			

Injection site reaction (6)

Periorbital swelling (2)

Site reaction (swelling) (2)

Irritation (skin) (2)

Pruritus (7)

Tachycardia (3)

Lethargy (11)

Pyrexia (1)

Vomiting (25)

Pale mucous membranes (6)

Restless (1)

Weakness (1)

Panting (3) Shaking (2)

BOVINE BLOOD

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Lack of effect (2)

BOVINE CORONAVIRUS (CA-5)

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Alopecia (localised) (1) Injection site reaction (1) Lump (local) (2)

BOVINE CORONAVIRUS (INACTIVATED)

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Alopecia (localised) (1) Injection site reaction (1) Lump (local) (2)

BOVINE CORONAVIRUS (WI-17)

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Alopecia (localised) (1)

Injection site reaction (1)

Lump (local) (2)

BOVINE ROTAVIRUS (04-1)

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Alopecia (localised) (1)

Injection site reaction (1)

Lump (local) (2)

BOVINE ROTAVIRUS (NCDV)

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Alopecia (localised) (1)

Injection site reaction (1)

Lump (local) (2)

CALCIUM GLUCONATE

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Constipation (1)

CANINE ADENOVIRUS TYPE 2 VACCINES

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

The most commonly reported presenting signs included facial oedema, vomiting, lethargy, injection site reaction, anaphylactoid reaction and coughing. 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 is low when compared with the number of doses sold in 2014 (less than 1 in 10000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

CANINE ADENO VIRUS TYPE 2

Canine

Year	Total Reports	Total Probable	Total Possible
2014	308	19	289

resenting signs (probable and possible)			
Aggression (2)	Cardiac arrhythmia (1)	Gagging (1)	
Agitation (2)	Circulatory collapse (3)	Haematemesis (1)	
Allergy (1)	Collapse (2)	Haemorrhagic gastroenteritis	
Alopecia (1)	Coughing (32)	(2)	
Anaphylactoid reaction (5)	Death (3)	Hives (4)	
Anaphylaxis (18)	Defaecation (2)	Hyperactivity (1)	
Anorexia (13)	Depression (2)	Hypersalivation (3)	
Ataxia (3)	Diarrhoea (3)	Hypersensitive to stimuli (1)	
Behavioural change (1)	Distress (2)	Hypersensitivity reaction (2)	
Capillary refill time (slow) (2)	Erythema (11)	Hypotension (1)	
Capillary Term time (Slow) (2)	Facial oedema (84)	Incontinence (3)	

Injection site reaction (12)	Ocular discharge (2)	Shaking (8)
Irritation (eye) (2)	Oedema (1)	Site reaction (1)
Irritation (skin) (2)	Pain (14)	Site reaction (swelling) (2)
Lack of effect (100)	Pale mucous membranes (8)	Sneezing (16)
Lethargy (39)	Panting (3)	Tachycardia (7)
Lump (local) (10)	Periorbital swelling (4)	Tachypnoea (2)
Malaise (1)	Pruritus (13)	Tremor (1)
Nasal discharge (11)	Pyrexia (11)	Urticaria (18)
Nausea (1)	Respiratory problems (16)	Vomiting (30)
Necrosis (1)	Restless (1)	Weakness (1)

CANINE ADENOVIRUS TYPE 2—LIVE (CAV II)

Canine

Year	Total Reports	Total Probable	Total Possible	
2014	15	0	15	
Presenting signs (pr	robable and possible)			
Aggression (1)	Diarrhoe	ea (1)	Pruritus (2)	
Anaphylaxis (2)	Erythem	na (2)	Shaking (1)	
Ataxia (1)	Facial o	edema (3)	Urticaria (1)	
Collapse (2)	Lack of	effect (6)	Vomiting (3)	

CANINE ADENOVIRUS TYPE 2—LIVE (INFECTIOUS HEPATITIS)

Canine

Year	Total Reports	Total Probable	Total Possible	
2014	29	2	27	
Presenting signs	s (probable and possible)			
A.II. (4)	Immune-	mediated haemolytic	Panting (1)	

Allergy (1) anaemia (1) Pyrexia (2) Anaphylaxis (3) Incontinence (1) Restless (1) Anorexia (1) Injection site reaction (2) Tachycardia (2) Ataxia (1) Lack of effect (3) Tachypnoea (1) Circling (1) Lethargy (1) Thrombocytopenia (1) Coughing (1) Lump (local) (5) Unconscious (1) Diarrhoea (1) Malaise (1) Urticaria (2) Erythema (1) Oedema (1) Vomiting (5) Facial oedema (6)

CANINE ADENOVIRUS TYPE 2 STRAIN MANHATTAN—LIVE

Pain (1)

Canine

Year	Total Reports	Total Probable	Total Possible
2014	32	4	28

Presenting signs (probable and possible)			
Abscess (1)	Lump (local) (4)	Pyrexia (2)	
Diarrhoea (3)	Malaise (1)	Swelling (local) (1)	
Facial oedema (4)	Pain (5)	Uveitis (1)	
Lack of effect (12)	Pale mucous membranes (2)	Vomiting (6)	
Lethargy (6)	Polyuria (1)		
Listless (1)	Pruritus (1)		

CANINE CORONAVIRUS VACCINE—ANTIGEN

Canine

Year	Total Reports	Total Probable	Total Possible	
2014	6	0	6	
Our continue of the Constraints and a continue				

Presenting signs (probable and possible)

Anaphylaxis (1)

Collapse (1)

Erythema (1)

Facial oedema (3)

Injection site reaction (2)

Urticaria (1)

CANINE DISTEMPER VACCINES

Canine Distemper 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 sign is Lack of effect. This vaccine is given with Canine Parvo virus, most commonly the issue relates to poor seroconversion of high challenge relating to the Parvovirus component. This is a known issue and if you are concerned, it is best to discuss this with your veterinarian. Other presenting signs include facial oedema, vomiting, lethargy, injection site reaction, anaphylactoid reaction and coughing. 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 distemper vaccine strains is low when compared with the number of doses sold in 2014 (less than 1 in 10000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

CANINE DISTEMPER VIRUS

Canine

Year T	otal Reports	Total Probable	Total Possible
2014 2	88	18	270
Presenting signs (probable a	and possible)		_
Aggression (1)	Facial oede	ema (76)	Ocular discharge (1)
Agitation (2)	Haematem	esis (1)	Oedema (2)
Allergy (2)	Haemorrha (1)	gic gastroenteritis	Pain (15)
Alopecia (1)	Hives (4)		Pale mucous membranes (7)
Anaphylactoid reaction (5)	Hyperactivi	ty (1)	Panting (4)
Anaphylaxis (19)	Hypersaliva	ation (2)	Periorbital swelling (3)
Anorexia (9)	Hvpersensi	tive to stimuli (1)	Pruritus (12)
Ataxia (3)		tivity reaction (2)	Pyrexia (10)
Behavioural change (1)	Hypotensio	, ,	Respiratory problems (1)
Capillary refill time (slow) (1)		ediated haemolytic	Restless (2)
Cardiac arrhythmia (1)	anaemia (1	diated flaemolytic	Shaking (7)
Circling (1)	Incontinend	ee (3)	Site reaction (1)
Circulatory collapse (2)	Injection sit	e reaction (14)	Site reaction (swelling) (2)
Collapse (2)	Irritation (ey	/e) (1)	Tachycardia (8)
Coughing (2)	Irritation (sk	kin) (2)	Tachypnoea (3)
Death (2)	Lack of effe	ect (103)	Thrombocytopenia (1)
Defaecation (2)	Lethargy (3	1)	Tremor (1)
Depression (2)	Lump (loca	I) (15)	Unconscious (1)
Diarrhoea (4)	Malaise (2)		Urticaria (17)
Distress (2)	Nausea (1)		Vomiting (33)
Erythema (10)	Necrosis (1)	Weakness (1)

CANINE DISTEMPER VIRUS STRAIN ONDERSTEPOORT

Canine

Year	Total Reports	Total Probable	Total Possible
2014	32	4	28

Abscess (1)	Lump (local) (4)	Pyrexia (2)
Diarrhoea (3)	Malaise (1)	Swelling (local) (1)
Facial oedema (4)	Pain (5)	Uveitis (1)
Lack of effect (12)	Pale mucous membranes (2)	Vomiting (6)
Lethargy (6)	Polyuria (1)	
Listless (1)	Pruritus (1)	

CANINE PARAINFLUENZA VACCINES

Canine parainfluenza virus and associated strains is a component of 'non-core' canine vaccine products that target common canine respiratory illnesses. 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 included injection site reaction, facial oedema, lethargy and coughing. 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 below the action level of 1 reaction in 10,000 doses sold in 2014. At this time no regulatory action is required, however vaccine products are continually monitored for unexpected or severe reactions.

