Australian Government
Australian Pesticides and
Veterinary Medicines Authority

REPORT OF ADVERSE EXPERIENCES FOR VETERINARY MEDICINES AND AGRICULTURAL CHEMICALS

CALENDAR YEAR 2006

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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 (Sections 2 and 3) and agricultural chemicals (Sections 4 and 5). This report is also available online from the APVMA website at www.apvma.gov.au .

During the 2006 calendar year AERP Vet received a total of 2129 reports and completed the classification of 1731 reports involving suspected adverse reactions in animals from veterinary surgeons, owners, members of the public and product registrants. With a total of 1086 reports were classified either 'probable' or 'possible'.

AERP Ag classified fewer reports through 2006. AERP Ag assessed, evaluated and classified 63 adverse experience reports, 20 human reports, six environmental reports and 37 standard reports.

Some of the activities undertaken during 2006 included:

- publishing the *Annual Report of Adverse Experiences for Veterinary Medicines 2005* (http://www.apvma.gov.au/qa/aerp.shtml)
- publishing 'APVMA Veterinary Pharmacovigilance Program: Suspected Adverse Experience Reports for 2005', *Australian Veterinary Journal*, P Linnett, (2006) 158: 418-420
- publishing 'Off-label oxytetracycline use in horses', *Australian Veterinary Journal*, P Linnett, (2006) 84:16.
- conducting seminars for industry representatives on the processes of the AERP
- publishing an outline of AERP and a copy of the reporting form in the foreward to the *2006 IVS Annual*, MIMs Australia
- contributing to the SMARTtrain training manual
- raising awareness in rural press and magazines of AERP issues
- publishing 'Ensuring safety in animal products', *Dogs Life*, July/August 2006.

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 2006 calendar year.

Throughout 2006 a number of risk management strategies aimed at mitigating and minimising the prevalence of adverse experiences were actioned.

These included:

- additional warning, precautionary or restraint statements on three products
- recommendation for standardisation of selenium products to carry a warning for the concurrent use of selenium products

Veterianry entries containing the active constituent fipronil which where classified in 2006 have not been included in this report.

Off-label reports are not included in this report. However, it is important to report all off-label adverse experiences as these can be very serious incidents, with animals and humans risking illness, injury and in some rare cases, death.

- Poor anaesthetic protocols have resulted in delayed recovery and death of animals, with some instances of protocols clearly contradicting the label.
- Concurrent use of medications, particularly non steroidal anti-inflammatory drugs, have resulted 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.
- Needlestick injuries continue to be of concern. Of the 94 human reports received in 2006, some 54 where related to needlestick injury. These involved a range of circumstances, however predictably, production animal treatment (specifically vaccination) was the most common scenario. Though many of these had no more adverse effects other than pain, a few individuals had significant after-effects with the most severe cases resulting in hospitalisation. Individuals involved in animal husbandry should take appropriate preventative action when injecting animals.

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' 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 the 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 facilitate the management of veterinary medicines and agricultural chemicals throughout their lifecycle. The program provides a means to identify 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 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 ironment, 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 this to be able to assess the true incidence of these side effects. 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 constitutes 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 of this so that the true incidence of these side effects can be assessed. It is important that all adverse experiences are reported.

1.3 Who can report an adverse experience?

Veterinary medicines

Anyone can report an adverse veterinary medicine experience. 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 report an adverse agricultural chemical experience. 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 and 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.

1.5 Benefits of the AERP

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

Benefits to the community

- ensures 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

- provide 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 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 (i.e. 'classification'; see 1.6 below). The APVMA also considers whether the product was used according to the label directions.
- The person making the report of an adverse experience will be advised of the outcome of the investigations as soon as possible.
- 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 description of the clinical signs should be consistent with, or at least plausible, given 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 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 is either unavailable or is 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 an issue.

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 (for vaccines) is one or more per 10,000 doses sold[1]. 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 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.

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

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 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 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 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:

Section 1—AERP Vet

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

Section 2—AERP Ag

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

1.11 For further information

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2. Veterinary Section 1 Part A—summary of adverse experience reports 2006 (animal)

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

The 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.

The number of reports

- Only adverse experience reports that were classified by the APVMA during the calander year 2006, 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.

The 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 AER's

Abamectin

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Anorexia	1
Ataxia	1
Lethargy	1
Vocalisation	1
Weakness	1

Equine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Anorexia	1
Hypersalivation	1

Aglepristone

Canine

Number of Reports	Probable	Possible
3	2	1

Presenting sign	Number of reports
Anorexia	2
Haemorrhage	1
Lethargy	1
Oedema	1
Reproduction disorder	1
Site reaction	1
Vomiting	1

Alphaxalone

Canine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Hypersensitive to stimuli	1
Mydriasis	1
Nystagmus	1
Opisthotonos	1
Paddling	1
Recovery (poor)	1
Seizure	1
Welts	1

Feline

Number of Reports	Probable	Possible
6	0	6

Presenting sign	Number of reports
Rales	2
Recovery (poor)	2
Hypersensitive to stimuli	1
Lack of effect	1
Paddling	1
Respiratory problems	1
Stiffness	1
Swelling (local)	1
Tremor	1

Aluminium hydroxide

Canine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Ataxia	1
Immune-mediated haemolytic anaemia	1
Lame	1
Lethargy	1
Panting	1

Amitraz

Bovine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Frothing at the mouth	1
Hypersalivation	1
Lethargy	1
Nasal discharge	1
Ocular discharge	1
Recumbency	1

Amoxycillin as amoxicillin trihydrate

Canine

Number of Reports	Probable	Possible
7	2	5

Presenting sign	Number of reports
Injection site reaction	3
Swelling (local)	2
Dermatitis	1
Facial oedema	1
Lesions	1
Tachypnoea	1
Urticaria	1
Vomiting	1

Amphotericin

Feline

Number of Reports	Probable	Possible
6	5	1

Presenting sign	Number of reports
Anorexia	3
Lethargy	3
Pain	3
Pyrexia	3
Behavioural change	2
Depression	2
Vocalisation	2
Vomiting	2
Respiratory problems	2
Aggression	1
Agitation	1
Distress	1
Erythema	1
Hypersensitive to stimuli	1
Irritation (ear)	1
Irritation (skin)	1
Pruritus	1
Adipsia	1
Diarrhoea	1
Listless	1

Arginine-L hydrochloride

Equine

Number of Reports	Probable	Possible
3	0	3

Presenting sign	Number of reports
Injection site reaction	3
Swelling (local)	3
Stiffness	2
Inflammation	1
Necrosis	1

Benazepril hydrochloride

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Behavioural change	1
Lethargy	1
Red eyes	1
Vocalisation	1

Feline

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Behavioural change	1
Vomiting	1
Weight gain	1
Weight loss	1

Betamethasone

Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Inflammation	1
Site reaction	1
Ulceration	1

Bordetella Bronchiseptica

Canine

Number of Reports	Probable	Possible
13	7	6

Presenting sign	Number of reports
Coughing	6
Sneezing	5
Anaphylaxis	1
Ataxia	1
Immune-mediated haemolytic anaemia	1
Lame	1
Lethargy	1
Panting	1
Shock	1
Swelling (local)	1

