Report of Adverse Experiences for Veterinary Medicines

Calendar Year 2005

Adverse Experience Reporting Program
for veterinary medicines

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EXECUTIVE SUMMARY

The Adverse Experience Reporting Program for veterinary medicines (AERP Vet) and the AERP for agricultural chemicals (AERP Ag) comprise the Australian post-registration quality assurance programs that facilitate the responsible management of veterinary medicines and agricultural chemicals throughout their lifecycle, from registration to end-product user. They also provide clear guidance for registrants in complying with their legislated obligations.

This report contains information on adverse experience reports for veterinary medicines. Further details of adverse experience reports for agricultural chemicals can be found on the APVMA Website.

During the 2005 calendar year, the AERP Vet **received a total of 1548 reports involving suspected adverse reactions in animals from veterinary surgeons, owners, members of the public and product registrants.** The implementation of a risk analysis framework for the AERP over the last 5 years, has enabled the APVMA to quickly and accurately identify issues involving veterinary medicines that require corrective action to minimise future adverse experiences from occurring.

Some of the activities undertaken during 2005 include:

- Various articles, letters and another scientific papers were also prepared based on analyses of adverse experience information and were submitted for publication in the Australian Veterinary Journal, and other national and international refereed journals.
- Seminars to industry representatives on the processes of the AERP.

This Annual 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 2005 Calendar Year. It is important to note that some reports relate to previous years, but because the APVMA only received them in late 2004 and they were classified in 2005, they are included in this report for completeness.

Throughout the 2005 calendar year a number of risk management strategies aimed at mitigating and minimising the prevalence of adverse experiences were actioned. These include:

- recommendations to change the label of products containing clomipramine hydrochloride to prevent use for treatment of aggression and note that urinary retention is a potential side effect;
- recommendation to change the label of avian products containing praziquantel to prevent use in Gouldian finches;
- recommendation to change labels of reptile products containing praziquantel and fenbendazole to prevent damage to oropharyngeal areas of reptiles; and
- recommendation to change labels of products containing chlorhexidine gluconate and miconazole nitrate to warn owners not to allow the animals to lick the product off the coat, and to ensure adequate rinsing occurs.

More information is provided on some of these changes in the following report under each respective active constituent. Entries for the active constituent 'fipronil' have not been included in this report as these products are currently under formal review by the APVMA. These entries will be published in a later report.

1. INTRODUCTION

1.1 Program Outline

The APVMA is the independent 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. 'Pesticides' include agricultural and many 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. 'Veterinary medicines' include all veterinary chemical products such as vaccines, antibiotics, worming treatments, flea and tick washes and other parasiticides for both domestic and production animals. Under the National Registration Scheme, the APVMA evaluates and registers agricultural and veterinary chemicals and manages quality assurance programs that monitor the safety and performance of registered products.

The Adverse Experience Reporting Program for veterinary medicines (AERP Vet) is a post-registration quality assurance program established by the APVMA to facilitate responsible management of veterinary medicines throughout their lifecycle. The program provides a means for identifying corrective actions necessary to assure the continued safety, quality and effectiveness of registered veterinary medicines. 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 Vet helps to ensure that products on the market:

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

1.2 What is an adverse experience?

An 'adverse experience' is defined by the APVMA 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 this so that the true incidence of these side effects can be assessed. 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 and adverse reactions in 'off-label' species. Such products may have originally been intended for use in humans or other animal species. So for this reason it is important that all adverse experiences whether associated with recommended label use or not are reported.

1.3 Who can report an adverse experience?

Anyone — voluntary reporting is encouraged from veterinarians, animal owners, farmers and other users of veterinary medicines.

Reporting under the AERP Vet also includes an obligation on the registrants of veterinary medicines.

1.4 Reporting an adverse experience

Adverse experiences with veterinary medicines may be reported using the Adverse Experience Reporting Form for veterinary medicines, which is also available from veterinarians and the AVA or via the online reporting system.

1.5 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 or not. 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/Territory government agencies, universities or other appropriate authorities. The APVMA also considers scientific information publicly available either on the Internet or from an international agency (such as in the UK, Canada or US).
- 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.