CANINE PARAINFLUENZA TYPE 2

Canine

Year	Total Reports	Total Probable	Total Possible
2014	115	7	108
Presenting signs (probak	ole and possible)		
Aggression (1)	Depression	n (1)	Injection site reaction (5)
Agitation (2)	Diarrhoea	(3)	Irritation (skin) (2)
Anaphylactoid reaction (2) Distress (2)	Lack of effect (22)
Anaphylaxis (14)	Erythema ((6)	Lethargy (13)
Anorexia (2)	Facial oed	ema (47)	Pain (4)
Ataxia (1)	Haematem	esis (1)	Pale mucous membranes (6)
Circulatory collapse (1)	Hives (2)		Panting (3)
Collapse (2)	Hypersaliv	ation (1)	Periorbital swelling (2)
Coughing (1)	Hypersens	itivity reaction (1)	Pruritus (9)
Death (1)	Hypotensio	on (1)	Pyrexia (3)
Defaecation (2)	Incontinen	ce (1)	Respiratory problems (1)

Restless (1) Tachycardia (3) Vomiting (25)

Shaking (3) Tachypnoea (1) Weakness (1)

Site reaction (swelling) (2) Urticaria (12)

CANINE PARAINFLUENZA VIRUS

Canine

Year	Total Reports	Total Probable	Total Possible		
2014	275	16	259		
Presenting signs (pro	Presenting signs (probable and possible)				
Abscess (1)	Haemate	mesis (1)	Oedema (2)		
Aggression (2)	Haemorri (1)	nagic gastroenteritis	Pain (19)		
Agitation (2)	Hives (4)		Pale mucous membranes (9)		
Allergy (2)	Hyperact		Panting (3)		
Alopecia (1)			Periorbital swelling (3)		
Anaphylactoid reaction	n (5)	vation (2)	Pneumonia (1)		
Anaphylaxis (19)	Hyperser	nsitive to stimuli (1)	Polyuria (1)		
Anorexia (15)	Hyperser	sitivity reaction (2)	Pruritus (13)		
. ,	Hypotens	sion (1)	Pyrexia (12)		
Ataxia (2)	Incontine	nce (2)	Respiratory problems (17)		
Behavioural change (2	2) Inflamma	tion (1)			
Capillary refill time (slo	ow) (1) Injection	site reaction (17)	Restless (2)		
Cardiac arrhythmia (1)	Irritation	(eye) (1)	Seizure (1)		
Cellulitis (1)	Irritation	(skin) (2)	Shaking (9)		
Circulatory collapse (2		, , , ,	Site reaction (1)		
Coughing (45)	Lethargy	. ,	Site reaction (swelling) (2)		
Death (2)			Sneezing (20)		
Defaecation (2)	Listless (,	Tachycardia (5)		
Depression (3)	Lump (lo	cal) (19)	Tachypnoea (2)		
	Malaise (2)	Urticaria (15)		
Diarrhoea (5)	Nasal dis	charge (17)	Uveitis (1)		
Distress (2)	Nausea (1)	Vocalisation (1)		
Erythema (9)	Necrosis	(1)	, ,		
Facial oedema (76)	Ocular di	scharge (1)	Vomiting (36)		
Gagging (1)			Weakness (1)		

CANINE PARAINFLUENZA VIRUS—INACTIVATED

Canine

Year	Total Reports	Total Probable	Total Possible
2014	24	0	24

Presenting signs (probable and possible)

Allergy (1)	Immune-mediated haemolytic anaemia (1)	Panting (1)
Anaphylaxis (3)	Incontinence (1)	Pyrexia (1)
Anorexia (1)	Injection site reaction (2)	Restless (1)
Ataxia (1)	Lethargy (2)	Shaking (1)
Circling (1)	Lump (local) (6)	Tachycardia (1)
Diarrhoea (1)	Malaise (1)	Thrombocytopenia (1)
Erythema (1)	Oedema (1)	Urticaria (2)
Facial oedema (4)	Pain (1)	Vomiting (6)
	raiii (1)	

CANINE PARAINFLUENZA VIRUS STRAIN CORNELL—LIVE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lump (local) (1) Pain (1)

CANINE PARVO VIRUS VACCINES

Canine parvovirus strains area 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 included lack of effect, anaphylactoid reaction, 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 most commonly reported presenting sign is Lack of effect. This commonly relates to poor seroconversion or high challenge of parvovirus. This is a known issue and if you are concerned, it is best to discuss this with your veterinarian.

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 below the action level of 1 reaction in 10,000 doses sold in 2014. At this time no regulatory action is required, however vaccine products are continually monitored for unexpected or severe reactions.

CANINE PARVO VIRUS

Canine

Year	Total Reports	Total Probable	Total Possible
2014	235	14	221

Aggression (1)	Circulatory collapse (2)	Facial oedema (67)
Agitation (2)	Collapse (2)	Haematemesis (1)
Allergy (1)	Coughing (1)	Haemorrhagic gastroenteritis (1)
Anaphylactoid reaction (5)	Death (1)	Hives (4)
Anaphylaxis (15)	Defaecation (2)	Hypersalivation (2)
Anorexia (4)	Depression (2)	Hypersensitive to stimuli (1)
Ataxia (1)	Diarrhoea (3)	,,
Behavioural change (1)	Distress (2)	Hypersensitivity reaction (2)
Capillary refill time (slow) (1)	Erythema (8)	Hypotension (1)

Incontinence (2) Oedema (1) Restless (1) Injection site reaction (9) Pain (7) Shaking (5) Irritation (eye) (1) Pale mucous membranes (7) Site reaction (swelling) (2) Irritation (skin) (2) Panting (3) Tachycardia (4) Lack of effect (98) Periorbital swelling (3) Tachypnoea (1) Lethargy (16) Pruritus (11) Urticaria (15) Lump (local) (10) Pyrexia (6) Vomiting (27) Ocular discharge (1) Respiratory problems (1) Weakness (1)

CANINE PARVO VIRUS 2B STRAIN CPV39 - ATTENUATED

Canine

Year	Total Reports	Total Probable	Total Possible	
2014	15	0	15	
Presenting signs (proba	able and possible)			
Aggression (1)	Diarrhoe	ea (1)	Pruritus (2)	
Anaphylaxis (2)	Erythem	a (2)	Shaking (1)	
Ataxia (1)	Facial o	edema (3)	Urticaria (1)	
Collapse (2)	Lack of	effect (6)	Vomiting (3)	

CANINE PARVO VIRUS TYPE 2

Canine

Year	Total Reports	Total Probable	Total Possible
2014	24	2	22

r receiting eigne (presente and pe	, 33.13.7	
Alopecia (1)	Hyperactivity (1)	Pruritus (1)
Anaphylaxis (1)	Injection site reaction (3)	Pyrexia (2)
Anorexia (4)	Lack of effect (2)	Shaking (2)
Ataxia (1)	Lethargy (14)	Site reaction (1)
Cardiac arrhythmia (1)	Malaise (1)	Tachycardia (2)
Death (1)	Nausea (1)	Tachypnoea (1)
Erythema (1)	Necrosis (1)	Tremor (1)
Facial oedema (3)	Pain (7)	Vomiting (1)

CANINE PARVOVIRUS—LIVE

Canine

Year	Total Reports	Total Probable	Total Possible	
2014	29	2	27	
Presenting signs	(probable and possible)			
Allergy (1)	Immune-ı	mediated haemolytic	Panting (1)	

anaemia (1) Pyrexia (2) Anaphylaxis (3) Incontinence (1) Restless (1) Anorexia (1) Injection site reaction (2) Tachycardia (2) Ataxia (1) Lack of effect (3) Tachypnoea (1) Circling (1) Lethargy (1) Thrombocytopenia (1) Coughing (1) Lump (local) (5) Unconscious (1) Diarrhoea (1) Malaise (1) Urticaria (2) Erythema (1) Oedema (1)

CANINE PARVOVIRUS STRAIN 154—LIVE

Canine

Facial oedema (6)

Year	Total Reports	Total Probable	Total Possible
2014	32	4	28

Pain (1)

Vomiting (5)

0 0 11	,	
Abscess (1)	Lump (local) (4)	Pyrexia (2)
Diarrhoea (3)	Malaise (1)	Swelling (local) (1)
Facial oedema (4)	Pain (5)	Uveitis (1)
Lack of effect (12)	Pale mucous membranes (2)	Vomiting (6)
Lethargy (6)	Polyuria (1)	
Listless (1)	Pruritus (1)	

CEFOVECIN SODIUM

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Incontinence (1)

Tremor (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lethargy (1)

CHLAMYDOPHILIA FELIS INACTIVATED

Feline

Year	Total Reports	Total Probable	Total Possible
2014	8	2	6
Presenting signs (probat	ple and possible)		

Tresenting signs (probable and	possible)	
Anaemia (1)	Cyanosis (1)	Lump (local) (1)
Anaphylaxis (1)	Dyspnoea (1)	Pyrexia (1)
Anorexia (3)	Jaundice (1)	Tachycardia (2)
Collapse (1)	Lethargy (2)	Tachypnoea (2)
Coughing (1)	Listless (1)	Vomiting (2)

CHLORFENVINPHOS

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Lack of effect (2)

CHLORHEXIDINE GLUCONATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	2	2	0

