



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



# REPORT OF ADVERSE EXPERIENCES

## FOR VETERINARY MEDICINES AND AGRICULTURAL CHEMICALS

CALENDER YEAR 2007

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# Executive summary

The Adverse Experience Reporting Program for veterinary medicines (AERP *Vet*) and the AERP for agricultural chemicals (AERP *Ag*) are quality assurance programs that facilitate the management of veterinary medicines and agricultural chemicals throughout their lifecycle, from registration to end product user.

This report contains information on adverse experience reports for veterinary medicines (Chapter 2 and 3) and agricultural chemicals (Chapter 4 and 5). This report is also available online from the APVMA website at [www.apvma.gov.au](http://www.apvma.gov.au).

During the 2007 calendar year staff classified 2075 AERP *Vet* reports involving suspected adverse reactions in animals submitted by veterinary surgeons, owners, members of the public and product registrants. Of these, a total of 1340 were reports classified either 'probable' or 'possible'.

Fewer AERP *Ag* reports were classified in 2007 than in 2006. A total of 65 adverse experience reports were classified; 28 were human reports, 4 environmental reports and 19 'standard' reports. In regard to agricultural chemicals standard reports include those relating to effects on animals or crops. There were 14 reports relating to lack of efficacy. In addition, numerous enquiries about agvet chemicals were received from members of the public.

This report contains a summary of all adverse experience reports assessed, evaluated and classified as 'probable' or 'possible' (see Section 1.6) by the APVMA during the 2007 calendar year.

Throughout 2007 a number of risk management strategies aimed at mitigating and minimising the number of adverse events were actioned.

These included:

- Label changes to seven product groups, including insect growth regulators to which sheep lice are showing resistance to.
- The updating of First Aid and Safety Directions for veterinary hormone products.

AERs for products containing the active constituent fipronil (which were classified in 2007) have been included in this report. In previous year these were not reported because fipronil was being reviewed under APVMA's Chemical Review Program.

The quality of the information provided in the reports was generally of a high standard, which in part reflects the good interaction between the APVMA, the veterinary profession and registrants.

Off-label incidents are not included in this report. However, it is valuable to report off-label adverse experiences as these can cover very serious incidents. For example:

- Poor anaesthetic treatment protocols have resulted in delayed recovery or death of animals, with some instances of treatment protocols clearly contradicting the label.

- Concurrent use of medications, particularly non-steroidal anti-inflammatory drugs, continues to result in a variety of adverse experience reports.
- The use of dog products on cats has caused serious injury to cats. This action is clearly off-label and the public should be aware that some ingredients are toxic to cats and that dose rates are significantly different between the two species.
- There were 129 human reports received in 2007 across AERP Ag and AERP Vet. Fifty-six percent of human reports were related to off-label product use, including needle stick injuries, which continue to cause concern. Individuals involved in animal husbandry should take appropriate preventative action when injecting animals.

Other activities undertaken during 2007 included:

- publishing the *Report of Adverse Experiences for Veterinary Medicines and Agricultural Chemicals 2006* <http://www.apvma.gov.au/qa/downloads/aerp2006.pdf>
- encouraging reporting through networks of the members of APVMA's Community Consultative Committee (CCC)
- launching a new online reporting facility for both veterinary and agricultural adverse experiences
- raising awareness of the AERP program in the wider community through presentations and advertising.

# Chapter 1. Introduction

## 1.1 Program outline

The APVMA is the Australian government authority responsible for the assessment and registration (marketing authorisation) of pesticides and veterinary medicines prior to sale, and their regulation up to and including the point of retail sale.

‘Veterinary medicines’ includes all veterinary chemical products such as vaccines, antibiotics, worming treatments, flea and tick washes, and other parasiticides for both domestic and production animals.

‘Pesticides’ and ‘Agricultural Chemicals’ includes agricultural and household chemicals such as insecticides, herbicides and fungicides; water treatment products including swimming pool products; products for treating algae and mould; products for preventing rot and infestation in marine structures; and other similar products.

Under the National Registration Scheme, the APVMA evaluates and registers agricultural and veterinary chemicals. The APVMA also manages quality assurance programs that monitor the safety and performance of registered products.

The Adverse Experience Reporting Program (AERP) is a post-registration quality assurance program established by the APVMA to help facilitate the management of veterinary medicines and agricultural chemicals throughout their lifecycle. The program provides a means of identifying corrective action that may be necessary to assure the continued safety, quality and effectiveness of registered products. Recording and investigating reports of adverse experiences is an important step in detecting unusual or rare conditions that were not evident in clinical or field trials and, as a result, could not be assessed during the product registration process. The AERP helps to ensure that products on the market:

- remain safe, effective and of acceptable quality
- are used in the best possible way
- include instructions and warnings on the label that are appropriate.

## 1.2 What is an adverse experience?

### Veterinary adverse experiences

The APVMA defines an AERP *Vet adverse experience* as:

An unintended or unexpected effect on animals, human beings or the environment, including injury, sensitivity reactions or lack of efficacy associated with the clinical use of a veterinary chemical product.

A number of veterinary medicines have known side effects when used as directed and it is useful to maintain a record of these to be able to assess their true incidence. Furthermore, because of the enormous diversity amongst animal species and the relatively small number of veterinary medicines in the marketplace, it is occasionally necessary to use products in circumstances where there is limited information available on the dose rates or adverse reactions in off-label species. Such products may have originally been intended for use in humans or other animal species. For this reason it is important that all adverse experiences, whether associated with recommended label use or not, are reported.

### Agricultural adverse experiences

The APVMA defines an *AERP Ag adverse experience* as:

An adverse experience is an unintended or unexpected effect (deleterious) on plants, plant products, animals, human beings or the environment, including injury, sensitivity reactions or lack of efficacy associated with the use of an agricultural chemical product when used according to label directions.

### Serious and minor adverse experiences

The following definitions outline what the APVMA considers are as *serious* and *minor* adverse experiences.

The APVMA defines a *serious adverse experience* as one that involves:

- widespread and significant crop and plant damage (e.g. crop death, severe stunting or significant yield loss)
- life-threatening or other significant effects in a human, including death
- farm, domestic and native animal deaths
- or
- significant environmental damage, including fish kills and water quality issues.

The APVMA defines a *minor adverse experience* as one that involves:

- crop and plant damage that is not widespread or significant (e.g. minor wilting or yellowing of crops, minor yield loss)
- human health effects that require medical attention, but are not life-threatening
- injury to domestic and native animals that require veterinary attention
- or
- minor environmental damage.

A number of agricultural chemicals have known side effects when used as directed and it is useful to maintain a record so that the true incidence of these side effects can be assessed. It is important to report all adverse experiences.



## 1.3 Who can report an adverse experience?

### Veterinary medicines

Anyone can submit an adverse veterinary medicine report. The APVMA encourages voluntary reporting, particularly from veterinarians, animal owners, farmers and other users of veterinary medicines and agricultural chemicals. Registrants of veterinary medicines also have a legal obligation to report to the AERP.

### Agricultural chemicals

Anyone can submit an adverse agricultural chemical report. The APVMA encourages voluntary reporting, particularly from members of the public, gardeners, farmers and other chemical users, agronomists, bystanders, health workers, and state and territory authorities. Under Section 161 of the *Agvet Code*, registrants must provide the APVMA with any new information that comes to their attention. This new information may include adverse experience information on human health issues, harm to animals, damage to plants, property or the environment, or lack of efficacy when the products are used according to label directions.

The registrant-reporting component of AERP Ag is one method by which registrants can meet certain legislative obligations of Section 161 of the *Agvet Code*.

## 1.4 Reporting an adverse experience

Adverse experiences can be reported online at <https://services.apvma.gov.au/AerpWebApp/> or by using the Adverse Experience Reporting Form, or by contacting the AERP directly (contact details are on page 7).

## 1.5 Benefits of the AERP

The AER Program provides numerous benefits to a wide range of stakeholders.

### Benefits to the community

- helps ensure the safety and efficacy of registered products in the marketplace
- provides confidence in the regulatory system.
- provides up-to-date safety information on registered products
- ensures that the latest safety information is available on product labels
- provides information on modifications needed to work practices to ensure safe use of chemicals
- identifies and acts on emerging issues quickly.

### Benefits to states/territories

- provides an integrated approach between national and state programs

- provides a format for communication of issues that cross over jurisdictional boundaries.

## 1.6 Evaluation of adverse experience reports

Reports received by the APVMA are assessed to determine whether the adverse experience is related to the use of, or exposure to, the product.

Procedures for dealing with adverse experience reports are as follows:

- Reports made directly to the APVMA (voluntary reports) are copied to the product registrant for investigation. The registrant may then contact either the reporting person or the attending veterinarian and discuss the matter to determine if any follow up laboratory, pathology or other veterinary work is required.
- The product registrant subsequently provides the APVMA with an investigation report into the incident. The APVMA assesses this information and determines whether any further investigative work is required. In some cases, additional expert opinion may be sought from e.g. the Australian Veterinary Association, relevant state or territory government agencies, universities or other appropriate authorities. The APVMA will also consider scientific information publicly available either on the Internet or from an international agency.
- In all cases a standard method of assessment is used to determine whether the adverse experience may have been related to the use of the veterinary medicine or agricultural chemical (i.e. 'classification'; see 1.7 below). The APVMA also considers whether the product was used according to the label directions.
- The person submitting making the report will be advised of the outcome of the investigations.
- If a report of an adverse experience is made directly to the product registrant, they will investigate the matter and provide a report to the APVMA (registrant reports). The APVMA will then assess this information and determine whether any further investigative or regulatory work is required.

## 1.7 Classification of adverse experience reports

The relationship between the use of a product and the reported clinical signs is determined after the incident has been investigated. This relationship is expressed in terms of *probable*, *possible*, *probable or possible off-label*, *unlikely* and *unknown*.

### Probable

For inclusion in the category *probable*, all of the following minimum criteria should be met:

- there should be a reasonable association between the administration of the product and onset and duration of the reported adverse experience
- the clinical signs should be consistent with, the known pharmacology and toxicology of the product

- there should be no other equally plausible explanation (or contributing factors) for the clinical signs.

When any of the above criteria cannot be satisfied (due to lack of sufficient information or conflicting data) then the association cannot be assessed as *probable*.

### Possible

For inclusion in the category *possible*, association of the adverse experience with administration of the primary suspect product is one of other possible and equally plausible explanations (or contributing factors) for the described adverse experience.

### Probable or possible off-label

This is as per the classification of *probable* or *possible* but where there is obvious evidence of off-label use (including use in species not listed on the product label, over-dosing or under-dosing). It is acknowledged that depending on state and territory legislation and veterinary prescribing privileges, APVMA permits and other legal exemptions may allow off-label use in some situations.

### Unlikely

Where sufficient information exists to establish that the described adverse experience was not likely to have been associated with administration or use of the product(s), or other more plausible explanations exist, the assessment should be categorised as *unlikely*.

### Unknown

All adverse experiences for which reliable data are either unavailable or are insufficient to make an assessment should be categorised as *unknown*.