Bordetella Bronchiseptica (inactivated cell-free extract)

Canine

Number of Reports	Probable	Possible
60	45	15

Presenting sign	Number of reports
Facial oedema	36
Lethargy	9
Urticaria	8
Vomiting	7
Pruritus	5
Swelling (local)	5
Periorbital swelling	4
Pyrexia	4
Oedema	3
Hypersensitivity reaction	3
Pale mucous membranes	3
Swollen lips and face	3
Injection site reaction	2
Pain	2
Abscess	2
Anorexia	2
Hives	2
Hypersalivation	2
Inflammation	2
Depression	1
Hyperactivity	1
Abdominal pain	1
Allergy	1
Ataxia	1
Capillary refill time (slow)	1
Collapse	1
Cyanosis	1
Diarrhoea	1
Hyperaesthesia	1
Necrosis	1
Restless	1
Shaking	1
Site reaction	1
Tachycardia	1

Bordetella Bronchiseptica killed vaccine

Canine

Number of Reports	Probable	Possible
49	1	48

Presenting sign	Number of reports
Facial oedema	18
Swelling (local)	16
Periorbital swelling	11
Pain	8
Depression	7
Injection site reaction	7
Lethargy	7
Vomiting	6
Urticaria	5
Pale mucous membranes	5
Erythema	3
Tachycardia	2
Tachypnoea	2
Ataxia	2
Behavioural change	2
Pyrexia	2
Weakness	2
Agitation	1
Irritation (ear)	1
Respiratory problems	1
Anaphylactoid reaction	1
Anorexia	1
Bradycardia	1
Collapse	1
Defecation	1
Diarrhoea	1
Dyspnoea	1
Haematoma	1
Haemorrhage	1
Hypersalivation	1
Immune-mediated haemolytic anaemia	1
Irritation (eye)	1
Lacrimation	1
Panting	1
Paralysis	1
Pawing at face	1
Pigmentation	1

Restless	1
Shaking	1
Swelling (vulva)	1
Swollen ears and face	1
Swollen lips and face	1
Unknown	1

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
Cardiac arrest	1
Vomiting	1

Canine adenovirus (canine hepatitis)

Canine

Number of Reports	Probable	Possible
3	2	1

Presenting sign	Number of reports
Lethargy	2
Anorexia	1
Diarrhoea	1
Shaking	1
Sneezing	1
Vomiting	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea, 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 adenovirus Type 2

Canine

Number of Reports	Probable	Possible
86	49	37

Presenting sign	Number of reports
Facial oedema	44
Swelling (local)	13
Lethargy	12
Vomiting	10
Urticaria	9
Injection site reaction	6
Periorbital swelling	6
Pruritus	5
Pale mucous membranes	5
Pyrexia	5
Pain	4
Depression	4
Coughing	4
Oedema	3
Abscess	3
Diarrhoea	3
Hives	3
Hypersensitivity reaction	3
Sneezing	3
Anaphylactoid reaction	2
Anorexia	2
Hypersalivation	2
Lack of effect	2
Swollen lips and face	2
Tachycardia	2
Hyperactivity	1
Abdominal pain	1
Allergy	1
Ataxia	1
Bradycardia	1
Capillary refill time (slow)	1
Collapse	1
Cyanosis	1
Defaecation	1
Dyspnoea	1
Erythema	1
Haemorrhage	1

Hyperaesthesia	1
Immune-mediated haemolytic anaemia	1
Inflammation	1
Irritation (eye)	1
Necrosis	1
Pawing at face	1
Restless	1
Shaking	1
Shock	1
Site reaction	1
Swollen ears and face	1
Tachypnoea	1

Canine adenovirus Type 2 strain V197

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Ataxia	1
Lame	1
Lethargy	1
Panting	1

Canine adenovirus Type 2—live (infectious hepatitis)

Canine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Site reaction	2

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea, 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

Canine

Number of Reports	Probable	Possible
26	3	23

Presenting sign	Number of reports
Facial oedema	10
Swelling (local)	8
Lethargy	5
Injection site reaction	4
Vomiting	4
Diarrhoea	3
Depression	3
Periorbital swelling	3
Lack of effect	2
Pain	2
Pale mucous membranes	2
Urticaria	2
Anorexia	1
Abscess	1
Anaphylactoid reaction	1
Anaphylaxis	1
Bradycardia	1
Defaecation	1
Dyspnoea	1
Erythema	1
Haemorrhage	1
Hives	1
Immune-mediated haemolytic anaemia	1
Irritation (eye)	1
Pawing at face	1
Pyrexia	1
Shaking	1
Shock	1
Sneezing	1
Swollen ears and face	1
Tachycardia	1
Tachypnoea	1

Canine distemper virus—living

Canine

Number of Reports	Probable	Possible
58	43	15

Presenting sign	Number of reports
Facial oedema	35
Lethargy	9
Urticaria	7
Vomiting	7
Pruritus	5
Swelling (local)	5
Pyrexia	4
Oedema	3
Hypersensitivity reaction	3
Pale mucous membranes	3
Periorbital swelling	3
Injection site reaction	2
Pain	2
Abscess	2
Anorexia	2
Hives	2
Hypersalivation	2
Swollen lips and face	2
Depression	1
Hyperactivity	1
Abdominal pain	1
Allergy	1
Ataxia	1
Capillary refill time (slow)	1
Collapse	1
Cyanosis	1
Diarrhoea	1
Hyperaesthesia	1
Inflammation	1
Necrosis	1
Restless	1
Shaking	1
Site reaction	1
Tachycardia	1

Canine adenovirus Type 2—live (infectious hepatitis)

Canine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Site reaction	2

Caine distemper virus strain Onderstepoort

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Ataxia	1
Lame	1
Lethargy	1
Panting	1

The most reported side effects of vaccinations include vomiting, coughing, lethargy and diarrhoea, 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 parainfluenza virus

Canine

Number of Reports	Probable	Possible
102	50	52

Presenting sign	Number of reports
Facial oedema	44
Lethargy	16
Swelling (local)	14
Vomiting	12
Periorbital swelling	10
Urticaria	9
Pain	8
Injection site reaction	7
Pale mucous membranes	6
Pruritus	5
Depression	5
Pyrexia	5
Anorexia	4
Ataxia	4
Coughing	4
Oedema	3
Hypersalivation	3
Hypersensitivity reaction	3
Sneezing	3
Swollen lips and face	3
Diarrhoea	2
Abscess	2
Behavioural change	2
Collapse	2
Hives	2
Immune-mediated haemolytic anaemia	2
Panting	2
Restless	2
Shaking	2
Weakness	2
Hyperactivity	1
Abdominal pain	1
Allergy	1
Capillary refill time (slow)	1
Cyanosis	1
Erythema	1

Haematoma	1
Hyperaesthesia	1
Inflammation	1
Lacrimation	1
Lame	1
Necrosis	1
Paralysis	1
Pigmentation	1
Site reaction	1
Swelling (vulva)	1
Tachycardia	1
Unknown	1