Presenting signs (probable and possible)

Erythema (1)

Irritation (skin) (1)

Pruritus (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lethargy (1)

CHONDROITIN SULFATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Coughing (1)

Swelling (local) (1)

Flatulence (1)

Vomiting (1)

CLAVULANIC ACID AS POTASSIUM CLAVULANATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Periorbital swelling (1)

CLOMIPRAMINE HYDROCHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	3	0	3

Presenting signs (probable and possible)

Haematology (abnormal) (2) Lethargy (2)

Hypersalivation (1) Vomiting (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	4	0	4

Presenting signs (probable and possible)

Anorexia (2) Hepatopathy (1) Stranguria (1)

Cardiac arrhythmia (1) Muscle twitching (1) Vomiting (1)

Convulsions (1) Sedation (1)

CLOSTRIDIUM BOTULINUM TYPE C-TOXOID

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

CLOSTRIDIUM BOTULINUM TYPE D-TOXOID

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

CLOSTRIDIUM CHAUVOEI-FORMOL CULTURE

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

CLOSTRIDIUM NOVYI TYPE B

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

CLOSTRIDIUM NOVYI TYPE B—TOXOID

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

CLOSTRIDIUM PERFRINGENS TYPE C—TOXOID

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Alopecia (localised) (1)

Injection site reaction (1)

Lump (local) (2)

CLOSTRIDIUM PERFRINGENS TYPE D—TOXOID

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	3	1	2

Presenting signs (probable and possible)

Alopecia (localised) (1)

Lack of effect (1)

Injection site reaction (1)

Lump (local) (2)

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

CLOSTRIDIUM SEPTICUM—TOXOID

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

CLOSTRIDIUM TETANI—TOXOID

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

CLOSTRIDIUM TETANI UF TOXOID

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

Pain (1)

Equine

Year	Total Reports	Total Probable	Total Possible
2014	14	4	10

Alopecia (localised) (3)	Lame (1)	Pyrexia (5)
Anorexia (2)	Lethargy (2)	Stiffness (4)
Ataxia (1)	Lump (local) (5)	Sweating (1)
Coat colour change (1)	Oedema (3)	Urticaria (1)
Hyperactivity (1)	Pain (5)	
Injection site reaction (8)	Pale mucous membranes (1)	

CLOTRIMAZOLE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	3	1	2

Presenting signs (probable and possible)

Deafness (2)

Inflammation (1)

Pain (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Facial oedema (1)

COBALT AS COBALT EDTA

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Death (1)

COPPER AS COPPER DISODIUM EDTA

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	4	1	3

Presenting signs (probable and possible)

Convulsions (1) Hepatopathy (1) Lump (local) (1)

Death (3) Injection site reaction (1)

COPPER INDOMETHACIN

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Urticaria (1)

CORYNEBACTERIUM PSEUDOTUBERCULOSIS (OVIS)—TOXOID

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

CYCLOSPORIN

Cyclosporin is a widely used immunosuppressant drug used in the treatment of immune-mediated conditions. The most commonly reported presenting signs are gastrointestinal related, most notably vomiting and diarrhoea.

The number of reports associated with Cyclosporin is low when compared with the number of doses sold in 2014 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

CYCLOSPORIN

Canine

Year	Total Reports	Total Probable	Total Possible
2014	64	36	28

Hyperactivity (1)	Nausea (1)	Shaking (1)
Lack of effect (7)	Neoplasia (1)	Tachypnoea (3)
Lesions (1)	Panting (1)	Tremor (3)
Lethargy (13)	Pruritus (14)	Vocalisation (1)
Muscle twitching (2)	QC (1)	Vomiting (26)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	17	14	3

Presenting signs (probable and possible)

Anorexia (1)	Hypersalivation (7)	Site reaction (1)
Behavioural change (2)	Lack of effect (1)	Vomiting (9)
Gingival soreness (2)	Lethargy (2)	Weight loss (1)

CYCLOSPORIN A

Feline

Year	Total Reports	Total Probable	Total Possible
2014	17	14	3

Presenting signs (probable and possible)

Anorexia (1)	Hypersalivation (7)	Site reaction (1)
Behavioural change (2)	Lack of effect (1)	Vomiting (9)
Gingival soreness (2)	Lethargy (2)	Weight loss (1)

CYPERMETHRIN

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

CYROMAZINE

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	4	1	3

Presenting signs (probable and possible)

Death (1)

Lack of effect (4)

D.A.P BULK SOLUTION

Canine

Year	Total Reports	Total Probable	Total Possible
2014	6	3	3

Presenting signs (probable and possible)

0.0.4	,	
Alopecia (localised) (2)	Gagging (1)	Odour (1)
Behavioural change (2)	Hyperexcitable (1)	Oral (irritation) (1)
Coughing (1)	Hypersensitive to stimuli (1)	Stomatitis (1)
Dermatitis (1)	Irritation (skin) (1)	
Erythema (1)	Lack of effect (1)	

DELTAMETHRIN

In 2012 a new product range was introduced to the market. It had a very high sales volume and a high number of reports related to canines were made. Reports peaked in 2014 and have decreased to a level below 1 report in 10,000 units sold. The reactions recorded describe reactions at the application site, including localised skin lesions lesion, dermatitis or erythema, pruritus and alopecia. These are mentioned on the label and the rapidly improve when exposure is stopped.

All other products containing this active continue to be well below the action incidence of 1 in 10,000.

DELTAMETHRIN

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

Canine

Year	Total Reports	Total Probable	Total Possible
2014	246	167	79
Presenting signs (probab	le and possible)		
abnormal breathing (1)	Incontinen	ce (1)	QC (2)
Agitation (20)	Insomnia ((1)	Rash (8)
Alopecia (localised) (22)	Irritation (e	ear) (1)	Red eyes (4)
Anorexia (8)	Irritation (e	eye) (3)	Respiratory problems (1)
Ataxia (10)	Irritation (s	skin) (46)	Restless (15)
Behavioural change (19)	Lack of eff	ect (23)	Rubbing (2)
Blepharospasm (1)	Lesions (5)	Scabs (9)
Coat discoloration (1)	Lethargy (27)	Seizure (5)
Coughing (1)	Low effica	cy (1)	Shaking (7)
Crusting skin (1)	Malaise (1)	Site reaction (10)
Dermatitis (6)	Muscle tw	itching (10)	Site reaction (swelling) (3)
Disorientation (3)	Mydriasis	(2)	Swelling (local) (1)
Erythema (42)	Pain (2)		Tremor (7)
Facial oedema (2)	Panting (1)	Ulceration (2)
Gagging (2)	Papules (2	2)	Urticaria (4)
Hyperactivity (2)	Paresis (1)	Vocalisation (7)
Hypersalivation (4)	Periorbital	swelling (1)	Vomiting (10)
Hypersensitive to stimuli (1) Pruritus (7	70)	Weakness (1)
Hypertonia (1)	Pyoderma	(4)	Welts (3)

DEOXYCORTONE PIVALATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	3	0	3

Presenting signs (probable and possible)

Alopecia (1) Anorexia (1)

Oedema (1)

Sterility (1)

DESLORELIN ACETATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	14	3	11

Presenting signs (probable and possible)

Irritation (skin) (1) QC (1)

Lack of effect (8) Recovery (prolonged) (1)

Low efficacy (1) Site reaction (2)

DIAZINON

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Alopecia (localised) (1) Dermatitis (1)

Anorexia (1) Lethargy (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	5	0	5

Presenting signs (probable and possible)

Coat discoloration (2) Lack of effect (3)

DICYCLANIL

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	6	2	4

Presenting signs (probable and possible)

Illness (1)

Lack of effect (3)

Low efficacy (2)

60

DIFLUBENZURON

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	3	0	3

Presenting signs (probable and possible)

Lack of effect (3)

DISODIUM EDETATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Erythema (1)

DORAMECTIN

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Burn(s) (1)

Lack of effect (1)

Site reaction (1)

EMODEPSIDE

Feline

Year	Total Reports	Total Probable	Total Possible
2014	7	5	2

Presenting signs (probable and possible)

Alopecia (5)

Erythema (2)

Pruritus (1)

Residue violation (1)

Site reaction (7)

ESCHERICHIA COLI K99 PILUS ANTIGENS

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Alopecia (localised) (1)

Injection site reaction (1)

Lump (local) (2)

FEBANTEL

Canine

Year	Total Reports	Total Probable	Total Possible
2014	9	3	6

Presenting signs (probable and possible)

Agitation (2)

Pruritus (3)

Vomiting (7)

Facial oedema (1)

Site reaction (1)

Lethargy (2)

Urticaria (1)

FELINE CALICIVIRUS

Feline

Year	Total Reports	Total Probable	Total Possible
2014	12	4	8

Agitation (1)	Lack of effect (1)	Pyoderma (1)
Alopecia (localised) (2)	Lame (1)	Pyrexia (4)
Anaemia (1)	Lethargy (6)	Self trauma (1)
Anorexia (2)	Lump (local) (3)	Vomiting (1)
Diarrhoea (1)	Pain (2)	Weight loss (1)
Injection site reaction (1)	Papules (1)	

