



Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**



Adverse Experience Reporting Program

Annual report of events occurring in 2015

December 2018

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How this report is set out

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

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

Chapter 3 sets out the results of AERP assessments in the years 2015 involving registered Agricultural Chemicals and adverse experiences relating to Humans.

Chapter 4 sets out the results of AERP assessments in the years 2015 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 in the years 2015 involving registered Veterinary Medicines products and adverse experiences involving humans.

Chapter 6 sets out the results of APVMA assessments in the years 2015 involving registered Veterinary Medicines and effects relating to animals.

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

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.

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.

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 in 2015, 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
2015	3	2	1

Presenting signs (probable and possible)

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

Pain (1)

2 SUMMARY OF EVENTS OCCURING IN 2015

2.1 Veterinary

A total of 4064 adverse experience reports involving registered veterinary products were reported to have occurred in 2015. Of these:

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

Of the 4064 adverse experiences reports assessed by the APVMA, 2704 were classified as either probable or possible.

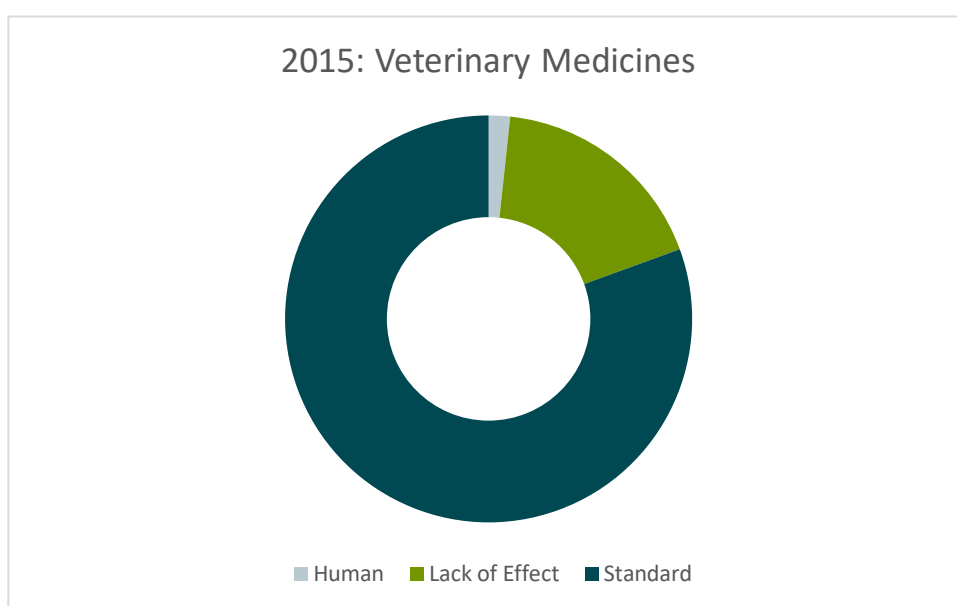


Figure 1: Adverse experience reports involving registered veterinary medicines that occurred in 2015

2.2 Agricultural

In 2015, a total of 36 adverse experience reports involving agricultural products were reported to have occurred. Of these:

- 33 per cent involved effects on crops or animals,
- 61 per cent involved human health issues, and
- 6 per cent involved effects on the environment (Figure 2).

Of the 36 reports assessed by the APVMA, 15 were classified as probable or possible.

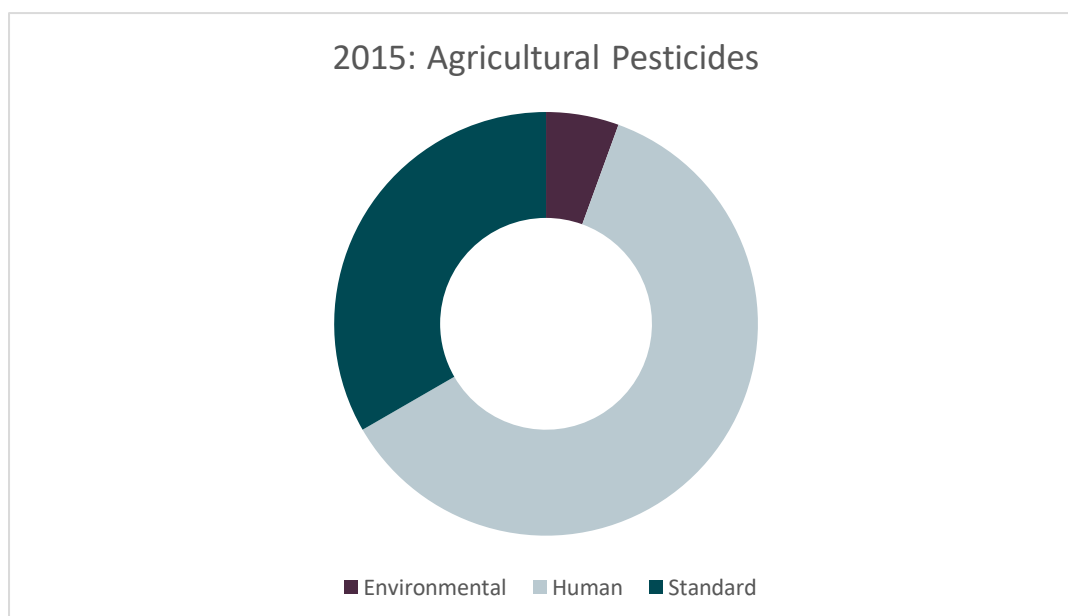


Figure 2: Adverse experience reports involving registered agriculture chemicals that occurred in 2015

2.3 Human

A total of 91 adverse experiences involving effects on humans from registered veterinary medicines and agricultural chemical products were reported to have occurred in 2015. Of these:

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

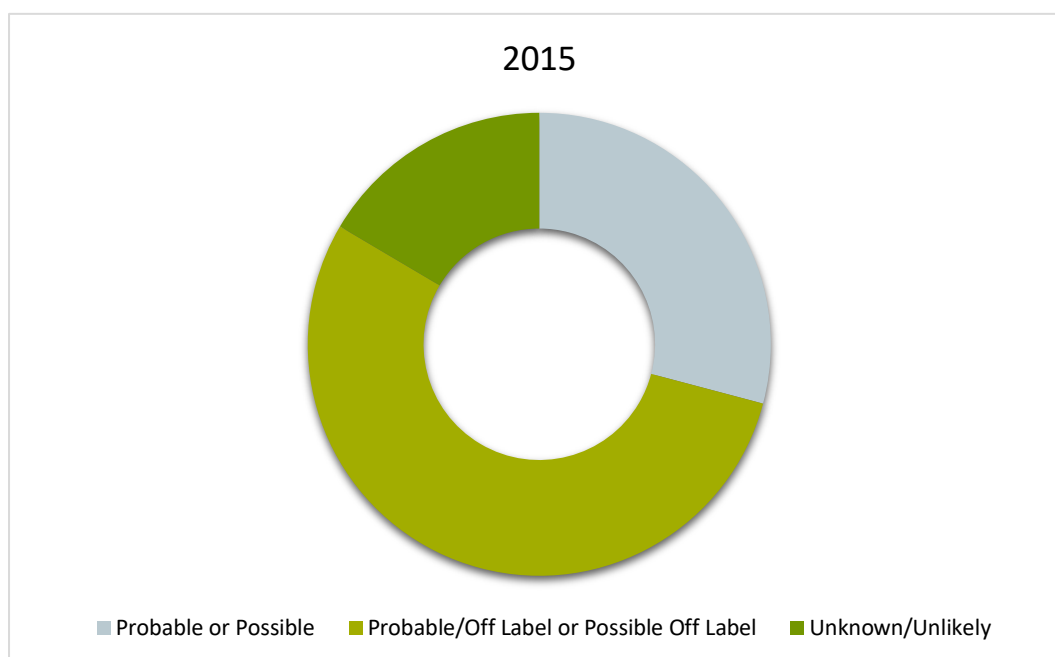


Figure 3: Classification ration of human reports of agricultural chemical and veterinary medicines

No adverse experience assessed and classified by the APVMA in 2015 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 2015. At the time of publication 36 reports had been received. Human health issues accounted for 61 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 in 2015 the following reviews were completed:

Fenthion is a broad-spectrum organophosphorus insecticide. Fenthion was used to control insect pests in agricultural, commercial and domestic situations and external parasites on cattle. Fenthion was also used to control pest birds in and around buildings. Following the completion of the review of fenthion in October 2014 all active approvals and product registrations were cancelled. Products containing fenthion may not be used or supplied as the phase-out period ended in November 2015

Fenamiphos was nominated for review following reports of bird and fish deaths possibly relating to the use of products containing fenamiphos. Additional reports of adverse experiences involved the potential for environmental contamination of groundwater and waterways, particularly due to leaching from the site of application

Dichlorvos was reviewed because of concerns relating to public and occupational health and safety, the environment, residues and trade. This action was based on reports of adverse experiences, regulatory action by the United States Environmental Protection Agency, and residue violations in cereals and cereal products.

APVMA determined that there was insufficient data for us to be satisfied that there was adequate protection for people in relation to occupational exposure, exposure arising from some domestic uses, and residues in some food commodities. Dichlorvos product labels did not conform to current safety standards and that labels did not contain adequate information to protect the environment.

Accordingly, the APVMA cancelled the registration of one home garden product, cancelled some specific uses (including use for grain fumigation) and required registrants to modify products labels in line with the review findings.

Azinphos-methyl review was completed in March 2015. Azinphos-methyl was nominated due to concerns about its toxicity and associated potential risks to the public, occupational health and safety and the environment. There were related concerns about residues and possible impacts on Australian trade. In finalising the review, the APVMA updated the product labels to bring them in line with the current First Aid and Safety Directions Handbook and added a restraint statement prohibiting the use of hand-held sprayers to protect workers.

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

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Burning sensation (1)	Respiratory problems (1)
Oral (burn) (1)	Sensitivity to chemicals (1)

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Irritation (skin) (1)

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Respiratory problems (1)	Sore throat (1)
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Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Allergy (1) Irritation (eye) (1) Rash (1)

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Allergy (1) Malaise (1) Respiratory problems (1)

3.7 PERMETHRIN

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Allergy (2) Malaise (1) Respiratory problems (1)
 Irritation (eye) (1) Rash (1)

3.8 PICLORAM PRESENT AS THE HEXYLOXYPROPYLAMINE SALT

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Unpleasant taste (1)

3.9 PIPERONYL BUTOXIDE

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

QC (1)

3.10 POLY (HEXAMETHYLENE BIGUANIDE) HYDROCHLORIDE

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Burning sensation (1) Respiratory problems (1)
 Oral (burn) (1) Sensitivity to chemicals (1)

3.11 PYRETHRIN

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

QC (1)

3.12 PYRETHRUM EXTRACT

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

QC (1)

3.13 SODIUM HYPOCHLORITE

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Irritation (skin) (1)

3.14 TRICLOPYR BUTOXYETHYL ESTER

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Unpleasant taste (2)

4 AGRICULTURAL – STANDARD

This chapter summarises classifications of APVMA assessments relating to events in 2015 of adverse experience reports involving agricultural chemicals that are not human cases, and were classified as probable or possible.

In 2015, a total of 36 adverse experience reports involving agricultural products were reported to have occurred. Of these:

- 33 per cent involved effects on crops or animals,
- 61 per cent involved human health issues, and
- 6 per cent involved effects on the environment (Figure 2).

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

4.1 (Z)-9 TRICOSENE

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Behavioural change (1) Lethargy (1)

4.2 COUMATETRALYL

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Poisoning (1)

4.3 IMIDACLOPRID

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Behavioural change (1) Lethargy (1)

4.4 SODIUM FLUOROACETATE

Year	Total Reports	Total Probable	Total Possible
2015	2	2	0

Presenting signs (probable and possible)

Agitation (1)

Death (2)

Vocalisation (2)

Behavioural change (1)

Incontinence (1)

Convulsions (1)

Paralysis (1)

5.3 CAMPYLOBACTER JEJUNI SUB-SPECIES JEJUNI - INACTIVATED

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Erythema (1) Injection site reaction (1) Pain (1)

5.4 CLOPROSTENOL SODIUM

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Vaginal discharge (1)

5.5 CLOSTRIDIUM CHAUVOEI - WHOLE CELL CULTURE

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Erythema (1) Swelling (local) (1)

5.6 CLOSTRIDIUM NOVII TYPE B - TOXIOD AND INACTIVATED CELLS

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Erythema (1) Swelling (local) (1)

5.7 CLOSTRIDIUM NOVII TYPE B

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Erythema (1) Swelling (local) (1)

5.8 CLOSTRIDIUM PERFRINGENS TYPE D - TOXOID

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Erythema (1) Swelling (local) (1)

5.9 CLOSTRIDIUM SEPTICUM - TOXOID

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Erythema (2) Swelling (local) (2)

5.10 CLOSTRIDIUM TETANI - TOXOID

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Erythema (1) Swelling (local) (1)

5.11 CORYNEBACTERIUM PSEUDOTUBERCULOSIS - TOXOID

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Erythema (1) Swelling (local) (1)

5.12 DIAZINON

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Epistaxis (2) Nausea (1) Unpleasant smell (1)

5.13 DIFLUBENZURON

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Headache (1)

Malaise (1)

Nausea (1)

5.14 FIPRONIL

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Headache (1)

5.15 IMIDACLOPRID

Year	Total Reports	Total Probable	Total Possible
2015	9	5	4

Presenting signs (probable and possible)

Allergy (1)

Pain (2)

Unpleasant smell (1)

Erythema (1)

Paraesthesia (1)

Unpleasant taste (2)

Irritation (eye) (1)

Pruritus (1)

Irritation (skin) (1)

Oral (irritation) (1)

Respiratory problems (1)

5.16 INDOXACARB

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Apnoea (3)

Hypersensitivity reaction (1)

Burning sensation (3)

Nausea (1)

5.17 METHYL LAURATE

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1) Oedema (1)
 Erythema (1) Unpleasant taste (1)

5.18 METHYL LINOLEATE

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1) Oedema (1)
 Erythema (1) Unpleasant taste (1)

5.19 METHYL MYRISTATE

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1) Oedema (1)
 Erythema (1) Unpleasant taste (1)

5.20 METHYL OLEATE

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1) Oedema (1)
 Erythema (1) Unpleasant taste (1)

5.21 METHYL PALMITATE

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1) Oedema (1)
 Erythema (1) Unpleasant taste (1)

5.22 METHYL PENTADECANOATE

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1) Oedema (1)
 Erythema (1) Unpleasant taste (1)

5.23 METHYL STEARATE

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1) Oedema (1)
 Erythema (1) Unpleasant taste (1)

5.24 MOXIDECTIN

Year	Total Reports	Total Probable	Total Possible
2015	6	4	2

Presenting signs (probable and possible)

Allergy (1) Pain (2) Unpleasant taste (2)
 Irritation (eye) (1) Paraesthesia (1)
 Oral (irritation) (1) Respiratory problems (1)

5.25 N-METHYL-2-PYRROLIDONE

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Headache (1) Malaise (1) Nausea (1)

5.26 PERMETHRIN

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Unpleasant smell (1)

5.27 SYNTHETIC ANALOGUE OF THE CANINE APPEASING PHEROMONE

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1)

Oedema (1)

Erythema (1)

Unpleasant taste (1)

5.28 TETANUS = CLOSTRIDIUM TETANI

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Erythema (1)

Swelling (local) (1)

5.29 TILMICOSIN

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Needle stick injury (1)

Site reaction (swelling) (1)

6 VETERINARY – STANDARD

This chapter summarises classifications of APVMA assessments of adverse experience reports involving registered veterinary medicines which occurred during 2015.