1.6 Classification of adverse experience reports

The relationship between the use of the veterinary medicine and the reported clinical signs is assessed after the incident has been investigated. The relationship is expressed in terms of:

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; and
- 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'.

Probable/Off-label

As per the classification of 'probable' and 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, veterinary prescribing privileges, APVMA Permits and other legal exemptions may allow off-label use in some situations.

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.

Possible/Off-label

As per the classification 'possible' and 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, 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 where reliable data is either unavailable or is insufficient to make an assessment should be categorised as 'unknown'.

1.7 Corrective action determination

There are many factors that need to be considered when determining whether corrective action is required and if so, what corrective action is needed to mitigate the issue. The APVMA takes into account a broad range of issues and options when deciding what, if any corrective action is required.

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 required.

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).

1.8 Outcomes of the program

Possible corrective actions stemming from the assessment, evaluation and classification of adverse experience information include:

- recommendations to the product registrant regarding certain aspects of the product (such as a label change or a formulation change);
- review of the active constituent under the APVMA's Chemical Review Program; and
- education of the veterinary profession, farming community or wider public on issues relating to use of products.

The information contained in this report is only a general reference to the type of adverse experience that veterinarians, animal owners, and others have reported either to the APVMA or to product registrants. This information should NOT be used for:

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

- associating clinical signs 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.

1.9 Report Structure

This report is arranged into the following sections:

- Section 1
  a summary of adverse experience reports for each animal species listed by active constituent, and
- Section 2
  a summary of all adverse experience reports involving human health.

1.10 For further information

For information about the Adverse Experience Reporting Program please contact:

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2. SECTION 1

2.1 A summary of adverse experience reports for each species 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. 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 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.

ABALONE POWDER

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Diarrhoea	1
Vomiting	1

ABAMECTIN

Equine

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Anorexia	1
Bloat	1
Colic	3
Death	1
Diarrhoea	1
Frothing at the mouth	1
Hyperexcitable	1
Pyrexia	1
Recumbency	1
Rolling	1
Sweating	2

ABAMECTIN

Ovine

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Anaemia	1
Bottle jaw	1
Death	1
Lack of effect	2

ALBENDAZOLE
(Registered Name: ALBENDAZOLE)

Ovine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1
Diarrhoea	1

(Registered Name: ALBENDAZOLE AS ALBENDAZOLE OXIDE)

Ovine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1
Dyspnoea	1
Frothing at the mouth	1
Muscle twitching	1
Spasm	1

ALPHA-CYPERMETHRIN

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1

ALPHAXALONE

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Coughing	1
Death	1

ALPHAXALONE

Feline

Number of reports	Probable	Possible
6	0	6

Presenting Signs	Number of reports
Apnoea	3
Bradycardia	2
Cardiac arrest	4
Cyanosis	3
Death	3
Pale mucous membranes	1
Respiratory problems	1

It is well recognised that anaesthetics are associated with a certain level of risk. Accordingly, the labels of these products contain appropriate precautionary information. These warnings mostly refer to taking special care with aged, sick and stressed animals.

AMITRAZ

Bovine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Hypersalivation	1
Lethargy	1
Recumbency	1

AMMONIUM FERRIC CITRATE

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

APOMORPHINE HYDROCHLORIDE

Canine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Lack of effect	1

BENAZEPRIL HYDROCHLORIDE

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Anorexia	1
Lethargy	1

BENZALKONIUM CHLORIDE

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Alopecia	1
Dermatitis	1
Erythema	1

BENZATHINE PENICILLIN

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lesions	1
Swelling (local)	1

BENZATHINE PENICILLIN

Equine

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Pain	1
Swelling (local)	2

BENZATHINE PENICILLIN

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lesions	1
Swelling (local)	1

BIOTIN—VITAMIN H

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

BLACK DISEASE = CLOSTRIDIUM OEDEMATIENS

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1
Scouring	1

BLACKLEG = CLOSTRIDIUM CHAUVOEI

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1
Scouring	1

BORDETELLA BRONCHISEPTICA

(Registered Name: BORDETELLA BRONCHISEPTICA)