FELINE CALICIVIRUS—INACTIVATED

Feline

Year	Total Reports	Total Probable	Total Possible
2014	27	11	16

Presenting signs (probable and possible)

Aggression (1)	Erythema (1)	Pain (1)
Alopecia (localised) (4)	Facial oedema (3)	Pruritus (2)
Anaemia (1)	Halitosis (1)	Pyrexia (7)
Anaphylaxis (1)	Inflammation (1)	Recumbency (1)
Anorexia (7)	Injection site reaction (2)	Site reaction (1)
Behavioural change (1)	Jaundice (1)	Tachycardia (3)
Collapse (1)	Lame (1)	Tachypnoea (2)
Coughing (1)	Lethargy (11)	Vocalisation (2)
Cyanosis (2)	Listless (1)	Vomiting (5)
Diarrhoea (1)	Lump (local) (1)	
Dyspnoea (1)	Malaise (1)	

FELINE CALICIVIRUS - LIVE

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Lethargy (1)

Shaking (1)

Vomiting (1)

FELINE CHLAMYDIA PSITTACI—INACTIVATED

Feline

Year	Total Reports	Total Probable	Total Possible
2014	2	2	0

Presenting signs (probable and possible)

Behavioural change (1) Injection site reaction (1) Tachycardia (1)

Halitosis (1)

Inflammation (1) Pyrexia (1)

FELINE IMMUNODEFICIENCY VIRUS(PETALUMA STRAIN)—INACTIVATED

Feline

Year	Total Reports	Total Probable	Total Possible
2014	5	1	4

Presenting signs (probable and possible)

Alopecia (localised) (1) Pruritus (1) Vocalisation (1)

Anorexia (1) Pyrexia (1) Vomiting (1)

Lethargy (2) Recumbency (1)

Pain (1) Tachypnoea (1)

FELINE IMMUNODEFICIENCY VIRUS(SHIZUOKA STRAIN)—INACTIVE

Feline

Year	Total Reports	Total Probable	Total Possible
2014	5	1	4

Presenting signs (probable and possible)

Alopecia (localised) (1) Pruritus (1) Vocalisation (1)

Anorexia (1) Pyrexia (1) Vomiting (1)

Lethargy (2) Recumbency (1)

Pain (1) Tachypnoea (1)

FELINE LEUKAEMIA VIRUS—INACTIVATED

Feline

Year	Total Reports	Total Probable	Total Possible
2014	6	4	2

Presenting signs (probable and possible)

Troconting digital (products and possible)			
Anorexia (3)	Inflammation (1)	Pruritus (1)	
Behavioural change (1)	Injection site reaction (1)	Pyrexia (1)	
Collapse (1)	Lethargy (2)	Tachycardia (1)	
Halitosis (1)	Lump (local) (1)	Tachypnoea (1)	

FELINE PANLEUCOPENIA

Feline

Year	Total Reports	Total Probable	Total Possible
2014	12	4	8

Presenting signs (probable and possible)

Agitation (1)	Lack of effect (1)	Pyoderma (1)
Alopecia (localised) (2)	Lame (1)	Pyrexia (4)
Anaemia (1)	Lethargy (6)	Self trauma (1)
Anorexia (2)	Lump (local) (3)	Vomiting (1)
Diarrhoea (1)	Pain (2)	Weight loss (1)
Injection site reaction (1)	Papules (1)	

FELINE PANLEUCOPENIA VIRUS—INACTIVATED

Feline

Year	Total Reports	Total Probable	Total Possible
2014	27	11	16

Aggression (1)	Anorexia (7)	Cyanosis (2)
Alopecia (localised) (4)	Behavioural change (1)	Diarrhoea (1)
Anaemia (1)	Collapse (1)	Dyspnoea (1)
Anaphylaxis (1)	Coughing (1)	Erythema (1)

Facial oedema (3)	Listless (1)	Site reaction (1)
Halitosis (1)	Lump (local) (1)	Tachycardia (3)
Inflammation (1)	Malaise (1)	Tachypnoea (2)
Injection site reaction (2)	Pain (1)	Vocalisation (2)
Jaundice (1)	Pruritus (2)	Vomiting (5)
Lame (1)	Pyrexia (7)	
Lethargy (11)	Recumbency (1)	

FELINE PANLEUCOPENIA VIRUS—LIVE

Feline

Total Reports	Total Probable	Total Possible
1	1	0
	Total Reports	Total Reports Total Probable 1 1

Presenting signs (probable and possible)

Lethargy (1) Shaking (1) Vomiting (1)

FELINE RHINOTRACHEITIS

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Lethargy (1) Shaking (1) Vomiting (1)

FELINE RHINOTRACHEITIS VIRUS—INACTIVATED

Feline

Year	Total Reports	Total Probable	Total Possible
2014	27	11	16

Aggression (1)	Behavioural change (1)	Dyspnoea (1)
Alopecia (localised) (4)	Collapse (1)	Erythema (1)
Anaemia (1)	Coughing (1)	Facial oedema (3)
Anaphylaxis (1)	Cyanosis (2)	Halitosis (1)
Anorexia (7)	Diarrhoea (1)	Inflammation (1)

Injection site reaction (2)	Malaise (1)	Tachycardia (3)
Jaundice (1)	Pain (1)	Tachypnoea (2)
Lame (1)	Pruritus (2)	Vocalisation (2)
Lethargy (11)	Pyrexia (7)	Vomiting (5)
Listless (1)	Recumbency (1)	
Lump (local) (1)	Site reaction (1)	

FIPRONIL

Canine

Ye	ar	Total Reports	Total Probable	Total Possible
20	14	27	1	26
Pres	senting signs (probable	e and possible)		
Agi	itation (1)	Irritation (eye) (1)	Seizure (1)
Alo	ppecia (localised) (2)	Lack of effect (10)	Site reaction (4)
Anc	orevia (3)	Lethargy (3)		Vomiting (2)

Anorexia (3)

Ataxia (1)

Lethargy (3)

Wornling (2)

Weakness (1)

Diarrhoea (1) Pruritus (5)

Erythema (4) Rash (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	11	0	11

Alopecia (localised) (6)	Erythema (4)	Pruritus (2)
Ataxia (1)	Lack of effect (2)	Site reaction (1)
Crusting skin (1)	Lethargy (1)	
Death (1)	Muscle twitching (1)	

FIROCOXIB

Canine

Year	Total Reports	Total Probable	Total Possible
2014	5	1	4

Presenting signs (probable and possible)

Anorexia (1) Polyuria (1) Ulceration (stomach) (1)

Azotaemia (2) Tenesmus (1) Vomiting (2)

Polydipsia (1) Ulceration (1)

FLUAZURON

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	3	0	3

Presenting signs (probable and possible)

Lack of effect (2) Low efficacy (1)

FLUMETHRIN

Canine

Year	Total Reports	Total Probable	Total Possible
2014	6	1	5

Presenting signs (probable and possible)

resenting signs (producte and possible)					
Alopecia (1)	Haemorrhage (1)	Pruritus (1)			
Blisters (1)	Lack of effect (2)	Site reaction (3)			
Erythema (3)	Lesions (1)	Swelling (local) (1)			

FLUOXETINE HYDROCHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Anorexia (1)

G GLYCOPROTEIN OF HENDRA VIRUS (SG - PROTEIN)

SG – Protein was first available under permit in 2012. The information received regarding adverse events occurring while the permit was active, were provided to the APVMA under a mandatory reporting regime required as a condition of the permit authorising the supply and use prior to the registration of the product. Please note that a mandatory reporting regime is expected to yield a higher reporting incidence than would be the case under a voluntary reporting arrangement.

In 2015 the product containing this active was registered. Reports continue to be made but the frequency of those reports is decreasing.

The most commonly reported presenting signs included lethargy, injection site reaction and anorexia. 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.