## 1.8 Corrective action determination

The APVMA takes into account a broad range of issues and options when deciding what, if any, corrective action is required to mitigate possible risks to humans, animals, or the environment.

For each registered veterinary medicine, and more broadly for each active constituent, the APVMA conducts a trend analysis of all adverse experience reports received. All reports that have been classified as probable or possible are compared to the total number of doses sold within the relevant financial year and a 'reporting incidence' is calculated (i.e. the number of adverse experience reports per number of doses sold). A control limit or 'warning line' for reporting incidence figures, which indicate that further action may be required is one or more per 10,000 doses sold<sup>1</sup>. This report also recommends that if the reporting incidence is greater than one per 10,000 in two out of three consecutive years or an exceptional incidence of three

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

or more per 10,000 occurs on any one occasion, or a consistent rising trend is seen over five years (irrespective of the reporting incidence), then action may be taken.

The APVMA considers other scientific literature and information relating to trend analysis and risk assessment when determining whether corrective action is required. The APVMA also takes into account whether the noted clinical signs are listed in warning statements on the product label, in which case a slightly higher reporting incidence may be acceptable, and also considers the severity of clinical signs (i.e. more severe signs may trigger corrective action at a lower reporting incidence).

## 1.9 Outcomes of the program

Based on the assessment of adverse experience reports certain risk mitigation strategies or corrective actions may be requested. These may include, but are not restricted to, the following:

- registration amendments, such as label changes, changes to the method of manufacture or the product's physical or chemical design, changes to container design, changes to production line processes, or suspension and/or cancellation of registration and approval
- review of the active constituent under the APVMA's Chemical Review Program
- referral for action, such as compliance action, including product and batch recalls, referral to state authorities for action, or nomination of products or active constituents for formal chemical review by the APVMA, (note that once the recommendation for review has been made by the AERP the review program will conduct consultation and scoping prior to determining whether a review is necessary or not)
- education and publicity, such as providing scientific papers or articles on issues identified for relevant journals, magazines or newspapers. When required education can be directed toward veterinary profession, farming community or wider public on issues relating to use of products.

The conclusions drawn by the APVMA during the investigation and evaluation of each adverse experience report will be provided to the reporting person. This will include an explanation of whether the APVMA considers that the observed adverse effects (including health symptoms) were related to the use of or exposure to the product. The APVMA will explain what these conclusions are and what corrective action, if any, will be taken in response to the information.

The information contained in this report is only a general reference to the type of adverse experience that have been reported either to the APVMA or to product registrants. This information should not be used for:

- associating adverse effects with a particular product or active constituent
- assessing the safety and efficacy of a product or active constituent
- establishing acceptable frequency of occurrence of an adverse experience  
or
- comparing one product or active constituent with another product or active constituent.

## 1.10 Report Structure

This report is arranged into the following sections:

### Chapters 2 and 3 AERP *Vet*

- Chapter 2 is a summary of adverse experience reports other than human health (including crop damage, environmental damage and lack of efficacy) listed by active constituent.
- Chapter 3 is a summary of adverse experience reports involving human health.

### Chapters 4 and 5 AERP *Ag*

- Chapter 4 is a summary of adverse experience reports other than human health (including crop damage, environmental damage and lack of efficacy) listed by active constituent.
- Chapter 5 is a summary of adverse experience reports involving human health.

Information is presented for each active and divided into species. Several species tables are may be present for each active constituent. Where the species is a human the reports are presented in chapters 3 and 5.

## ACTIVE CONSTITUENT

### SPECIES AFFECTED

Number of Reports	Probable	Possible
X+Y	X	Y

Presenting sign	Number of reports
Burn(s)	A
Scabs	B
Skin slough	C

## 1.11 For further information

For information about the Adverse Experience Reporting Program please contact:

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# Chapter 2. Veterinary - summary of AERs 2007 (animal)

## 2.1 Adverse experience report summaries for each species listed by active constituent

### Active constituent name

- Each active constituent is listed alphabetically, with a summary of the adverse experience reports. Related actives are grouped together.
- It is important to note that the number of adverse experience reports and the presenting signs observed may be listed under more than one active constituent if they refer to a product that contains multiple active constituents.

### The species

- For each active constituent, the adverse experience reports are listed by species in alphabetical order.

### Number of reports

- Only adverse experience reports that were classified by the APVMA during the calendar year 2007 as being either probable or possible have been included in these lists. The summary table indicates how many reports were classified as probable and how many were classified as possible.

### Presenting signs

- All observed clinical signs for reports that were classified as probable and possible are listed in order of frequency.
- It is important to note that multiple clinical signs have been noted in some individual reports. Therefore the list of clinical signs observed does not relate directly to the total number of reports received.

### Summary of corrective action

- No regulatory action was required for many of the active constituents as the frequency of adverse experience reports received was relatively low when compared with the total number of doses sold. A short narrative is provided on any corrective action taken as a result of assessment of the adverse experience information for an active constituent.
- In many instances, the potential for adverse reactions to many veterinary medicines was recognised at the time of product registration. When adverse experiences are reported for such medicines, the need for corrective action is considered against the data assessed at the time of product registration.

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## 2.2 Veterinary – standard AERs

### ABAMECTIN

Bovine

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Burn(s)	1
Scabs	1
Skin slough	1

Equine

Number of Reports	Probable	Possible
5	1	4

Presenting sign	Number of reports
Abortion	1
Ataxia	1
Death	1
Diarrhoea	1
Hypersalivation	1
Oral (lesions)	1
Worms	1

Ovine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Death	1
Lame	1

## ACEPROMAZINE MALEATE

Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1
Respiratory problems	1
Sedation (prolonged)	1

## ADENOSINE TRIPHOSPHATE

Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Death	1
Collapse	1

## ALPHA-CYPERMETHRIN

Ovine

Number of Reports	Probable	Possible
3	1	2

Presenting sign	Number of reports
Lack of effect	3

## ALPHAXALONE

### Canine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Aggression	1
Aggression	1
Cyanosis	1
Recovery (poor)	1

### Feline

Number of Reports	Probable	Possible
10	1	9

Presenting sign	Number of reports
Death	6
Respiratory problems	3
Cardiac arrest	2
Induction (poor)	2
Aggression	1
CNS dysfunction	1
Erythema	1
Hypersalivation	1
Hypersensitive to noise	1
Hypersensitive to stimuli	1
Hypotension	1
Pulmonary oedema	1
Recovery (prolonged)	1
Welts	1

## ALUMINIUM HYDROXIDE

### Canine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Collapse	1
Erythema	1

Facial oedema	1
Vomiting	1

### Feline

Number of Reports	Probable	Possible
4	0	4

Presenting sign	Number of reports
Anorexia	4
Lethargy	4
Vomiting	2

## AMITRAZ

### Bovine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Hypersalivation	1
Recumbency	1

### Canine

Number of Reports	Probable	Possible
4	2	2

Presenting sign	Number of reports
Lack of effect	2
Anorexia	1
Haematemesis	1
Listless	1
Self trauma	1
Site reaction	1
Vomiting	1

## AMOXYCILLIN AS AMOXYCILLIN TRIHYDRATE

Canine

Number of Reports	Probable	Possible
3	0	3

Presenting sign	Number of reports
Vomiting	2
Hepatopathy	1
Injection site reaction	1
Jaundice	1
Seroma	1

Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Bradycardia	1
Collapse	1
Death	1
Respiratory problems	1

## AMOXYCILLIN TRIHYDRATE

Feline

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Hypersalivation	1
Pulmonary oedema	1
Vomiting	1

## ANAPLASMA CENTRALE

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

## APRAMYCIN

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Depression	1

## ARGININE-L HYDROCHLORIDE

Equine

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Injection site reaction	1
Oedema	1
Pyrexia	1
Swelling (local)	1

## BABESIA BIGEMINA

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

## BABESIA BOVIS

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

## BACITRACIN ZINC

Feline

Number of Reports	Probable	Possible
2	2	0

Presenting sign	Number of reports
Anaphylactoid reaction	1
Anaphylaxis	1
Collapse	1
Diarrhoea	1
Periorbital swelling	1
Respiratory problems	1
Vomiting	1

## BENAZEPRIL HYDROCHLORIDE

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Hyperactivity	1
Swollen lips and face	1
Vomiting	1

Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Mydriasis	1
Ocular damage	1

## BENZATHINE PENICILLIN

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Facial oedema	1
Hives	1

## BLACKLEG = CLOSTRIDIUM CHAUVOEI

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lame	1



## BORDETELLA BRONCHISEPTICA

Canine

Number of Reports	Probable	Possible
28	3	25

Presenting sign	Number of reports
Coughing	12
Injection site reaction	12
Anorexia	6
Lethargy	4
Pain	4
Swelling (local)	4
Death	3
Collapse	2
Dyspnoea	2
Pyrexia	2
Shock	2
Site reaction	2
Sneezing	2
Vomiting	2
Abdominal pain	1
Abscess	1
Anaphylactoid reaction	1
Anaphylaxis	1
Ataxia	1
Circling	1
Depression	1
Facial oedema	1
Haemorrhage	1
Inflammation	1
Lack of effect	1
Nasal discharge	1
Petechiae	1
Respiratory problems	1
Seizure	1
Stiffness	1
Thrombocytopenia	1

## BORDETELLA BRONCHISEPTICA (INACTIVATED CELL FREE EXTRACT)

### Canine

Number of Reports	Probable	Possible
261	157	104

Presenting sign	Number of reports
Lethargy	95
Injection site reaction	80
Pain	59
Vomiting	35
Anorexia	29
Swollen lips and face	28
Facial oedema	24
Pyrexia	20
Pale mucous membranes	13
Pruritus	11
Shaking	11
Diarrhoea	9
Hypo-reflexia	8
Swelling (local)	7
Urticaria	7
Ataxia	6
Behavioural change	6
Collapse	5
Malaise	5
Tremor	5
Adipsia	4
Site reaction (swelling)	4
Bradycardia	3
Defaecation	3
Depression	3
Hypersalivation	3
Listless	3
Periorbital swelling	3
Recumbency	3
Tachypnoea	3
Vocalisation	3
Walking (difficult)	3
Erythema	2
Hyperaesthesia	2
Lame	2
Oedema	2

Panting	2
Site reaction	2
Tachycardia	2
Urination	2
Wheals	2
Abdominal pain	1
Agitation	1
Anaphylaxis	1
Conjunctivitis	1
Haematology (abnormal)	1
Hives	1
Hypersensitivity reaction	1
Hypotension	1
Irritation (ear)	1
Irritation (paws)	1
Lack of effect	1
Lesions	1
Lump (local)	1
Melaena	1
Muscle stiffness	1
Parvovirus	1
Pawing at face	1
Polyarthritis	1
Rash	1
Respiratory problems	1
Restless	1
Seroma	1
Stiffness	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