Canine

Number of reports	Probable	Possible
18	4	14

Presenting Signs	Number of reports
Agitation	1
Coughing	6
Death	1
Depression	2
Erythema	1
Inflammation	1
Injection site reaction	5
Irritation (paws)	1
Irritation (skin)	1
Nasal discharge	1
Pain	2
Panting	1
Pruritis	1
Pulmonary oedema	1
Pyrexia	1
Sneezing	5
Stiffness	1
Swelling (local)	5
URTI	3

(Registered Name: BORDETELLA BRONCHISEPTICA) (INACTIVATED CELL FREE EXTRACT)

Canine

Number of reports	Probable	Possible
40	30	10

Presenting Signs	Number of reports
Agitation	1
Behavioural change	1
Collapse	2
Depression	1
Dermatitis	1
Distress	1
Dyspnoea	2
Erythema	8
Facial oedema	21
Hyperactivity	1
Lethargy	2
Oedema	10
Pale mucous membranes	1
Periorbital swelling	2
Pruritis	5
Respiratory problems	1
Swelling (local)	1
Urticaria	9
Vomiting	15

(Registered Name: BORDETELLA BRONCHISEPTICA KILLED VACCINE)

Canine

Number of reports	Probable	Possible
27	23	4

Presenting Signs	Number of reports
Anaphylactoid reaction	1
Bradycardia	1
Cardiac arrhythmia	1
Collapse	4
Death	1
Defaecation	1
Depression	1
Dyspnoea	2
Erythema	1
Facial oedema	7
Haemorrhagic gastroenteritis	1
Hives	1
Injection site reaction	2
Lethargy	5
Oedema	4
Pale mucous membranes	2
Periorbital swelling	7
Pruritis	4
Restless	1
Seizure	1
Swelling (local)	3
Swollen lips and face	2
Urticaria	3
Vomiting	7
Weakness	2
Welts	1

There are numerous vaccines that contain Bordetella bronchiseptica in live, attenuated, inactivated and killed forms. The most frequently reported side effects for these types of vaccines include facial oedema, urticaria, vomiting and coughing. Appropriate information and warnings are included on product labels as required.

Overall, 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 continued monitoring for future adverse experience reports.

CANINE ADENOVIRUS

(Registered Name: CANINE ADENO VIRUS TYPE 2)

Canine

Number of reports	Probable	Possible
64	34	30

Presenting Signs	Number of reports
Agitation	3
Anaphylactoid reaction	1
Anaphylaxis	1
Anorexia	1
Ataxia	1
Behavioural change	2
Blindness	1
Collapse	4
Conjunctivitis	1
Coughing	5
Death	1
Defaecation	1
Depression	3
Dermatitis	1
Distress	1
Dyspnoea	3
Erythema	9
Facial oedema	22
Hyperactivity	1
Inflammation	1
Injection site reaction	1
Irritation (paws)	2
Irritation (skin)	2
Lethargy	4
Malaise	1
Nasal discharge	1
Ocular damage	1
Oedema	11
Pale mucous membranes	2

Presenting Signs	Number of reports
Panting	3
Periorbital swelling	2
Pruritis	7
Pyrexia	3
Respiratory problems	1
Shaking	1
Sneezing	5
Stiffness	2
Swelling (local)	2
Tachypnoea	1
Tremor	1
URTI	3
Urticaria	8
Vocalisation	2
Vomiting	20
Weakness	1

There are numerous vaccines that contain Canine Adenovirus Type 2 in live, attenuated, inactivated and killed forms. The most frequently reported side effects reported, include vomiting, lethargy, coughing and diarrhoea. These clinical signs can occur rarely with most vaccines and appropriate warning statements and information is made available on product labels.

Taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continued monitoring for future adverse experience reports.

Registered Name: HEPATITIS CANINE = CANINE ADENOVIRUS)

Canine

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Anorexia	2
Death	1
Depression	1
Haematology (abnormal)	1
Pyrexia	1
Renal failure	1
Tachycardia	1
Urticaria	1
Vomiting	3

CANINE CORONAVIRUS VACCINE—ANTIGEN

Canine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Bradycardia	1
Collapse	1
Cyanosis	1
Seizure	1

CANINE DISTEMPER

(Registered Name: CANINE DISTEMPER)

Canine

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Anorexia	2
Death	1
Depression	1
Haematology (abnormal)	1
Pyrexia	1
Renal failure	1
Tachycardia	1
Urticaria	1
Vomiting	3