There were 4064 adverse experience events reported, which occurred in 2015 involving registered veterinary medicines of which:

- 80 per cent involved animal safety
- 18 per cent involved lack of efficacy and
- 2 per cent involved human health issues

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

6.1 (S)-METHOPRENE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Frothing at the mouth (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	6	3	3

Presenting signs (probable and possible)

Ataxia (1)	Death (1)	Listless (1)
Behavioural change (1)	Foaming (3)	Seizure (2)
Convulsions (1)	Hypersalivation (4)	Vomiting (2)

6.2 ABALONE POWDER

Canine

Year	Total Reports	Total Probable	Total Possible
2015	4	1	3

Presenting signs (probable and possible)

Diarrhoea (4)	Melaena (2)	Pruritus (2)
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6.3 ABAMECTIN

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Ataxia (2) Collapse (1) Recumbency (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	4	2	2

Presenting signs (probable and possible)

Death (4) Malaise (1) Spasm (2)

Lethargy (2) Recumbency (1) Stiffness (1)

6.4 ACEPROMAZINE MALEATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Bradycardia (1) Hypothermia (1) Respiratory problems (1)

Hypotension (1) Recovery (prolonged) (1) Sedation (prolonged) (1)

Equine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Injection site reaction (1) Swelling (local) (1) Urticaria (1)

6.5 ACETYL GLUCOSAMINE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	2	0

Presenting signs (probable and possible)

Bradycardia (1)	Nasal discharge (1)	Weakness (1)
Collapse (1)	Sneezing (1)	

Equine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Coat discoloration (1)

AFOXOLANER

Afoxolaner was registered in December 2014. Known side effects include vomiting, dry/flaky skin, diarrhoea, lethargy, and lack of appetite. Very rare are more serious adverse reactions have occurred including seizure and / or pyrexia (raised body temperature; fever).

In 2015, 18 AERs reported neurological issues, these are a serious reaction to the product. While the frequency of all reactions was not sufficient to trigger regulatory action (<1:10,000), public concern and the severity of some reactions supported a label change.

The registrant engaged with the APVMA to implement a label change in June 2016.

"Afoxolaner is part of the isoxazoline family of chemicals. Adverse reactions to this family of chemicals are rarely observed but may include vomiting, diarrhoea, lethargy, inappetence, itching and very rarely, seizures. Most adverse reactions are self-limiting and of short duration. If you have any concerns, please speak to your veterinarian."

6.6 AFOXOLANER

Canine

Year	Total Reports	Total Probable	Total Possible
2015	286	87	199

Presenting signs (probable and possible)

Adipsia (2)	Haematemesis (1)	Rash (4)
Aggression (1)	Hives (3)	Recumbency (1)
Agitation (15)	Hyperactivity (1)	Red eyes (1)
Alopecia (2)	Hypersalivation (5)	Restless (5)
Anisocoria (1)	Incoordination (1)	Retching (2)
Anorexia (29)	Irritation (ear) (1)	Seizure (6)
Ataxia (5)	Irritation (skin) (9)	Self-trauma (4)
Behavioural change (7)	Lesions (1)	Shaking (2)
Blood in faeces (1)	Lethargy (60)	Stiffness (1)
Collapse (4)	Malaise (10)	Swelling (local) (1)
Constipation (1)	Melaena (6)	Tachycardia (1)
Convulsions (1)	Muscle twitching (3)	Tremor (3)
Dehydration (1)	Nasal discharge (1)	Urticaria (1)
Depression (2)	Oedema (1)	Vocalisation (1)
Diarrhoea (35)	Panting (11)	Vomiting (126)
Disorientation (2)	Periorbital swelling (1)	Weakness (1)
Distress (4)	Polydipsia (5)	Welts (2)
Dyspnoea (1)	Polyuria (3)	Wheals (1)
Erythema (23)	Pruritus (71)	Xerostomia (1)
Facial oedema (1)	Pyrexia (7)	

6.7 AGLEPRISTONE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	2	0

Presenting signs (probable and possible)

Ataxia (1)	Pyrexia (1)
Lack of effect (1)	Vaginal discharge (1)

6.8 ALBENDAZOLE

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Presenting signs (probable and possible)

Death (2)	Malaise (1)
Lethargy (2)	Stiffness (1)

6.9 ALPHAXALONE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	14	0	14

Presenting signs (probable and possible)

Anaesthesia (deep) (1)	Injected mucous membranes (2)	Respiratory problems (2)
Death (1)	Nystagmus (2)	Seizure (1)
Erythema (1)	Opisthotonos (1)	Stiffness (1)
Facial oedema (2)	Paddling (4)	Tremor (1)
Hives (2)	Periorbital swelling (2)	Vocalisation (1)
		Vomiting (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	5	0	5

Presenting signs (probable and possible)

Apnoea (1)	Opisthotonos (1)	Respiratory problems (1)
Death (1)	Recovery (prolonged) (2)	Stiffness (1)

6.10 ALUMINIUM HYDROXIDE**Canine**

Year	Total Reports	Total Probable	Total Possible
2015	24	0	24

Presenting signs (probable and possible)

Allergy (1)	Hyperaesthesia (1)	Recumbency (1)
Anaphylactoid reaction (1)	Injection site reaction (10)	Red eyes (1)
Anaphylaxis (2)	Lethargy (4)	Swelling (local) (1)
Anorexia (1)	Lump (local) (7)	Tremor (1)
Apnoea (1)	Masticatory myositis (1)	Urticaria (1)
Bradycardia (1)	Pain (2)	Vocalisation (1)
Collapse (1)	Pale mucous membranes (1)	Vomiting (4)
Diarrhoea (1)	Periorbital swelling (1)	
Facial oedema (6)	Pyrexia (1)	

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anorexia (1)	Lethargy (1)	Pyrexia (1)
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6.11 AMITRAZ

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Presenting signs (probable and possible)

Ataxia (1)	Milk production decrease (1)	Recumbency (1)
Lethargy (1)	Panting (1)	

Canine

Year	Total Reports	Total Probable	Total Possible
2015	5	2	3

Presenting signs (probable and possible)

Agitation (1)	Lethargy (2)	Vomiting (1)
Diarrhoea (1)	Restless (1)	
Lack of effect (3)	Tremor (1)	

6.12 AMOXYCILLIN TRIHYDRATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	4	1	3

Presenting signs (probable and possible)

Injection site reaction (2)	Paralysis (1)	Vomiting (2)
Lesions (1)	Site reaction (1)	
Pain (2)	Swelling (local) (1)	

Feline

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Injection site reaction (2)	Lesions (1)	Swelling (local) (1)
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6.13 AMPHOTERICIN B

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anorexia (1)

Lethargy (1)

6.14 ATROPINE SULFATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Respiratory problems (1)

6.15 AZELAIC ACID

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Lethargy (1)

Pruritus (1)

Sneezing (1)

6.16 BACITRACIN ZINC

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Vomiting (1)

6.17 BENAZEPRIL HYDROCHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	9	0	9

Presenting signs (probable and possible)

Diarrhoea (2)	Polydipsia (1)	Vomiting (5)
Haemorrhage (1)	Polyuria (1)	
Melaena (2)	Seizure (2)	

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Abnormal Biochemistry (1)	Dehydration (1)	Weight loss (1)
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6.18 BENZALKONIUM CHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Erythema (1)	Site reaction (1)	Ulceration (1)
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6.19 BETAMETHASONE VALERATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	4	2	2

Presenting signs (probable and possible)

Anorexia (1)	Erythema (1)	Malaise (1)
Blisters (1)	Irritation (eye) (1)	Ulceration (1)
Deafness (2)	Lethargy (1)	

6.20 BIOTA ORIENTALIS SEED OIL

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Presenting signs (probable and possible)

Diarrhoea (2)

Melaena (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. 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 a specific product 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 2015. At this time no regulatory action is required, however vaccine products are continually monitored for unexpected or severe reactions.

6.21 BORDETELLA BRONCHISEPTICA

Canine

Year	Total Reports	Total Probable	Total Possible
2015	169	23	146

Presenting signs (probable and possible)

Agitation (2)	Haemorrhage (2)	Pulmonary oedema (1)
Allergy (2)	Hives (1)	Pyrexia (12)
Alopecia (1)	Hyperaesthesia (1)	Rash (4)
Anaphylactoid reaction (2)	Hypersalivation (3)	Recumbency (1)
Anaphylaxis (9)	Hypotension (2)	Red eyes (2)
Anorexia (10)	Incontinence (2)	Respiratory problems (5)
Apnoea (1)	Injection site reaction (38)	Retching (1)
Ataxia (1)	Irritation (skin) (1)	Seizure (1)
Behavioural change (6)	Lack of effect (3)	Seroma (1)
Blisters (1)	Lame (1)	Shaking (3)
Bradycardia (2)	Lethargy (25)	Site reaction (2)
Collapse (3)	Lump (local) (29)	Sneezing (22)
Coughing (34)	Malaise (4)	Swelling (local) (6)
Death (1)	Masticatory myositis (1)	Swelling (vulva) (1)
Defaecation (1)	Nasal discharge (8)	Tachycardia (2)
Dermatitis (1)	Oedema (1)	Tachypnoea (2)
Diarrhoea (8)	Pain (16)	Thrombocytopenia (1)
Dyspnoea (1)	Pale mucous membranes (6)	Tremor (2)
Erythema (1)	Panting (1)	Urticaria (2)
Facial oedema (23)	Paraesthesia (1)	Vocalisation (3)
Frothing at the mouth (1)	Periorbital swelling (7)	Vomiting (32)
Gagging (1)	Polyarthritis (1)	Weakness (1)
Haematoma (1)	Pruritus (3)	

6.22 BORDETELLA BRONCHISEPTICA KILLED VACCINE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	45	2	43

Presenting signs (probable and possible)

Anaphylaxis (8)	Hypersalivation (1)	Respiratory problems (1)
Anorexia (2)	Hypotension (1)	Restless (1)
Ataxia (1)	Injection site reaction (4)	Shaking (1)
Bradycardia (1)	Lethargy (3)	Swelling (local) (1)
Capillary refill time (slow) (2)	Listless (1)	Tachycardia (3)
Circulatory collapse (1)	Lump (local) (1)	Tachypnoea (2)
Collapse (4)	Pain (3)	Thrombocytopenia (1)
Diarrhoea (3)	Pale mucous membranes (2)	Urticaria (6)
Disorientation (1)	Panting (1)	Vocalisation (1)
Facial oedema (15)	Polydipsia (1)	Vomiting (17)
Haematemesis (2)	Pruritus (5)	Weakness (1)
Hives (2)	Pyrexia (4)	

6.23 BOVINE CORONAVIRUS (CA-5)

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Abscess (1)	Stiffness (1)
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6.24 BOVINE CORONAVIRUS (INACTIVATED)

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Abscess (1) Stiffness (1)

6.25 BOVINE CORONAVIRUS (WI-17)

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Abscess (1) Stiffness (1)

6.26 BOVINE PESTIVIRUS - BEGA STRAIN -INACTIVATED

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anaphylactoid reaction (1) Lethargy (1)

Anorexia (1) Malaise (1)

6.27 BOVINE PESTIVIRUS - TRANGIE STRAIN - INACTIVATED

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anaphylactoid reaction (1) Lethargy (1)

Anorexia (1) Malaise (1)

Bovine

6.32 BUTORPHANOL TARTRATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Death (2)

6.33 CAMPYLOBACTER FETUS (VIBRO FETUS)

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anorexia (1)

Lethargy (1)

Pain (1)

6.34 CAMPYLOBACTER JEJUNI SUB-SPECIES JEJUNI - INACTIVATED

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anorexia (1)

Lethargy (1)

Pain (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, allergic reactions and coughing. These symptoms occur occasionally with vaccines. 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 2015 (less than 1 in 10000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

6.35 CANINE ADENOVIRUS TYPE 2

Canine

Year	Total Reports	Total Probable	Total Possible
2015	131	20	111

Presenting signs (probable and possible)

Agitation (3)	Haematoma (1)	Pruritus (9)
Alopecia (2)	Hives (3)	Pyrexia (14)
Anaphylactoid reaction (1)	Hypersalivation (3)	Rash (2)
Anaphylaxis (15)	Hypotension (4)	Respiratory problems (5)
Anorexia (6)	Incontinence (1)	Restless (1)
Apnoea (1)	Injection site reaction (20)	Seizure (1)
Ataxia (3)	Lame (1)	Shaking (6)
Behavioural change (3)	Lethargy (17)	Sneezing (17)
Bradycardia (3)	Listless (1)	Stomatitis (1)
Capillary refill time (slow) (2)	Lump (local) (14)	Swelling (local) (2)
Circulatory collapse (1)	Malaise (2)	Swelling (vulva) (2)
Collapse (7)	Nasal discharge (4)	Tachycardia (4)
Coughing (27)	Oedema (2)	Tachypnoea (4)
Deafness (1)	Pain (14)	Thrombocytopenia (1)
Death (1)	Pale mucous membranes (7)	Tremor (1)
Depression (1)	Panting (2)	Urticaria (8)
Diarrhoea (6)	Paraesthesia (1)	Vocalisation (2)
Disorientation (1)	Periorbital swelling (3)	Vomiting (37)
Facial oedema (27)	Polyarthritis (1)	Weakness (3)
Haematemesis (2)	Polydipsia (1)	