## BORDETELLA BRONCHISEPTICA KILLED VACCINE

Canine

Number of Reports	Probable	Possible
37	3	34

Presenting sign	Number of reports
Vomiting	17
Swollen lips and face	15
Lethargy	7
Injection site reaction	5
Urticaria	5
Pruritus	4
Ataxia	3
Defaecation	3
Diarrhoea	3
Pale mucous membranes	3
Respiratory problems	3
Collapse	2
Hives	2
Irritation (skin)	2
Pain	2
Tachycardia	2
Tachypnoea	2
Agitation	1
Anorexia	1
Cardiac arrest	1
Cyanosis	1
Death	1
Depression	1
Hypersensitive to stimuli	1
Hypersensitivity reaction	1
Hypothermia	1
Inflammation	1
Leucocytosis	1
Listless	1
Melaena	1
Miosis	1
Periorbital swelling	1
Pupillary light reflex (abnormal)	1
Pyrexia	1
Rash	1
Recumbency	1
Restless	1

Seizure	1
Seroma	1
Shock	1
Site reaction	1
Weakness	1
Welts	1
Wheals	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

## BROWN SNAKE ANTIVENOM

Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Urticaria	1

## CAMPHOR

Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Blisters	1
Site reaction	1
Swelling (local)	1

## CANINE ADENOVIRUS TYPE 2

Canine

Number of Reports	Probable	Possible
71	12	59

Presenting sign	Number of reports
Pain	13
Vomiting	13
Swollen lips and face	10
Lethargy	9
Coughing	7
Injection site reaction	7
Anorexia	6
Pyrexia	6
Swelling (local)	6
Behavioural change	5
Death	5
Pale mucous membranes	5
Diarrhoea	4
Site reaction	4
Adipsia	3
Facial oedema	3
Pruritus	3
Respiratory problems	3
Shaking	3
Stiffness	3
Abscess	2
Anaphylaxis	2
Ataxia	2
Collapse	2
Depression	2
Dyspnoea	2
Haemorrhage	2
Hypersensitivity reaction	2
Lack of effect	2
Malaise	2
Parvovirus	2
Shock	2
Sneezing	2
Tremor	2
Urticaria	2
Vocalisation	2
Abdominal pain	1

Anaphylactoid reaction	1
Cardiac arrest	1
Cyanosis	1
Haematology (abnormal)	1
Hyperaesthesia	1
Hypersalivation	1
Hypersensitive to stimuli	1
Inflammation	1
Irritation (ear)	1
Listless	1
Lump (local)	1
Petechiae	1
Recumbency	1
Seroma	1
Tachycardia	1
Thrombocytopenia	1
Urination	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

## CANINE ADENO VIRUS TYPE 2 STRAIN V197

Canine

Number of Reports	Probable	Possible
30	1	29

Presenting sign	Number of reports
Vomiting	15
Swollen lips and face	8
Lethargy	6
Injection site reaction	4
Pruritus	4
Ataxia	3
Collapse	3
Defaecation	3
Diarrhoea	3
Pain	3
Pale mucous membranes	3
Pyrexia	3
Urticaria	3
Hives	2
Tachypnoea	2
Anorexia	1
Bradycardia	1
Depression	1
Hypersalivation	1
Hypothermia	1
Inflammation	1
Irritation (skin)	1
Lack of effect	1
Leucocytosis	1
Listless	1
Miosis	1
Parvovirus	1
Periorbital swelling	1
Polyarthritis	1
Pupillary light reflex (abnormal)	1
Rash	1
Recumbency	1
Respiratory problems	1
Seizure	1
Shock	1
Swollen ears and face	1
Tachycardia	1



Weakness	1
Wheals	1

## CANINE ADENOVIRUS TYPE 2 - LIVE (INFECTIOUS HEPATITIS)

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Collapse	1
Erythema	1
Vomiting	1

## CANINE ADENOVIRUS TYPE 2 LIVE (CAV II)

Canine

Number of Reports	Probable	Possible
103	63	40

Presenting sign	Number of reports
Lethargy	47
Injection site reaction	33
Pain	31
Anorexia	12
Facial oedema	12
Vomiting	9
Pyrexia	8
Pale mucous membranes	6
Swollen lips and face	6
Diarrhoea	4
Pruritus	4
Bradycardia	2
Collapse	2
Hypersalivation	2
Lame	2
Recumbency	2
Shaking	2
Tachypnoea	2
Urticaria	2
Walking (difficult)	2
Adipsia	1

Agitation	1
Anaphylaxis	1
Ataxia	1
Conjunctivitis	1
Defaecation	1
Depression	1
Hives	1
Hyperaesthesia	1
Irritation (paws)	1
Lesions	1
Listless	1
Melaena	1
Muscle stiffness	1
Pawing at face	1
Periorbital swelling	1
Respiratory problems	1
Restless	1
Site reaction	1
Site reaction (swelling)	1
Swelling (local)	1
Tachycardia	1
Urination	1
Wheals	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

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## CANINE CORONAVIRUS VACCINE - ANTIGEN

Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Collapse	1
Pale mucous membranes	1
Pruritus	1

## CANINE DISTEMPER

Canine

Number of Reports	Probable	Possible
14	1	13

Presenting sign	Number of reports
Lack of effect	3
Swollen lips and face	3
Dyspnoea	2
Facial oedema	2
Lethargy	2
Parvovirus	2
Vomiting	2
Anorexia	1
Death	1
Irritation (skin)	1
Melaena	1
Pain	1
Pyrexia	1
Respiratory problems	1
Seroma	1
Site reaction	1
Tachycardia	1

## CANINE DISTEMPER VIRUS

Canine

Number of Reports	Probable	Possible
26	2	24

Presenting sign	Number of reports
Vomiting	6
Lethargy	5
Death	4
Injection site reaction	4
Swollen lips and face	4
Pain	3
Pale mucous membranes	3
Anaphylaxis	2
Collapse	2
Haemorrhage	2
Pyrexia	2
Respiratory problems	2
Shock	2
Site reaction	2
Swelling (local)	2
Urticaria	2
Abdominal pain	1
Abscess	1
Anaphylactoid reaction	1
Ataxia	1
Cardiac arrest	1
Cyanosis	1
Diarrhoea	1
Facial oedema	1
Hyperaesthesia	1
Hypersensitive to stimuli	1
Hypersensitivity reaction	1
Lack of effect	1
Parvovirus	1
Petechiae	1
Pruritus	1
Stiffness	1
Thrombocytopenia	1

## CANINE DISTEMPER VIRUS - LIVING

### Canine

Number of Reports	Probable	Possible
140	71	69

Presenting sign	Number of reports
Lethargy	51
Pain	40
Injection site reaction	37
Anorexia	17
Vomiting	17
Facial oedema	14
Swollen lips and face	12
Pyrexia	11
Pale mucous membranes	8
Diarrhoea	7
Pruritus	6
Behavioural change	5
Shaking	5
Adipsia	4
Collapse	3
Depression	3
Hypersalivation	3
Recumbency	3
Site reaction	3
Swelling (local)	3
Ataxia	2
Bradycardia	2
Lame	2
Listless	2
Malaise	2
Tachycardia	2
Tachypnoea	2
Tremor	2
Urination	2
Urticaria	2
Vocalisation	2
Walking (difficult)	2
Abscess	1
Agitation	1
Anaphylaxis	1
Conjunctivitis	1

Death	1
Defaecation	1
Erythema	1
Haematology (abnormal)	1
Hives	1
Hyperaesthesia	1
Hypersensitivity reaction	1
Irritation (ear)	1
Irritation (paws)	1
Lack of effect	1
Lesions	1
Lump (local)	1
Melaena	1
Muscle stiffness	1
Parvovirus	1
Pawing at face	1
Periorbital swelling	1
Respiratory problems	1
Restless	1
Seroma	1
Site reaction (swelling)	1
Stiffness	1
Wheals	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

## CANINE DISTEMPER VIRUS STRAIN ONDERSTEPSPOORT

Canine

Number of Reports	Probable	Possible
30	1	29

Presenting sign	Number of reports
Vomiting	15
Swollen lips and face	8
Lethargy	6
Injection site reaction	4
Pruritus	4
Ataxia	3
Collapse	3
Defaecation	3
Diarrhoea	3
Pain	3
Pale mucous membranes	3
Pyrexia	3
Urticaria	3
Hives	2
Tachypnoea	2
Anorexia	1
Bradycardia	1
Depression	1
Hypersalivation	1
Hypothermia	1
Inflammation	1
Irritation (skin)	1
Lack of effect	1
Leucocytosis	1
Listless	1
Miosis	1
Parvovirus	1
Periorbital swelling	1
Polyarthritis	1
Pupillary light reflex (abnormal)	1
Rash	1
Recumbency	1
Respiratory problems	1
Seizure	1
Shock	1
Swollen ears and face	1
Tachycardia	1

Weakness	1
Wheals	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

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## CANINE PARAINFLUENZA

Canine

Number of Reports	Probable	Possible
12	2	10

Presenting sign	Number of reports
Coughing	7
Dyspnoea	2
Sneezing	2
Swelling (local)	2
Anorexia	1
Inflammation	1
Injection site reaction	1
Pain	1
Pyrexia	1
Respiratory problems	1
Stiffness	1

## CANINE PARAINFLUENZA TYPE 2

Canine

Number of Reports	Probable	Possible
42	2	40

Presenting sign	Number of reports
Vomiting	18
Swollen lips and face	11
Lethargy	9
Injection site reaction	6
Pale mucous membranes	5
Pruritus	5



Urticaria	5
Ataxia	4
Pain	4
Pyrexia	4
Collapse	3
Defaecation	3
Diarrhoea	3
Respiratory problems	3
Death	2
Hives	2
Lack of effect	2
Parvovirus	2
Tachypnoea	2
Anorexia	1
Bradycardia	1
Cardiac arrest	1
Cyanosis	1
Depression	1
Hyperaesthesia	1
Hypersalivation	1
Hypersensitive to stimuli	1
Hypersensitivity reaction	1
Hypothermia	1
Inflammation	1
Irritation (skin)	1
Leucocytosis	1
Listless	1
Miosis	1
Periorbital swelling	1
Polyarthritis	1
Pupillary light reflex (abnormal)	1
Rash	1
Recumbency	1
Seizure	1
Shock	1
Swollen ears and face	1
Tachycardia	1
Weakness	1
Wheals	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

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## CANINE PARAINFLUENZA VIRUS

### Canine

Number of Reports	Probable	Possible
156	70	86

Presenting sign	Number of reports
Lethargy	54
Pain	42
Injection site reaction	38
Vomiting	20
Anorexia	19
Facial oedema	16
Swollen lips and face	15
Pyrexia	12
Diarrhoea	7
Pale mucous membranes	7
Pruritus	6
Site reaction	6
Behavioural change	5
Shaking	5
Swelling (local)	5
Adipsia	4
Collapse	4
Death	4
Depression	4
Ataxia	3
Lack of effect	3
Parvovirus	3
Recumbency	3
Tachycardia	3
Anaphylaxis	2
Bradycardia	2
Hypersalivation	2
Lame	2
Listless	2
Malaise	2
Melaena	2
Seroma	2