(Registered Name: CANINE DISTEMPER VIRUS)

Canine

Number of reports	Probable	Possible
13	2	11

Presenting Signs	Number of reports
Agitation	2
Anaphylactoid reaction	1
Anaphylaxis	1
Behavioural change	1
Blindness	1
Collapse	2
Conjunctivitis	1
Death	1
Defaecation	1
Depression	1
Dyspnoea	2
Facial oedema	2
Hyperactivity	1
Injection site reaction	1
Irritation (paws)	2
Irritation (skin)	2
Lethargy	1
Ocular damage	1
Oedema	2
Pale mucous membranes	1
Panting	2
Pruritis	3
Pyrexia	2
Shaking	1
Stiffness	1
Swelling (local)	1
Urticaria	1
Vocalisation	2
Vomiting	5
Weakness	1

(Registered Name: CANINE DISTEMPER VIRUS—LIVING)

Canine

Number of reports	Probable	Possible
41	32	9

Presenting Signs	Number of reports
Anorexia	1
Ataxia	1
Behavioural change	1
Collapse	2
Depression	1
Dermatitis	1
Distress	1
Dyspnoea	1
Erythema	8
Facial oedema	21
Lethargy	3
Malaise	1
Oedema	9
Pale mucous membranes	1
Periorbital swelling	2
Pruritis	4
Respiratory problems	1
Swelling (local)	1
Tachypnoea	1
Tremor	1
Urticaria	7
Vomiting	16

Canine Distemper Virus is found in a variety of different vaccines in live, attenuated, inactivated and killed forms. The most frequently reported side effects reported, such as vomiting, lethargy and diarrhoea occur very occasionally with most vaccines. Warning statements and information are included in product literature as required.

Taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continued monitoring for future adverse experience reports.

CANINE PARAINFLUENZA

(Registered Name: CANINE PARAINFLUENZA)

Canine

Number of reports	Probable	Possible
10	0	10

Presenting Signs	Number of reports
Agitation	1
Coughing	5
Depression	1
Erythema	1
Inflammation	1
Nasal discharge	1
Panting	1
Pyrexia	1
Sneezing	5
Stiffness	1
URTI	3

(Registered Name: CANINE PARAINFLUENZA TYPE 2)

Canine

Number of reports	Probable	Possible
10	1	9

Presenting Signs	Number of reports
Agitation	2
Anaphylactoid reaction	1
Behavioural change	1
Blindness	1
Collapse	2
Conjunctivitis	1
Death	1
Defaecation	1
Depression	1
Dyspnoea	2
Facial oedema	2
Hyperactivity	1
Irritation (paws)	2
Irritation (skin)	2
Lethargy	1
Ocular damage	1
Oedema	2
Pale mucous membranes	1
Panting	1
Pruritis	3
Pyrexia	1
Shaking	1
Urticaria	1
Vocalisation	2
Vomiting	5
Weakness	1

(Registered Name: CANINE PARAINFLUENZA VIRUS)

Canine

Number of reports	Probable	Possible
48	34	14

Presenting Signs	Number of reports
Anorexia	2
Behavioural change	1
Collapse	2
Death	1
Depression	2
Dermatitis	1
Distress	1
Dyspnoea	1
Erythema	8
Facial oedema	21
Haematology (abnormal)	1
Injection site reaction	5
Irritation (paws)	1
Irritation (skin)	1
Lethargy	2
Oedema	9
Pain	2
Pale mucous membranes	1
Periorbital swelling	2
Pruritis	5
Pulmonary oedema	1
Renal failure	1
Respiratory problems	1
Swelling (local)	6
Tachypnoea	1
Urticaria	8
Vomiting	16

Canine Parainfluenza Virus is found in a variety of different vaccines in live, attenuated, inactivated and killed forms. Frequently reported side effects 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 continued monitoring for future adverse experience reports.