6.36 CANINE ADENOVIRUS TYPE 2 - LIVE (INFECTIOUS HEPATITIS)

Canine

Year	Total Reports	Total Probable	Total Possible
2015	29	0	29

Presenting signs (probable and possible)

Allergy (1)	Hyperaesthesia (1)	Recumbency (1)
Anaphylactoid reaction (1)	Injection site reaction (8)	Red eyes (1)
Anaphylaxis (4)	Lethargy (5)	Swelling (local) (1)
Anorexia (1)	Lump (local) (5)	Tremor (1)
Apnoea (1)	Masticatory myositis (1)	Vocalisation (1)
Bradycardia (1)	Pain (2)	Vomiting (5)
Collapse (1)	Pale mucous membranes (1)	Welts (1)
Erythema (1)	Periorbital swelling (1)	
Facial oedema (11)	Pyrexia (1)	

6.37 CANINE ADENOVIRUS TYPE 2 - LIVE (CAV II)

Canine

Year	Total Reports	Total Probable	Total Possible
2015	15	0	15

Presenting signs (probable and possible)

Anorexia (1)	Facial oedema (4)	Pyrexia (2)
Bradycardia (1)	Haematemesis (1)	Rash (1)
Capillary refill time (slow) (1)	Hives (1)	Sneezing (1)
Collapse (1)	Lethargy (1)	Tachycardia (1)
Coughing (2)	Pain (1)	Tachypnoea (1)
Depression (1)	Pale mucous membranes (2)	Urticaria (1)
Diarrhoea (1)	Pruritus (1)	Vomiting (6)

6.38 CANINE ADENOVIRUS TYPE 2 STRAIN MANHATTAN - LIVE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	34	2	32

Presenting signs (probable and possible)

Allergy (1)	Haemorrhage (1)	Pruritus (2)
Anaphylaxis (3)	Hives (1)	Pulmonary oedema (1)
Anorexia (3)	Hypersalivation (2)	Pyrexia (3)
Ataxia (1)	Incontinence (1)	Rash (3)
Behavioural change (3)	Injection site reaction (2)	Red eyes (1)
Blisters (1)	Irritation (skin) (1)	Respiratory problems (1)
Death (2)	Lethargy (6)	Site reaction (1)
Defaecation (1)	Lump (local) (3)	Swelling (local) (1)
Dermatitis (1)	Nasal discharge (2)	Tachycardia (1)
Diarrhoea (4)	Pain (3)	Urticaria (1)
Dyspnoea (1)	Pale mucous membranes (2)	Vomiting (12)
Facial oedema (9)	Periorbital swelling (4)	

6.39 CANINE CORONAVIRUS VACCINE - ANTIGEN

Canine

Year	Total Reports	Total Probable	Total Possible
2015	6	0	6

Presenting signs (probable and possible)

Anaphylaxis (1)	Injection site reaction (1)	Rash (1)
Facial oedema (1)	Lump (local) (1)	Swelling (vulva) (1)
Hives (1)	Periorbital swelling (1)	Vomiting (2)

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 Parvovirus, 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, allergic 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 2015 (less than 1 in 10000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

6.40 CANINE DISTEMPER VIRUS

Canine

Year	Total Reports	Total Probable	Total Possible
2015	143	15	128

Presenting signs (probable and possible)

Agitation (4)	Haematoma (2)	Pruritus (9)
Allergy (1)	Hives (4)	Pyrexia (14)
Alopecia (1)	Hyperaesthesia (1)	Rash (2)
Anaphylactoid reaction (2)	Hypersalivation (2)	Recumbency (1)
Anaphylaxis (17)	Hypotension (3)	Red eyes (1)
Anorexia (7)	Incontinence (1)	Respiratory problems (2)
Apnoea (2)	Injection site reaction (29)	Restless (1)
Ataxia (3)	Lame (2)	Seizure (1)
Behavioural change (2)	Lethargy (21)	Shaking (6)
Bradycardia (4)	Listless (1)	Sneezing (6)
Capillary refill time (slow) (3)	Lump (local) (20)	Stomatitis (1)
Circulatory collapse (1)	Malaise (2)	Swelling (local) (3)
Collapse (9)	Masticatory myositis (1)	Swelling (vulva) (1)
Coughing (11)	Nasal discharge (1)	Tachycardia (5)
Deafness (1)	Oedema (2)	Tachypnoea (5)
Death (1)	Pain (17)	Thrombocytopenia (1)
Depression (2)	Pale mucous membranes (8)	Tremor (1)
Diarrhoea (7)	Panting (2)	Urticaria (9)
Disorientation (1)	Paraesthesia (1)	Vocalisation (3)
Erythema (1)	Periorbital swelling (2)	Vomiting (45)
Facial oedema (40)	Polyarthritis (1)	Weakness (2)
Haematemesis (3)	Polydipsia (1)	Welts (1)

6.41 CANINE DISTEMPER VIRUS STRAIN ONDERSTEEPOORT

Canine

Year	Total Reports	Total Probable	Total Possible
2015	34	2	32

Presenting signs (probable and possible)

Allergy (1)	Haemorrhage (1)	Pruritus (2)
Anaphylaxis (3)	Hives (1)	Pulmonary oedema (1)
Anorexia (3)	Hypersalivation (2)	Pyrexia (3)
Ataxia (1)	Incontinence (1)	Rash (3)
Behavioural change (3)	Injection site reaction (2)	Red eyes (1)
Blisters (1)	Irritation (skin) (1)	Respiratory problems (1)
Death (2)	Lethargy (6)	Site reaction (1)
Defaecation (1)	Lump (local) (3)	Swelling (local) (1)
Dermatitis (1)	Nasal discharge (2)	Tachycardia (1)
Diarrhoea (4)	Pain (3)	Urticaria (1)
Dyspnoea (1)	Pale mucous membranes (2)	Vomiting (12)
Facial oedema (9)	Periorbital swelling (4)	

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 2015. At this time no regulatory action is required, however vaccine products are continually monitored for unexpected or severe reactions.

6.42 CANINE PARAINFLUENZA TYPE 2

Canine

Year	Total Reports	Total Probable	Total Possible
2015	58	2	56

Presenting signs (probable and possible)

Agitation (2)	Haematemesis (2)	Pyrexia (4)
Anaphylactoid reaction (1)	Hives (2)	Respiratory problems (1)
Anaphylaxis (11)	Hypersalivation (1)	Restless (1)
Anorexia (2)	Hypotension (2)	Shaking (1)
Ataxia (1)	Incontinence (1)	Sneezing (1)
Bradycardia (2)	Injection site reaction (4)	Swelling (local) (1)
Capillary refill time (slow) (2)	Lethargy (8)	Tachycardia (4)
Circulatory collapse (1)	Listless (1)	Tachypnoea (4)
Collapse (6)	Lump (local) (1)	Thrombocytopenia (1)
Coughing (1)	Pain (5)	Urticaria (7)
Deafness (1)	Pale mucous membranes (4)	Vocalisation (1)
Depression (1)	Panting (2)	Vomiting (22)
Diarrhoea (4)	Paraesthesia (1)	Weakness (1)
Disorientation (1)	Polydipsia (1)	
Facial oedema (19)	Pruritus (7)	

6.43 CANINE PARAINFLUENZA VIRUS

Canine

Year	Total Reports	Total Probable	Total Possible
2015	182	25	157

Presenting signs (probable and possible)

Agitation (3)	Erythema (1)	Pain (22)
Allergy (1)	Facial oedema (30)	Pale mucous membranes (6)
Alopecia (1)	Frothing at the mouth (1)	Panting (2)
Anaphylactoid reaction (2)	Gagging (1)	Paraesthesia (1)
Anaphylaxis (16)	Haematemesis (1)	Periorbital swelling (6)
Anorexia (13)	Haematoma (1)	Polyarthritis (1)
Ataxia (2)	Haemorrhage (2)	Polydipsia (1)
Behavioural change (7)	Hives (2)	Pruritus (9)
Blisters (1)	Hypersalivation (4)	Pulmonary oedema (1)
Bradycardia (2)	Hypotension (3)	Pyrexia (16)
Capillary refill time (slow) (1)	Incontinence (2)	Rash (4)
Circulatory collapse (1)	Injection site reaction (36)	Red eyes (1)
Collapse (5)	Irritation (skin) (1)	Respiratory problems (6)
Coughing (30)	Lack of effect (3)	Restless (1)
Deafness (1)	Lame (1)	Retching (1)
Death (1)	Lethargy (29)	Seizure (1)
Defaecation (1)	Listless (1)	Seroma (1)
Dermatitis (1)	Lump (local) (24)	Shaking (4)
Diarrhoea (9)	Malaise (7)	Site reaction (2)
Disorientation (1)	Nasal discharge (8)	Sneezing (20)
Dyspnoea (1)	Oedema (1)	Swelling (local) (6)

Swelling (vulva) (1)	Thrombocytopenia (2)	Vocalisation (3)
Tachycardia (4)	Tremor (1)	Vomiting (44)
Tachypnoea (3)	Urticaria (7)	Weakness (2)

6.44 CANINE PARAINFLUENZA VIRUS - INACTIVATED

Canine

Year	Total Reports	Total Probable	Total Possible
2015	24	0	24

Presenting signs (probable and possible)

Allergy (1)	Hyperaesthesia (1)	Recumbency (1)
Anaphylactoid reaction (1)	Injection site reaction (10)	Red eyes (1)
Anaphylaxis (2)	Lethargy (4)	Swelling (local) (1)
Anorexia (1)	Lump (local) (7)	Tremor (1)
Apnoea (1)	Masticatory myositis (1)	Urticaria (1)
Bradycardia (1)	Pain (2)	Vocalisation (1)
Collapse (1)	Pale mucous membranes (1)	Vomiting (4)
Diarrhoea (1)	Periorbital swelling (1)	
Facial oedema (6)	Pyrexia (1)	

CANINE PARVO VIRUS VACCINES

Canine parvovirus strains are 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 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 2015. At this time no regulatory action is required, however vaccine products are continually monitored for unexpected or severe reactions.

6.45 CANINE PARVO VIRUS

Canine

Year	Total Reports	Total Probable	Total Possible
2015	106	15	91

Presenting signs (probable and possible)

Agitation (3)	Haematemesis (2)	Polydipsia (1)
Alopecia (1)	Haematoma (1)	Pruritus (8)
Anaphylactoid reaction (1)	Hives (3)	Pyrexia (9)
Anaphylaxis (13)	Hypersalivation (2)	Rash (1)
Anorexia (4)	Hypotension (3)	Respiratory problems (2)
Apnoea (1)	Incontinence (1)	Restless (1)
Ataxia (3)	Injection site reaction (15)	Seizure (1)
Behavioural change (2)	Lame (1)	Shaking (4)
Bradycardia (2)	Lethargy (12)	Sneezing (5)
Capillary refill time (slow) (2)	Listless (1)	Stomatitis (1)
Circulatory collapse (1)	Lump (local) (14)	Swelling (local) (1)
Collapse (7)	Nasal discharge (1)	Swelling (vulva) (1)
Coughing (9)	Oedema (2)	Tachycardia (4)
Deafness (1)	Pain (9)	Tachypnoea (4)
Death (1)	Pale mucous membranes (5)	Thrombocytopenia (1)
Depression (1)	Panting (2)	Urticaria (7)
Diarrhoea (6)	Paraesthesia (1)	Vocalisation (2)
Disorientation (1)	Periorbital swelling (1)	Vomiting (31)
Facial oedema (24)	Polyarthritis (1)	Weakness (2)

6.46 CANINE PARVO VIRUS 2B STRAIN CPV39 - ATTENUATED

Canine

Year	Total Reports	Total Probable	Total Possible
2015	15	0	15

Presenting signs (probable and possible)

Anorexia (1)	Facial oedema (4)	Pyrexia (2)
Bradycardia (1)	Haematemesis (1)	Rash (1)
Capillary refill time (slow) (1)	Hives (1)	Sneezing (1)
Collapse (1)	Lethargy (1)	Tachycardia (1)
Coughing (2)	Pain (1)	Tachypnoea (1)
Depression (1)	Pale mucous membranes (2)	Urticaria (1)
Diarrhoea (1)	Pruritus (1)	Vomiting (6)

6.47 CANINE PARVO VIRUS TYPE 2

Canine

Year	Total Reports	Total Probable	Total Possible
2015	7	0	7

Presenting signs (probable and possible)

Anorexia (1)	Malaise (2)	Swelling (local) (1)
Facial oedema (1)	Pain (5)	Urticaria (1)
Injection site reaction (5)	Pyrexia (2)	Vomiting (1)
Lethargy (3)	Shaking (1)	

6.48 CANINE PARVO VIRUS - INACTIVATED

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Facial oedema (1)	Urticaria (1)
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6.49 CANINE PARVO VIRUS - LIVE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	32	0	32

Presenting signs (probable and possible)

Agitation (1)	Haematoma (1)	Pyrexia (1)
Allergy (1)	Hyperaesthesia (1)	Recumbency (1)
Anaphylactoid reaction (1)	Injection site reaction (9)	Red eyes (1)
Anaphylaxis (4)	Lame (1)	Shaking (1)
Anorexia (1)	Lethargy (5)	Swelling (local) (1)
Apnoea (1)	Lump (local) (6)	Tremor (1)
Bradycardia (1)	Masticatory myositis (1)	Vocalisation (1)
Collapse (1)	Pain (2)	Vomiting (7)
Erythema (1)	Pale mucous membranes (1)	Welts (1)
Facial oedema (11)	Periorbital swelling (1)	

6.50 CANINE PARVO VIRUS STRAIN 154 - LIVE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	34	2	32

Presenting signs (probable and possible)

Allergy (1)	Defaecation (1)	Hypersalivation (2)
Anaphylaxis (3)	Dermatitis (1)	Incontinence (1)
Anorexia (3)	Diarrhoea (4)	Injection site reaction (2)
Ataxia (1)	Dyspnoea (1)	Irritation (skin) (1)
Behavioural change (3)	Facial oedema (9)	Lethargy (6)
Blisters (1)	Haemorrhage (1)	Lump (local) (3)
Death (2)	Hives (1)	Nasal discharge (2)