Shock	2
Tachypnoea	2
Urination	2
Urticaria	2
Vocalisation	2
Walking (difficult)	2
Abdominal pain	1
Abscess	1
Agitation	1
Anaphylactoid reaction	1
Circling	1
Conjunctivitis	1
Coughing	1
Defaecation	1
Haematology (abnormal)	1
Haemorrhage	1
Hives	1
Hyperaesthesia	1
Hypersensitivity reaction	1
Irritation (ear)	1
Irritation (paws)	1
Irritation (skin)	1
Lesions	1
Lump (local)	1
Muscle stiffness	1
Pawing at face	1
Periorbital swelling	1
Petechiae	1
Respiratory problems	1
Restless	1
Seizure	1
Site reaction (swelling)	1
Stiffness	1
Thrombocytopenia	1
Tremor	1
Wheals	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

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## CANINE PARAINFLUENZA VIRUS - INACTIVATED

Canine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Collapse	1
Erythema	1
Facial oedema	1
Vomiting	1

## CANINE PARVO VIRUS

Canine

Number of Reports	Probable	Possible
32	2	30

Presenting sign	Number of reports
Vomiting	8
Swollen lips and face	7
Lethargy	6
Death	4
Injection site reaction	3
Pain	3
Pale mucous membranes	3
Site reaction	3
Anaphylaxis	2
Collapse	2
Facial oedema	2
Haemorrhage	2
Lack of effect	2
Parvovirus	2
Pyrexia	2
Respiratory problems	2
Shock	2
Swelling (local)	2
Urticaria	2
Abdominal pain	1
Abscess	1
Anaphylactoid reaction	1

Ataxia	1
Cardiac arrest	1
Cyanosis	1
Diarrhoea	1
Hyperaesthesia	1
Hypersensitive to stimuli	1
Hypersensitivity reaction	1
Irritation (skin)	1
Melaena	1
Petechiae	1
Pruritus	1
Seroma	1
Stiffness	1
Tachycardia	1
Thrombocytopenia	1

## CANINE PARVO VIRUS K3I STRAIN

Canine

Number of Reports	Probable	Possible
30	1	29

Presenting sign	Number of reports
Vomiting	15
Swollen lips and face	8
Lethargy	6
Injection site reaction	4
Pruritus	4
Ataxia	3
Collapse	3
Defaecation	3
Diarrhoea	3
Pain	3
Pale mucous membranes	3
Pyrexia	3
Urticaria	3
Hives	2
Tachypnoea	2
Anorexia	1
Bradycardia	1
Depression	1
Hypersalivation	1

Hypothermia	1
Inflammation	1
Irritation (skin)	1
Lack of effect	1
Leucocytosis	1
Listless	1
Miosis	1
Parvovirus	1
Periorbital swelling	1
Polyarthritis	1
Pupillary light reflex (abnormal)	1
Rash	1
Recumbency	1
Respiratory problems	1
Seizure	1
Shock	1
Swollen ears and face	1
Tachycardia	1
Weakness	1
Wheals	1

## CANINE PARVO VIRUS TYPE 2

### Canine

Number of Reports	Probable	Possible
139	71	68

Presenting sign	Number of reports
Lethargy	51
Pain	40
Injection site reaction	37
Anorexia	17
Vomiting	16
Facial oedema	14
Swollen lips and face	12
Pyrexia	11
Pale mucous membranes	8
Diarrhoea	7
Pruritus	6
Behavioural change	5
Shaking	5
Adipsia	4
Depression	3

Hypersalivation	3
Recumbency	3
Site reaction	3
Swelling (local)	3
Ataxia	2
Bradycardia	2
Collapse	2
Lame	2
Listless	2
Malaise	2
Tachycardia	2
Tachypnoea	2
Tremor	2
Urination	2
Urticaria	2
Vocalisation	2
Walking (difficult)	2
Abscess	1
Agitation	1
Anaphylaxis	1
Conjunctivitis	1
Death	1
Defaecation	1
Haematology (abnormal)	1
Hives	1
Hyperaesthesia	1
Hypersensitivity reaction	1
Irritation (ear)	1
Irritation (paws)	1
Lack of effect	1
Lesions	1
Lump (local)	1
Melaena	1
Muscle stiffness	1
Parvovirus	1
Pawing at face	1
Periorbital swelling	1
Respiratory problems	1
Restless	1
Seroma	1
Site reaction (swelling)	1
Stiffness	1
Wheals	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

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## CANINE PARVOVIRUS - LIVE

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Collapse	1
Erythema	1
Vomiting	1

## CAPSICUM OLEORESIN

Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Necrosis	1
Oral (lesions)	1

## CARBARYL

Canine

Number of Reports	Probable	Possible
3	3	0

Presenting sign	Number of reports
Lack of effect	2
Hypersalivation	1



## CARPROFEN

Canine

Number of Reports	Probable	Possible
5	0	5

Presenting sign	Number of reports
Lethargy	2
Nil	2
Vomiting	2
Anorexia	1
Diarrhoea	1
Hives	1
Jaundice	1
Wheals	1

## CHLAMYDOPHILIA FELIS BAKER STRAIN - LIVE, ATTENUATED

Feline

Number of Reports	Probable	Possible
12	8	4

Presenting sign	Number of reports
Lethargy	4
Site reaction	4
Alopecia	3
Anorexia	3
Death	2
Diarrhoea	2
Erythema	2
Vomiting	2
Alopecia (localised)	1
Anaphylactoid reaction	1
Ataxia	1
Convulsions	1
Dehydration	1
Facial oedema	1
Hyperactivity	1
Injection site reaction	1
Melaena	1
Pain	1

Panting	1
Respiratory problems	1
Scabs	1
Shaking	1
Vocalisation	1

## CHLORHEXIDINE GLUCONATE

Feline

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Frothing at the mouth	1
Premature birth	1
Stillbirth	1

## CHLORPHENIRAMINE MALEATE

Canine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Ataxia	1
Mydriasis	1
Pupillary light reflex (abnormal)	1
Tachycardia	1

## CHLORPYRIFOS

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Ataxia	1
Hyperactivity	1
Pruritus	1
Tachypnoea	1

## CLA = CORYNEBACTERIUM PSEUDOTUBERCULOSIS OVIS

Ovine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Death	1
Lame	1

## CLAVULANIC ACID

Canine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Hepatopathy	1
Injection site reaction	1
Jaundice	1
Seroma	1
Vomiting	1

Feline

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Bradycardia	1
Collapse	1
Death	1
Hypersalivation	1
Respiratory problems	1
Vomiting	1

## CLOMIPRAMINE HYDROCHLORIDE

### Canine

Number of Reports	Probable	Possible
3	1	2

Presenting sign	Number of reports
Aggression	1
Seizure	1
Somnolence	1

### Feline

Number of Reports	Probable	Possible
3	0	3

Presenting sign	Number of reports
Anorexia	1
Haematology (abnormal)	1
Hepatopathy	1
Lethargy	1
Mammary hyperplasia	1
Vomiting	1

## CLOPROSTENOL (AS THE SODIUM SALT)

### Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Colic	1
Sweating	1

## CLOSTRIDIUM CHAUVOEI - FORMOL CULTURE

Ovine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Death	1
Lame	1

## CLOSTRIDIUM CHAUVOEI - TOXOID

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Milk production decrease	1

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Abscess	1
Lame	1

## CLOSTRIDIUM NOVYI TYPE B

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1

## CLOSTRIDIUM NOVYI TYPE B - ANTISERA/ANTIGEN

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lame	1

## CLOSTRIDIUM NOVYI TYPE B - TOXOID

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Milk production decrease	1

Ovine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Lame	2
Abscess	1

## CLOSTRIDIUM PERFRINGENS TYPE D - ANTISERA/ANTIGEN

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lame	1

## CLOSTRIDIUM PERFRINGENS TYPE D TOXOID

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Milk production decrease	1

Ovine

Number of Reports	Probable	Possible
3	0	3

Presenting sign	Number of reports
Lame	2
Abscess	1
Death	1

## CLOSTRIDIUM SEPTICUM - TOXOID

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Milk production decrease	1

Ovine

Number of Reports	Probable	Possible
3	0	3

Presenting sign	Number of reports
Lame	2
Abscess	1
Death	1

## CLOSTRIDIUM TETANI - ANTITOXIN

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Hives	1
Facial oedema	1

## CLOSTRIDIUM TETANI - TOXOID

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Milk production decrease	1

Ovine

Number of Reports	Probable	Possible
3	0	3

Presenting sign	Number of reports
Lame	2
Abscess	1
Death	1

## COBALT DISODIUM ETHYLENEDIAMINE TETRAACETATE

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1



## CONTAGIOUS PUSTULAR DERMATITIS VIRUS, LIVING, CELL CULTURE

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1
Scabby mouth	1

## CORONAVIRUS

Canine

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Anorexia	1
Injection site reaction	1
Lethargy	1
Pain	1
Pyrexia	1

## CORYNEBACTERIUM PSEUDOTUBERCULOSIS - TOXOID

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Abscess	1
Lame	1

## CORYNEBACTERIUM PSEUDOTUBERCULOSIS (OVIS) - TOXOID

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lame	1

## COUMATETRALYL

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Coagulopathy	1

## CYCLOSPORIN

Canine

Number of Reports	Probable	Possible
27	20	7

Presenting sign	Number of reports
Vomiting	17
Diarrhoea	5
Lethargy	5
Pruritus	4
Hyperactivity	2
Panting	2
Alopecia	1
Anorexia	1
Ataxia	1
Hypothermia	1
Pale mucous membranes	1
Recumbency	1
Shaking	1
Tachypnoea	1
Tenesmus	1
Urination	1

Urticaria	1
Weakness	1
Wheals	1

## CYROMAZINE

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

## D, ALPHA-TOCOPHEROL (68 I.U./ML VITAMIN E)

Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Collapse	1
Death	1

## DELTAMETHRIN

Bovine

Number of Reports	Probable	Possible
1	8	1

Presenting sign	Number of reports
Lack of effect	9

## DERACOXIB

Canine

Number of Reports	Probable	Possible
4	1	3

Presenting sign	Number of reports
Melaena	2
Vomiting	2
Anaemia	1
Collapse	1
Diarrhoea	1
Haematemesis	1
Hypersalivation	1
Incontinence	1
Urination	1

## DESLORELIN AS DESLORELIN ACETATE

Canine

Number of Reports	Probable	Possible
3	1	2

Presenting sign	Number of reports
Lack of effect	3

## DEXTROMETHORPHAN HYDROBROMIDE

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Tachycardia	1

## DIAZINON

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

## DICHLORVOS

Equine

Number of Reports	Probable	Possible
4	4	0

Presenting sign	Number of reports
Colic	4
Abdominal pain	1

## DICYCLANIL

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

## DIFLUBENZURON

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

Ovine

Number of Reports	Probable	Possible
73	12	61

Presenting sign	Number of reports
Lack of effect	71
Coat discoloration	1
Wool damage	1

Diflubenzuron is an insect growth-regulating compound (IGR). An IGR is a material that controls the life cycle of pests such as roaches and fleas by inhibiting maturation of the pests. The sheep and wool industry rely heavily on the use of the insect growth regulator (IGR) group of chemicals for treating lice. Unfortunately there are lice with reduced susceptibility to IGR chemicals.