Canine parainfluenza Type 2

Canine

Number of Reports	Probable	Possible
19	1	18

Presenting sign	Number of reports
Facial oedema	8
Swelling (local)	7
Injection site reaction	3
Lethargy	3
Periorbital swelling	3
Depression	2
Diarrhoea	2
Lack of effect	2
Pain	2
Urticaria	2
Vomiting	2
Abscess	1
Anaphylactoid reaction	1
Anaphylaxis	1
Dyspnoea	1
Erythema	1
Haemorrhage	1
Hives	1
Irritation (eye)	1
Pale mucous membranes	1
Pawing at face	1
Shock	1
Swollen ears and face	1
Tachycardia	1
Tachypnoea	1

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

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Canine parvovirus

Canine

Number of Reports	Probable	Possible
55	2	53

Presenting sign	Number of reports
Facial oedema	17
Swelling (local)	17
Periorbital swelling	10
Injection site reaction	9
Lethargy	8
Pain	8
Depression	7
Vomiting	7
Pale mucous membranes	5
Urticaria	4
Ataxia	2
Behavioural change	2
Diarrhoea	2
Erythema	2
Immune-mediated haemolytic anaemia	2
Lack of effect	2
Pyrexia	2
Weakness	2
Abscess	1
Anaphylactoid reaction	1
Anaphylaxis	1
Anorexia	1
Bradycardia	1
Collapse	1
Defaecation	1
Dyspnoea	1
Haematoma	1
Haemorrhage	1
Hives	1
Hypersalivation	1
Irritation (eye)	1
Lacrimation	1
Panting	1
Paralysis	1
Pawing at face	1
Pigmentation	1
Restless	1

Shaking	1
Shock	1
Swelling (vulva)	1
Swollen ears and face	1
Swollen lips and face	1
Tachycardia	1
Tachypnoea	1
Unknown	1

Canine parvovirus—live

Canine

Number of Reports	Probable	Possible
8	3	5

Presenting sign	Number of reports
Site reaction	2
Lethargy	2
Erythema	2
Anorexia	1
Diarrhoea	1
Depression	1
Dermatitis	1
Pruritus	1
Pyrexia	1
Seizure	1
Shaking	1
Sneezing	1
Swelling (local)	1
Vomiting	1

Canine parvovirus Type 2

Canine

Number of Reports	Probable	Possible
57	43	14

Presenting sign	Number of reports
Facial oedema	35
Lethargy	9
Urticaria	7
Vomiting	7
Pruritus	5
Swelling (local)	4
Pyrexia	4
Oedema	3
Hypersensitivity reaction	3
Pale mucous membranes	3
Periorbital swelling	3
Injection site reaction	2
Pain	2
Abscess	2
Anorexia	2
Hives	2
Hypersalivation	2
Swollen lips and face	2
Depression	1
Hyperactivity	1
Abdominal pain	1
Allergy	1
Ataxia	1
Capillary refill time (slow)	1
Collapse	1
Cyanosis	1
Diarrhoea	1
Hyperaesthesia	1
Inflammation	1
Necrosis	1
Restless	1
Shaking	1
Site reaction	1
Tachycardia	1

Canine parvovirus K3I strain

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Ataxia	1
Lame	1
Lethargy	1
Panting	1

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Carbaryl

Canine

Number of Reports	Probable	Possible
2	2	0

Presenting sign	Number of reports
Hypersalivation	1
Lethargy	1
Pruritus	1
Shaking	1

Carnitine-L

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lame	1
Lethargy	1
Pain	1
Swelling (local)	1
Tachycardia	1
Tachypnoea	1

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Behavioural change	1
Injection site reaction	1
Pain	1

Carprofen

Canine

Number of Reports	Probable	Possible
3	0	3

Presenting sign	Number of reports
Lethargy	2
Polyuria	1
Pyoderma	1

Ceftiofur (as ceftiofur sodium)

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Diarrhoea	1

Cephalexin

Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Tachycardia	1
Tachypnoea	1
Urticaria	1

Corynebacterium Pseudotuberculosis Ovis (CLA)

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lame	1

Clavulanic acid as potassium clavulanate

Canine

Number of Reports	Probable	Possible
7	2	5

Presenting sign	Number of reports
Injection site reaction	3
Swelling (local)	2
Dermatitis	1
Facial oedema	1
Hypersalivation	1
Lesions	1
Tachypnoea	1
Urticaria	1
Vomiting	1

Clenbuterol hydrochloride

Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Sweating	1

Clomipramine hydrochloride

Canine

Number of Reports	Probable	Possible
3	0	3

Presenting sign	Number of reports
Aggression	1
Anorexia	1
Hypersalivation	1
Lethargy	1
Panting	1
Sedation	1

Feline

Number of Reports	Probable	Possible
3	2	1

Presenting sign	Number of reports
Lethargy	2
Anorexia	1
Mammary hyperplasia	1
Mydriasis	1
Weight loss	1

Clostridium Chauvoei

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lame	1

Clostridium Chauvoei—killed

Bovine

Number of Reports	Probable	Possible
2	0	2

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

Clostridium Chauvoei—toxoid

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Swelling (local)	1

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1
Lack of effect	1

Clostridium Novyi Type B antisera/antigen

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lame	1

Clostridium Perfringens Type D—killed

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1

Clostridium Perfringens Type D—toxoid

Bovine

Number of Reports	Probable	Possible
2	1	1

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

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1
Lack of effect	1

Clostridium Septicum

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lame	1

Clostridium Septicum—killed

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1

Clostridium Septicum—toxoid

Bovine

Number of Reports	Probable	Possible
2	1	1

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

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1
Lack of effect	1

Clostridium Tetani

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lame	1

Clostridium Tetani—killed

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1

Clostridium Tetani—toxoid

Bovine

Number of Reports	Probable	Possible
2	1	1

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

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1
Lack of effect	1

Clostridium Tetani UF—toxoid

Equine

Number of Reports	Probable	Possible
7	3	4

Presenting sign	Number of reports
Injection site reaction	3
Oedema	2
Ataxia	1
Collapse	1
Dermatitis	1
Dyspnoea	1
Hives	1
Lesions	1
Lethargy	1
Lymphadenopathy	1
Paddling	1
Pain	1
Recumbency	1
Swelling (local)	1
Tachycardia	1

Clotrimazole

Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Inflammation	1
Site reaction	1
Ulceration	1

Cobalt EDTA

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1

Coronavirus

Canine

Number of Reports	Probable	Possible
4	2	2

Presenting sign	Number of reports
Anorexia	1
Diarrhoea	1
Facial oedema	1
Lethargy	2
Shaking	1
Sneezing	1
Vomiting	1

Cyclosporin

Canine

Number of Reports	Probable	Possible
15	6	9

Presenting sign	Number of reports
Vomiting	8
Diarrhoea	6
Anorexia	2
Lethargy	2
Pruritus	2
Haemorrhage	1
Muscle stiffness	1
Panting	1
Prolapsed third eyelid	1
Restless	1
Spasm	1
Vocalisation	1
Walking (difficult)	1
Weakness	1
Weight loss	1

Cyclosporin A

Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Inflammation	1
Ocular discharge	1
Site reaction	1