Pain (3)	Pyrexia (3)	Swelling (local) (1)
Pale mucous membranes (2)	Rash (3)	Tachycardia (1)
Periorbital swelling (4)	Red eyes (1)	Urticaria (1)
Pruritus (2)	Respiratory problems (1)	Vomiting (12)
Pulmonary oedema (1)	Site reaction (1)	

6.51 CARBIMAZOLE

Feline

Year	Total Reports	Total Probable	Total Possible
2015	4	0	4

Presenting signs (probable and possible)

Anaemia (1)	Behavioural change (1)	Lame (1)
Ataxia (2)	Dyspnoea (1)	Tachycardia (1)

6.52 CARPROFEN

Canine

Year	Total Reports	Total Probable	Total Possible
2015	5	0	5

Presenting signs (probable and possible)

Abscess (1)	Anorexia (1)	Lethargy (1)
Anaphylactoid reaction (1)	Facial oedema (1)	Pruritus (1)
Anaphylaxis (1)	Injection site reaction (1)	Urticaria (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Alopecia (localised) (1)	Injection site reaction (1)	Ulceration (1)
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6.53 CEFOVECIN SODIUM

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Vomiting (2)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Alopecia (localised) (2)

Injection site reaction (2)

Ulceration (2)

6.54 CEPHALEXIN MONOHYDRATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Agitation (2)

Lump (local) (2)

Injection site reaction (2)

Pain (2)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Diarrhoea (2)

Lethargy (2)

Vomiting (4)

6.55 CETRIMIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Erythema (1) Site reaction (1) Ulceration (1)

6.56 CHLAMYDOPHILIA FELIS INACTIVATED

Feline

Year	Total Reports	Total Probable	Total Possible
2015	16	11	5

Presenting signs (probable and possible)

Alopecia (localised) (3) Erythema (1) Oedema (2)

Anorexia (2) Facial oedema (3) Pain (1)

Cellulitis (1) Injection site reaction (6) Pruritus (2)

Death (1) Lethargy (6) Pyrexia (5)

Diarrhoea (1) Lump (local) (1) Site reaction (1)

Distress (1) Nausea (1) Vomiting (3)

6.57 CHLORAMPHENICOL

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Sneezing (1)

6.58 CHLORFENVINPHOS

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Ataxia (1)	Panting (1)
Lethargy (1)	Recumbency (1)

6.59 CHLORHEXIDINE GLUCONATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	3	0	3

Presenting signs (probable and possible)

Erythema (2)	Irritation (skin) (2)	Pruritus (2)
Gagging (1)	Malaise (2)	Retching (1)
Irritation (paws) (2)	Pododermatitis (2)	

6.60 CHLORPHENIRAMINE MALEATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	3	1	2

Presenting signs (probable and possible)

Lethargy (1)	Malaise (1)	Vomiting (2)
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6.61 CLAVULANIC ACID AS POTASSIUM CLAVULANATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	4	1	3

Presenting signs (probable and possible)

Injection site reaction (2)	Paralysis (1)	Vomiting (1)
Lesions (1)	Site reaction (1)	
Pain (2)	Swelling (local) (1)	

Feline

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Injection site reaction (2)	Lesions (1)	Swelling (local) (1)
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6.62 CLOMIPRAMINE HYDROCHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	6	1	5

Presenting signs (probable and possible)

Anorexia (1)	Elevated ALP (1)	Pain (1)
Behavioural change (1)	Elevated ALT (1)	Pruritus (2)
Diarrhoea (1)	Listless (1)	Vomiting (5)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	2	2	0

Presenting signs (probable and possible)

Constipation (1)	Urinary retention (2)
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6.63 CLOSTRIDIUM PERFRINGENS TYPE C - TOXOID

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Abscess (1) Stiffness (1)

6.64 CLOSTRIDIUM PERFRINGENS TYPE D - TOXOID

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Abscess (1) Stiffness (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

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

6.65 CLOSTRIDIUM TETANI - TOXOID

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

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

6.66 CLOSTRIDIUM TETANI UF TOXOID

Equine

Year	Total Reports	Total Probable	Total Possible
2015	26	13	13

Presenting signs (probable and possible)

Allergy (1)	Inflammation (1)	Stiffness (5)
Anorexia (2)	Injection site reaction (17)	Sweating (1)
Ataxia (1)	Lethargy (9)	Swelling (local) (4)
Coat colour change (1)	Lump (local) (1)	Urticaria (1)
Colic (1)	Oedema (11)	Walking (difficult) (1)
Death (1)	Pain (4)	
Diarrhoea (1)	Pyrexia (2)	

6.67 CLOTRIMAZOLE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	6	4	2

Presenting signs (probable and possible)

Anorexia (1)	Erythema (1)	Lethargy (1)
Blisters (1)	Irritation (ear) (1)	Malaise (1)
Deafness (3)	Irritation (eye) (1)	Ulceration (1)

6.68 COBALT AS COBALT EDTA

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Ataxia (1)	Collapse (1)
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Ovine

Year	Total Reports	Total Probable	Total Possible
2015	4	2	2

Presenting signs (probable and possible)

Death (4)	Malaise (1)	Spasm (2)
Lethargy (2)	Recumbency (1)	Stiffness (1)

6.69 COBALT OXIDE**Bovine**

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anorexia (1)	Hypersalivation (1)	Lethargy (1)
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6.70 COPPER AS COPPER DISODIUM EDTA**Bovine**

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)	Site reaction (swelling) (1)
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6.71 COPPER OXIDE (I AND II)**Bovine**

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anorexia (1)	Hypersalivation (1)	Lethargy (1)
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6.72 CORONAVIRUS

Canine

Year	Total Reports	Total Probable	Total Possible
2015	3	0	3

Presenting signs (probable and possible)

Agitation (1)	Lame (1)	Vomiting (2)
Haematoma (1)	Lump (local) (1)	
Injection site reaction (1)	Shaking (1)	

6.73 CORYNEBACTERIUM PSEUDOTUBERCULOSIS - TOXOID

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Injection site reaction (1)	Lame (1)	Lump (local) (1)
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6.74 CORYNEBACTERIUM PSEUDOTUBERCULOSIS (OVIS) - TOXOID

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Injection site reaction (1)	Lame (1)	Lump (local) (1)
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6.75 CUPRIC OXIDE

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anorexia (1)	Hypersalivation (1)	Lethargy (1)
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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 2015 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions

6.76 CYCLOSPORIN

Canine

Year	Total Reports	Total Probable	Total Possible
2015	40	23	17

Presenting signs (probable and possible)

Anorexia (3)	Horner's Syndrome (1)	Pancreatitis (1)
Ataxia (2)	Hyperactivity (1)	Panting (1)
Behavioural change (1)	Illness (1)	Papules (1)
Collapse (1)	Incontinence (2)	Polydipsia (1)
Constipation (1)	Insomnia (1)	Polyuria (1)
Dermatitis (1)	Lack of effect (1)	Pruritus (4)
Diabetes (2)	Lame (1)	Pyoderma (1)
Diarrhoea (5)	Lesions (2)	Retching (1)
Erythema (2)	Lethargy (3)	Tremor (3)
Facial oedema (1)	Leukopenia (1)	Unconscious (1)
Gingival hyperplasia (1)	Malaise (1)	Vocalisation (1)
Gingival soreness (1)	Melaena (1)	Vomiting (21)
Hives (1)	Nausea (1)	Weakness (2)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	5	4	1

Presenting signs (probable and possible)

Alopecia (1)	Diarrhoea (3)	Hypersalivation (1)
Anorexia (1)	Epiphora (1)	Polyphagia (1)
Coat discoloration (1)	Frothing at the mouth (1)	Vomiting (2)

6.77 CYCLOSPORIN A**Canine**

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Behavioural change (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	5	4	1

Presenting signs (probable and possible)

Alopecia (1)	Diarrhoea (3)	Hypersalivation (1)
Anorexia (1)	Epiphora (1)	Polyphagia (1)
Coat discoloration (1)	Frothing at the mouth (1)	Vomiting (2)

6.78 CYROMAZINE**Ovine**

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Low efficacy (1)

6.79 D.A.P BULK SOLUTION

Canine

Year	Total Reports	Total Probable	Total Possible
2015	9	8	1

Presenting signs (probable and possible)

Agitation (1)	Facial oedema (1)	Rash (1)
Alopecia (2)	Lesions (3)	Site reaction (3)
Dermatitis (1)	Pruritus (3)	
Erythema (5)	Pyoderma (3)	

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 in 2015 decreased dramatically, to 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.

6.80 DELTAMETHRIN

Canine

Year	Total Reports	Total Probable	Total Possible
2015	16	8	8

Presenting signs (probable and possible)

Agitation (3)	Dermatitis (1)	Pruritus (7)
Alopecia (1)	Erythema (5)	Restless (2)
Alopecia (localised) (2)	Hyperactivity (1)	Site reaction (swelling) (1)
Ataxia (1)	Lame (1)	Spasm (1)
Behavioural change (5)	Lesions (2)	Vocalisation (1)
Collapse (1)	Lethargy (3)	

6.81 DESLORELIN ACETATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	3	0	3

Presenting signs (probable and possible)

Injection site reaction (2) Low efficacy (4) Site reaction (swelling) (2)

6.82 DETOMIDINE HYDROCHLORIDE

Equine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Urticaria (1)

6.83 DEXAMETHASONE PHENYLPROPIONATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Anaphylaxis (1) Elevated ALT (1) Malaise (1)

Anorexia (1) Lethargy (1)

6.84 DEXAMETHASONE SODIUM PHOSPHATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Anaphylaxis (1) Elevated ALT (1) Malaise (1)

Anorexia (1) Lethargy (1)

6.85 DEXTROMETHORPHAN HYDROBROMIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Lethargy (1) Malaise (1)

6.86 DIAZEPAM

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Ataxia (1) Tachycardia (1) Vomiting (1)

Site reaction (1) Tremor (1)

6.87 DIAZINON

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Death (1) Foaming (1)

6.88 DICHLOROPHEN

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Ataxia (1) Shaking (1)

Ovine

6.93 DISODIUM TILUDRONATE

Equine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Anorexia (1) Polydipsia (1)

6.94 DL-ALPHA-TOCOPHERYL ACETATE

Porcine

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Anorexia (1) Lethargy (1) Seizure (1)
 Death (1) Pyrexia (1) Site reaction (swelling) (1)
 Injection site reaction (1) Recumbency (1) Vomiting (1)

6.95 DORAMECTIN

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Collapse (1) Vomiting (1)

6.96 DOXYCYCLINE MONOHYDRATE

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anorexia (2) Renal failure (2)
 Anuria (2) Vomiting (2)

6.97 EMODEPSIDE

Feline

Year	Total Reports	Total Probable	Total Possible
2015	8	3	5

Presenting signs (probable and possible)

Alopecia (7)	Lethargy (1)	Site reaction (5)
Alopecia (localised) (1)	Listless (1)	
Anorexia (2)	Pruritus (1)	

6.98 ENROFLOXACIN

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Hypersalivation (1)	Vomiting (1)
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6.99 EPHEDRINE HYDROCHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Lethargy (1)	Malaise (1)
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6.100 EQUINE HERPES VIRUS 1 (EHV-1) 438/77 STRAIN

Equine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Lethargy (1)	Pyrexia (1)
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Panting (3)	Tachycardia (1)	Vomiting (66)
Pruritus (1)	Unpleasant taste (1)	
Pyrexia (2)	Vocalisation (1)	

6.104 FELINE CALICIVIRUS

Feline

Year	Total Reports	Total Probable	Total Possible
2015	8	3	5

Presenting signs (probable and possible)

Anaphylaxis (1)	Hypoproteinaemia (1)	Lump (local) (1)
Anorexia (5)	Immune-mediated haemolytic anaemia (1)	Panting (1)
Ataxia (1)	Injection site reaction (1)	Pyrexia (3)
Death (1)	Lame (1)	Swelling (local) (1)
Distress (1)	Lethargy (4)	Tachypnoea (1)
Hypersalivation (1)		Vomiting (1)

6.105 FELINE CALICIVIRUS - INACTIVATED

Feline

Year	Total Reports	Total Probable	Total Possible
2015	34	19	15

Presenting signs (probable and possible)

Adipsia (1)	Death (3)	Lethargy (13)
Alopecia (1)	Diarrhoea (3)	Lump (local) (2)
Alopecia (localised) (3)	Distress (1)	Melaena (2)
Anaphylaxis (3)	Dyspnoea (2)	Nausea (1)
Anorexia (8)	Erythema (3)	Oedema (2)
Ataxia (1)	Facial oedema (3)	Pain (5)
Cellulitis (1)	Injection site reaction (10)	Pale mucous membranes (1)
Collapse (1)	Lame (1)	Pancreatitis (1)

Paraesthesia (1)	Site reaction (swelling) (1)	Vocalisation (1)
Pruritus (2)	Tachycardia (1)	Vomiting (6)
Pyrexia (10)	Tachypnoea (2)	
Site reaction (2)	Unconscious (1)	

6.106 FELINE CHLAMYDIA PSITTACI - INACTIVATED

Feline

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Adipsia (1)	Erythema (1)	Pain (1)
Anorexia (1)	Injection site reaction (1)	Pyrexia (1)
Ataxia (1)	Lethargy (1)	Tachypnoea (1)

6.107 FELINE IMMUNODEFICIENCY VIRUS (PETALUMA STRAIN) - INACTIVE

Feline

Year	Total Reports	Total Probable	Total Possible
2015	16	5	11

Presenting signs (probable and possible)

Alopecia (1)	Diarrhoea (1)	Pyrexia (5)
Alopecia (localised) (2)	Erythema (1)	Site reaction (1)
Anorexia (4)	Injection site reaction (5)	Tachycardia (2)
Cellulitis (1)	Lethargy (8)	Tachypnoea (1)
Death (1)	Lump (local) (1)	Vomiting (3)
Dehydration (1)	Oedema (2)	

6.108 FELINE IMMUNODEFICIENCY VIRUS (SHIZUOKA STRAIN) - INACTIVE

Feline

Year	Total Reports	Total Probable	Total Possible
2015	16	5	11

Presenting signs (probable and possible)