## DI-ISOPROPYLAMINE DICHLOROACETATE

Equine

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Collapse	1
Death	1
Pain	1
Site reaction	1
Swelling (local)	1

## EMODEPSIDE

Feline

Number of Reports	Probable	Possible
19	13	6

Presenting sign	Number of reports
Site reaction	11
Alopecia (localised)	9
Ataxia	2
Coat discoloration	2
Diarrhoea	2
Agitation	1
Hypersalivation	1
Lethargy	1
Vomiting	1

## ENROFLOXACIN

Feline

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Death	1
Nystagmus	1
Pulmonary oedema	1

## EPHEDRINE HYDROCHLORIDE

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Tachycardia	1

## ESCHERICHIA COLI 987P PILUS ANTIGENS

Porcine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Abscess	1
Injection site reaction	1

## ESCHERICHIA COLI K88AB PILUS ANTIGENS

Porcine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Abscess	1
Injection site reaction	1

## ESCHERICHIA COLI K88AC PILUS ANTIGENS

Porcine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Abscess	1
Injection site reaction	1

## ESCHERICHIA COLI K99 PILUS ANTIGENS

Porcine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Abscess	1
Injection site reaction	1



## FEBANTEL

Canine

Number of Reports	Probable	Possible
23	18	5

Presenting sign	Number of reports
Vomiting	11
Hyperactivity	8
Lack of effect	2
Diarrhoea	1
Hyperexcitable	1
Shaking	1
Worms	1

## FELINE CALICIVIRUS - INACTIVATED

Feline

Number of Reports	Probable	Possible
39	20	19

Presenting sign	Number of reports
Lethargy	21
Anorexia	19
Pyrexia	5
Injection site reaction	4
Pain	4
Site reaction	4
Vomiting	4
Alopecia	3
Diarrhoea	3
Facial oedema	3
Behavioural change	2
Convulsions	2
Death	2
Erythema	2
Hyperactivity	2
Alopecia (localised)	1
Anaphylactoid reaction	1
Anaphylaxis	1
Ataxia	1

Collapse	1
Dehydration	1
Depression	1
Hives	1
Lack of effect	1
Melaena	1
Mydriasis	1
Ocular discharge	1
Panting	1
Pruritus	1
Respiratory problems	1
Scabs	1
Shaking	1
Sneezing	1
Tachycardia	1
Tachypnoea	1
Urticaria	1
Vocalisation	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

## FELINE IMMUNODEFICIENCY VIRUS (PETALUMA STRAIN) INACTIVE

### Feline

Number of Reports	Probable	Possible
5	1	4

Presenting sign	Number of reports
Lethargy	4
Anorexia	2
Alopecia	1
Dehydration	1
Injection site reaction	1
Pain	1
Site reaction	1

## FELINE LEUKAEMIA VIRUS – INACTIVATED

Feline

Number of Reports	Probable	Possible
4	2	2

Presenting sign	Number of reports
Lethargy	2
Alopecia (localised)	1
Anorexia	1
Ataxia	1
Dehydration	1
Diarrhoea	1
Injection site reaction	1
Pain	1
Site reaction	1
Vocalisation	1

## FELINE PANLEUCOPENIA VIRUS - INACTIVATED

Feline

Number of Reports	Probable	Possible
39	20	19

Presenting sign	Number of reports
Lethargy	21
Anorexia	19
Pyrexia	5
Injection site reaction	4
Pain	4
Site reaction	4
Vomiting	4
Alopecia	3
Diarrhoea	3
Facial oedema	3
Behavioural change	2
Convulsions	2
Death	2
Erythema	2
Hyperactivity	2
Alopecia (localised)	1

Anaphylactoid reaction	1
Anaphylaxis	1
Ataxia	1
Collapse	1
Dehydration	1
Depression	1
Hives	1
Lack of effect	1
Melaena	1
Mydriasis	1
Ocular discharge	1
Panting	1
Pruritus	1
Respiratory problems	1
Scabs	1
Shaking	1
Sneezing	1
Tachycardia	1
Tachypnoea	1
Urticaria	1
Vocalisation	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

## FELINE RHINOTRACHEITIS VIRUS - INACTIVATED

### Feline

Number of Reports	Probable	Possible
39	20	19

Presenting sign	Number of reports
Lethargy	21
Anorexia	19
Pyrexia	5
Injection site reaction	4
Pain	4
Site reaction	4
Vomiting	4
Alopecia	3

Diarrhoea	3
Facial oedema	3
Behavioural change	2
Convulsions	2
Death	2
Erythema	2
Hyperactivity	2
Alopecia (localised)	1
Anaphylactoid reaction	1
Anaphylaxis	1
Ataxia	1
Collapse	1
Dehydration	1
Depression	1
Hives	1
Lack of effect	1
Melaena	1
Mydriasis	1
Ocular discharge	1
Panting	1
Pruritus	1
Respiratory problems	1
Scabs	1
Shaking	1
Sneezing	1
Tachycardia	1
Tachypnoea	1
Urticaria	1
Vocalisation	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea. These occur very occasionally with most vaccines.

Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

## FENBENDAZOLE

Ovine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Death	2
Collapse	1

## FIPRONIL

Canine

Number of Reports	Probable	Possible
59	21	38

Presenting sign	Number of reports
Site reaction	27
Irritation (skin)	20
Erythema	10
Alopecia	8
Dermatitis	5
Lethargy	5
Pruritus	5
Rubbing	5
Scabs	5
Vomiting	5
Coat discoloration	4
Lesions	4
Behavioural change	3
Pain	3
Self trauma	3
Anorexia	2
Blisters	2
Diarrhoea	1
Irritation (ear)	1
Listless	1
Nausea	1
Necrosis	1
Rash	1
Shaking	1
Swelling (local)	1

## Feline

Number of Reports	Probable	Possible
44	21	23

Presenting sign	Number of reports
Alopecia	31
Site reaction	29
Irritation (skin)	8
Lesions	6
Erythema	5
Scabs	5
Lethargy	3
Dermatitis	2
Anorexia	1
Behavioural change	1
Diarrhoea	1
Hypersalivation	1
Vomiting	1

Fipronil is a broad-spectrum phenyl pyrazole insecticide acting on the nervous system of insects by contact or ingestion. These are relatively new products in the market place and have a very high volume of sales.

Fipronil is currently under review. Progress of the review can be monitored on the APVMA website (<http://www.apvma.gov.au/chemrev/ChemRevProgram.shtml>).

## FIROCOXIB

### Canine

Number of Reports	Probable	Possible
4	0	4

Presenting sign	Number of reports
Anorexia	3
Vomiting	3
Lethargy	2
Melaena	2
Death	1
Depression	1
Diarrhoea	1
Renal disease	1
Shock	1

## FLUMETHRIN

Canine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Erythema	1
Irritation (ear)	1
Rash	1
Site reaction	1

## FRAMYCETIN SULFATE

Feline

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Anaphylactoid reaction	1
Collapse	1
Periorbital swelling	1

## FRUSEMIDE

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Hyperactivity	1
Swollen lips and face	1
Vomiting	1



## GNRF - PROTEIN CONJUGATE

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Anorexia	1
Swelling (local)	1

## HEPATITIS CANINE = CANINE ADENOVIRUS

Canine

Number of Reports	Probable	Possible
15	1	14

Presenting sign	Number of reports
Lack of effect	3
Swollen lips and face	3
Dyspnoea	2
Facial oedema	2
Lethargy	2
Parvovirus	2
Vomiting	2
Anorexia	1
Death	1
Injection site reaction	1
Irritation (skin)	1
Melaena	1
Pain	1
Pyrexia	1
Respiratory problems	1
Seroma	1
Site reaction	1
Tachycardia	1

## HYDROXY PROGESTERONE HEXANOATE

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Pain	1
Site reaction	1
Stiffness	1

## HYDROXYPROGESTERONE CAPROATE

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Site reaction	1

## IMIDACLOPRID

Canine

Number of Reports	Probable	Possible
259	190	69

Presenting sign	Number of reports
Irritation (skin)	106
Agitation	103
Site reaction	29
Lethargy	26
Vomiting	25
Self trauma	19
Lack of effect	18
Dermatitis	15
Coat discoloration	11
Hyperactivity	11
Rolling	10
Rubbing	9
Anorexia	7
Irritation (ear)	7

Restless	7
Behavioural change	6
Diarrhoea	6
Shaking	5
Alopecia (localised)	4
Hypersalivation	4
Ataxia	3
Pruritus	3
Tick paralysis	3
Tremor	3
Alopecia	2
Listless	2
Malaise	2
Panting	2
Paraesthesia	2
Rash	2
Scabs	2
Urticaria	2
Vocalisation	2
Blisters	1
Circling	1
Convulsions	1
Distress	1
Erythema	1
Hyperexcitable	1
Hypersensitive to stimuli	1
Hypersensitivity reaction	1
Illness	1
Lump (local)	1
Odour	1
Pain	1
Somnolence	1
Walking (difficult)	1
Welts	1

### Feline

Number of Reports	Probable	Possible
52	31	21

Presenting sign	Number of reports
Alopecia (localised)	14
Site reaction	12
Hypersalivation	9
Ataxia	7
Dermatitis	4

Lack of effect	4
Lethargy	4
Agitation	3
Alopecia	3
Self trauma	3
Behavioural change	2
Coat discoloration	2
Scabs	2
Distress	1
Fasciculation	1
Frothing at the mouth	1
Irritation (eye)	1
Irritation (skin)	1
Mydriasis	1
Respiratory problems	1
Shaking	1
Vocalisation	1

These are relatively new products on the market place and have a very high volume of sales. Reporting incidence for 2007 has decreased, this may be attributed to label changes in several products that occurred in 2006.