Cypermethrin

Feline

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Ataxia	1
Hypersalivation	1

Zeta-cypermethrin

Bovine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Irritation (skin)	1

Cyromazine

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1
Lack of effect	1

Deltamethrin

Bovine

Number of Reports	Probable	Possible
3	0	2

Presenting sign	Number of reports
Lack of effect	3

Deslorelin (as deslorelin acetate)

Canine

Number of Reports	Probable	Possible
2	2	0

Presenting sign	Number of reports
Alopecia	1
Reproduction disorder	1
Self trauma	1
Site reaction	1

Diazinon

Bovine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Lack of effect	1

Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Ataxia	1
Collapse	1

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

Diflubenzuron

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Dermatitis	1
Lesions	1

Di-isopropylamine dichloroacetate

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Inflammation	1
Injection site reaction	1
Necrosis	1
Swelling (local)	1

Di-N-propyl isocinchomeronate

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Hives	1
Rash	1

1-dodecyl-2-pyrrolidinone

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

Enrofloxacin

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Vomiting	1

Feline

Number of Reports	Probable	Possible
3	0	3

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

Eprinomectin

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

Febantel

Canine

Number of Reports	Probable	Possible
14	4	10

Presenting sign	Number of reports
Vomiting	7
Diarrhoea	5
Behavioural change	2
Hyperactivity	2
Aggression	1
Agitation	1
Ataxia	1
Hyperexcitable	1
Excitation	1

Feline calicivirus—live

Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Anorexia	1
Lethargy	1
Pyrexia	1

Feline calicivirus—inactivated

Feline

Number of Reports	Probable	Possible
42	26	16

Presenting sign	Number of reports
Lethargy	25
Anorexia	14
Pyrexia	13
Injection site reaction	9
Pain	6
Vomiting	6
Alopecia	4

Behavioural change	3
Depression	3
Vocalisation	3
Swelling (local)	3
Respiratory problems	2
Adipsia	2
Diarrhoea	2
Listless	2
Nasal discharge	2
Ocular discharge	2
Sneezing	2
Aggression	1
Agitation	1
Distress	1
Erythema	1
Hypersensitive to stimuli	1
Irritation (ear)	1
Irritation (skin)	1
Pruritus	1
Tachycardia	1
Arthropathy	1
Ataxia	1
Defaecation	1
Haemorrhage	1
Hyperaesthesia	1
Hypersensitivity reaction	1
Inflammation	1
Lame	1
Mydriasis	1
Oedema	1
Panting	1
Seizure	1
Stiffness	1

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

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

Feline Chlamydia Psittaci—inactivated

Feline

Number of Reports	Probable	Possible
12	11	1

Presenting sign	Number of reports
Lethargy	8
Anorexia	5
Pyrexia	5
Pain	4
Behavioural change	2
Depression	2
Vocalisation	2
Vomiting	2
Respiratory problems	2
Aggression	1
Agitation	1
Distress	1
Erythema	1
Hypersensitive to stimuli	1
Irritation (ear)	1
Irritation (skin)	1
Pruritus	1
Adipsia	1
Ataxia	1
Diarrhoea	1
Listless	1
Mydriasis	1
Panting	1

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Feline herpes virus

Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Anorexia	1
Lethargy	1
Pyrexia	1

Feline immunodeficiency virus (Petaluma strain) inactive

Feline

Number of Reports	Probable	Possible
3	1	2

Presenting sign	Number of reports
Anorexia	2
Injection site reaction	1
Lethargy	2
Pain	1
Pyrexia	2
Swelling (local)	1

Feline leukaemia virus—inactivated

Feline

Number of Reports	Probable	Possible
10	9	1

Presenting sign	Number of reports
Lethargy	6
Pyrexia	5
Anorexia	4
Pain	4
Behavioural change	2
Depression	2
Vocalisation	2
Vomiting	2
Respiratory problems	2
Aggression	1
Agitation	1
Distress	1
Erythema	1
Hypersensitive to stimuli	1
Irritation (ear)	1
Irritation (skin)	1
Pruritus	1
Adipsia	1
Diarrhoea	1
Listless	1
Mydriasis	1
Panting	1

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Feline panleucopenia virus—live

Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Anorexia	1
Lethargy	1
Pyrexia	1

Feline panleucopenia virus—inactivated

Feline

Number of Reports	Probable	Possible
42	26	16

Presenting sign	Number of reports
Lethargy	25
Anorexia	14
Pyrexia	13
Injection site reaction	9
Pain	6
Vomiting	6
Alopecia	4
Behavioural change	3
Depression	3
Vocalisation	3
Swelling (local)	3
Respiratory problems	2
Adipsia	2
Diarrhoea	2
Listless	2
Nasal discharge	2
Ocular discharge	2
Sneezing	2
Aggression	1
Agitation	1
Distress	1
Erythema	1
Hypersensitive to stimuli	1
Irritation (ear)	1

Irritation (skin)	1
Pruritus	1
Tachycardia	1
Arthropathy	1
Ataxia	1
Defaecation	1
Haemorrhage	1
Hyperaesthesia	1
Hypersensitivity reaction	1
Inflammation	1
Lame	1
Mydriasis	1
Oedema	1
Panting	1
Seizure	1
Stiffness	1

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Feline rhinotracheitis virus—inactivated

Feline

Number of Reports	Probable	Possible
42	26	16

Presenting sign	Number of reports
Lethargy	25
Anorexia	14
Pyrexia	13
Injection site reaction	9
Pain	6
Vomiting	6
Alopecia	4
Behavioural change	3
Depression	3
Vocalisation	3
Swelling (local)	3
Respiratory problems	2
Adipsia	2

Diarrhoea	2
Listless	2
Nasal discharge	2
Ocular discharge	2
Sneezing	2
Aggression	1
Agitation	1
Distress	1
Erythema	1
Hypersensitive to stimuli	1
Irritation (ear)	1
Irritation (skin)	1
Pruritus	1
Tachycardia	1
Arthropathy	1
Ataxia	1
Defaecation	1
Haemorrhage	1
Hyperaesthesia	1
Hypersensitivity reaction	1
Inflammation	1
Lame	1
Mydriasis	1
Oedema	1
Panting	1
Seizure	1
Stiffness	1

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Firocoxib

Canine

Number of Reports	Probable	Possible
3	0	3

Presenting sign	Number of reports
Vomiting	2
Collapse	1
Melaena	1
Ulceration (stomach)	1

Fluazuron

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

Flumethrin

Canine

Number of Reports	Probable	Possible
7	1	6

Presenting sign	Number of reports
Site reaction	3
Lethargy	2
Rash	2
Behavioural change	1
Comatose	1
Dermatitis	1
Malaise	1
Seizure	1
Vomiting	1
Weakness	1

Flunixin meglumine

Equine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Injection site reaction	2
Sweating	1

Gentamicin

Canine

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Inflammation	1
Nystagmus	1
Site reaction	1
Ulceration	1

GNRF-protein conjugate

Equine

Number of Reports	Probable	Possible
4	1	3

Presenting sign	Number of reports
Injection site reaction	4
Pain	3
Lethargy	1
Pyrexia	1
Swelling (local)	1