Alopecia (1)	Diarrhoea (1)	Pyrexia (5)
Alopecia (localised) (2)	Erythema (1)	Site reaction (1)
Anorexia (4)	Injection site reaction (5)	Tachycardia (2)
Cellulitis (1)	Lethargy (8)	Tachypnoea (1)
Death (1)	Lump (local) (1)	Vomiting (3)
Dehydration (1)	Oedema (2)	

6.109 FELINE LEUKAEMIA VIRUS - INACTIVATED

Feline

Year	Total Reports	Total Probable	Total Possible
2015	9	7	2

Presenting signs (probable and possible)

Alopecia (localised) (1)	Injection site reaction (2)	Pruritus (1)
Anorexia (2)	Lethargy (4)	Pyrexia (3)
Diarrhoea (1)	Lump (local) (1)	Vomiting (2)
Distress (1)	Nausea (1)	
Facial oedema (2)	Pain (1)	

6.110 FELINE PANLEUCOPENIA

Feline

Year	Total Reports	Total Probable	Total Possible
2015	8	3	5

Presenting signs (probable and possible)

Anaphylaxis (1)	Hypoproteinaemia (1)	Lump (local) (1)
Anorexia (5)	Immune-mediated haemolytic anaemia (1)	Panting (1)
Ataxia (1)	Injection site reaction (1)	Pyrexia (3)
Death (1)	Lame (1)	Swelling (local) (1)
Distress (1)	Lethargy (4)	Tachypnoea (1)
Hypersalivation (1)		Vomiting (1)

6.111 FELINE PANLEUCOPENIA VIRUS - INACTIVATED

Feline

Year	Total Reports	Total Probable	Total Possible
2015	34	19	15

Presenting signs (probable and possible)

Adipsia (1)	Erythema (3)	Paraesthesia (1)
Alopecia (1)	Facial oedema (3)	Pruritus (2)
Alopecia (localised) (3)	Injection site reaction (10)	Pyrexia (10)
Anaphylaxis (3)	Lame (1)	Site reaction (2)
Anorexia (8)	Lethargy (13)	Site reaction (swelling) (1)
Ataxia (1)	Lump (local) (2)	Tachycardia (1)
Cellulitis (1)	Melaena (2)	Tachypnoea (2)
Collapse (1)	Nausea (1)	Unconscious (1)
Death (3)	Oedema (2)	Vocalisation (1)
Diarrhoea (3)	Pain (5)	Vomiting (6)
Distress (1)	Pale mucous membranes (1)	
Dyspnoea (2)	Pancreatitis (1)	

6.112 FELINE RHINOTRACHEITIS

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Anaphylaxis (1) Death (1)

6.113 FELINE RHINOTRACHEITIS VIRUS - INACTIVATED

Feline

Year	Total Reports	Total Probable	Total Possible
2015	34	19	15

Presenting signs (probable and possible)

Adipsia (1)	Erythema (3)	Paraesthesia (1)
Alopecia (1)	Facial oedema (3)	Pruritus (2)
Alopecia (localised) (3)	Injection site reaction (10)	Pyrexia (10)
Anaphylaxis (3)	Lame (1)	Site reaction (2)
Anorexia (8)	Lethargy (13)	Site reaction (swelling) (1)
Ataxia (1)	Lump (local) (2)	Tachycardia (1)
Cellulitis (1)	Melaena (2)	Tachypnoea (2)
Collapse (1)	Nausea (1)	Unconscious (1)
Death (3)	Oedema (2)	Vocalisation (1)
Diarrhoea (3)	Pain (5)	Vomiting (6)
Distress (1)	Pale mucous membranes (1)	
Dyspnoea (2)	Pancreatitis (1)	

6.114 FENBENDAZOLE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	6	0	6

Presenting signs (probable and possible)

Anorexia (3)	Pale mucous membranes (1)	Vomiting (6)
Capillary refill time (slow) (1)	Pyrexia (1)	Weight loss (1)
Collapse (1)	Tachycardia (1)	
Diarrhoea (4)	Tachypnoea (1)	

Caprine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anorexia (1)	Diarrhoea (1)	Weakness (1)
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6.115 FIPRONIL

Canine

Year	Total Reports	Total Probable	Total Possible
2015	3	3	0

Presenting signs (probable and possible)

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

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Alopecia (localised) (1)

6.116 FIROCOXIB

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Diarrhoea (1) Vomiting (2)

6.117 FLUAZURON

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Alopecia (1) Lesions (1) Pruritus (1)

6.118 FLUMETHRIN

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	2	0

Presenting signs (probable and possible)

Agitation (1) Dyspnoea (1)
Ataxia (1) Hypersalivation (1)

6.119 FLUNIXIN MEGLUMINE

Equine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Collapse (2)

FLURALANER

Fluralaner was registered in early 2015. A high number of adverse reports relating to the use of fluralaner were received in the first year. Side effects reported included vomiting, diarrhoea, lethargy, inappetence and itching, and to a much lesser extent, seizures. Media reports and members of the public expressed concern, this in conjunction with limited information available on labels and the reports received caused the APVMA to engage the product registrant to amend their product labels to include additional warnings.

These updated labels are now entering the market and include the following statement:

'Fluralaner is part of the isoxazoline family of chemicals. Adverse reactions to this family of chemicals are rarely observed but may include vomiting, diarrhoea, lethargy, inappetence, itching and very rarely, seizures. Most adverse reactions are self-limiting and of short duration. If you have any concerns, please speak to your veterinarian.'

6.120 FLURALANER

Canine

Year	Total Reports	Total Probable	Total Possible
2015	255	131	124

Presenting signs (probable and possible)

Adipsia (2)	Disorientation (2)	Papules (1)
Agitation (1)	Distress (1)	Polydipsia (1)
Alopecia (1)	Elevated ALT (1)	Pruritus (8)
Anorexia (16)	Erythema (3)	Pyrexia (2)
Ataxia (1)	Flatulence (3)	Retching (1)
Behavioural change (1)	Hypersalivation (1)	Seizure (1)
Bloat (1)	Lethargy (23)	Shaking (1)
Dehydration (1)	Malaise (4)	Somnolence (1)
Diarrhoea (21)	Melaena (2)	Vomiting (226)

6.121 FRUSEMIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Vomiting (1)

G GLYCOPROTEIN OF HENDRA VIRUS (SG - PROTEIN)

G Glycoprotein Hendra Virus 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. At this time the permit condition was lifted and the reporting regime was reverted to voluntary reporting. Thus Veterinarians who used the vaccine were no longer obliged to report adverse effects to the registrant. 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.

6.122 G GLYCOPROTEIN OF HENDRA VIRUS (SG - PROTEIN)

Equine

Year	Total Reports	Total Probable	Total Possible
2015	254	202	52

Presenting signs (probable and possible)

Abnormal breathing (2)	Epistaxis (1)	Polydipsia (2)
Abortion (1)	Facial oedema (1)	Pruritus (1)
Adipsia (2)	Fasciculation (1)	Pyrexia (43)
Aggression (2)	Hives (3)	Rash (1)
Allergy (1)	Incoordination (1)	Recumbency (3)
Alopecia (2)	Injection site reaction (141)	Respiratory problems (2)
Alopecia (localised) (2)	Lame (4)	Shaking (1)
Anorexia (54)	Laminitis (2)	Site reaction (swelling) (1)
Anuria (1)	Lethargy (84)	Stiffness (41)
Ataxia (10)	Listless (5)	Sweating (9)
Behavioural change (3)	Lump (local) (18)	Swelling (local) (78)
Coat discoloration (1)	Lymphadenitis - 107 (2)	Tachypnoea (1)
Colic (17)	Malaise (5)	Urticaria (11)
Coughing (1)	Metritis (1)	Walking (difficult) (5)
Death (1)	Muscle stiffness (1)	Weakness (2)
Depression (8)	Nasal discharge (11)	Weight loss (2)
Dermatitis (1)	Oedema (24)	Welts (2)
Diarrhoea (1)	Pain (68)	

6.123 GENTAMICIN SULFATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	7	4	3

Presenting signs (probable and possible)

Anorexia (1)	Erythema (1)	Lethargy (1)
Blisters (1)	Irritation (ear) (1)	Malaise (1)
Deafness (5)	Irritation (eye) (1)	Ulceration (1)

6.124 GNRF - PROTEIN CONJUGATE

Porcine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Death (1)	Distress (1)	Vomiting (1)
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6.125 GREEN LIPPED MUSSEL

Canine

Year	Total Reports	Total Probable	Total Possible
2015	5	2	3

Presenting signs (probable and possible)

Anaphylaxis (1)	Diarrhoea (2)	Vomiting (1)
Ataxia (1)	Melaena (1)	
Death (1)	QC (1)	

6.126 HYDROCORTISONE ACEPONATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Deafness (1)

6.127 HYDROCORTISONE ACETATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Sneezing (1)

Vomiting (2)

6.128 IMEPITOIN

Canine

Year	Total Reports	Total Probable	Total Possible
2015	3	0	3

Presenting signs (probable and possible)

Anorexia (1)

Collapse (1)

Sedation (1)

Ataxia (3)

Hyperactivity (2)

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.

Imadacloprid has an extremely high sales volume. The number of reports associated with imadacloprid is low when compared with the number of doses sold in 2015 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

6.129 IMIDACLOPRID

Canine

Year	Total Reports	Total Probable	Total Possible
2015	183	58	125

Presenting signs (probable and possible)

Abnormal breathing (1)	Excitation (1)	Pustules (1)
Abscess (2)	Facial oedema (5)	Pyoderma (1)
Adipsia (3)	Fasciculation (1)	Pyrexia (1)
Agitation (35)	Haemorrhage (1)	Rash (4)
Allergy (2)	Hives (2)	Restless (10)
Alopecia (6)	Hyperactivity (4)	Retching (2)
Alopecia (localised) (8)	Hypersalivation (7)	Rolling (5)
Anorexia (15)	Inflammation (3)	Scabs (2)
Ataxia (12)	Insomnia (1)	Seizure (1)
Behavioural change (21)	Irritation (eye) (1)	Self-trauma (28)
Blindness (1)	Irritation (skin) (4)	Shaking (2)
Blisters (1)	Lesions (7)	Site reaction (71)
Burn(s) (5)	Lethargy (56)	Site reaction (swelling) (2)
Chemical reaction (unexpected) (1)	Lump (local) (1)	Tachycardia (2)
Coat colour change (2)	Malaise (3)	Tachypnoea (3)
Collapse (1)	Melaena (1)	Tremor (9)
Dermatitis (1)	Muscle twitching (6)	Urination (1)
Diarrhoea (10)	Odour (1)	Urticaria (2)
Disorientation (1)	Pain (2)	Vocalisation (6)
Distress (3)	Panting (8)	Vomiting (27)
Dyspnoea (3)	Paraesthesia (16)	Weight loss (1)
Erythema (26)	Polydipsia (2)	Welts (1)
	Pruritus (62)	

Feline

Year	Total Reports	Total Probable	Total Possible
2015	108	28	80

Presenting signs (probable and possible)

Adipsia (1)	Erythema (13)	Polydipsia (1)
Agitation (9)	Foaming (1)	Pruritus (14)
Alopecia (8)	Frothing at the mouth (2)	Pyoderma (1)
Alopecia (localised) (35)	Hyperactivity (4)	Pyrexia (1)
Anorexia (13)	Hyperexcitable (1)	Rash (1)
Ataxia (7)	Hypersalivation (18)	Scabs (3)
Behavioural change (9)	Incontinence (1)	Seizure (1)
Burn(s) (6)	Inflammation (1)	Self-trauma (2)
Chemical reaction (unexpected) (1)	Irritation (skin) (2)	Shaking (1)
Coat colour change (1)	Lesions (7)	Site reaction (51)
Comatose (2)	Lethargy (19)	Tachycardia (2)
Defaecation (1)	Lump (local) (1)	Tremor (1)
Diarrhoea (5)	Mydriasis (1)	Ulceration (1)
Disorientation (1)	Oedema (1)	Vocalisation (3)
Dyspnoea (1)	Pale mucous membranes (1)	Vomiting (13)
	Paraesthesia (10)	

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Burn(s) (1)	Chemical reaction (unexpected) (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.

2015 demonstrated an increasing frequency of reactions, particularly in cats. A rising trend for 3 years or repeated frequency over 1 report in 10,000 can initiate regulatory action.