## INACTIVATED RABBIT CALICIVIRUS DISEASE VIRUS

### Rabbit

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1
Incoordination	1
Lethargy	1

## IODINE AS ETHYLENEDIAMINE DIHYDRIODIDE

### Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1

## IRON AS FERRIC HYDROXIDE SUCROSE COMPOUND

Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Cardiac arrest	1
Death	1

## ISOPROPYL ALCOHOL

Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Blisters	1
Site reaction	1
Swelling (local)	1

## IVERMECTIN

Bovine

Number of Reports	Probable	Possible
9	1	8

Presenting sign	Number of reports
Lack of effect	4
Alopecia (localised)	2
Ataxia	2
Death	2
Tremor	2
Alopecia	1
Burn(s)	1
Depression	1
Diarrhoea	1
Frothing at the mouth	1
Pruritus	1
Recumbency	1

## Equine

Number of Reports	Probable	Possible
5	3	2

Presenting sign	Number of reports
Lethargy	2
Diarrhoea	1
Hypersalivation	1
Lesions	1
Swelling (local)	1
Swollen lips and face	1

## KETAMINE (AS KETAMINE HYDROCHLORIDE)

### Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Pulmonary oedema	1

## LACTIC ACID

### Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Urticaria	1

## LEPTOSPIRA ICTEROHAEMORRHAGIAE ANTIGEN

### Canine

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Collapse	1
Injection site reaction	1
Pale mucous membranes	1

Pruritus	1
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### LEPTOSPIRA INTERROGANS SEROVAR HARDJO

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Milk production decrease	1

### LEPTOSPIRA INTERROGANS SEROVAR POMONA

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Milk production decrease	1

### LEPTOSPIROSIS - DOG - LEPTOSPIRA ICTEROHAEMORRHAGIAE

Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Anorexia	1
Lethargy	1
Pain	1
Pyrexia	1

## LEVAMISOLE

Canine

Number of Reports	Probable	Possible
3	1	2

Presenting sign	Number of reports
Lack of effect	1
Worms	2

Ovine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Death	2
Collapse	1

## LUFENURON

Canine

Number of Reports	Probable	Possible
20	9	11

Presenting sign	Number of reports
Vomiting	8
Lethargy	7
Anorexia	3
Pruritus	3
Dermatitis	2
Diarrhoea	2
Lack of effect	2
Urticaria	2
Abdominal pain	1
Adipsia	1
Ataxia	1
Melaena	1
Erythema	1
Flatulence	1
Hyperactivity	1
Jaundice	1
Seizure	1



Swollen lips and face	1
Tremor	1

## LYSINE-L HYDROCHLORIDE

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Injection site reaction	1

## MAGNESIUM ASPARTATE

Equine

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Collapse	1
Death	1
Injection site reaction	1

## MAGNESIUM FLUROSILICATE

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

## MALIGNANT OEDEMA = CLOSTRIDIUM SEPTICUM

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lame	1

## MARBOFLOXACIN

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Oedema	1

## MEDETOMIDINE HYDROCHLORIDE

Feline

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Pulmonary oedema	1
Sedation (prolonged)	1

## MELOXICAM

Canine

Number of Reports	Probable	Possible
4	1	3

Presenting sign	Number of reports
Melaena	3
Anorexia	2
Vomiting	2
Hepatopathy	1
Jaundice	1
Lethargy	1

Feline

Number of Reports	Probable	Possible
3	0	3

Presenting sign	Number of reports
Death	2
Pulmonary oedema	2
Bradycardia	1
Collapse	1
Respiratory problems	1

## MENTHOL

Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Blisters	1
Site reaction	1
Swelling (local)	1

## METHOPRENE

Canine

Number of Reports	Probable	Possible
4	0	4

Presenting sign	Number of reports
Lack of effect	2
Diarrhoea	1
Respiratory problems	1

Feline

Number of Reports	Probable	Possible
4	4	0

Presenting sign	Number of reports
Hypersalivation	4

## METHOPRENE - RS

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

Feline

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Lethargy	1

## MICONAZOLE NITRATE

Feline

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Stillbirth	1
Premature birth	1
Frothing at the mouth	1

## MILBEMYCIN OXIME

Canine

Number of Reports	Probable	Possible
29	14	15

Presenting sign	Number of reports
Vomiting	11
Lethargy	9
Anorexia	4
Diarrhoea	4
Lack of effect	4
Pruritus	3
Dermatitis	2
Seizure	2
Urticaria	2
Abdominal pain	1
Adipsia	1
Ataxia	1
Melaena	1
Convulsions	1
Dyspnoea	1
Erythema	1
Facial oedema	1
Flatulence	1
Hyperactivity	1
Jaundice	1
Rales	1
Somnolence	1
Swollen feet	1
Swollen lips and face	1

Tachycardia	1
Tremor	1

### Feline

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Anorexia	1
Dyspnoea	1
Lethargy	1
Vomiting	1

## MONENSIN (AS MONENSIN SODIUM)

### Bovine

Number of Reports	Probable	Possible
10	3	7

Presenting sign	Number of reports
Lack of effect	6
Death	4
Bloat	3
Choking	1
Pyrexia	1
Recumbency	1
Scouring	1
Throat infection	1
Weight loss	1

## MORANTEL TARTRATE

### Equine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Diarrhoea	1
Hypersalivation	1
Oral (lesions)	1

## MOXIDECTIN

Bovine

Number of Reports	Probable	Possible
3	1	2

Presenting sign	Number of reports
Lack of effect	2
Recumbency	1

Canine

Number of Reports	Probable	Possible
132	28	104

Presenting sign	Number of reports
Lethargy	36
Vomiting	35
Injection site reaction	22
Pain	13
Urticaria	13
Diarrhoea	8
Facial oedema	8
Pale mucous membranes	7
Pruritus	7
Swollen lips and face	7
Lack of effect	7
Collapse	6
Site reaction	6
Ataxia	5
Abscess	5
Anorexia	5
Defaecation	5
Anaphylaxis	4
Hypersalivation	4
Pyrexia	4
Swelling (local)	4
Agitation	3
Behavioural change	3
Coat discoloration	3
Melaena	3
Periorbital swelling	3
Seroma	3
Shaking	3

Tachycardia	3
Tremor	3
Alopecia	2
Bradycardia	2
Hyperaesthesia	2
Hypersensitivity reaction	2
Hypo-reflexia	2
Malaise	2
Swollen ears and face	2
Vocalisation	2
Weakness	2
Wheals	2
Abdominal pain	1
Adipsia	1
Alopecia (localised)	1
Capillary refill time (slow)	1
Circling	1
Convulsions	1
Cyanosis	1
Depression	1
Dermatitis	1
Erythema	1
Haematemesis	1
Haemorrhage	1
Haemorrhagic gastroenteritis	1
Hypotension	1
Illness	1
Irritation (paws)	1
Irritation (skin)	1
Lame	1
Odour	1
Oedema	1
Pawing at face	1
Petechiae	1
Pupillary light reflex (abnormal)	1
Rash	1
Recumbency	1
Respiratory problems	1
Restless	1
Seizure	1
Somnolence	1
Shock	1
Swelling (vulva)	1
Tachypnoea	1



Thrombocytopenia	1
Walking (difficult)	1
Welts	1

### Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Lack of effect	1

### Feline

Number of Reports	Probable	Possible
33	16	17

Presenting sign	Number of reports
Alopecia (localised)	9
Site reaction	7
Ataxia	6
Lack of effect	4
Hypersalivation	3
Lethargy	3
Agitation	2
Behavioural change	2
Coat discoloration	2
Dermatitis	2
Alopecia	1
Distress	1
Fasciculation	1
Frothing at the mouth	1
Irritation (skin)	1
Mydriasis	1
Respiratory problems	1
Self trauma	1
Shaking	1

### Ovine

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Ataxia	1
Death	1
Lame	1

Moxidectin is often used in conjunction with other products, resulting in a higher incidence of reporting. These products have a very high volume of sales and several new products have been released. A few products have a reporting incidence approaching warning levels and these products are being closely monitored, for AERs.

Moxidectin and moxidectin microspheres are reported under the active Moxidectin in this report.

## MYCOBACTERIUM PARATUBERCULOSIS

Ovine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Abscess	1
Injection site reaction	1

## NAPHTHALOPHOS

Ovine

Number of Reports	Probable	Possible
7	0	7

Presenting sign	Number of reports
Death	6
Anorexia	1
Collapse	1
Malaise	1
Unknown	1

## NEOMYCIN SULFATE

Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Erythema multiforme	1
Swollen lips and face	1

## Feline

Number of Reports	Probable	Possible
2	2	0

Presenting sign	Number of reports
Anaphylaxis	1
Conjunctivitis	1
Diarrhoea	1
Epiphora	1
Respiratory problems	1
Vomiting	1

## NICLOSAMIDE

### Canine

Number of Reports	Probable	Possible
3	1	2

Presenting sign	Number of reports
Worms	2
Lack of effect	1

## NICOTINIC ACID

### Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Collapse	1
Death	1

## NITENPYRAM

### Canine

Number of Reports	Probable	Possible
6	3	3

Presenting sign	Number of reports
Agitation	3

Lethargy	2
Polydipsia	2
Allergy	1
Anorexia	1
Ocular pathology	1
Oedema	1
Panting	1
Pruritus	1
Urticaria	1

### Feline

<b>Number of Reports</b>	<b>Probable</b>	<b>Possible</b>
5	3	2

<b>Presenting sign</b>	<b>Number of reports</b>
Hyperactivity	3
Agitation	2
Panting	2
Pyrexia	2
Dyspnoea	1
Hypersalivation	1
Pruritus	1
Tachypnoea	1
Vocalisation	1

## N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE

### Canine

<b>Number of Reports</b>	<b>Probable</b>	<b>Possible</b>
22	9	13

<b>Presenting sign</b>	<b>Number of reports</b>
Lack of effect	13
Pruritus	3
Behavioural change	1
Death	1
Dermatitis	1
Diarrhoea	1
Respiratory problems	1
Vomiting	1
Weakness	1

Feline

Number of Reports	Probable	Possible
5	5	0

Presenting sign	Number of reports
Hypersalivation	4
Lethargy	1

## NONIVAMIDE

Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Necrosis	1
Oral (lesions)	1

## OESTRADIOL 17-BETA

Bovine

Number of Reports	Probable	Possible
3	3	0

Presenting sign	Number of reports
Preputial prolapse	2
Preputial swelling	1

## OESTRADIOL BENZOATE

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Pain	1
Site reaction	1
Stiffness	1

## OESTRADIOL DIPROPIONATE

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Site reaction	1

## OESTRADIOL VALERATE

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Pain	1
Site reaction	1
Stiffness	1

## OXANTEL EMBONATE

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Vomiting	1

## OXFENDAZOLE

Equine

Number of Reports	Probable	Possible
5	4	1

Presenting sign	Number of reports
Colic	5
Abdominal pain	1

## PARVOVIRUS - LIVE

Canine

Number of Reports	Probable	Possible
7	1	6

Presenting sign	Number of reports
Dyspnoea	2
Anorexia	1
Facial oedema	1
Injection site reaction	1
Lack of effect	1
Lethargy	1
Pain	1
Pyrexia	1
Respiratory problems	1

## PENETHAMATE HYDRIODIDE

Bovine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Collapse	1
Death	1
Shaking	1

## PENTOBARBITONE SODIUM

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

## PERMETHRIN

Canine

Number of Reports	Probable	Possible
223	180	43

Presenting sign	Number of reports
Irritation (skin)	105
Agitation	99
Site reaction	28
Self trauma	20
Lethargy	19
Dermatitis	14
Vomiting	14
Hyperactivity	11
Lack of effect	11
Rolling	10
Coat discoloration	8
Rubbing	8
Irritation (ear)	7
Restless	7
Anorexia	7
Shaking	6
Rash	5
Behavioural change	5
Pruritus	4
Alopecia (localised)	3
Tick paralysis	3
Alopecia	2
Erythema	2
Listless	2
Malaise	2
Panting	2
Paraesthesia	2
Scabs	2
Vocalisation	2
Blisters	1
Circling	1
Hyperexcitable	1
Hypersalivation	1
Hypersensitive to stimuli	1
Pain	1
Urticaria	1
Walking (difficult)	1



## Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Lack of effect	1

Permethrin is a common synthetic chemical, widely used as an insecticide, acaricide, and insect repellent. Permethrin is often used in conjunction with other products, resulting in a higher incidence of reporting. These products have a very high volume of sales.