CANINE PARVO VIRUS

(Registered Name: CANINE PARVO VIRUS)

Canine

Number of reports	Probable	Possible
16	2	14

Presenting Signs	Number of reports
Agitation	2
Anaphylactoid reaction	1
Anaphylaxis	1
Anorexia	2
Behavioural change	1
Blindness	1
Collapse	2
Conjunctivitis	1
Defaecation	1
Depression	1
Dyspnoea	2
Facial oedema	2
Haematology (abnormal)	1
Hyperactivity	1
Injection site reaction	1
Irritation (paws)	2
Irritation (skin)	2
Lethargy	1
Ocular damage	1
Oedema	2
Pale mucous membranes	1
Panting	2
Pruritis	3
Pyrexia	2
Renal failure	1
Shaking	1
Stiffness	1
Swelling (local)	1

Presenting Signs	Number of reports
Urticaria	2
Vocalisation	2
Vomiting	7
Weakness	1

(Registered Name: CANINE PARVO VIRUS TYPE 2)

Canine

Number of reports	Probable	Possible
41	32	9

Presenting Signs	Number of reports
Anorexia	1
Ataxia	1
Behavioural change	1
Collapse	2
Depression	1
Dermatitis	1
Distress	1
Dyspnoea	1
Erythema	8
Facial oedema	21
Lethargy	3
Malaise	1
Oedema	9
Pale mucous membranes	1
Periorbital swelling	2
Pruritis	4
Respiratory problems	1
Swelling (local)	1
Tachypnoea	1
Tremor	1
Urticaria	7
Vomiting	16

(Registered Name: CANINE PARVOVIRUS (INACTIVATED))

Canine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Anorexia	1
Facial oedema	1
Panting	1
Pyrexia	1
Recumbency	1

(Registered Name: PARVOVIRUS — LIVE)

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1
Depression	1
Pyrexia	1
Tachycardia	1
Vomiting	1

Canine Parvovirus is found in a variety of different vaccines in live, attenuated, inactivated and killed forms. Frequently reported side effects include vomiting, lethargy and pruritis occur very occasionally with most vaccines. Taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continued monitoring for future adverse experience reports.

CARBARYL

Canine

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Irritation (eye)	1
Rash	1
Seizure	1
Welts	1

CARBARYL

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lethargy	1

CARPROFEN

Canine

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Collapse	1
Haematology (abnormal)	1
Hepatopathy	1
Jaundice	1
Melaena	1
Mydriasis	1
Petechiae	1
Pruritis	2
Pyoderma	2
Vomiting	1

CETRIMIDE

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Alopecia	1
Dermatitis	1
Erythema	1

CHLORFENVINPHOS

Bovine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Frothing at the mouth	1
Lack of effect	1
Weakness	1

CHLORFENVINPHOS

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Coat discoloration	1

CHLORHEXIDINE GLUCONATE

Canine

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Collapse	1
Hypersalivation	1
Vasculitis	1
Vomiting	1
Wheals	1

CHLORHEXIDINE GLUCONATE

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Respiratory problems	1

CHOLINE BITARTRATE

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

CLA = CORYNEBACTERIUM PSEUDOTUBERCULOSIS OVIS

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1
Scouring	1

CLOMIPRAMINE HYDROCHLORIDE

Canine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Anorexia	2
Death	1
Dehydration	1
Diarrhoea	1
Lethargy	1
Sedation	1
Somnolence	1
Vomiting	1

CLOMIPRAMINE HYDROCHLORIDE

Feline

Number of reports	Probable	Possible
7	3	4

Presenting Signs	Number of reports
Anorexia	3
Constipation	3
Haematuria	1
Lethargy	3
Mydriasis	1
Stranguria	2
Urinary retention	4

Based on the adverse experience reports received for these products the AERP recommended changes to the product labels to prevent use for treatment of aggression and note that urinary retention is a potential side effect.