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

G GLYCOPROTEIN OF HENDRA VIRUS (SG - PROTEIN)

Equine

Year	Total Reports	Total Probable	Total Possible			
2014	456	381	75			
Presenting signs (probable and possible)						
abnormal breathing (1)	Coat colour	change (4)	Eczema (1)			
Adipsia (2)	Colic (12)		Hives (1)			
Agitation (1)	Confusion (1)	Hyperactivity (1)			
Alopecia (2)	Coughing (4)	Hypersalivation (1)			
Alopecia (localised) (9)	Death (3)		Hypersensitive to stimuli (1)			
Anorexia (75)	Depression	(9)	Hypersensitivity reaction (2)			
Ataxia (15)	Dermatitis ((1)	Inflammation (1)			
Azoturia (1)	Diarrhoea (2)	Injection site reaction (279)			
Behavioural change (9)	Disorientati	on (2)	Lame (10)			
	Distress (2)		Laminitis (4)			

Lethargy (140) Paresis (1) Sweating (16) Listless (9) Preputial swelling (2) Swelling (local) (36) Lump (local) (48) Pruritus (2) Tachycardia (3) Lymphadenopathy (4) Pyrexia (84) Tachypnoea (2) Malaise (16) Recumbency (9) Tremor (1) Muscle stiffness (20) Respiratory problems (1) Urine (abnormal) (1) Nasal discharge (3) Restless (2) Urticaria (23) Walking (difficult) (2) Oedema (145) Scrotitis (1) Pain (135) Shaking (3) Weight loss (4) Pale mucous membranes (2) Stiffness (66) Welts (1) Panting (3) Stranguria (2)

GENTAMICIN SULFATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	3	1	2

Presenting signs (probable and possible)

Deafness (2) Inflammation (1) Pain (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Facial oedema (1)

GLUCOSAMINE HYDROCHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Coughing (1)

Flatulence (1)

Swelling (local) (1)

Vomiting (1)

GLUTAMIC ACID-L SODIUM SALT

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Constipation (1)

GREEN LIPPED MUSSEL

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Flatulence (1)

Lethargy (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	2	2	0

Presenting signs (probable and possible)

Diarrhoea (2)

HYDROCORTISONE ACEPONATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Agitation (1) Erythema (1) Vomiting (1)

HYOSCINE METHOBROMIDE

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Constipation (1)

IMADACLOPRID

Imidacloprid is a systemic insecticide that acts as an insect neurotoxin and belongs to a class of chemicals called the neonicotinoids which act on the central nervous system of insects. The types of reactions observed and listed here are expected to occur in rare instances.

The most commonly reported presenting signs included site reactions, such as pruritus (itching) and agitation. These are localised reactions related to the application of the product and are generally only observed for a short duration.

The number of reports associated with Imadacloprid is low when compared with the number of doses sold in 2014 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Total Probable

Total Reports

Total Possible

IMIDACLOPRID

Canine

Year

Teal	Total Reports	Total Flobable	Total Possible		
2014	117	16	101		
Presenting signs (probab	Presenting signs (probable and possible)				
Agitation (18)	Hypersen	sitivity reaction (1)	Retching (1)		
Alopecia (4)	Inflammat	ion (1)	Scabs (1)		
Alopecia (localised) (3)	Irritation (skin) (1)	Seizure (2)		
Anorexia (9)	Lack of ef	fect (14)	Shaking (3)		
Ataxia (7)	Lesions (6	3)	Site reaction (45)		
Behavioural change (5)	Lethargy ((26)	Spasm (2)		
Burn(s) (6)	Lump (loc	al) (2)	Swelling (local) (2)		
Coat colour change (4)	Malaise (5	5)	Tachycardia (1)		
Coat discoloration (1)	Muscle tw	ritching (3)	Tachypnoea (1)		
Dermatitis (1)	Pain (1)		Tremor (5)		
Diarrhoea (4)	Panting (3	3)	Vocalisation (3)		
Disorientation (1)	Paraesthe	esia (20)	Vomiting (12)		
Erythema (13)	Paralysis	(1)	Weakness (2)		
Hyperactivity (10)	Pruritus (4	17)			
Hypersalivation (3)	Pustules ((1)			

Feline

Year	Total Reports	Total Probable	Total Possible
2014	34	10	24

Presenting signs (probable and possible)

0 0 1	,	
Agitation (1)	Erythema (10)	Mydriasis (1)
Alopecia (2)	Foaming (1)	Pain (1)
Alopecia (localised) (16)	Frothing at the mouth (2)	Paraesthesia (2)
Apnoea (1)	Hyperexcitable (1)	Pruritus (6)
Behavioural change (4)	Hypersalivation (7)	Pyoderma (1)
Burn(s) (2)	Injection site reaction (1)	Seizure (2)
Dermatitis (1)	Lesions (1)	Site reaction (16)
Diarrhoea (1)	Lethargy (5)	Vocalisation (1)
Disorientation (1)	Malaise (1)	Vomiting (2)

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Dermatitis (1) Necrosis (1) Site reaction (1)

INDOXACARB

Indoxacarb is a widely used systemic parasiticide that disrupts the development cycle of fleas. Indoxacarb is present in a large number of registered veterinary chemical products. It is often present in combination with other active constituents and so has a higher number of reports associated with it.

The most commonly reported presenting signs included site reaction, gastrointestinal signs, vomiting and diarrhoea.

The number of reports associated with Indoxacarb is low when compared with the number of doses sold in the same period and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

INDOXACARB

Canine

Year	Total Reports	Total Probable	Total Possible	
2014	25	15	10	
Presenting signs (probable and possible)				
Agitation (1)	Diarrhoea	(1)	Retching (1)	
Alopecia (localised) (2)	Erythema	(4)	Rubbing (1)	
Anorexia (1)	Hypersaliv	vation (1)	Scabs (1)	
Ataxia (1)	Lethargy ((4)	Shaking (1)	
Behavioural change (4)	Malaise (1)	Site reaction (4)	

Pain (1)

Pruritus (8)

Restless (1)

Feline

Coat discoloration (2)

Coughing (2)

Crusting skin (1)

Year	Total Reports	Total Probable	Total Possible
2014	70	52	18

Urticaria (1)

Vomiting (3)

Welts (1)

Presenting signs (probable and possible)

abnormal breathing (1)	Ataxia (10)	Convulsions (3)
Aggression (1)	Behavioural change (9)	Defaecation (1)
Agitation (3)	Coat colour change (1)	Dehydration (1)
Alopecia (localised) (29)	Collapse (1)	Diarrhoea (1)

Dyspnoea (1) Muscle twitching (2) Spasm (1) Erythema (1) Mydriasis (6) Stiffness (1) Hyperaesthesia (2) Panting (2) Tachycardia (2) Hyper-reflexia (1) Photophobia (1) Tachypnoea (1) Hypersalivation (9) Pruritus (8) Tremor (2) Hypothermia (1) Recumbency (2) Ulceration (2) Incoordination (1) Restless (1) Vocalisation (6) Irritation (skin) (4) Seizure (1) Vomiting (15) Lesions (2) Self trauma (1) Walking (difficult) (1) Lethargy (5) Site reaction (5)

IVERMECTIN

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Alopecia (localised) (1)

Low efficacy (1)

Canine

Year	Total Reports	Total Probable	Total Possible
2014	4	1	3

Presenting signs (probable and possible)

Anorexia (1)

Lethargy (2)

Tremor (1)

Diarrhoea (3)

Prolapsed third eyelid (1)

Hypersalivation (1)

Toxicity (1)

KAOLIN LIGHT

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Constipation (1)

LEPTOSPIRA ICTEROHAEMORRHAGIAE ANTIGEN

Canine

Year	Total Reports	Total Probable	Total Possible
2014	6	0	6

Presenting signs (probable and possible)

Anaphylaxis (1) Facial oedema (3) Vomiting (1)

Collapse (1) Injection site reaction (2)

Erythema (1) Urticaria (1)

LEVAMISOLE

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Ataxia (1) Lethargy (1) Torticollis (1)

Collapse (1) Muscle twitching (1)

Death (1) Recumbency (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Death (1)

LIVE FELINE HERPES VIRUS

Feline

Year	Total Reports	Total Probable	Total Possible
2014	13	5	8

Presenting signs (probable and possible)

Agitation (1)	Lack of effect (1)	Pyoderma (1)
Alopecia (localised) (2)	Lame (1)	Pyrexia (4)
Anaemia (1)	Lethargy (7)	Self trauma (1)
Anorexia (2)	Lump (local) (3)	Shaking (1)
Diarrhoea (1)	Pain (2)	Vomiting (2)
Injection site reaction (1)	Papules (1)	Weight loss (1)

LUFENURON

Canine

Year	Total Reports	Total Probable	Total Possible
2014	41	20	21

Presenting signs (probable and possible)

Eczema (1)	Pruritus (6)
Erythema (2)	Somnolence (1)
Flatulence (1)	Urticaria (1)
Haemorrhagic gastroenteritis (1)	Vomiting (23)
	Weakness (1)
Lethargy (8)	Weight loss (1)
	Erythema (2) Flatulence (1) Haemorrhagic gastroenteritis (1) Lack of effect (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

MANGANESE EDTA

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	4	1	3

Presenting signs (probable and possible)

Convulsions (1) Hepatopathy (1)

Lump (local) (1)

Death (3)

Injection site reaction (1)

MAVACOXIB

Canine

Year	Total Reports	Total Probable	Total Possible
2014	4	2	2

Presenting signs (probable and possible)

Anaemia (1) Disorientation (1) Neoplasia (1)

Ataxia (1) Hepatopathy (1) Renal failure (1)

MEDETOMIDINE HYDROCHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Deafness (1) Lack of effect (1) Recovery (prolonged) (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Cardiac arrest (1)

Lack of effect (1)

Laryngospasm (1)

MELOXICAM

Canine

Year	Total Reports	Total Probable	Total Possible
2014	7	0	7

Presenting signs (probable and possible)

Anorexia (2)

Distress (1)

Rash (1)

Blood in faeces (1)

Facial oedema (2)

Injection site reaction (1)

Self trauma (1)