## PIMOBENDAN

### Canine

Number of Reports	Probable	Possible
3	1	2

Presenting sign	Number of reports
Diarrhoea	1
Hyperactivity	1
Lethargy	1
Swollen lips and face	1
Vomiting	1

## PIPERONYL BUTOXIDE

### Canine

Number of Reports	Probable	Possible
25	12	13

Presenting sign	Number of reports
Lack of effect	13
Pruritus	5
Behavioural change	1
Death	1
Dermatitis	1
Diarrhoea	1
Rash	1
Respiratory problems	1
Vomiting	1
Weakness	1

## Feline

Number of Reports	Probable	Possible
5	5	0

Presenting sign	Number of reports
Hypersalivation	4
Lethargy	1

## POLYMYXIN B SULFATE

### Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Erythema multiforme	1
Swollen lips and face	1

### Feline

Number of Reports	Probable	Possible
3	3	0

Presenting sign	Number of reports
Anaphylactoid reaction	1
Anaphylaxis	1
Collapse	1
Conjunctivitis	1
Diarrhoea	1
Epiphora	1
Periorbital swelling	1
Respiratory problems	1
Vomiting	1

## POTASSIUM ASPARTATE

### Equine

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Collapse	1
Death	1

Injection site reaction	1
-------------------------	---

## PRAZIQUANTEL

Canine

Number of Reports	Probable	Possible
51	32	19

Presenting sign	Number of reports
Vomiting	23
Hyperactivity	9
Lethargy	9
Diarrhoea	5
Anorexia	4
Lack of effect	4
Pruritus	3
Dermatitis	2
Seizure	2
Urticaria	2
Abdominal pain	1
Adipsia	1
Ataxia	1
Melaena	1
Convulsions	1
Dyspnoea	1
Erythema	1
Facial oedema	1
Flatulence	1
Hyperexcitable	1
Jaundice	1
Rales	1
Shaking	1
Somnolence	1
Swollen feet	1
Swollen lips and face	1
Tachycardia	1
Tremor	1

## Equine

Number of Reports	Probable	Possible
8	5	3

Presenting sign	Number of reports
Abortion	1
Ataxia	1
Death	1
Diarrhoea	1
Hypersalivation	1
Lack of effect	1
Lesions	1
Lethargy	1
Swelling (local)	1
Swollen lips and face	1
Worms	1

## Feline

Number of Reports	Probable	Possible
28	16	12

Presenting sign	Number of reports
Site reaction	11
Alopecia (localised)	9
Ataxia	7
Vomiting	4
Anorexia	3
Lethargy	3
Coat discoloration	2
Diarrhoea	2
Agitation	1
Dyspnoea	1
Hypersalivation	1
Hypersensitive to stimuli	1
Sedation	1
Tachycardia	1

## Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lame	1

Praziquantel is a systemic anthelmintic used primarily to treat worm infections. Due to the low number of reports when taking into consideration the large number of animals treated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

## PREDNISOLONE

Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Erythema multiforme	1
Swollen lips and face	1

Feline

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Conjunctivitis	1
Epiphora	1

## PROCAINE PENICILLIN

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Facial oedema	1
Hives	1

## PROPANTHELINE BROMIDE

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Colic	1

## PROPOFOL

Canine

Number of Reports	Probable	Possible
7	2	5

Presenting sign	Number of reports
Apnoea	4
Cardiac arrest	3
Cyanosis	2
Death	2
Erythema	1
Hives	1
Injection site reaction	1
Self trauma	1
Swelling (local)	1
Urticaria	1

Feline

Number of Reports	Probable	Possible
3	0	3

Presenting sign	Number of reports
Blindness	1
Cardiac arrest	1
CNS dysfunction	1
Cyanosis	1
Death	1
Rales	1
Recovery (prolonged)	1
Respiratory problems	1

## PROPOXUR

Canine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Erythema	1
Irritation (ear)	1
Rash	1
Site reaction	1

## PYRANTEL

Canine

Number of Reports	Probable	Possible
24	18	6

Presenting sign	Number of reports
Vomiting	12
Hyperactivity	8
Diarrhoea	1
Hyperexcitable	1
Lack of effect	2
Shaking	1

Feline

Number of Reports	Probable	Possible
6	3	3

Presenting sign	Number of reports
Ataxia	5
Vomiting	2
Anorexia	1
Hypersensitive to stimuli	1
Sedation	1
Tachycardia	1

## Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Colic	1

## PYRETHRINS

### Canine

Number of Reports	Probable	Possible
25	12	13

Presenting sign	Number of reports
Lack of effect	13
Pruritus	5
Behavioural change	1
Death	1
Dermatitis	1
Diarrhoea	1
Rash	1
Respiratory problems	1
Vomiting	1
Weakness	1

### Feline

Number of Reports	Probable	Possible
5	5	0

Presenting sign	Number of reports
Hypersalivation	1
Lethargy	1

## PYRIPROXYFEN

### Canine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Alopecia	1



Pruritus	1
Rash	1
Site reaction	1

## QUIL

Feline

Number of Reports	Probable	Possible
4	0	4

Presenting sign	Number of reports
Anorexia	4
Lethargy	4
Vomiting	2

## RECOMBINANT GP70 SUB-TYPE A

Canine

Number of Reports	Probable	Possible
4	0	4

Presenting sign	Number of reports
Anorexia	4
Lethargy	4
Vomiting	2

## ROMIFIDINE HYDROCHLORIDE

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Colic	1

## ROTENONE FROM DERRIS

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

## (S)-METHOPRENE

Canine

Number of Reports	Probable	Possible
57	20	37

Presenting sign	Number of reports
Site reaction	26
Irritation (skin)	19
Erythema	10
Alopecia	8
Dermatitis	5
Lethargy	5
Pruritus	5
Rubbing	5
Scabs	5
Coat discoloration	4
Lesions	4
Behavioural change	3
Pain	3
Self trauma	3
Anorexia	2
Blisters	2
Diarrhoea	1

Irritation (ear)	1
Listless	1
Nausea	1
Necrosis	1
Rash	1
Shaking	1
Swelling (local)	1
Vomiting	1

## Feline

Number of Reports	Probable	Possible
42	20	22

Presenting sign	Number of reports
Alopecia	30
Site reaction	29
Irritation (skin)	8
Lesions	6
Erythema	5
Scabs	5
Dermatitis	2
Lethargy	2
Behavioural change	1
Diarrhoea	1
Hypersalivation	1
Vomiting	1

(S)-methoprene is often used in conjunction with other products resulting in a higher incidence of reporting. (S)-methoprene is a pesticide that acts as a juvenile hormone mimic disrupting the development of insects and preventing the larvae from emerging as adults.

## SALICYLIC ACID

### Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Urticaria	1

## SELAMECTIN

Canine

Number of Reports	Probable	Possible
5	4	1

Presenting sign	Number of reports
Alopecia (localised)	5
Site reaction	4

Feline

Number of Reports	Probable	Possible
25	17	8

Presenting sign	Number of reports
Alopecia (localised)	16
Site reaction	6
Lethargy	3
Irritation (skin)	2
Alopecia	1
Diarrhoea	1
Disorientation	1
Erythema	1
Injection site reaction	1
Pruritus	1
Pyoderma	1
Self trauma	1
Vomiting	1

## SELENIUM

Ovine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Death	1
Lame	1

## SELENIUM (AS SODIUM SELENATE)

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Injection site reaction	1

Ovine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Abscess	1
Death	1
Lame	1

## SELENIUM (AS SODIUM SELENITE)

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Collapse	1
Death	1

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lesions	1
Site reaction	1

## SODIUM GLUCURONATE

Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Oedema	1
Pyrexia	1
Swelling (local)	1

## SODIUM PENTOSAN POLYSULFATE

Canine

Number of Reports	Probable	Possible
6	5	1

Presenting sign	Number of reports
Vomiting	5
Anorexia	1
Ataxia	1
Depression	1
Diarrhoea	1
Lethargy	1
Melaena	1
Panting	1
Shaking	1
Shock	1

Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Injection site reaction	1
Pain	1

## SPINOSAD

Ovine

Number of Reports	Probable	Possible
15	1	14

Presenting sign	Number of reports
Lack of effect	15
Flystrike	5
Death	1

## SULFACETAMIDE SODIUM

Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Erythema multiforme	1
Swollen lips and face	1

Feline

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Conjunctivitis	1
Epiphora	1

## SULFUR

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

## TEPOXALIN

Canine

Number of Reports	Probable	Possible
3	0	3

Presenting sign	Number of reports
Elevated ALP	1
Epistaxis	1
Haemorrhage	1

## TETANUS = CLOSTRIDIUM TETANI

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lame	1

## THIOMERSAL

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Milk production decrease	1

Canine

Number of Reports	Probable	Possible
57	12	45

Presenting sign	Number of reports
Vomiting	5
Swollen lips and face	4
Collapse	3
Death	3



Facial oedema	3
Injection site reaction	3
Pruritus	3
Swelling (local)	3
Lethargy	2
Malaise	2
Pain	2
Shock	2
Site reaction	2
Abdominal pain	1
Abscess	1
Anaphylactoid reaction	1
Anaphylaxis	1
Anorexia	1
Ataxia	1
Bradycardia	1
Circling	1
Depression	1
Haemorrhage	1
Irritation (ear)	1
Lack of effect	1
Lump (local)	1
Pale mucous membranes	1
Parvovirus	1
Petechiae	1
Pyrexia	1
Seizure	1
Seroma	1
Thrombocytopenia	1

### Equine

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Swelling (local)	2
Anorexia	1
Oedema	1
Pyrexia	1

### Feline

Number of Reports	Probable	Possible
101	54	47

Presenting sign	Number of reports
Lethargy	20
Anorexia	18
Pain	6
Pyrexia	5
Vomiting	5
Injection site reaction	4
Alopecia	3
Convulsions	3
Diarrhoea	3
Facial oedema	3
Site reaction	3
Behavioural change	2
Death	2
Erythema	2
Hyperactivity	2
Shaking	2
Anaphylaxis	1
Ataxia	1
Collapse	1
Dehydration	1
Depression	1
Hives	1
Lack of effect	1
Melaena	1
Mydriasis	1
Ocular discharge	1
Panting	1
Pruritus	1
Scabs	1
Sneezing	1
Tachycardia	1
Tachypnoea	1
Urticaria	1
Vocalisation	1

## Ovine

Number of Reports	Probable	Possible
5	1	4

Presenting sign	Number of reports
Lame	3
Abscess	1
Injection site reaction	1

Death	1
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#### Porcine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Abscess	1
Injection site reaction	1

#### Rabbit

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1
Incoordination	1
Lethargy	1

Thiomersal is a preservative component of many vaccines for large and small animals. It is included to prevent bacterial and fungal contamination, particularly in multi-dose vials or containers<sup>2</sup>. Assessment for each vaccine has been considered when assessing the safety of these products. No further action is considered necessary at this time beyond ongoing monitoring.