Hydroxyprogesterone caproate

Equine

Number of Reports	Probable	Possible
1	0	1

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

Imidacloprid

Canine

Number of Reports	Probable	Possible
488	388	100

Presenting sign	Number of reports
Agitation	182
Site reaction	119
Self trauma	103
Pruritus	83
Alopecia	65
Irritation (skin)	50
Lethargy	38
Behavioural change	30
Rolling	29
Vomiting	28
Dermatitis	26
Erythema	17
Shaking	17
Rubbing	15
Hyperactivity	15
Scabs	15
Irritation (ear)	14
Anorexia	14
Coat discoloration	13
Paraesthesia	12
Restless	8
Vocalisation	7
Ataxia	6
Hypersalivation	6
Inflammation	6

Panting	6
Distress	5
Tremor	5
Burn(s)	4
Diarrhoea	4
Irritation (paws)	4
Lesions	4
Rash	4
Depression	3
Blisters	3
Facial oedema	3
Hypersensitivity reaction	3
Listless	3
Swollen lips and face	3
Hyperaesthesia	2
Muscle twitching	2
Pain	2
QC	2
Lack of effect	1
Aggression	1
CNS dysfunction	1
Coughing	1
Crusting skin	1
Defaecation	1
Eczema	1
Frothing at the mouth	1
Illness	1
Malaise	1
Nil	1
Pododermatitis	1
Pyoderma	1
Respiratory problems	1
Scooting	1
Seizure	1
Stiffness	1
Ulceration	1
Urination	1
Weakness	1

These are relatively new products, on the market place and have a very high volume of sales. Several products have a label change pending.

Inactivated rabbit calicivirus disease virus

Rabbit

Number of Reports	Probable	Possible
4	4	0

Presenting sign	Number of reports
Alopecia	2
Injection site reaction	2
Dermatitis	1
Lethargy	1
Necrosis	1
Oedema	1
Self trauma	1
Shaking	1

Isoleucine-L

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Behavioural change	1
Injection site reaction	1
Pain	1

Ivermectin

Bovine

Number of Reports	Probable	Possible
6	2	4

Presenting sign	Number of reports
Lack of effect	2
Death	1
Scouring	1
Anorexia	1
Lethargy	1
Malaise	1
Ectoparasitosis	1
Rubbing	1

Photosensitization	1
Skin slough	1
Alopecia	1

Canine

Number of Reports	Probable	Possible
3	2	1

Presenting sign	Number of reports
Lethargy	1
Vomiting	2

Ixodes Holocyclus (paralysis tick) antiserum

Feline

Number of Reports	Probable	Possible
2	2	0

Presenting sign	Number of reports
Cardiac arrest	2
Death	2
Respiratory problems	2
Vocalisation	1
Vomiting	1

Ketamine (as ketamine hydrochloride)

Equine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Lack of effect	1
Induction (poor)	1
Nystagmus	1
Paddling	1
Sweating	1

Leptospira Borgpetersenii Serovar Hardjo

Bovine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Death	1

Leptospira Icterohaemorrhagiae antigen

Canine

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Anorexia	1
Diarrhoea	1
Lethargy	1
Facial oedema	1

Leptospirosis—dog—Leptospira Icterohaemorrhagiae

Canine

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Lethargy	1
Shaking	1
Sneezing	1
Vomiting	1

Leptospira Interrogans Serovar Hardjo

Bovine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Death	1

Leptospira Interrogans Serovar Pomona

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1

Levamisole hydrochloride

Avian

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Death	1

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1

Levamisole (as levamisole base)

Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Behavioural change	1
Pruritus	1

Lufenuron

Canine

Number of Reports	Probable	Possible
20	8	12

Presenting sign	Number of reports
Vomiting	9
Lethargy	8
Diarrhoea	5
Anorexia	4
Pruritus	3
Behavioural change	2
Urticaria	1
Weakness	1
Abdominal pain	1
Depression	1
Haemorrhage	1
Hepatopathy	1
Hypersalivation	1
Lack of effect	1
Melaena	1
Odour	1
Regurgitation	1
Shaking	1
Sneezing	1
Tachycardia	1
Tachypnoea	1
Urination	1

Lysine-L hydrochloride

Equine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Injection site reaction	2
Stiffness	2
Swelling (local)	2

Lysine hydrochloride

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Inflammation	1
Injection site reaction	1
Necrosis	1
Swelling (local)	1

Magnesium aspartate

Equine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Injection site reaction	2
Stiffness	2
Swelling (local)	2

Melarsomine dihydrochloride

Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Abscess	1
Injection site reaction	1

Meloxicam

Canine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Diarrhoea	1
Collapse	1

Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1
Haematuria	1

Methoprene-RS

Feline

Number of Reports	Probable	Possible
2	2	0

Presenting sign	Number of reports
Hypersalivation	2
Shaking	1

1-methyl-2-pyrrolidinone

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

Milbemycin oxime

Canine

Number of Reports	Probable	Possible
27	11	16

Presenting sign	Number of reports
Lethargy	11
Vomiting	11
Diarrhoea	7
Pruritus	4
Anorexia	4
Behavioural change	3
Abdominal pain	2
Lack of effect	2
Hyperactivity	1
Swelling (local)	1
Urticaria	1
Weakness	1
Anaemia	1
Depression	1
Flatulence	1
Haemorrhage	1
Hepatopathy	1

Hypersalivation	1
Melaena	1
Odour	1
Pale mucous membranes	1
Regurgitation	1
Shaking	1
Sneezing	1
Tachycardia	1
Tachypnoea	1
Urination	1

Feline

Number of Reports	Probable	Possible
4	2	2

Presenting sign	Number of reports
Lethargy	3
Ataxia	2
Muscle twitching	1
Pyrexia	1
Recumbency	1
Weakness	1

Monensin (as monensin sodium)

Bovine

Number of Reports	Probable	Possible
6	0	6

Presenting sign	Number of reports
Lack of effect	5
Pneumonia	1

Morantel tartrate

Equine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Anorexia	1
Hypersalivation	1

Moxidectin

Canine

Number of Reports	Probable	Possible
104	43	61

Presenting sign	Number of reports
Vomiting	23
Lethargy	18
Site reaction	16
Facial oedema	13
Alopecia	11
Pruritus	11
Injection site reaction	8
Diarrhoea	7
Erythema	7
Anorexia	6
Pale mucous membranes	6
Swelling (local)	6
Behavioural change	5
Abscess	4
Agitation	4
Ataxia	4
Oedema	4
Periorbital swelling	4
Self trauma	4
Defaecation	3
Depression	3
Dermatitis	3
Irritation (skin)	3
Lesions	3
Scabs	3
Shaking	3
Tachycardia	3
Urticaria	3
Bradycardia	2
Capillary refill time (slow)	2
Coat discoloration	2
Collapse	2
Distress	2
Haemorrhage	2
Pain	2
Panting	2
Pyrexia	2

Rash	2
Rolling	2
Swollen lips and face	2
Tachypnoea	2
Weakness	2
Wheals	2
Anaphylactoid reaction	1
Burn(s)	1
Cardiac arrest	1
Hives	1
Hypersalivation	1
Hypersensitivity reaction	1
Immune-mediated haemolytic anaemia	1
Inflammation	1
Injected mucous membranes	1
Irritation (ear)	1
Irritation (paws)	1
Lack of effect	1
Lacrimation	1
Listless	1
Necrosis	1
Paralysis	1
Paresis	1
Pigmentation	1
Pododermatitis	1
QC	1
Respiratory problems	1
Seizure	1
Seroma	1
Vocalisation	1

Feline

Number of Reports	Probable	Possible
49	44	5

Presenting sign	Number of reports
Site reaction	32
Alopecia	27
Pruritus	5
Scabs	5
Lethargy	4
Self trauma	4
Vomiting	4
Agitation	2
Ataxia	2

Burn(s)	2
Erythema	2
Hypersalivation	2
Irritation (skin)	2
Aggression	1
Behavioural change	1
Dermatitis	1
Diarrhoea	1
Lesions	1
Pyoderma	1
Restless	1

Ovine

Number of Reports	Probable	Possible
2	2	0

Presenting sign	Number of reports
Lame	1
Lack of effect	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 reporting incidence approaching warning levels and these products are being closely monitored, along with ongoing monitoring of all products.