6.130 INDOXACARB

Canine

Year	Total Reports	Total Probable	Total Possible
2015	29	21	8

Presenting signs (probable and possible)

Alopecia (2)	Hepatopathy (2)	Pruritus (28)
Alopecia (localised) (4)	Hypersalivation (2)	Pyoderma (4)
Anorexia (4)	Hypotension (2)	Scabs (2)
Behavioural change (4)	Irritation (skin) (4)	Site reaction (14)
Coat colour change (2)	Lesions (8)	Sneezing (2)
Crusting skin (2)	Lethargy (12)	Tachycardia (2)
Dermatitis (4)	Malaise (2)	Vocalisation (2)
Diarrhoea (2)	Mydriasis (2)	Vomiting (6)
Erythema (8)	Oedema (2)	

Feline

Year	Total Reports	Total Probable	Total Possible
2015	77	46	31

Presenting signs (probable and possible)

Agitation (8)	Distress (2)	Paraesthesia (3)
Alopecia (5)	Dysphagia (1)	Pruritus (10)
Alopecia (localised) (18)	Dyspnoea (1)	Restless (1)
Anorexia (2)	Elevated ALT (1)	Scabs (1)
Ataxia (13)	Erythema (2)	Seizure (5)
Behavioural change (18)	Frothing at the mouth (1)	Shaking (5)
Blepharitis (1)	Hyperactivity (1)	Site reaction (5)
Blindness (2)	Hyperexcitable (1)	Skin slough (1)
Blurred vision (1)	Hypersalivation (12)	Stiffness (1)
Cardiac arrest (1)	Incontinence (1)	Swelling (local) (1)
Cardiac arrhythmia (1)	Incoordination (1)	Tachycardia (1)
Circling (1)	Irritation (skin) (1)	Tachypnoea (3)
Coat colour change (1)	Lesions (3)	Tremor (1)
Convulsions (1)	Lethargy (7)	Ulceration (1)
Deafness (1)	Muscle twitching (2)	Vocalisation (6)
Death (1)	Mydriasis (9)	Vomiting (9)
Diarrhoea (1)	Pain (1)	Weakness (1)
Disorientation (2)	Panting (1)	

6.131 INSULIN

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Injection site reaction (1) Pain (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Blindness (1) Head pressing (1) Hypoglycaemia (1)

6.132 IVERMECTIN

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Alopecia (localised) (1) Irritation (skin) (1) Site reaction (1)

Canine

Year	Total Reports	Total Probable	Total Possible
2015	4	0	4

Presenting signs (probable and possible)

Distress (1) Muscle twitching (1) Vomiting (2)

Erythema (1) Pruritus (1)

Equine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Colic (1)

6.133 KETAMINE HYDROCHLORIDE

Equine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Low efficacy (2)

6.134 LACTIC ACID

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Deafness (1)

6.135 LASALOCID SODIUM

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Paralysis (1)

Weakness (1)

6.136 LEPTOSPIRA ICTEROHAEMORRHAGIAE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Agitation (1)

Lame (1)

Vomiting (1)

Haematoma (1)

Lump (local) (1)

Injection site reaction (1)

Shaking (1)

6.137 LEPTOSPIRA ICTEROHAEMORRHAGIAE ANTIGEN

Canine

Year	Total Reports	Total Probable	Total Possible
2015	6	0	6

Presenting signs (probable and possible)

Anaphylaxis (1)	Injection site reaction (1)	Rash (1)
Facial oedema (1)	Lump (local) (1)	Swelling (vulva) (1)
Hives (1)	Periorbital swelling (1)	Vomiting (2)

6.138 LEVAMISOLE

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Ataxia (1)	Collapse (1)
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Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Diarrhoea (2)

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	4	2	2

Presenting signs (probable and possible)

Death (7)	Malaise (2)	Spasm (4)
Lethargy (3)	Recumbency (1)	Stiffness (2)

6.139 LIGNOCAINE HYDROCHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Vomiting (2)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Ataxia (1)

Shaking (1)

6.140 LIVE FELINE HERPES VIRUS

Feline

Year	Total Reports	Total Probable	Total Possible
2015	7	2	5

Presenting signs (probable and possible)

Anorexia (5)

Immune-mediated haemolytic
anaemia (1)

Panting (1)

Ataxia (1)

Pyrexia (3)

Injection site reaction (1)

Distress (1)

Swelling (local) (1)

Lame (1)

Hypersalivation (1)

Tachypnoea (1)

Lethargy (4)

Hypoproteinaemia (1)

Vomiting (1)

Lump (local) (1)

6.141 LUFENURON

Canine

Year	Total Reports	Total Probable	Total Possible
2015	33	22	11

Presenting signs (probable and possible)

Agitation (1)	Dysphagia (1)	Panting (1)
Anorexia (3)	Erythema (1)	Polydipsia (1)
Behavioural change (1)	Hypersalivation (1)	Pruritus (4)
Coughing (2)	Lack of effect (2)	Shaking (1)
Dermatitis (1)	Lethargy (6)	Vomiting (21)
Diarrhoea (7)	Melaena (1)	

6.142 MANGANESE EDTA

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)	Site reaction (swelling) (1)
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Ovine

Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Presenting signs (probable and possible)

Injection site reaction (2)	Lame (1)	Lump (local) (2)
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6.143 MAROPITANT CITRATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	3	0	3

Presenting signs (probable and possible)

Anaemia (2)	Lethargy (6)	Vomiting (6)
Diarrhoea (6)	Tremor (2)	

6.144 MELOXICAM

Canine

Year	Total Reports	Total Probable	Total Possible
2015	6	2	4

Presenting signs (probable and possible)

Anorexia (1)	Hives (1)	Pruritus (1)
Diarrhoea (1)	Lethargy (3)	Tachypnoea (2)
Erythema (1)	Pain (1)	Vomiting (4)
Haematemesis (1)	Paraesthesia (2)	

Feline

Year	Total Reports	Total Probable	Total Possible
2015	4	0	4

Presenting signs (probable and possible)

Anaphylactoid reaction (1)	Behavioural change (1)	Ulceration (stomach) (1)
Anorexia (3)	Depression (1)	Vomiting (2)
Anuria (1)	Haematuria (1)	
Azotaemia (1)	Renal failure (2)	

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Hives (1) Respiratory problems (1)

Canine

Year	Total Reports	Total Probable	Total Possible
2015	9	8	1

Agitation (1)	Facial oedema (1)	Rash (1)
Alopecia (2)	Lesions (3)	Site reaction (3)
Dermatitis (1)	Pruritus (3)	
Erythema (5)	Pyoderma (3)	

Canine

Year	Total Reports	Total Probable	Total Possible
2015	9	8	1

Agitation (1)	Facial oedema (1)	Rash (1)
Alopecia (2)	Lesions (3)	Site reaction (3)
Dermatitis (1)	Pruritus (3)	
Erythema (5)	Pyoderma (3)	

6.148 METHYL MYRISTATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	9	8	1

Presenting signs (probable and possible)

Agitation (1)	Facial oedema (1)	Rash (1)
Alopecia (2)	Lesions (3)	Site reaction (3)
Dermatitis (1)	Pruritus (3)	
Erythema (5)	Pyoderma (3)	

6.149 METHYL OLEATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	9	8	1

Presenting signs (probable and possible)

Agitation (1)	Facial oedema (1)	Rash (1)
Alopecia (2)	Lesions (3)	Site reaction (3)
Dermatitis (1)	Pruritus (3)	
Erythema (5)	Pyoderma (3)	

6.150 METHYL PALMITATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	9	8	1

Presenting signs (probable and possible)

Agitation (1)	Facial oedema (1)	Rash (1)
Alopecia (2)	Lesions (3)	Site reaction (3)
Dermatitis (1)	Pruritus (3)	
Erythema (5)	Pyoderma (3)	

6.151 METHYL PENTADECANOATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	9	8	1

Presenting signs (probable and possible)

Agitation (1)	Facial oedema (1)	Rash (1)
Alopecia (2)	Lesions (3)	Site reaction (3)
Dermatitis (1)	Pruritus (3)	
Erythema (5)	Pyoderma (3)	

6.152 METHYL STEARATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	9	8	1

Presenting signs (probable and possible)

Agitation (1)	Facial oedema (1)	Rash (1)
Alopecia (2)	Lesions (3)	Site reaction (3)
Dermatitis (1)	Pruritus (3)	
Erythema (5)	Pyoderma (3)	

6.153 METHYLPREDNISOLONE ACETATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anorexia (1)	Lethargy (1)
Elevated ALT (1)	Malaise (1)

6.154 MICONAZOLE NITRATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	7	0	7

Presenting signs (probable and possible)

Alopecia (localised) (1)	Diarrhoea (2)	Gagging (1)
Deafness (4)	Erythema (2)	Retching (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.

The number of reports associated with milbemycin oxime is low when compared with the number of doses sold in 2015 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

6.155 MILBEMYCIN OXIME

Canine

Year	Total Reports	Total Probable	Total Possible
2015	193	105	88

Presenting signs (probable and possible)

Adipsia (3)	Dermatitis (3)	Irritation (skin) (1)
Agitation (3)	Diarrhoea (24)	Lack of effect (5)
Anorexia (22)	Distress (2)	Lethargy (48)
Ataxia (7)	Dysphagia (1)	Lump (local) (2)
Behavioural change (2)	Erythema (3)	Malaise (3)
Collapse (2)	Facial oedema (3)	Melaena (1)
Convulsions (1)	Hypersalivation (3)	Nausea (2)
Coughing (3)	Injection site reaction (2)	Neurological disorder (2)

Pancreatitis (1)	Rash (2)	Tremor (3)
Panting (1)	Retching (4)	Unpleasant taste (5)
Periorbital swelling (1)	Seizure (3)	Vocalisation (1)
Polydipsia (1)	Shaking (2)	Vomiting (141)
Pruritus (12)	Sneezing (1)	Weight loss (1)
Pyrexia (3)	Tachycardia (1)	

Feline

Year	Total Reports	Total Probable	Total Possible
2015	18	1	17

Presenting signs (probable and possible)

Anorexia (5)	Lethargy (6)	Seizure (1)
Ataxia (14)	Miosis (1)	Shaking (2)
Behavioural change (1)	Muscle twitching (3)	Somnolence (1)
Bloat (1)	Mydriasis (1)	Tachypnoea (1)
Blurred vision (1)	Pain (1)	Tremor (4)
Comatose (2)	Panting (1)	Unconscious (1)
Convulsions (1)	Paresis (1)	Vomiting (2)
Distress (1)	Pyrexia (1)	Weakness (1)
Hypersalivation (2)	Recumbency (1)	

6.156 MOMETASONE FUROATE MONOHYDRATE**Canine**

Year	Total Reports	Total Probable	Total Possible
2015	2	2	0

Presenting signs (probable and possible)

Deafness (1)	Irritation (ear) (1)
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6.157 MONENSIN SODIUM

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Death (3) Weakness (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 2015 (less than 1 in 10 000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions

6.158 MOXIDECTIN

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	3	2	1

Presenting signs (probable and possible)

Apnoea (1) Hypersalivation (1)

Ataxia (1) Lack of effect (3)

Canine

Year	Total Reports	Total Probable	Total Possible
2015	136	28	108

Presenting signs (probable and possible)

Adipsia (2)	Anaphylactoid reaction (3)	Behavioural change (6)
Agitation (11)	Anaphylaxis (19)	Blindness (1)
Allergy (2)	Anorexia (8)	Blisters (1)
Alopecia (2)	Apnoea (1)	Bradycardia (5)
Alopecia (localised) (2)	Ataxia (8)	Burn(s) (2)

Capillary refill time (slow) (1)	Hypersalivation (3)	Rash (2)
Chemical reaction (unexpected) (1)	Hypotension (1)	Recumbency (1)
Circulatory collapse (1)	Incontinence (2)	Respiratory problems (1)
Coat colour change (1)	Injection site reaction (16)	Restless (3)
Collapse (9)	Lesions (1)	Seizure (1)
Coughing (2)	Lethargy (36)	Seroma (1)
Defaecation (1)	Lump (local) (9)	Shaking (4)
Diarrhoea (12)	Malaise (7)	Site reaction (10)
Distress (1)	Oedema (2)	Sneezing (2)
Dyspnoea (1)	Pain (8)	Swelling (local) (4)
Erythema (3)	Pale mucous membranes (7)	Tachycardia (1)
Facial oedema (13)	Panting (4)	Tachypnoea (4)
Haematemesis (1)	Paraesthesia (5)	Tremor (3)
Hives (3)	Periorbital swelling (1)	Urticaria (4)
Hyperactivity (4)	Pruritus (10)	Vomiting (62)
	Pyrexia (8)	

Feline

Year	Total Reports	Total Probable	Total Possible
2015	86	22	64

Presenting signs (probable and possible)

Adipsia (1)	Burn(s) (5)	Dyspnoea (1)
Agitation (8)	Chemical reaction (unexpected) (1)	Erythema (11)
Alopecia (7)	Coat colour change (1)	Frothing at the mouth (1)
Alopecia (localised) (25)	Comatose (2)	Hyperactivity (3)
Anorexia (12)	Defaecation (1)	Hypersalivation (16)
Ataxia (7)	Diarrhoea (5)	Incontinence (1)
Behavioural change (7)	Disorientation (1)	Irritation (skin) (2)

Lesions (7)	Polydipsia (1)	Tachycardia (2)
Lethargy (15)	Pruritus (11)	Tremor (1)
Lump (local) (1)	Pyoderma (1)	Ulceration (1)
Mydriasis (1)	Pyrexia (1)	Vocalisation (3)
Oedema (1)	Rash (1)	Vomiting (12)
Pale mucous membranes (1)	Scabs (2)	
Paraesthesia (7)	Site reaction (40)	

6.159 MOXIDECTIN MICROSPHERES

Canine

Year	Total Reports	Total Probable	Total Possible
2015	88	16	72

Presenting signs (probable and possible)

Adipsia (1)	Diarrhoea (9)	Paraesthesia (1)
Agitation (5)	Facial oedema (11)	Periorbital swelling (1)
Allergy (1)	Haematemesis (1)	Pruritus (2)
Anaphylactoid reaction (3)	Hives (2)	Pyrexia (8)
Anaphylaxis (19)	Hyperactivity (2)	Rash (2)
Anorexia (3)	Hypersalivation (1)	Recumbency (1)
Apnoea (1)	Hypotension (1)	Respiratory problems (1)
Ataxia (1)	Incontinence (2)	Seroma (1)
Behavioural change (2)	Injection site reaction (16)	Shaking (4)
Blisters (1)	Lethargy (17)	Site reaction (2)
Bradycardia (5)	Lump (local) (9)	Sneezing (2)
Capillary refill time (slow) (1)	Malaise (6)	Swelling (local) (4)
Circulatory collapse (1)	Oedema (2)	Tachycardia (1)
Collapse (8)	Pain (8)	Tachypnoea (4)
Coughing (2)	Pale mucous membranes (7)	Urticaria (3)
Defaecation (1)	Panting (2)	Vomiting (49)

6.160 MYCOBACTERIUM PARATUBERCULOSIS

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anaphylaxis (1)

Caprine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Ataxia (1)

Death (1)

Recumbency (1)

CNS dysfunction (1)

Nystagmus (1)

6.161 MYCOPLASMA HYOPNEUMONIAE - INACTIVATED ANTIGEN

Porcine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anaphylaxis (1)

Death (1)

6.162 MYCOPLASMA HYOPNEUMONIAE STRAIN J

Porcine

Year	Total Reports	Total Probable	Total Possible
2015	3	1	2

Presenting signs (probable and possible)

Collapse (1)

Lethargy (2)

Seizure (1)

Death (2)

Pyrexia (1)

Tremor (1)

Depression (1)

Recumbency (2)

Vomiting (1)

6.163 NAPHTHALOPHOS

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Ataxia (1)

Death (1)

Weakness (1)

6.164 NEOMYCIN

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anorexia (1)

Lethargy (1)

6.165 NEOMYCIN SULFATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Vomiting (3)

6.166 NICLOSAMIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Diarrhoea (1)

6.167 NITENPYRAM

Canine

Year	Total Reports	Total Probable	Total Possible
2015	3	1	2

Presenting signs (probable and possible)