### TIGER SNAKE ANTIVENOM

#### Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Urticaria	1

### TILETAMINE AS THE HYDROCHLORIDE

#### Feline

Number of Reports	Probable	Possible
1	0	1

<sup>2</sup> Source [www.ncirs.usyd.edu.au/facts/f-thiomersal.html](http://www.ncirs.usyd.edu.au/facts/f-thiomersal.html)

Presenting sign	Number of reports
Death	1

## TILMICOSIN

Bovine

Number of Reports	Probable	Possible
5	3	2

Presenting sign	Number of reports
Death	3
Residue violation	2
Convulsions	1

## TRICHLORFON

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Adipsia	1
Anorexia	1
Colic	1
Diarrhoea	1
Spasm	1
Tachypnoea	1

## TRIFLUMURON

Ovine

Number of Reports	Probable	Possible
22	3	19

Presenting sign	Number of reports
Burn(s)	2
Lack of effect	20

## VIRGINIAMYCIN

Equine

<b>Number of Reports</b>	<b>Probable</b>	<b>Possible</b>
1	0	1

  

<b>Presenting sign</b>	<b>Number of reports</b>
Colic	1

## VITAMIN B12 = CYANOCOBALAMIN

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Injection site reaction	1

## VITAMIN B12A = HYDROXOCOBALAMIN

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1

## VITAMIN B3 = NICOTINAMIDE

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Injection site reaction	1

## ZOLAZEPAM AS THE HYDROCHLORIDE

Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1

# Chapter 3. Veterinary - summary of AERs 2007 (human)

## 3.1 Adverse experience report summaries involving humans listed by active constituent

The following information is contained in this section:

### Active constituent name

Each active constituent is listed alphabetically, with a summary of the adverse experience reports. It is important to note that the number of adverse experience reports and the presenting signs observed may be listed under more than one active constituent if they refer to a product that contains multiple active constituents.

### Number of reports

Only adverse experience reports that were classified by the APVMA during the calendar year 2007, as being either probable or possible have been included in these lists. The summary table indicates how many reports were classified as probable and how many were classified as possible.

### Presenting signs

All observed clinical signs for reports that were classified as probable and possible are listed in order of frequency.

It is important to note that multiple clinical signs may have been noted in some individual reports. Therefore the list of clinical signs observed does not relate directly to the total number of reports received.

### Summary of corrective action

A short narrative is provided on any corrective action taken as a result of assessment of the adverse experience information for each active constituent.

### 3.2 Veterinary – human AERs

#### CARBARYL

Human

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Rash	1

#### CLOPROSTENOL (AS THE SODIUM SALT)

Human

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Paraesthesia	1

#### CONTAGIOUS PUSTULAR DERMATITIS VIRUS, LIVING, CELL CULTURE

Human

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Dermatitis	1
Inflammation	1
Pain	1
Swelling (local)	1



## DELTAMETHRIN

Human

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Burning sensation	1

## DIFLUBENZURON

Human

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Irritation (skin)	1

## EPRINOMECTIN

Human

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Erythema	1
Irritation (skin)	1
Rash	1

## FENTHION

Human

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Blurred vision	1
Irritation (eye)	1
Nausea	1

## FLUAZURON

Human

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Diarrhoea	1
Pruritus	2
Swelling (local)	1
Vomiting	1

## IMIDACLOPRID

Human

Number of Reports	Probable	Possible
7	3	4

Presenting sign	Number of reports
Numbness	2
Swelling (local)	2
Blisters	1
Burning sensation	1
Irritation (eye)	1
Irritation (skin)	1
Ocular discharge	1
Rash	1
Site reaction	1
Site reaction	1
Sneezing	1
Sore throat	1

## INACTIVATED BOVINE PESTIVIRUS - BEGA STRAIN

Human

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Pain	1
Stiffness	1

## INACTIVATED BOVINE PESTIVIRUS - TRANGIE STRAIN

Human

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Pain	1
Stiffness	1

## IVERMECTIN

Human

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Irritation (eye)	1
Irritation (skin)	1

## MOXIDECTIN

Human

Number of Reports	Probable	Possible
4	1	3

Presenting sign	Number of reports
Swelling (local)	2
Sore throat	1
Blisters	1
Numbness	1
Rash	1
Site reaction	1

## MYCOBACTERIUM PARATUBERCULOSIS

Human

Number of Reports	Probable	Possible
2	2	0

Presenting sign	Number of reports
Abscess	1
Dermatitis	1
Injection site reaction	1

## N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE

Human

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Rash	1

## PERMETHRIN

Human

Number of Reports	Probable	Possible
3	2	1

Presenting sign	Number of reports
Burning sensation	1
Irritation (eye)	1
Irritation (skin)	1
Numbness	1
Ocular discharge	1
Site reaction	1
Sneezing	1

## PIPERONYL BUTOXIDE

Human

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Rash	1

## PYRETHRINS

Human

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Rash	1

## SELAMECTIN

Human

<b>Number of Reports</b>	<b>Probable</b>	<b>Possible</b>
1	1	0

<b>Presenting sign</b>	<b>Number of reports</b>
Blisters	1

# Chapter 4. Agriculture - summary of AERs 2007 (standard)

## 4.1 Adverse experience report summaries involving crop damage, domestic animal harm, environmental damage or lack of efficacy listed by active constituent

The following information is contained in this section:

### Active constituent name

- Each active constituent is listed alphabetically, with a summary of the adverse experience reports.
- It is important to note that the number of adverse experience reports and the presenting signs observed may be listed under more than one active constituent if they refer to a product that contains multiple active constituents.

### Number of reports

- Only adverse experience reports that were classified by the APVMA during the calendar year 2007, as being either probable or possible have been included in these lists. The summary table indicates how many reports were classified as probable and how many were classified as possible.

### Presenting signs

- All observed effects for reports that were classified as probable and possible are listed in order of frequency.
- It is important to note that multiple adverse effects have been noted in some individual reports. Therefore the list of observed effects does not relate directly to the total number of reports received.

### Summary of corrective action

- A short narrative is provided on any corrective action taken as a result of assessment of the adverse experience information for each active constituent.

## ***4.2 Agriculture Chemical – standard AERs***

### **2,4-D**

#### Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Ataxia	1
Electrolyte changes	1

## COUMATETRALYL

Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Coagulopathy	1
Haematemesis	1

## POLYBUTENE

Avian

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Death	1



# Chapter 5. Agriculture - summary of AERs 2007 (human)

## 5.1 Adverse experience report summaries involving humans listed by active constituent

The following information is contained in this section:

### Active constituent name

Each active constituent is listed alphabetically, with a summary of the adverse experience reports.

It is important to note that the number of adverse experience reports and the presenting signs observed may be listed under more than one active constituent if they refer to a product that contains multiple active constituents.

### Number of reports

Only adverse experience reports that were classified by the APVMA during the calendar year 2007, as being either probable or possible have been included in these lists. The summary table indicates how many reports were classified as 'probable' and how many were classified as possible.

### Presenting signs

All observed clinical signs for reports that were classified as probable and possible are listed in order of frequency.

It is important to note that multiple adverse effects have been noted in some individual reports. Therefore the list of observed effects does not relate directly to the total number of reports received.

### Summary of corrective action

A short narrative is provided on any corrective action taken as a result of assessment of the adverse experience information for each active constituent.

## 5.2 Agriculture Chemical – human AERs

### ALPHA-CYPERMETHRIN

Human

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Burning sensation	1
Irritation (skin)	1

### ALUMINIUM PHOSPHIDE

Human

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Quality Control	1

### BIFENTHRIN

Human

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Irritation (skin)	1
Rash	1

## CAPTAN

Human

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Irritation (skin)	1
Rash	1

## IMIDACLOPRID

Human

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Rash	1

## METSULFURON-METHYL

Human

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Blurred vision	1

# Chapter 6. Glossary

Adipsia	- absence of thirst or avoidance of drinking
Alopecia	- absence of hair from areas where it is normally present.
Analgesic	- pain relieving treatment
Anaphylactoid	- an anaphylactic-type reaction
Anaphylaxis/anaphylactic	- an exaggerated allergic reaction of an animal to a foreign protein or other substances
Anorexia	- lack or loss of appetite
Anthelmintic	- an agent destructive to worms
Antimicrobial	- an agent that kills micro-organisms or suppresses their multiplication or growth
Ataxia	- impairment of the ability to perform smoothly coordinated voluntary movements
Ataxia	- unsteady walking action due to muscular incoordination
Bradycardia	- excessive slowness in the action of the heart
Coagulopathy	- disease affecting the coagulability of the blood
Colic	- a general term for abdominal pain
Conjunctivitis	- conjunctivitis is the inflammation of the conjunctiva, a thin, delicate membrane that covers the eyeball and lines the eyelid.
Cyanosis	- cyanosis is a physical sign causing bluish discoloration of the skin and mucous membranes. Cyanosis is caused by a lack of oxygen in the blood.
Cyanosis	- blue discoloration of the mucous membranes and other tissues due to a lack of circulating oxygen in the blood
Dermatitis	- inflammation of the skin.
Dyspnoea	- laboured breathing
Elevated ALP	- elevated liver enzymes (Alkaline Phosphatase)
Epiphora	- diseases of the lacrimal apparatus.
Epistaxis	- bleeding from the nose.
Erythema	- abnormal redness of the skin due to local congestion, as in inflammation
Fasciculation	- involuntary contractions or twitchings of groups of muscle fibers
Folliculitis	- inflammation of the follicles
Haematemesis	- vomiting of blood.
Haemorrhage	- bleeding
Hepatopathy	- disease or disorder of the liver
Hypersalivation	- excessive salivation
Hypersensitivity	- an excessive reaction to an allergen
Intramammary	- within or into the mammary gland

Jaundice	- yellowish staining of the skin and mucous membranes
Melaena	- Condition marked by black, tarry stool or vomit, resulting from a hemorrhage along the digestive tract
Mydriasis	- dilation of pupils to greater
Nausea	- unpleasant sensation in the stomach
Necrosis	- pathological process associated with severe cellular trauma
Oedematous	- abnormal accumulation of fluid in body cavities and under the skin
Paraesthesia	- an abnormal sensation
Parasiticide	- an agent that is destructive to parasites
Parvovirus	- viral infection of dogs that is characterised by diarrhoea, dehydration and pyrexia
Periorbital	- surrounding the eyes
Petechiae	- purplish or brownish red discoloration, caused by hemorrhage into the tissues.
Preputial	- of or pertaining to the prepuce
Prolapse	- to fall or slip out of place.
Pruritus	- irritation and itching
Pyrexia	- high fever
Rales	- noises, normal and abnormal, heard on auscultation over any part of the respiratory tract.
Registrant	- the commercial party that is responsible for the marketing of the product
Seizure	- clinical or subclinical disturbances of cortical function
Seroma	- a collection of serum in the body, producing a tumor-like mass
Somnolence	- state of drowsiness; sleepiness.
Tachycardia	- excessive rapidity in the action of the heart
Tachypnoea	- rapid shallow breaths
Tenesmus	- a painfully urgent but ineffectual attempt to urinate or defecate
Thrombocytopenia	- decrease in the number of blood platelets
Urticaria	- vascular reaction of the skin as a result of contact with a chemical or may be immunologically based
Wheals	- a small swelling on the skin, as from an insect bite, that usually itches or burns
Withholding period	- the time interval after the withdrawal of a drug or chemical use, to either the time of re-entry, harvesting or use of an animal or animal product for human consumption.

# List of Active Constituents

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