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

Neomycin

Feline

Number of Reports	Probable	Possible
9	6	3

Presenting sign	Number of reports
Anorexia	5
Lethargy	5
Pyrexia	5
Pain	4
Behavioural change	2
Depression	2
Vocalisation	2
Vomiting	2
Respiratory problems	2
Aggression	1
Agitation	1
Distress	1
Erythema	1
Hypersensitive to stimuli	1
Irritation (ear)	1
Irritation (skin)	1
Pruritus	1
Adipsia	1
Diarrhoea	1
Injection site reaction	1
Listless	1
Swelling (local)	1

Niclosamide

Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Behavioural change	1
Pruritus	1

Nitenpyram

Feline

Number of Reports	Probable	Possible
3	0	3

Presenting sign	Number of reports
Hyperactivity	2
Hyperexcitable	1
Panting	1
Tachycardia	1
Vocalisation	1

N-methylpyrrolidone

Canine

Number of Reports	Probable	Possible
321	274	47

Presenting sign	Number of reports
Agitation	170
Self trauma	95
Pruritus	58
Irritation (skin)	43
Site reaction	38
Rolling	27
Lethargy	24
Behavioural change	23
Dermatitis	18
Shaking	16
Rubbing	15
Hyperactivity	15
Irritation (ear)	13
Paraesthesia	12
Coat discoloration	11
Vomiting	11
Anorexia	10
Erythema	9
Restless	7
Vocalisation	6
Panting	5
Tremor	5
Distress	4

Ataxia	4
Depression	3
Inflammation	3
Irritation (paws)	3
Alopecia	2
Hyperaesthesia	2
Hypersalivation	2
Listless	2
Muscle twitching	2
Scabs	2
Swollen lips and face	2
Blisters	1
CNS dysfunction	1
Coughing	1
Crusting skin	1
Defaecation	1
Diarrhoea	1
Eczema	1
Lesions	1
Malaise	1
Nil	1
Pain	1
QC	1
Rash	1
Scooting	1
Stiffness	1
Ulceration	1
Urination	1
Weakness	1

These are relatively new products on the market place and have a very high volume of sales. A label change is pending on several individual products.

N-octyl bicycloheptene dicarboximide

Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Lack of effect	1
Tick paralysis	1

Feline

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Hypersalivation	2
Shaking	1

Octyl methoxycinnamate

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Erythema	1
Facial oedema	1
Pustules	1
Swelling (local)	1

1-octyl-2-pyrrolidinone

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

Oestradiol 17 beta

Bovine

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Preputial prolapse	1
Preputial swelling	1
Prolapsed uterus	1

Oestradiol benzoate

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Agitation	1
Hives	1
Swelling (local)	1

Oestradiol dipropionate

Equine

Number of Reports	Probable	Possible
1	0	1

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

Oxantel embonate

Canine

Number of Reports	Probable	Possible
5	3	2

Presenting sign	Number of reports
Vomiting	2
Agitation	1
Erythema	1

Irritation (ear)	1
Periorbital swelling	1
Swelling (local)	1
Tachycardia	1
Tachypnoea	1
Urticaria	1
Collapse	1
Facial oedema	1
Pawing at face	1

Oxfendazole

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Colic	1

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1

Oxibendazole

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Anorexia	1
Ataxia	1
Lethargy	1
Vocalisation	1
Weakness	1

Oxybenzone

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Erythema	1
Facial oedema	1
Pustules	1
Swelling (local)	1

Permethrin

Canine

Number of Reports	Probable	Possible
31	26	5

Presenting sign	Number of reports
Self trauma	18
Irritation (skin)	10
Agitation	9
Site reaction	6
Dermatitis	4
Pruritus	4
Lethargy	3
Anorexia	2
Irritation (ear)	2
Alopecia	1
Behavioural change	1
Coat discoloration	1
Crusting skin	1
Distress	1
Erythema	1
Hyperactivity	1
Hyperaesthesia	1
Inflammation	1
Irritation (paws)	1
Malaise	1
Paraesthesia	1
Rolling	1
Vomiting	1

Permethrin (40:60::CIS:Trans)

Canine

Number of Reports	Probable	Possible
290	248	42

Presenting sign	Number of reports
Agitation	161
Self trauma	77
Pruritus	54
Irritation (skin)	33
Site reaction	32
Rolling	26
Behavioural change	22
Lethargy	21
Shaking	16
Rubbing	15
Dermatitis	14
Hyperactivity	14
Irritation (ear)	11
Paraesthesia	11
Coat discoloration	10
Vomiting	10
Erythema	8
Anorexia	8
Restless	7
Vocalisation	6
Panting	5
Tremor	5
Ataxia	4
Depression	3
Distress	3
Hypersalivation	2
Inflammation	2
Irritation (paws)	2
Listless	2
Muscle twitching	2
Scabs	2
Swollen lips and face	2
Alopecia	1
Blisters	1
CNS dysfunction	1
Coughing	1
Defaecation	1

Diarrhoea	1
Eczema	1
Hyperaesthesia	1
Lesions	1
Nil	1
Pain	1
QC	1
Rash	1
Scooting	1
Stiffness	1
Ulceration	1
Urination	1
Weakness	1

Feline

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Ataxia	1
Behavioural change	1
Seizure	1
Shaking	1

Phenol

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Vomiting	1

Feline

Number of Reports	Probable	Possible
3	2	1

Presenting sign	Number of reports
Cardiac arrest	3
Death	2
Respiratory problems	2
Vomiting	2
Vocalisation	1

Phenylalanine-D

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Behavioural change	1
Injection site reaction	1
Pain	1

Piperonyl butoxide

Canine

Number of Reports	Probable	Possible
4	2	2

Presenting sign	Number of reports
Lack of effect	1
Tick paralysis	1
Behavioural change	1
Hypersalivation	1
Irritation (skin)	1
Muscle twitching	1
Vomiting	1
Hives	1
Rash	1