Death (1)

Vocalisation (1)

Dehydration (1)

Lethargy (2)

Vomiting (3)

Diarrhoea (4)

Pruritus (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Oedema (1)

Ulceration (stomach) (2)

METHADONE HCL

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Cardiac arrest (1)

METHYL LAURATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	6	3	3

Presenting signs (probable and possible)

Alopecia (localised) (2) Gagging (1) Odour (1)

Behavioural change (2) Hyperexcitable (1) Oral (irritation) (1)

Coughing (1) Hypersensitive to stimuli (1) Stomatitis (1)

Dermatitis (1) Irritation (skin) (1)

Erythema (1) Lack of effect (1)

METHYL LINOLEATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	6	3	3

Presenting signs (probable and possible)

Alopecia (localised) (2) Gagging (1) Odour (1)

Behavioural change (2) Hyperexcitable (1) Oral (irritation) (1)

Coughing (1) Hypersensitive to stimuli (1) Stomatitis (1)

Dermatitis (1) Irritation (skin) (1)

Erythema (1) Lack of effect (1)

METHYL MYRISTATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	6	3	3

Presenting signs (probable and possible)

Alopecia (localised) (2) Gagging (1) Odour (1)

Behavioural change (2) Hyperexcitable (1) Oral (irritation) (1)

Coughing (1) Hypersensitive to stimuli (1) Stomatitis (1)

Dermatitis (1) Irritation (skin) (1)

Erythema (1) Lack of effect (1)

METHYL OLEATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	6	3	3

Presenting signs (probable and possible)

Alopecia (localised) (2) Gagging (1) Odour (1)

Behavioural change (2) Hyperexcitable (1) Oral (irritation) (1)

Coughing (1) Hypersensitive to stimuli (1) Stomatitis (1)

Dermatitis (1) Irritation (skin) (1)

Erythema (1) Lack of effect (1)

METHYL PALMITATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	6	3	3

Presenting signs (probable and possible)

Alopecia (localised) (2) Gagging (1) Odour (1)

Behavioural change (2) Hyperexcitable (1) Oral (irritation) (1)

Coughing (1) Hypersensitive to stimuli (1) Stomatitis (1)

Dermatitis (1) Irritation (skin) (1)

Erythema (1) Lack of effect (1)

METHYL PENTADECANOATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	6	3	3

Presenting signs (probable and possible)

Alopecia (localised) (2) Gagging (1) Odour (1)

Behavioural change (2) Hyperexcitable (1) Oral (irritation) (1)

Coughing (1) Hypersensitive to stimuli (1) Stomatitis (1)

Dermatitis (1) Irritation (skin) (1)

Erythema (1) Lack of effect (1)

METHYL STEARATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	6	3	3

Presenting signs (probable and possible)

Alopecia (localised) (2) Gagging (1) Odour (1)

Behavioural change (2) Hyperexcitable (1) Oral (irritation) (1)

Coughing (1) Hypersensitive to stimuli (1) Stomatitis (1)

Dermatitis (1) Irritation (skin) (1)

Erythema (1) Lack of effect (1)

METOCLOPRAMIDE HYDROCHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Aggression (1) Hyperaesthesia (1) Paddling (1)

Behavioural change (1) Hypersensitive to noise (1)

MICONAZOLE NITRATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	6	4	2

Presenting signs (probable and possible)

Deafness (2) Irritation (skin) (1) Pruritus (1)

Erythema (3) Pain (1) Rash (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lethargy (1)

MILBEMYCIN OXIME

Milbemycin oxime is a veterinary drug from the group of milbemycins, used as a broad spectrum antiparasitic. It is active against worms (anthelmintic) and mites (miticide). 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.

Total Reports

181

The number of reports associated with milbemycin oxime is low when compared with the number of doses sold in 2014 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

Total Probable

111

Total Possible

70

Weight loss (1)

MILBEMYCIN OXIME

Canine

Year

2014

Eczema (2)

2011			. •	
Presenting signs (probabl	e and possible)			
Abnormal Biochemistry (1)	Erythe	ma (2)	Oedema (1)	
Allergy (1)	Flatule	ence (3)	Pain (2)	
Alopecia (2)	Haemo (1)	orrhagic gastroenteritis	Photophobia (1)	
Anorexia (9)		salivation (2)	Pruritus (8)	
Ataxia (3)			Pyrexia (4)	
Behavioural change (1)	Hypers	sensitive to stimuli (1)	Seizure (2)	
5 ()	Hypers	sensitivity reaction (1)	Shaking (3)	
Blood in faeces (3)	Inconti	nence (1)	Somnolence (6)	
Collapse (1)	Incoor	dination (2)		
Convulsions (1)	Lack o	f effect (6)	Tremor (2)	
Coughing (1)	l ethar	gy (37)	Urticaria (2)	
Dermatitis (3)			Vocalisation (2)	
Diarrhoea (21)	Low ef	ficacy (8)	Vomiting (119)	
, ,	Malais	e (1)	Weakness (2)	
Dyspnoea (1)	Muscle	e twitching (1)	, ,	

Feline

Year	Total Reports	Total Probable	Total Possible
2014	17	5	12

86

Presenting signs (probable and possible)

Anorexia (2) Hypersalivation (1) Tachypnoea (1)

Ataxia (3) Lethargy (12) Tremor (2)

CNS dysfunction (1) Muscle twitching (3) Vomiting (5)

Facial oedema (1) Recumbency (1)

MOMETASONE FUROATE MONOHYDRATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Deafness (1)

MONENSIN SODIUM

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Anorexia (1) Death (1) Lack of effect (1)

MORANTEL TARTRATE

Equine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Oral (irritation) (1) Unpleasant taste (1)

MORAXELLA BOVIS

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	6	1	5

Presenting signs (probable and possible)

Alopecia (localised) (1)

Lack of effect (3)

Injection site reaction (2)

Lump (local) (3)

MORAXELLA BOVIS STRAIN EPP63

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	6	1	5

Presenting signs (probable and possible)

Alopecia (localised) (1)

Lack of effect (3)

Injection site reaction (2)

Lump (local) (3)

MORAXELLA BOVIS STRAIN FLA 64

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	6	1	5

Presenting signs (probable and possible)

Alopecia (localised) (1)

Lack of effect (3)

Injection site reaction (2)

Lump (local) (3)

MORAXELLA BOVIS STRAIN SAH38

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	6	1	5

Presenting signs (probable and possible)

Alopecia (localised) (1)

Lack of effect (3)

Injection site reaction (2)

Lump (local) (3)

MOXIDECTIN

Moxidectin are 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 number of reports associated with moxidectin is low when compared with the number of doses sold in 2014 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions

MOXIDECTIN

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Alopecia (localised) (1)

Skin slough (1)

Canine

Year	Total Reports	Total Probable	Total Possible
2014	21	1	20

Presenting signs (probable and possible)

	-	
Agitation (1)	Facial oedema (1)	Pustules (1)
Alopecia (localised) (1)	Hyperactivity (4)	Site reaction (6)
Anorexia (1)	Lack of effect (1)	Tachypnoea (1)
Behavioural change (1)	Lethargy (9)	Tremor (3)
Coat colour change (1)	Pain (1)	Vocalisation (1)
Diarrhoea (1)	Panting (1)	Vomiting (3)
Disorientation (1)	Paraesthesia (1)	
Erythema (2)	Pruritus (3)	

Equine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Anorexia (1)

Lethargy (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	21	7	14

Presenting signs (probable and possible)

Alopecia (2)	Erythema (8)	Pain (1)
Alopecia (localised) (10)	Hyperexcitable (1)	Paraesthesia (1)
Apnoea (1)	Hypersalivation (3)	Pruritus (3)
Behavioural change (2)	Injection site reaction (1)	Seizure (1)
Burn(s) (1)	Lethargy (2)	Site reaction (11)
Disorientation (1)	Mydriasis (1)	Vomiting (1)

MOXIDECTIN MICROSPHERES

Canine

Year	Total Reports	Total Probable	Total Possible	
2014	47	10	37	
Presenting signs	(probable and possible)			

P Defaecation (1) Nausea (1) Abscess (1) Diarrhoea (5) Necrosis (1) Aggression (1) Distress (1) Oedema (2) Agitation (1) Erythema (3) Pain (5) Allergy (1) Facial oedema (13) Pale mucous membranes (1) Alopecia (1) Haemorrhagic gastroenteritis Pruritus (4) Anaphylactoid reaction (3) (1) Pyrexia (1) Anaphylaxis (8) Hives (1) Shaking (1) Anorexia (3) Hypersensitive to stimuli (2) Tachycardia (1) Ataxia (1) Injection site reaction (2) Unconscious (1) Blood in faeces (1) Irritation (skin) (1) Urticaria (7) Cellulitis (1) Lethargy (6) Vomiting (11) Circulatory collapse (1) Lump (local) (2) Weakness (1) Collapse (1)

MYCOBACTERIUM PARATUBERCULOSIS

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Death (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Confusion (1) Incoordination (1)