CLOSANTEL

Ovine

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Anaemia	1
Bottle jaw	1
Death	1
Lack of effect	2

CLOSTRIDIUM CHAUVOEI — FORMOL CULTURE

Bovine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Collapse	1

CLOSTRIDIUM CHAUVOEI — TOXOID

Bovine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Death	1
Injection site reaction	1

CLOSTRIDIUM NOVYI TYPE B — TOXOID

Bovine

Number of reports	Probable	Possible
3	2	1

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

CLOSTRIDIUM PERFRINGENS TYPE D TOXOID

Bovine

Number of reports	Probable	Possible
3	2	1

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

CLOSTRIDIUM PERFRINGENS TYPE D TOXOID

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1
Scouring	1

CLOSTRIDIUM SEPTICUM — TOXOID

Bovine

Number of reports	Probable	Possible
3	2	1

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

CLOSTRIDIUM TETANI — ANTITOXIN

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Agitation	1
Collapse	1
Death	1
Muscle twitching	1

CLOSTRIDIUM TETANI — TOXOID

Bovine

Number of reports	Probable	Possible
3	2	1

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

CLOSTRIDIUM TETANI — TOXOID

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1
Scouring	1

CLOSTRIDIUM TETANI UF TOXOID

Equine

Number of reports	Probable	Possible
5	3	2

Presenting Signs	Number of reports
Agitation	1
Anorexia	1
Collapse	1
Death	1
Injection site reaction	4
Muscle twitching	1

COBALT (II) SULFATE

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

COPPER INDOMETHACIN

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Ulceration	1

COPPER SULFATE

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

CRESYLIC ACID

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Coat discoloration	1

CYCLOSPORIN

Canine

Number of reports	Probable	Possible
19	4	15

Presenting Signs	Number of reports
Abdominal pain	1
Adipsia	1
Alopecia	1
Anorexia	1
Ataxia	1
Behavioural change	3
Colic	1
Depression	2
Dermatitis	2
Diarrhoea	9
Erythema	1
Gingival hyperplasia	1
Hyperactivity	1
Hyperkeratosis	1
Lesions	1
Lethargy	3
Otitis externa	1
Pododermatitis	1
Pruritis	8
Restless	4
Self trauma	1
Tachycardia	1
Tachypnoea	3
Tenesmus	1
Tremor	2
Vocalisation	1
Vomiting	8
Weakness	1
Weight loss	1

CYPERMETHRIN

Bovine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Frothing at the mouth	1
Lack of effect	1
Weakness	1

DELTAMETHRIN

Bovine

Number of reports	Probable	Possible
16	0	16

Presenting Signs	Number of reports
Agitation	2
Lack of effect	14
Milk production decrease	2

DIAZEPAM

Canine

Number of reports	**Probable**	**Possible**
1	0	1

Presenting Signs	**Number of reports**
Lame	1
Proprioception deficit	1

DIFLUBENZURON

Ovine

Number of reports	**Probable**	**Possible**
21	0	21

Presenting Signs	**Number of reports**
Death	2
Lack of effect	21
Rubbing	3
Wool damage	1

EIMERIA ACERVULINA OOCYSTS

Avian

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Lack of effect	4

EIMERIA MAXIMA OOCYSTS

Avian

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Lack of effect	4

EIMERIA NECATRIX OOCYSTS

Avian

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Lack of effect	4

EPRINOMECTIN

Bovine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Alopecia	1
Milk production decrease	1
Site reaction	1
Weight loss	1

EUCALYPTUS OIL

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Coat discoloration	1

FEBANTEL

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lethargy	1
Vomiting	1

FELINE CALICIVIRUS — INACTIVATED

Feline

Number of reports	Probable	Possible
91	78	13

Presenting Signs	Number of reports
Abscess	1
Adipsia	3
Anaphylaxis	1
Anorexia	47
Arthropathy	1
Ataxia	2
Behavioural change	7
Comatose	1
Death	1
Depression	4
Diarrhoea	4
Disorientation	1
Haemorrhagic gastroenteritis	1
Hyperaesthesia	2
Hypersalivation	1
Hypothermia	1
Illness	2
Incoordination	1
Injection site reaction	10
Lethargy	64
Malaise	5
Nasal discharge	1
Pain	28
Paresis	1
Prolapsed third eyelid	2
Pruritis	1
Pyrexia	30
Shaking	5
Sneezing	1
Somnolence	2

Presenting Signs	Number of reports
Stiffness	3
Swelling (local)	2
Tachycardia	1
Tachypnoea	1
Vocalisation	1
Vomiting	9
Weakness	2

There are numerous vaccines that contain Feline Calicivirus in live, attenuated, inactivated and killed forms. The most frequently reported side effects reported, such as anorexia, lethargy and pyrexia occur fairly commonly with many feline vaccines. Taking into consideration the large number of cats vaccinated each year, no further regulatory action is required other than continued monitoring for future adverse experience reports.