Feline

Number of Reports	Probable	Possible
3	3	0

Presenting sign	Number of reports
Hypersalivation	3
Ataxia	1
Shaking	1

Polymyxin B

Feline

Number of Reports	Probable	Possible
9	6	3

Presenting sign	Number of reports
Anorexia	5
Lethargy	5
Pyrexia	5
Pain	4
Behavioural change	2
Depression	2
Vocalisation	2
Vomiting	2
Respiratory problems	2
Aggression	1
Agitation	1
Distress	1
Erythema	1
Hypersensitive to stimuli	1
Irritation (ear)	1
Irritation (skin)	1
Pruritus	1
Adipsia	1
Diarrhoea	1
Injection site reaction	1
Listless	1
Swelling (local)	1

Potassium aspartate

Equine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Injection site reaction	2
Stiffness	2
Swelling (local)	2

Praziquantel

Avian

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Death	1

Canine

Number of Reports	Probable	Possible
46	18	28

Presenting sign	Number of reports
Vomiting	19
Lethargy	12
Diarrhoea	11
Anorexia	5
Behavioural change	5
Pruritus	4
Hyperactivity	3
Swelling (local)	2
Urticaria	2
Agitation	2
Tachycardia	2
Tachypnoea	2
Weakness	2
Abdominal pain	2
Ataxia	2
Lack of effect	2
Erythema	1
Irritation (ear)	1
Periorbital swelling	1
Aggression	1
Anaemia	1
Collapse	1
Depression	1
Facial oedema	1
Flatulence	1
Haemorrhage	1
Hepatopathy	1
Hyperexcitable	1
Hypersalivation	1
Melaena	1

Odour	1
Pale mucous membranes	1
Pawing at face	1
Regurgitation	1
Shaking	1
Sneezing	1
Urination	1
Vocalisation	1
Excitation	1

Feline

Number of Reports	Probable	Possible
14	11	3

Presenting sign	Number of reports
Ataxia	11
Lethargy	3
Hypersalivation	2
Disorientation	2
Vomiting	1
Anorexia	1
Dizziness	1
Muscle twitching	1
Pyrexia	1
Recumbency	1
Weakness	1

Procaine penicillin

Equine

Number of Reports	Probable	Possible
2	1	1

Presenting sign	Number of reports
Collapse	2
Death	2
Paddling	1

Propofol

Canine

Number of Reports	Probable	Possible
66	61	5

Presenting sign	Number of reports
Urticaria	23
Facial oedema	23
Hives	12
Periorbital swelling	10
Welts	9
Wheals	7
Swollen ears and face	5
Swelling (local)	3
Swollen lips and face	2
Hypersensitivity reaction	2
Bradycardia	2
Cardiac arrest	2
Death	2
Hypersalivation	2
Erythema	1
Rash	1
Anaesthesia (light)	1
Apnoea	1
Cyanosis	1
Hypotension	1
Paddling	1
Seizure	1
Shaking	1

Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1

Propoxur

Canine

Number of Reports	Probable	Possible
7	1	6

Presenting sign	Number of reports
Site reaction	3
Lethargy	2
Rash	2
Behavioural change	1
Comatose	1
Dermatitis	1
Malaise	1
Seizure	1
Vomiting	1
Weakness	1

Pyrantel embonate

Canine

Number of Reports	Probable	Possible
20	8	12

Presenting sign	Number of reports
Vomiting	9
Diarrhoea	5
Agitation	2
Behavioural change	2
Hyperactivity	2
Erythema	1
Irritation (ear)	1
Periorbital swelling	1
Swelling (local)	1
Tachycardia	1
Tachypnoea	1
Urticaria	1
Aggression	1
Ataxia	1
Collapse	1
Facial oedema	1
Hyperexcitable	1

Lethargy	1
Pawing at face	1
Excitation	1

Feline

Number of Reports	Probable	Possible
10	9	1

Presenting sign	Number of reports
Ataxia	9
Hypersalivation	2
Disorientation	2
Vomiting	1
Dizziness	1

Pyrethrins

Canine

Number of Reports	Probable	Possible
3	2	1

Presenting sign	Number of reports
Lack of effect	1
Tick paralysis	1
Behavioural change	1
Hypersalivation	1
Irritation (skin)	1
Muscle twitching	1
Vomiting	1

Feline

Number of Reports	Probable	Possible
2	2	0

Presenting sign	Number of reports
Hypersalivation	2
Shaking	1

Pyriproxyfen

Feline

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Ataxia	1
Behavioural change	1
Seizure	1
Shaking	1

Selamectin

Canine

Number of Reports	Probable	Possible
10	5	5

Presenting sign	Number of reports
Alopecia	4
Site reaction	4
Pruritus	2
Dermatitis	2
Distress	1
Hypersalivation	1
Tachypnoea	1
Anorexia	1
Coat colour change	1
Depression	1
Diarrhoea	1
Lethargy	1
Pigmentation	1
Vomiting	1

Feline

Number of Reports	Probable	Possible
47	35	12

Presenting sign	Number of reports
Alopecia	40
Site reaction	29
Dermatitis	13
Pruritus	2
Ataxia	1
Behavioural change	1
Coat colour change	1
Coat discoloration	1
Gastroenteritis	1
Haematuria	1
Lack of effect	1
Lethargy	1
Vocalisation	1
Worms	1

Sodium pentosan polysulfate

Canine

Number of Reports	Probable	Possible
4	2	2

Presenting sign	Number of reports
Vomiting	4
Diarrhoea	2
Anorexia	1
Bradycardia	1
Haemorrhage	1
Lethargy	1
Somnolence	1

Selenium (as sodium selenate)

Equine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Injection site reaction	2
Stiffness	2
Swelling (local)	2

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1

Streptococcus Equi

Equine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Inflammation	1
Injection site reaction	1
Pyrexia	1

Streptococcus Equi (as cell-free extract)

Equine

Number of Reports	Probable	Possible
6	3	3

Presenting sign	Number of reports
Injection site reaction	3
Oedema	2
Ataxia	1
Dermatitis	1
Hives	1
Lesions	1

Lethargy	1
Lymphadenopathy	1
Pain	1
Swelling (local)	1

Sulfadiazine

Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Haematuria	1
Polyuria	1
Stranguria	1

Equine

Number of Reports	Probable	Possible
3	2	1

Presenting sign	Number of reports
Sweating	3
Dyspnoea	1
Lethargy	1
Pyrexia	1
Tachycardia	1
Tachypnoea	1

Feline

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Dyspnoea	1
Lethargy	1

Tepoxalin

Canine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Haemorrhage	1
Hyperactivity	1
Vomiting	1

Testosterone propionate

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Agitation	1
Hives	1
Swelling (local)	1

Tetrachlorvinphos

Bovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Lack of effect	1

Thiomersal

Bovine

Number of Reports	Probable	Possible
2	0	2

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

Canine

Number of Reports	Probable	Possible
54	43	11

Presenting sign	Number of reports
Facial oedema	34
Lethargy	7
Urticaria	6
Vomiting	6
Pruritus	5
Swelling (local)	5
Oedema	3
Hypersensitivity reaction	3
Periorbital swelling	3
Pyrexia	3
Injection site reaction	2
Abscess	2
Hives	2
Hypersalivation	2
Pale mucous membranes	2
Swollen lips and face	2
Pain	1
Depression	1
Hyperactivity	1
Abdominal pain	1
Allergy	1
Anorexia	1
Ataxia	1
Capillary refill time (slow)	1
Collapse	1
Cyanosis	1
Diarrhoea	1
Inflammation	1
Necrosis	1
Restless	1
Shaking	1
Tachycardia	1