Death (1) Lack of effect (1)

MYCOPLASMA HYOPNEUMONIAE STRAIN J

Porcine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Death (1)

NAPHTHALOPHOS

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Death (2)

NARASIN

Avian

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Lack of effect (2)

NEOMYCIN

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Anorexia (1)

Lethargy (1)

NEOMYCIN SULFATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Irritation (eye) (1)

NICARBAZIN

Avian

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

NITENPYRAM

Canine

Year	Total Reports	Total Probable	Total Possible	
2014	9	6	3	
Presenting signs (probable and possible)				

Hyperactivity (2) Shaking (1) Agitation (1)

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

Muscle twitching (1) Distress (1)

Pruritus (4) Facial oedema (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	10	7	3

Presenting signs (probable and possible)

Lethargy (2) Tachypnoea (3) Anorexia (1)

Low efficacy (1) Vocalisation (2) Diarrhoea (1)

Vomiting (1) Mydriasis (1) Distress (1)

Pruritus (2) Dyspnoea (4)

Tachycardia (2) Hyperactivity (4)

N-METHYL-2-PYRROLIDONE

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

CNS dysfunction (1)

Hypersalivation (1)

Rabbit

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Respiratory problems (1)

Tremor (1)

OATMEAL EXTRACT

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Erythema (2)

OESTRADIOL

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Abscess (1)

Preputial prolapse (1)

Prolapse (1)

OLEIC ACID

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

94

Presenting signs (probable and possible)

Allergy (1)

Sneezing (1)

OXANTEL EMBONATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Diarrhoea (1)

Toxicity (1)

OXFENDAZOLE

Equine

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Anorexia (1)

Lethargy (1)

Lack of effect (1)

Malaise (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Death (1)

OXIBENDAZOLE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

OXYCLOZANIDE

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Ataxia (1) Lethargy (1) Torticollis (1)

Collapse (1) Muscle twitching (1)

Death (1) Recumbency (1)

OXYTETRACYCLINE AS THE DIHYDRATE

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lump (local) (1)

PALMITIC ACID

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Allergy (1) Sneezing (1)

PARAFFIN

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

PENICILLIN

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Facial oedema (1)

Pruritus (1)

Tachypnoea (1)

Lethargy (1)

Tachycardia (1)

Equine

Year	Total Reports	Total Probable	Total Possible
2014	3	2	1

Presenting signs (probable and possible)

Agitation (1)

Excitation (1)

Anaphylaxis (1)

Hyperactivity (2)

PENTOBARBITONE SODIUM

Canine

Year	Total Reports	Total Probable	Total Possible
2014	4	0	4

Presenting signs (probable and possible)

abnormal breathing (3)

Lack of effect (2)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

PENTOSAN POLYSULFATE SODIUM

Canine

Year	Total Reports	Total Probable	Total Possible
2014	21	10	11

Presenting signs (probable and possible)

Abscess (1)	Distress (1)	Listless (1)
Agitation (1)	Elevated ALP (1)	Pain (2)
Anaphylaxis (1)	Epistaxis (1)	Pyrexia (1)
Anorexia (2)	Facial oedema (1)	Stiffness (1)
Ataxia (1)	Hypo-reflexia (1)	Tachycardia (2)
Blindness (1)	Incontinence (1)	Urticaria (1)
Collapse (3)	Injection site reaction (1)	Vocalisation (1)
Defaecation (1)	Lame (1)	Vomiting (5)
Diarrhoea (3)	Lethargy (6)	Weakness (1)

Equine

Year	Total Reports	Total Probable	Total Possible
2014	5	5	0

Presenting signs (probable and possible)

Agitation (1)	Hives (1)	Sweating (1)
Alopecia (localised) (2)	Injection site reaction (1)	Tachycardia (1)
Coat colour change (2)	Pruritus (1)	Urticaria (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Hypersalivation (1)	Retching (1)	Vomiting (1)
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PERMETHRIN

Permethrin is an insecticide in the **pyrethroid** family. Pyrethroids are synthetic chemicals that act like natural extracts from the chrysanthemum flower. **Permethrin** is used in a number of ways to control insects.

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 addressed <u>permethrin toxicity in cats</u> can be found on the APVMA website

The number of reports associated with permethrin has remained consistently high. It was considered in the majority of cases that the presenting sign accounting for most reports (i.e. skin irritation, pruritus or agitation) involved brief period from which the animal recovered very quickly. In light of this and the fact that the product labels contain warnings regarding expected reactions, no further action was considered necessary other than ongoing monitoring.

Total Probable

Total Possible

Total Reports

PERMETHRIN

Canine

Year

2014	101	14	87		
Presenting signs (proba	Presenting signs (probable and possible)				
Agitation (17)	Ну	persensitivity reaction (1)	Retching (1)		
Alopecia (4)	Inf	lammation (1)	Scabs (1)		
Alopecia (localised) (2)	Irri	itation (skin) (2)	Seizure (2)		
Anorexia (10)	La	ck of effect (13)	Shaking (3)		
Ataxia (7)	Le	sions (6)	Site reaction (37)		
Behavioural change (4)	Le	thargy (23)	Spasm (2)		
Burn(s) (5)	Lu	mp (local) (2)	Swelling (local) (2)		
Coat colour change (3)	Ma	alaise (5)	Tachycardia (1)		
Dermatitis (1)	М	uscle twitching (3)	Tachypnoea (1)		
Diarrhoea (3)	Pa	in (1)	Tremor (2)		
Erythema (10)	Pa	anting (2)	Vocalisation (2)		
Hyperactivity (7)	Pa	araesthesia (19)	Vomiting (9)		
Hypersalivation (3)	Pa	aralysis (1)	Weakness (2)		
	Pr	uritus (44)			

Equine

Year	Total Reports	Total Probable	Total Possible
2014	2	2	0

Presenting signs (probable and possible)

Agitation (1)

Hypersalivation (1)

Irritation (skin) (1)

PHENYLBUTAZONE

Equine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Death (1)

PHTHALYLSULFATHIAZOLE

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Constipation (1)

PIMELIC ACID

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Allergy (1)

Sneezing (1)

PIMOBENDAN

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Seizure (1)

PIPERONYL BUTOXIDE

Avian

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Death (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

CNS dysfunction (1)

Hypersalivation (1)

Rabbit

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Respiratory problems (1)

Tremor (1)

POLY(HEXAMETHYLENE BIGUANIDE) HYDROCHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Erythema (1)

POLYMIXIN B

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Anorexia (1)

Lethargy (1)

POLYMYXIN B SULFATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	5	3	2

Presenting signs (probable and possible)

Deafness (2) Irritation (eye) (1) Rash (1)

Erythema (2) Pain (1)

POTASSIUM BROMIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

POTASSIUM CLAVULANATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Periorbital swelling (1)

POTASSIUM GLUCONATE

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Constipation (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, lethargy and diarrhoea. It is used in many products and has a very high sales volume.

The number of reports associated with praziquantel is low when compared with the number of doses sold in 2014 (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

Year	Total Reports	Total Probable	Total Possible				
2014	87	39	48				
Presenting signs (probable and possible)							
Abnormal Biochemistry (1)	Dyspnoea	(1)	Pruritus (9)				
Agitation (2)	Eczema (2	2)	Seizure (1)				
Allergy (1)	Erythema	(2)	Shaking (1)				
Alopecia (2)	Facial oed	ema (1)	Site reaction (1)				
Anorexia (4)	Flatulence	(3)	Somnolence (1)				
Ataxia (2)		agic gastroenteritis	Toxicity (1)				
Behavioural change (1)	(1)	ation (4)	Tremor (2)				
Blood in faeces (3)	Hypersaliv	. ,	Urticaria (3)				
Convulsions (1)		sitivity reaction (1)	Vocalisation (1)				
Coughing (1)	Lack of eff	, ,	Vomiting (49)				
Dermatitis (3)	Lethargy (•	Weakness (1)				
Diarrhoea (17)	Oedema (1	1)	Weight loss (1)				

Equine

Year	Total Reports	Total Probable	Total Possible
2014	3	0	3

Presenting signs (probable and possible)

Anorexia (2)

Lethargy (2)

Lack of effect (1)

Malaise (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	24	10	14

Presenting signs (probable and possible)

Alopecia (5)

Hypersalivation (1)

Site reaction (7)

Anorexia (2)

Lethargy (12)

Tachypnoea (1)

Ataxia (3)

Muscle twitching (3)

Tremor (2)

CNS dysfunction (1)

Pruritus (1)

Vomiting (5)

Erythema (2)

Recumbency (1)

Facial oedema (1)

Residue violation (1)

PREDNISOLONE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	4	2	2

Presenting signs (probable and possible)

Deafness (2)

Pain (1)

Erythema (2)

Rash (1)

PROLIGESTONE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Pain (1)

PROPENTOFYLLINE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Disorientation (1)

Hyperexcitable (1)

Tachycardia (1)

PROPOFOL

Canine

Year	Total Reports	Total Probable	Total Possible
2014	4	0	4

Presenting signs (probable and possible)