Agitation (1)	Lethargy (1)	Vocalisation (1)
Convulsions (1)	Panting (1)	
Lack of effect (1)	Pruritus (1)	

Feline

Year	Total Reports	Total Probable	Total Possible
2015	7	3	4

Presenting signs (probable and possible)

Agitation (4)	Panting (2)	Seizure (2)
Anaphylaxis (1)	Pyrexia (1)	Tachypnoea (1)
Diarrhoea (1)	Respiratory problems (2)	Vocalisation (2)
Hyperactivity (1)	Restless (1)	

6.168 N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Presenting signs (probable and possible)

Adipsia (1)	Ataxia (1)	Hypersalivation (1)
Anorexia (1)	Frothing at the mouth (1)	Malaise (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	12	6	6

Presenting signs (probable and possible)

Ataxia (2)	Foaming (3)	Pale mucous membranes (1)
Behavioural change (2)	Frothing at the mouth (1)	Respiratory problems (1)
Convulsions (1)	Hyperaesthesia (1)	Seizure (3)
Death (1)	Hypersalivation (7)	Spasm (1)
Dyspnoea (1)	Listless (1)	Vomiting (2)

6.169 OATMEAL EXTRACT**Canine**

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Allergy (1)	Pruritus (2)
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6.170 OLEIC ACID**Feline**

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Lethargy (1)	Pruritus (1)	Sneezing (1)
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6.171 OXANTEL EMBONATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	5	0	5

Presenting signs (probable and possible)

Alopecia (1)	Erythema (1)	Vomiting (3)
Anorexia (1)	Lethargy (1)	
Diarrhoea (2)	Pruritus (1)	

6.172 OXFENDAZOLE

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Ataxia (1)	Collapse (1)
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Equine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Diarrhoea (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Presenting signs (probable and possible)

Death (2)	Spasm (2)
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6.173 OXIBENDAZOLE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Diarrhoea (1)

6.174 OXYTETRACYCLINE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Pyrexia (1)

Swelling (local) (1)

6.175 OXYTETRACYCLINE HYDROCHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Pyrexia (1)

Swelling (local) (1)

6.176 PALMITIC ACID

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Lethargy (1)

Pruritus (1)

Sneezing (1)

6.177 PARAFFIN

Porcine

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Anorexia (1)	Lethargy (1)	Seizure (1)
Death (1)	Pyrexia (1)	Site reaction (swelling) (1)
Injection site reaction (1)	Recumbency (1)	Vomiting (1)

6.178 PENICILLIN

Equine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Convulsions (2)	Death (2)
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6.179 PENTOBARBITONE SODIUM

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Lack of effect (1)

6.180 PENTOSAN POLYSULFATE SODIUM

Canine

Year	Total Reports	Total Probable	Total Possible
2015	8	4	4

Presenting signs (probable and possible)

Bradycardia (1)	Diarrhoea (1)	Injection site reaction (1)
Collapse (1)	Hives (1)	Lethargy (1)

Lump (local) (1)	Sneezing (1)	Urticaria (1)
Nasal discharge (1)	Swelling (local) (1)	Vomiting (3)
Seroma (1)	Thrombocytopenia (1)	Weakness (1)

Equine

Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Presenting signs (probable and possible)

Coat discoloration (1)	Shaking (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 [permethrin toxicity in cats](#) 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.

6.181 PERMETHRIN

Canine

Year	Total Reports	Total Probable	Total Possible
2015	124	42	82

Presenting signs (probable and possible)

Abnormal breathing (1)	Alopecia (localised) (7)	Coat colour change (1)
Abscess (1)	Anorexia (18)	Dermatitis (1)
Adipsia (3)	Ataxia (4)	Diarrhoea (10)
Agitation (31)	Behavioural change (17)	Disorientation (1)
Allergy (1)	Blisters (1)	Distress (2)
Alopecia (2)	Burn(s) (4)	Dyspnoea (1)

Erythema (20)	Muscle twitching (6)	Self-trauma (27)
Excitation (1)	Pain (2)	Shaking (2)
Facial oedema (2)	Panting (6)	Site reaction (64)
Fasciculation (2)	Paraesthesia (16)	Site reaction (swelling) (2)
Haemorrhage (1)	Polydipsia (2)	Tachycardia (1)
Hyperactivity (2)	Pruritus (57)	Tachypnoea (1)
Hypersalivation (4)	Pustules (1)	Tremor (7)
Inflammation (4)	Pyoderma (1)	Urination (1)
Insomnia (1)	Pyrexia (1)	Urticaria (1)
Irritation (skin) (5)	Rash (2)	Vocalisation (6)
Lesions (6)	Restless (7)	Vomiting (22)
Lethargy (41)	Retching (2)	Weight loss (2)
Lump (local) (1)	Rolling (5)	Welts (1)
Malaise (3)	Scabs (2)	

6.182 PERNA CANALICULUS

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Presenting signs (probable and possible)

Diarrhoea (2) Melaena (1)

6.183 PHENOBARBITONE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Seizure (1) Tremor (1)

6.184 PIMELIC ACID

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Lethargy (1)

Pruritus (1)

Sneezing (1)

6.185 PIMOBENDAN

Canine

Year	Total Reports	Total Probable	Total Possible
2015	4	0	4

Presenting signs (probable and possible)

Diarrhoea (1)

Haemorrhage (1)

Melaena (2)

6.186 PIPERONYL BUTOXIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Presenting signs (probable and possible)

Adipsia (1)

Ataxia (1)

Hypersalivation (1)

Anorexia (1)

Frothing at the mouth (1)

Malaise (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	15	7	8

Presenting signs (probable and possible)

Alopecia (1)	Foaming (3)	Pruritus (1)
Ataxia (3)	Frothing at the mouth (1)	Respiratory problems (1)
Behavioural change (2)	Hyperaesthesia (1)	Seizure (3)
Convulsions (1)	Hypersalivation (7)	Shaking (1)
Death (1)	Listless (1)	Spasm (1)
Diarrhoea (1)	Pale mucous membranes (1)	Vomiting (3)
Dyspnoea (1)	Paraesthesia (1)	

6.187 PIROCTONE OLAMINE**Canine**

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Allergy (1)	Erythema (1)	Pruritus (1)
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6.188 POLYMXIN B**Feline**

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anorexia (1)	Lethargy (1)
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6.189 POLYMYXIN B SULFATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	6	0	6

Presenting signs (probable and possible)

Alopecia (localised) (1)	Diarrhoea (2)	Vomiting (1)
Deafness (2)	Erythema (2)	

6.190 PORCINE CIRCOVIRUS TYPE 2 ORF2 PROTEIN

Porcine

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Anaphylaxis (1)	Lethargy (1)	Seizure (1)
Death (2)	Recumbency (1)	Vomiting (1)

6.191 PORCINE CIRCOVIRUS TYPE 2 ORF2 SUBUNIT ANTIGEN

Porcine

Year	Total Reports	Total Probable	Total Possible
2015	2	0	2

Presenting signs (probable and possible)

Anorexia (1)	Lethargy (1)	Seizure (1)
Death (1)	Pyrexia (1)	Site reaction (swelling) (1)
Injection site reaction (1)	Recumbency (1)	Vomiting (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 2015 (less than 1 in 10,000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

6.192 PRAZIQUANTEL

Canine

Year	Total Reports	Total Probable	Total Possible
2015	181	66	115

Presenting signs (probable and possible)

Adipsia (1)	Erythema (5)	Polydipsia (1)
Agitation (3)	Facial oedema (1)	Pruritus (14)
Alopecia (1)	Hyperactivity (4)	Pyrexia (3)
Anaphylaxis (1)	Hypersalivation (2)	Rash (1)
Anorexia (15)	Hypotension (1)	Respiratory problems (1)
Ataxia (2)	Incontinence (1)	Retching (2)
Behavioural change (2)	Injection site reaction (3)	Seizure (2)
Capillary refill time (slow) (1)	Irritation (skin) (1)	Shaking (1)
Collapse (4)	Lack of effect (5)	Sneezing (1)
Convulsions (1)	Lethargy (29)	Tachycardia (2)
Coughing (3)	Lump (local) (3)	Tachypnoea (1)
Dermatitis (1)	Malaise (5)	Unpleasant taste (1)
Diarrhoea (23)	Melaena (1)	Vocalisation (1)
Distress (1)	Pale mucous membranes (2)	Vomiting (135)
Dysphagia (1)	Panting (4)	Weight loss (1)

Equine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Colic (1)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	37	7	30

Presenting signs (probable and possible)

Alopecia (7)	Hypersalivation (6)	Recumbency (1)
Alopecia (localised) (1)	Lethargy (13)	Seizure (1)
Anorexia (8)	Listless (1)	Shaking (2)
Ataxia (20)	Miosis (1)	Site reaction (6)
Behavioural change (1)	Muscle twitching (3)	Somnolence (1)
Bloat (1)	Mydriasis (1)	Tachypnoea (2)
Blurred vision (1)	Pain (2)	Tremor (5)
Comatose (2)	Panting (1)	Unconscious (1)
Convulsions (1)	Paresis (1)	Vomiting (5)
Diarrhoea (2)	Pruritus (1)	Weakness (1)
Distress (1)	Pyrexia (3)	

6.193 PREDNISOLONE**Canine**

Year	Total Reports	Total Probable	Total Possible
2015	5	0	5

Presenting signs (probable and possible)

Alopecia (localised) (1)	Diarrhoea (2)
Deafness (2)	Erythema (2)

6.194 PROCAINE HYDROCHLORIDE

Equine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Convulsions (1) Death (1)

6.195 PROPENTOFYLLINE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anuria (1) Incontinence (1) Polydipsia (1)

6.196 PROPOFOL

Canine

Year	Total Reports	Total Probable	Total Possible
2015	3	0	3

Presenting signs (probable and possible)

Apnoea (1) Erythema (1) Urticaria (2)

Bradycardia (1) Hives (1) Wheals (1)

6.197 PROPOXUR

Canine

Year	Total Reports	Total Probable	Total Possible
2015	2	2	0

Presenting signs (probable and possible)

Agitation (1)	Dyspnoea (1)
Ataxia (1)	Hypersalivation (1)

PYRANTEL EMBONATE

Pyrantel embonate is a systemic anthelmintic chemical primarily used to treat worm infections in domestic animals. It is a very commonly used active and is present in many different dog and cat worming products. The most commonly reported presenting signs included vomiting, lethargy and diarrhoea. It works by making the worms unable to move (paralyzed) so that the body can remove them naturally in the stool.

The number of reports associated with Pyrantel embonate is low when compared with the number of doses sold in 2015 (less than 1 in 10,000 doses) and therefore no regulatory action is required other than continued monitoring for unexpected or severe reactions.

6.198 PYRANTEL EMBONATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	87	22	65

Presenting signs (probable and possible)

Agitation (2)	Hyperactivity (8)	Panting (6)
Alopecia (1)	Hypersalivation (2)	Pruritus (3)
Anaphylaxis (2)	Hypotension (2)	Pyrexia (5)
Anorexia (6)	Incontinence (2)	Tachycardia (3)
Capillary refill time (slow) (1)	Injection site reaction (2)	Tachypnoea (1)
Collapse (7)	Lethargy (14)	Unpleasant taste (2)
Death (1)	Low efficacy (2)	Vocalisation (2)
Diarrhoea (16)	Lump (local) (2)	Vomiting (141)
Erythema (3)	Malaise (6)	Weight loss (1)
Facial oedema (2)	Pale mucous membranes (4)	

Year	Total Reports	Total Probable	Total Possible
2015	2	2	0

[illegible]

Year	Total Reports	Total Probable	Total Possible
2015	11	3	8

Anorexia (2)	Lethargy (7)	Tachypnoea (2)
Ataxia (10)	Pain (2)	Tremor (1)
Diarrhoea (1)	Pyrexia (4)	Vomiting (2)
Hypersalivation (3)	Site reaction (2)	

Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Adipsia (3)	Ataxia (3)	Hypersalivation (3)
Anorexia (3)	Frothing at the mouth (1)	Malaise (3)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	15	7	8

Presenting signs (probable and possible)

Alopecia (1)	Foaming (3)	Pruritus (1)
Ataxia (5)	Frothing at the mouth (3)	Respiratory problems (2)
Behavioural change (2)	Hyperaesthesia (3)	Seizure (5)
Convulsions (1)	Hypersalivation (13)	Shaking (1)
Death (1)	Listless (1)	Spasm (3)
Diarrhoea (1)	Pale mucous membranes (1)	Vomiting (3)
Dyspnoea (1)	Paraesthesia (1)	

6.200 PYRETHRUM EXTRACT**Feline**

Year	Total Reports	Total Probable	Total Possible
2015	3	1	2

Presenting signs (probable and possible)

Ataxia (1)	Dyspnoea (1)	Vomiting (1)
Behavioural change (1)	Pale mucous membranes (1)	
Diarrhoea (1)	Shaking (1)	

6.201 PYRIPROXYFEN**Canine**

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Agitation (1)	Paraesthesia (1)
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Feline

Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Presenting signs (probable and possible)

Hypersalivation (2) Pruritus (2)

Incontinence (2) Tremor (2)

6.202 QUIL**Feline**

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

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

6.203 RABBIT CALICIVIRUS DISEASE VIRUS -INACTIVATED**Rabbit**

Year	Total Reports	Total Probable	Total Possible
2015	3	1	2

Presenting signs (probable and possible)

Anaphylaxis (1) Death (2) Dyspnoea (1)

Anorexia (1) Diarrhoea (1) Lethargy (1)

6.204 RECOMBINANT GP70 SUB-TYPE A**Feline**

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

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

6.205 ROBENACOXIB

Canine

Year	Total Reports	Total Probable	Total Possible
2015	4	2	2

Presenting signs (probable and possible)

Behavioural change (1) Lethargy (1)

Coughing (1) Vomiting (2)

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Behavioural change (1)

6.206 SALICYLIC ACID

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Deafness (1)

6.207 SELAMECTIN

Feline

Year	Total Reports	Total Probable	Total Possible
2015	33	27	6

Presenting signs (probable and possible)

Agitation (4)	Frothing at the mouth (1)	Pruritus (6)
Alopecia (1)	Hives (1)	Scabs (2)
Alopecia (localised) (25)	Hypersalivation (1)	Site reaction (27)
Anisocoria (1)	Lack of effect (1)	Vomiting (4)
Ataxia (1)	Lethargy (1)	Welts (1)
Dermatitis (1)	Malaise (1)	
Erythema (8)	Pain (2)	

6.208 SELENIUM

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Anorexia (1)	Hypersalivation (1)	Lethargy (1)
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Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Ataxia (1) Collapse (1)

Year	Total Reports	Total Probable	Total Possible
2015	4	2	2

Death (4)	Malaise (1)	Spasm (2)
Lethargy (2)	Recumbency (1)	Stiffness (1)

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Injection site reaction (1)	Site reaction (swelling) (1)
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Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Injection site reaction (2)	Lame (1)	Lump (local) (2)
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6.211 SHARK CARTILAGE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	4	1	3

Presenting signs (probable and possible)

Diarrhoea (2)

Melaena (1)

Pruritus (2)

6.212 SODIUM FLUOROACETATE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	4	2	2

Presenting signs (probable and possible)

Death (4)

Poisoning (1)

Vocalisation (2)

Frothing at the mouth (2)

Seizure (2)

6.213 SODIUM SELENATE

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Ataxia (1)

Collapse (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Presenting signs (probable and possible)

Death (2)

Malaise (1)

Stiffness (1)

Lethargy (2)

Recumbency (1)

6.214 SODIUM SELENITE

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Presenting signs (probable and possible)

Injection site reaction (2) Lame (1) Lump (local) (2)

SPINOSAD

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

Vomiting is a known side effect and is recorded on the label. Vomiting is of short duration only involving a single instance from which the animal recovers 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.