FELINE CHLAMYDIA PSITTACI (INACTIVATED)

Feline

Number of reports	Probable	Possible
80	71	9

Presenting Signs	Number of reports
Abscess	1
Adipsia	3
Anaphylaxis	1
Anorexia	39
Arthropathy	1
Ataxia	2
Behavioural change	5
Comatose	1
Death	1
Depression	3
Diarrhoea	3
Disorientation	1
Hyperaesthesia	2
Hypersalivation	1
Illness	2
Incoordination	1

Presenting Signs	Number of reports
Injection site reaction	8
Lethargy	59
Malaise	4
Nasal discharge	1
Pain	27
Paresis	1
Pyrexia	25
Shaking	5
Sneezing	1
Somnolence	2
Stiffness	3
Swelling (local)	2
Tachypnoea	1
Vocalisation	1
Vomiting	6
Weakness	2

The most frequently reported side effects, such as lethargy, anorexia and pyrexia occur fairly commonly with many feline vaccines. Taking into consideration the large number of cats vaccinated each year, no further regulatory action is required other than continued monitoring for future adverse experience reports.

FELINE IMMUNODEFICIENCY VIRUS(PETALUMA STRAIN) INACTIVE

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Anorexia	1
Injection site reaction	1
Pain	1

FELINE LEUKAEMIA VIRUS — INACTIVATED

Feline

Number of reports	Probable	Possible
12	10	2

Presenting Signs	Number of reports
Adipsia	1
Anorexia	7
Behavioural change	2
Disorientation	1
Hyperaesthesia	1
Incoordination	1
Injection site reaction	2
Lethargy	9
Pain	6
Pyrexia	3
Stiffness	3
Swelling (local)	1
Tachypnoea	1

FELINE PANLEUCOPENIA VIRUS — INACTIVATED

Feline

Number of reports	Probable	Possible
91	78	13

Presenting Signs	Number of reports
Abscess	1
Adipsia	3
Anaphylaxis	1
Anorexia	47
Arthropathy	1
Ataxia	2
Behavioural change	7
Comatose	1
Death	1

Presenting Signs	Number of reports
Depression	4
Diarrhoea	4
Disorientation	1
Haemorrhagic gastroenteritis	1
Hyperaesthesia	2
Hypersalivation	1
Hypothermia	1
Illness	2
Incoordination	1
Injection site reaction	10
Lethargy	64
Malaise	5
Nasal discharge	1
Pain	28
Paresis	1
Prolapsed third eyelid	2
Pruritis	1
Pyrexia	30
Shaking	5
Sneezing	1
Somnolence	2
Stiffness	3
Swelling (local)	2
Tachycardia	1
Tachypnoea	1
Vocalisation	1
Vomiting	9
Weakness	2

There are numerous vaccines that contain Feline Panleucopenia virus in live, attenuated, inactivated and killed forms. The most frequently reported side effects reported, such as lethargy, anorexia and pyrexia occur fairly commonly with many feline vaccines. Taking into consideration the large number of cats vaccinated each year, no further regulatory action is required other than continued monitoring for future adverse experience reports

FELINE RHINOTRACHEITIS VIRUS — INACTIVATED

Feline

Number of reports	Probable	Possible
91	78	13

Presenting Signs	Number of reports
Abscess	1
Adipsia	3
Anaphylaxis	1
Anorexia	47
Arthropathy	1
Ataxia	2
Behavioural change	7
Comatose	1
Death	1
Depression	4
Diarrhoea	4
Disorientation	1
Haemorrhagic gastroenteritis	1
Hyperaesthesia	2
Hypersalivation	1
Hypothermia	1
Illness	2
Incoordination	1
Injection site reaction	10
Lethargy	64
Malaise	5
Nasal discharge	1
Pain	28
Paresis	1
Prolapsed third eyelid	2
Pruritis	1
Pyrexia	30
Shaking	5
Sneezing	1

Presenting Signs	Number of reports
Somnolence	2
Stiffness	3
Swelling (local)	2
Tachycardia	1
Tachypnoea	1
Vocalisation	1
Vomiting	9
Weakness	2

There are numerous vaccines that contain Feline Rhinotracheitis virus in live, attenuated, inactivated and killed forms. The most frequently reported side effects reported, such as lethargy, anorexia and pyrexia occur fairly commonly with many feline vaccines. Taking into consideration the large number of cats vaccinated each year, no further regulatory action is required other than continued monitoring for future adverse experience reports.