Facial oedema (1)

Lack of effect (1)

Injection site reaction (1)

Periorbital swelling (1)

PROPOXUR

Canine

Year	Total Reports	Total Probable	Total Possible
2014	6	1	5

Presenting signs (probable and possible)

Alopecia (1)

Haemorrhage (1)

Pruritus (1)

Blisters (1)

Lack of effect (2)

Site reaction (3)

Erythema (3)

Lesions (1)

Swelling (local) (1)

PYRANTEL EMBONATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	12	4	8

Presenting signs (probable and possible)

Agitation (2) Facial oedema (1) Site reaction (1)

Anorexia (1) Lethargy (3) Toxicity (1)

Diarrhoea (2) Pruritus (3) Urticaria (1)

Vomiting (7)

Equine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

PYRETHRIN

Avian

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Death (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

CNS dysfunction (1)

Hypersalivation (1)

Rabbit

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Respiratory problems (1)

Tremor (1)

PYRETHRUM EXTRACT

Rabbit

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Respiratory problems (1)

Tremor (1)

PYRIPROXYFEN

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Site reaction (1)

QUIL

Feline

Year	Total Reports	Total Probable	Total Possible
2014	4	0	4

Weight loss (1)

Presenting signs (probable and possible)

Anorexia (1) Lump (local) (2)

Injection site reaction (1)

Lethargy (1) Pyrexia (1)

RABBIT CALICIVIRUS DISEASE VIRUS -INACTIVATED

Rabbit

Year	Total Reports	Total Probable	Total Possible
2014	6	6	0

Presenting signs (probable and possible)

Alopecia (1)

Alopecia (localised) (1)

Eczema (1)

Lump (local) (1)

Anorexia (2)

Lump (local) (1)

Self trauma (1)

RECOMBINANT GP70 SUB-TYPE A

Feline

Year	Total Reports	Total Probable	Total Possible
2014	4	0	4

Presenting signs (probable and possible)

Anorexia (1) Lump (local) (2) Weight loss (1)

Injection site reaction (1)

Lethargy (1) Pyrexia (1)

RESERPINE

Equine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Dyspnoea (1)

Lethargy (1)

ROBENACOXIB

Canine

Year	Total Reports	Total Probable	Total Possible
2014	10	1	9

Presenting signs (probable and possible)

Abnormal Biochemistry (3) Hepatopathy (3) Thrombocytopenia (2)

Anorexia (1) Jaundice (1) Tremor (1)

Ataxia (1) Lame (1) Ulceration (stomach) (1)

Coughing (1) Lethargy (3) Vomiting (4)

Elevated ALP (2) Malaise (1)

Elevated ALT (2)

SALMONELLA DUBLIN & TYPHIMURIUM ANTIGENS - INACTIVATED

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

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

Diarrhoea (1) Milk production decrease (1)

SELAMECTIN

Canine

Year	Total Reports	Total Probable	Total Possible
2014	2	2	0

Presenting signs (probable and possible)

Anorexia (1)

Behavioural change (1)

Lethargy (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	22	21	1

Presenting signs (probable and possible)

Alopecia (5)

Alopecia (localised) (13)

Burn(s) (1)

Coat discoloration (1)

Erythema (2)

Hypersalivation (1)

Inflammation (1)

Scabs (2)

Self trauma (2)

Site reaction (19)

Vomiting (1)

SELENIUM AS SODIUM SELENATE

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Ataxia (1)

Lethargy (1)

Shaking (1)

Death (1)

Recumbency (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Death (1)

SELENIUM AS SODIUM SELENITE

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	4	1	3

Presenting signs (probable and possible)

Convulsions (1)

Hepatopathy (1)

Lump (local) (1)

Death (3)

Injection site reaction (1)

SODIUM CHONDROITIN SULFATE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Vomiting (1)

SODIUM SALICYLATE

Equine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Death (1)

SODIUM SELENATE

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Ataxia (1) Lethargy (1) Shaking (1)

Death (1) Recumbency (1)

Total Reports

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Death (1)

SPINOSAD

Spinosad is an insecticidal chemical that disrupts the insect nervous system. The most commonly reported presenting signs included vomiting, lethargy, lack of effect, anorexia, diarrhoea and depression.

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

Total Probable

Total Possible

SPINOSAD

Canine

Year

2014	413	243	170	
Presenting signs (probable and possible)				
Allergy (2)	Diarrhoea	(14)	Listless (3)	
Anorexia (12)	Disorienta	tion (1)	Low efficacy (8)	
Ataxia (8)	Dizziness	(3)	Malaise (4)	
Behavioural change (2)	Erythema	(4)	Muscle stiffness (1)	
Blindness (3)	Facial oed	ema (1)	Muscle twitching (1)	
Blood in faeces (1)	Foaming (1)	Mydriasis (1)	
Bruising (1)	Hypersaliv	ation (7)	Nausea (2)	
CNS dysfunction (2)	Hypersens	sitive to stimuli (1)	Oedema (1)	
Collapse (2)	Incontinen	ce (1)	Pain (2)	
Coughing (1)	Incoordina	tion (2)	Photophobia (1)	
Death (1)	Lack of eff	ect (64)	Prolapsed third eyelid (2)	
Depression (3)	Lethargy (60)	Pruritus (10)	

Pupillary light reflex (abnormal) (1)	Retching (1)	Tremor (2)
Pustules (1)	Sedation (2)	Urticaria (1)
Pyrexia (4)	Seizure (8)	Vocalisation (2)
Rash (2)	Shaking (7)	Vomiting (272)
· ,	Somnolence (7)	Walking (difficult) (1)
Red eyes (1)	Tachycardia (1)	Weakness (3)
Restless (3)	Thrombocytopenia (1)	

Equine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Irritation (skin) (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2014	23	12	11

Presenting signs (probable and possible)

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Ataxia (1)	Muscle twitching (1)	Tremor (3)
Hypersalivation (1)	Panting (1)	Vomiting (13)
Lack of effect (2)	Pyrexia (1)	
Lethargy (6)	Somnolence (1)	

STREPTOCOCCUS EQUI

Equine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Injection site reaction (1) Lump (local) (1) Pain (1)

STREPTOCOCCUS EQUI AS CELL FREE EXTRACT

Equine

Year	Total Reports	Total Probable	Total Possible
2014	12	4	8

Presenting signs (probable and possible)

Alopecia (localised) (3)	Injection site reaction (7)	Pain (4)
Anorexia (2)	Lame (1)	Pale mucous membranes (1)
Ataxia (1)	Lethargy (1)	Pyrexia (4)
Coat colour change (1)	Lump (local) (5)	Stiffness (3)
Hyperactivity (1)	Oedema (2)	Sweating (1)

STREPTOCOCCUS EQUI INACTIVATED, CELL-FREE EXTRACT

Equine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)	Lump (local) (1)	Pain (1)
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SULFADIAZINE

Equine

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Death (2)

SULFADIMIDINE AS SODIUM SULFADIMIDINE

Equine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Death (1)

SYNTHETIC ANALOGUE OF F3 FRACTION FELINE FACIAL PHEROMON

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Allergy (1)

Sneezing (1)

SYNTHETIC ANALOGUE OF THE CANINE APPEASING PHEROMONE

Canine

Year	Total Reports	Total Probable	Total Possible
2014	6	3	3

Presenting signs (probable and possible)

Alopecia (localised) (2)

Gagging (1)

Odour (1)

Behavioural change (2)

Hyperexcitable (1)

Oral (irritation) (1)

Coughing (1)

Hypersensitive to stimuli (1)

Stomatitis (1)

Dermatitis (1)

Irritation (skin) (1)

Erythema (1)

Lack of effect (1)

TEMEPHOS

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	2	0	2

Presenting signs (probable and possible)

Death (1)

Nasal discharge (1)

Respiratory problems (1)

Frothing at the mouth (2)

Pulmonary oedema (1)

Shaking (1)

TETANUS = CLOSTRIDIUM TETANI

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

THIACLOPRID

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Pneumonia (1)

THIAMAZOLE

Feline

Year	Total Reports	Total Probable	Total Possible
2014	2	1	1

Presenting signs (probable and possible)

Eosinophilia (1)

Lethargy (1)

Haematology (abnormal) (1)

Pyrexia (1)

TILMICOSIN

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

TOCERANIB

Canine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Hepatopathy (1)

TRENBOLONE ACETATE

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	1	0

Presenting signs (probable and possible)

Prolapse (1)

TRICLABENDAZOLE

Ovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Death (1)

TRIMETHOPRIM

Equine

Year	Total Reports	Total Probable	Total Possible
2014	3	0	3

Presenting signs (probable and possible)

Death (3)

YELLOW BEESWAX

Feline

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

ZETA-CYPERMETHRIN

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

ZINC AS ZINC DISODIUM EDTA

Bovine

Year	Total Reports	Total Probable	Total Possible
2014	4	1	3

Presenting signs (probable and possible)

Convulsions (1) Hepatopathy (1) Lump (local) (1)

Death (3) Injection site reaction (1)

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