Equine

Number of Reports	Probable	Possible
12	5	7

Presenting sign	Number of reports
Injection site reaction	8
Pain	4
Oedema	2
Lethargy	2
Pyrexia	2
Swelling (local)	2
Ataxia	1
Collapse	1
Dermatitis	1
Dyspnoea	1
Hives	1
Inflammation	1
Lesions	1
Lymphadenopathy	1
Paddling	1
Recumbency	1
Tachycardia	1

Feline

Number of Reports	Probable	Possible
39	21	18

Presenting sign	Number of reports
Lethargy	22
Anorexia	14
Pyrexia	13
Injection site reaction	10
Pain	6
Vomiting	6
Alopecia	4
Swelling (local)	4
Behavioural change	3
Depression	3
Vocalisation	3
Respiratory problems	2
Adipsia	2
Diarrhoea	2
Listless	2
Nasal discharge	2

Ocular discharge	2
Sneezing	2
Aggression	1
Agitation	1
Distress	1
Erythema	1
Hypersensitive to stimuli	1
Irritation (ear)	1
Irritation (skin)	1
Pruritus	1
Tachycardia	1
Arthropathy	1
Defaecation	1
Haemorrhage	1
Hyperaesthesia	1
Hypersensitivity reaction	1
Inflammation	1
Lame	1
Oedema	1
Seizure	1
Stiffness	1

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1
Lack of effect	1

Rabbit

Number of Reports	Probable	Possible
4	4	0

Presenting sign	Number of reports
Alopecia	2
Injection site reaction	2
Dermatitis	1
Lethargy	1
Necrosis	1
Oedema	1
Self trauma	1
Shaking	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[2]. 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

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Vomiting	1

Feline

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Cardiac arrest	1
Vomiting	1

Tiletamine (as the hydrochloride)

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Abdominal pain	1
Ataxia	1
Recovery (poor)	1
Vocalisation	1
Vomiting	1

[2] Source www.ncirs.usyd.edu.au/facts/f-thiomersal.html

Triclabendazole

Bovine

Number of Reports	Probable	Possible
4	0	4

Presenting sign	Number of reports
Death	1
Scouring	1
Anorexia	1
Lethargy	1
Malaise	1
Photosensitization	1
Skin slough	1
Lack of effect	1

Trimethoprim

Canine

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Haematuria	1
Polyuria	1
Stranguria	1

Equine

Number of Reports	Probable	Possible
3	2	1

Presenting sign	Number of reports
Sweating	3
Dyspnoea	1
Lethargy	1
Pyrexia	1
Tachycardia	1
Tachypnoea	1

Feline

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Hypersalivation	1
Vomiting	1

Vitamin B3 (nicotinamide)

Equine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Injection site reaction	2
Stiffness	2
Swelling (local)	2

Vitamin B12 (cyanocobalamin)

Equine

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Injection site reaction	2
Stiffness	2
Swelling (local)	2

Xylazine hydrochloride

Equine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Induction (poor)	1
Nystagmus	1
Paddling	1
Sweating	1

Zinc EDTA

Ovine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Death	1

Zolazepam (as the hydrochloride)

Canine

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Abdominal pain	1
Ataxia	1
Recovery (poor)	1
Vocalisation	1
Vomiting	1

3. Veterinary Section 1 Part B—summary of adverse experience reports 2006 (human)

3.1 Adverse experience report summaries involving humans listed by active constituent

The following information is contained in this section:

The 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.

The number of reports

Only adverse experience reports that were classified by the APVMA during the calander year 2006, 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.

The 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 AER's

Carbaryl

Number of Reports	Probable	Possible
2	0	2

Presenting sign	Number of reports
Rash	2

Di-n-propyl isoinchomeronate

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Rash	1
Hive	1

Flumethrin

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Anaphylactoid reaction	1

Imacloprid

Number of Reports	Probable	Possible
3	0	3

Presenting sign	Number of reports
Rash	1
Blisters	1
Hypersensitivity reaction	1

N-octyl bicyloheptene dicarboximide

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Rash	1
Hive	1

Piperonyl butoxide

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Rash	1
Hive	1

Propoxur

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Anaphylactoid reaction	1

Pyrethrins

Number of Reports	Probable	Possible
1	0	1

Presenting sign	Number of reports
Rash	1
Hive	1

4. Agriculture Section 2 Part A—summary of adverse experience reports 2006 (animal)

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:

The 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.

The number of reports

- Only adverse experience reports that were classified by the APVMA during the calander year 2006, 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.

The 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 Agricultural Chemical – standard AER's

Hexazinone

Environmental

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Environmental damage	1

Simazine

Environmental

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Environmental damage	1

5. Agriculture Section 2 Part B—summary of adverse experience reports 2006 (human)

5.1 Adverse experience report summaries involving humans listed by active constituent

The following information is contained in this section:

The 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.

The number of reports

Only adverse experience reports that were classified by the APVMA during the calander year 2006, 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.

The 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 Agricultural Chemical – human AER's

Aluminium Phosphide

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Nil	1

Bifenthrin

Number of Reports	Probable	Possible
2	2	0

Presenting sign	Number of reports
Headache	2
Abdominal pain	1
Coughing	1
Dizziness	1
Fatigue	1
Irritation (eye)	1
Lacrimation	1
Malaise	1
Nasal discharge	1
Nausea	1
Numbness	1
Respiratory problems	1
Sore throat	1
Stomatitis	1
Unpleasant taste	1

Fipronil

Number of Reports	Probable	Possible
1	1	0

Presenting sign	Number of reports
Burning sensation	1
Facial oedema	1
Swelling (local)	1

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

6. Glossary

Analgesic	- pain relieving treatment
Anaphylaxis/anaphylactic	- an exaggerated allergic reaction of an animal to a foreign protein or other substances
Anaphylactoid	- an anaphylactic-type reaction
Anthelmintic	- an agent destructive to worms
Antimicrobial	- an agent that kills micro-organisms or suppresses their multiplication or growth
Ataxic	- unsteady walking action due to muscular incoordination
Colic	- a general term for abdominal pain
Cyanotic	- blue discolouration of the mucous membranes and other tissues due to a lack of circulating oxygen in the blood
Erythema	- abnormal redness of the skin due to local congestion, as in inflammation
Folliculitis	- inflammation of the follicles
Hypersalivation	- excessive salivation
Hypersensitivity	- an excessive reaction to an allergen
Intramammary	- within or into the mammary gland
Oedematous	- abnormal accumulation of fluid in body cavities and under the skin
Parasiticide	- an agent that is destructive to parasites
Parvovirus	- viral infection of dogs that is characterised by diarrhoea, dehydration and pyrexia
Pruritus	- irritation and itching
Pyrexic	- animal suffering from a high fever
Registrant	- the commercial party that is responsible for the marketing of the product
Urticaria	- vascular reaction of the skin as a result of contact with a chemical or may be immunologically based
Withholding period	- the time interval after the withdrawal of a drug or chemical from the treatment of an animal before the animal or its products can be used for human food

6 List of Actives