6.215 SPINOSAD

Canine

Year	Total Reports	Total Probable	Total Possible
2015	279	160	119

Presenting signs (probable and possible)

Adipsia (3)	Dysphagia (1)	Malaise (5)
Agitation (3)	Erythema (1)	Mydriasis (1)
Anaphylactoid reaction (1)	Facial oedema (4)	Nausea (4)
Anorexia (24)	Flatulence (3)	Neurological disorder (2)
Ataxia (14)	Gagging (1)	Pancreatitis (1)
Behavioural change (1)	Hyperaesthesia (2)	Periorbital swelling (1)
Collapse (2)	Hypersalivation (9)	Pruritus (5)
Constipation (1)	Hypersensitive to stimuli (1)	Pyrexia (4)
Dermatitis (3)	Irritation (skin) (1)	QC (1)
Diarrhoea (30)	Lack of effect (2)	Rash (1)
Distress (2)	Lethargy (57)	Regurgitation (1)

Restless (2)	Tachycardia (1)	Vomiting (220)
Retching (2)	Tremor (9)	Weight loss (2)
Seizure (3)	Unpleasant taste (8)	Welts (1)
Shaking (3)	Vocalisation (3)	

Feline

Year	Total Reports	Total Probable	Total Possible
2015	118	60	58

Presenting signs (probable and possible)

Abnormal breathing (1)	Hyperactivity (1)	Pruritus (3)
Agitation (3)	Hypersalivation (7)	Pyrexia (3)
Anorexia (6)	Lame (1)	Recumbency (1)
Ataxia (19)	Lethargy (21)	Restless (3)
Behavioural change (2)	Malaise (2)	Shaking (2)
Bloat (1)	Miosis (1)	Somnolence (2)
CNS dysfunction (1)	Muscle twitching (4)	Tachypnoea (1)
Collapse (1)	Mydriasis (1)	Tremor (6)
Comatose (2)	Nystagmus (1)	Vocalisation (1)
Diarrhoea (4)	Panting (1)	Vomiting (87)
Disorientation (1)	Paresis (1)	Weakness (1)
Distress (1)	Polydipsia (1)	
Erythema (2)	Proprioception deficit (1)	

6.216 STREPTOCOCCUS EQUI AS CELL FREE EXTRACT

Equine

Year	Total Reports	Total Probable	Total Possible
2015	25	12	13

Presenting signs (probable and possible)

Allergy (1)	Diarrhoea (1)	Pyrexia (2)
Anorexia (2)	Inflammation (1)	Stiffness (5)
Ataxia (1)	Injection site reaction (16)	Sweating (1)
Coat colour change (1)	Lethargy (8)	Swelling (local) (4)
Colic (1)	Oedema (11)	Urticaria (1)
Death (1)	Pain (4)	

6.217 SYNTHETIC ANALOGUE OF F3 FRACTION FELINE FACIAL PHEROMONE

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Lethargy (1)	Pruritus (1)	Sneezing (1)
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6.218 SYNTHETIC ANALOGUE OF THE CANINE APPEASING PHEROMONE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	9	8	1

Presenting signs (probable and possible)

Agitation (1)	Facial oedema (1)	Rash (1)
Alopecia (2)	Lesions (3)	Site reaction (3)
Dermatitis (1)	Pruritus (3)	
Erythema (5)	Pyoderma (3)	

6.219 TELMISARTAN

Feline

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Diarrhoea (1)

6.220 TEMEPHOS

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Lame (1)

6.221 THIAMAZOLE

Feline

Year	Total Reports	Total Probable	Total Possible
2015	5	2	3

Presenting signs (probable and possible)

Abnormal Biochemistry (1)	Hepatopathy (1)	Malaise (2)
Anorexia (3)	Jaundice (1)	Restless (1)
Elevated ALP (1)	Lethargy (2)	Vomiting (3)
Elevated ALT (1)	Leukopenia (1)	Weight loss (1)

6.222 TILETAMINE AS THE HYDROCHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Recovery (prolonged) (1)

6.223 TILUDRONIC ACID AS DISODIUM TILUDRONATE

Equine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Anorexia (1) Polydipsia (1)

6.224 TITANIUM DIOXIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Erythema (1) Site reaction (1) Ulceration (1)

6.225 TRICLABENDAZOLE

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Lack of effect (1)

6.226 XYLAZINE HYDROCHLORIDE

Equine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Injection site reaction (1) Swelling (local) (1) Urticaria (1)

6.227 ZETA-CYPERMETHRIN

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Agitation (1)

6.228 ZINC AS ZINC DISODIUM EDTA

Bovine

Year	Total Reports	Total Probable	Total Possible
2015	1	1	0

Presenting signs (probable and possible)

Injection site reaction (1)

Site reaction (swelling) (1)

Ovine

Year	Total Reports	Total Probable	Total Possible
2015	2	1	1

Presenting signs (probable and possible)

Injection site reaction (2)

Lame (1)

Lump (local) (2)

6.229 ZINC OXIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Erythema (1)

Site reaction (1)

Ulceration (1)

6.230 ZOLAZEPAM AS THE HYDROCHLORIDE

Canine

Year	Total Reports	Total Probable	Total Possible
2015	1	0	1

Presenting signs (probable and possible)

Recovery (prolonged) (1)

(S)-METHOPRENE	21	CORYNEBACTERIUM	16, 54
(Z)-9 TRICOSENE	12	COUMATETRALYL	9, 12
ABALONE POWDER	21	CYCLOSPORIN	55, 56
ABAMECTIN	22	CYROMAZINE	56
ACEPROMAZINE MALEATE	22	D.A.P BULK SOLUTION	56
ACETYL GLUCOSAMINE	22	DELTAMETHRIN	57
AFOXOLANER	23	DESLORELIN ACETATE	57
AGLEPRISTONE	24	DETOMIDINE HYDROCHLORIDE	58
ALBENDAZOLE	24	DEXAMETHASONE PHENYLPROPIONATE	58
ALPHAXALONE	25	DEXAMETHASONE SODIUM PHOSPHATE	58
ALUMINIUM HYDROXIDE	25	DEXTROMETHORPHAN HYDROBROMIDE	58
AMITRAZ	26	DIAZEPAM	59
AMOXYCILLIN TRIHYDRATE	26	DIAZINON	16, 59
AMPHOTERICIN	27	DICHLOROPHEN	59
ATROPINE	27	DICYCLANIL	59
AZELAIC ACID	27	DIFLUBENZURON	17, 60
BACITRACIN ZINC	28	DISODIUM EDETATE	60
BENAZEPRIL HYDROCHLORIDE	28	DISODIUM MANGANONS ETHYLENE DIAMINE TETRAACETATE	60
BENZALKONIUM CHLORIDE	9, 28	DISODIUM TILUDRONATE	60, 116
BETAMETHASONE VALERATE	29	DL-ALPHA-TOCOPHERYL ACETATE	61
BIOTA ORIENTALIS SEED OIL	29	DORAMECTIN	61
BORDETELLA	29, 30, 31	DOXYCYCLINE MONOHYDRATE	61
BOVINE VIRAL DIARRHOEA VIRUS	33	EMODEPSIDE	61
BUTORPHANOL TARTRATE	34	ENROFLOXACIN	62
CAMPYLOBACTER	14, 15, 34	EPHEDRINE HYDROCHLORIDE	62
CANINE ADENOVIRUS	34, 35, 36, 37	EQUINE HERPES VIRUS	62
CANINE DISTEMPER	38, 39	ESCHERICHIA COLI	63
CANINE PARAINFLUENZA	40, 41, 42	FEBANTEL	63
CANINE PARVO VIRUS	43, 44, 45, 46	FELINE CALICIVIRUS	64
CARBIMAZOLE	46	FELINE CHLAMYDIA PSITTACI	65
CARPROFEN	47	FELINE HERPES	81
CEFOVECIN SODIUM	47	FELINE IMMUNODEFICIENCY VIRUS	65
CEPHALEXIN MONOHYDRATE	48	FELINE LEUKAEMIA VIRUS	66
CETRIMIDE	48	FELINE PANLEUCOPENIA	66, 67
CHLAMYDOPHILIA FELIS	48	FELINE RHINOTRACHEITIS	67, 68
CHLORAMPHENICOL	49	FENBENDAZOLE	68
CHLORFENVINPHOS	49	FIPRONIL	17, 69
CHLORHEXIDINE GLUCONATE	49	FIROCOXIB	69
CHLORINE	9	FLUAZURON	69
CHLORPHENIRAMINE MALEATE	50	FLUMETHRIN	70
CLAVULANIC ACID	50	FLUNIXIN MEGLUMINE	70
CLOMIPRAMINE HYDROCHLORIDE	50	FLURALANER	70
CLOPROSTENOL SODIUM	15	FLURALANER	70
CLOSTRIDIUM	15, 16, 20, 51, 52	FRUSEMIDE	71
CLOTRIMAZOLE	52	G GLYCOPROTEIN OF HENDRA VIRUS	71, 72
COBALT AS COBALT EDTA	52	GENTAMICIN SULFATE	73
COBALT OXIDE	53	GNRF - PROTEIN	73
COPPER DISODIUM EDTA	53	GREEN LIPPED MUSSEL	73
COPPER OXIDE	53	HYDROCORTISONE	73, 74
CORONAVIRUS	31, 32, 37, 54		

IMADACLOPRID	74	PERNA CANALICULUS	100
IMEPITOIN	74	PESTIVIRUS	32
IMIDACLOPRID	12, 17, 74	PHENOBARBITONE	100
IMIPROTHRIN	9	PHEROMONE	19, 115
INDOXACARB	17, 76, 77	PICLORAM	10
INSULIN	78	PIMELIC ACID	100
IVERMECTIN	78	PIMOBENDAN	100
KETAMINE HYDROCHLORIDE	79	PIPERONYL BUTOXIDE	10, 101
LACTIC ACID	79	PIROCTONE OLAMINE	101
LAMBDA-CYHALOTHRIN	9	POLY (HEXAMETHYLENE BIGUANIDE) HYDROCHLORIDE	10
LASALOCID SODIUM	79	POLYMYXIN B	102
LEPTOSPIRA	80	POLYMYXIN B SULFATE	102
LEVAMISOLE	80	PORCINE CIRCOVIRUS	102
LIGNOCAINE HYDROCHLORIDE	81	PRAZQUANTEL	103
LUFENURON	82	PREDNISOLONE	104
MANGANESE EDTA	82	PROCAINE HYDROCHLORIDE	105
MAROPITANT CITRATE	83	PROPENTOFYLLINE	105
MELOXICAM	83	PROPOFOL	105
METHADONE	84	PROPOXUR	105
METHYL LAURATE	17, 84	PYRANTEL EMBONATE	106
METHYL LINOLEATE	18, 84	PYRETHRIN	10, 107
METHYL MYRISTATE	18, 85	PYRETHRUM	11, 108
METHYL OLEATE	18, 85	PYRIPROXYFEN	108
METHYL PALMITATE	18, 85	QUIL	108
METHYL PENTADECANOATE	18, 86	RABBIT CALICIVIRUS	109
METHYL STEARATE	19, 86	RECOMBINANT GP70	109
MILBEMYCIN OXIME	87	ROBENACOXIB	109
MOMETASONE FUROATE MONOHYDRATE	88	ROTAVIRUS	33
MONENSIN SODIUM	89	SALICYLIC ACID	110
MONEPANTEL	14	SELAMECTIN	110
MOXIDECTIN	19, 89, 91	SELENIUM	110, 111
MYCOBACTERIUM PARATUBERCULOSIS	92	SHARK CARTILAGE	111
MYCOPLASMA HYOPNEUMONIAE	92	SODIUM FLUOROACETATE	12, 112
NAPHTHALOPHOS	93	SODIUM HYPOCHLORITE	11
NEOMYCIN	93	SODIUM SELENATE	111, 112
NICLOSAMIDE	93	SODIUM SELENITE	111, 112
NITENPYRAM	94	SPINOSAD	113
N-METHYL-2-PYRROLIDONE	19	STREPTOCOCCUS EQUI	114
N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE	94	TELMISARTAN	115
OATMEAL EXTRACT	95	TEMEPHOS	115
OLEIC ACID	95	THIAMAZOLE	116
OXANTEL EMBONATE	95	TILETAMINE	116
OXFENDAZOLE	96	TILMICOSIN	20
OXIBENDAZOLE	96	TITANIUM DIOXIDE	116
OXYTETRACYCLINE	96, 97	TRICLABENDAZOLE	117
PALMITIC ACID	97	TRICLOPYR BUTOXYETHYL ESTER	11
PARAFFIN	97	XYLAZINE HYDROCHLORIDE	117
PENICILLIN	97	ZETA-CYPERMETHRIN	117
PENTOBARBITONE SODIUM	98	ZINC	117, 118
PENTOSAN POLYSULFATE SODIUM	98	ZOLAZEPAM	118
PERMETHRIN	10, 19, 98, 99		