FENBENDAZOLE

Other

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1

Based on the adverse experience report received for an avian product, a recommendation was made to change the label to restrict use in Gouldian finches.

FENTHION

Canine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Lethargy	1
Nausea	1
Rash	1

FLUAZURON

Bovine

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Lack of effect	3

GLYCINE

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

GNRF — PROTEIN CONJUGATE

Equine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Injection site reaction	2

GNRF — PROTEIN CONJUGATE

Porcine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Anaphylaxis	1
Death	1

HAEMOPHILUS PARASUIS

Porcine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Coughing	1

HYDROXY PROGESTERONE HEXANOATE

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Alopecia	1
Papules	1
Pruritis	1
Tremor	1

HYDROXYPROGESTERONE CAPROATE

Equine

Number of reports	Probable	Possible
5	5	0

Presenting Signs	Number of reports
Injection site reaction	5

IMIDACLOPRID

Canine

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Agitation	1
Alopecia	1
Dermatitis	2
Pruritis	1
Rolling	1
Site reaction	2

IMIDACLOPRID

Feline

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Alopecia	2
Irritation (skin)	2

INOSITOL

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

IVERMECTIN

Bovine

Number of reports	Probable	Possible
4	2	2

Presenting Signs	Number of reports
Alopecia	2
Death	1
Erythema	2
Lack of effect	1
Recumbency	1
Scouring	1
Site reaction	1

IVERMECTIN

Canine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Anorexia	1
Jaundice	1
Lethargy	1
Vomiting	1

IXODES HOLOCYCLUS ANTITOXIN

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Anaphylaxis	1

LEPTOSPIRA BORGPETERSENII SEROVAR HARDJO

Bovine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Collapse	1

LEPTOSPIRA ICTEROHAEMORRHAGIAE ANTIGEN

Canine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Bradycardia	1
Collapse	1
Cyanosis	1
Seizure	1

LEPTOSPIRA INTERROGANS SEROVAR HARDJO

Bovine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Death	1
Injection site reaction	1

LEPTOSPIRA INTERROGANS SEROVAR POMONA

Bovine

Number of reports	Probable	Possible
3	2	1

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

LEVAMISOLE

(Registered Name: LEVAMISOLE AS LEVAMISOLE HYDROCHLORIDE)

Ovine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1
Dyspnoea	1
Frothing at the mouth	1
Muscle twitching	1
Spasm	1

(Registered Name: LEVAMISOLE HYDROCHLORIDE)

Avian

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1
Weakness	1

(Registered Name: LEVAMISOLE HYDROCHLORIDE)

Bovine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Lack of effect	1

LUFENURON

Canine

Number of reports	Probable	Possible
9	5	4

Presenting Signs	Number of reports
Abdominal pain	1
Anorexia	4
Ataxia	2
Depression	1
Diarrhoea	1
Distress	1
Hypersalivation	1
Lethargy	4
Panting	1
Paresis	1
Somnolence	2
Tremor	1
Vocalisation	1
Vomiting	7

LUFENURON

Feline

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Alopecia	1
Anorexia	2
Injection site reaction	1
Lethargy	2

LYSINE-L HYDROCHLORIDE

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

MALDISON

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
CNS dysfunction	1
Proprioception deficit	1

MALDISON

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
CNS dysfunction	1
Proprioception deficit	1

MALIGNANT OEDEMA = CLOSTRIDIUM SEPTICUM

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1
Scouring	1

MEDETOMIDINE HYDROCHLORIDE

Canine

Number of reports	Probable	Possible
4	3	1

Presenting Signs	Number of reports
Bradycardia	3
Cyanosis	1
Death	1
Dyspnoea	1
Pulmonary oedema	1
Recumbency	1
Vomiting	1

MEDETOMIDINE HYDROCHLORIDE

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Blindness	1
Mydriasis	1

MELARSOMINE DIHYDROCHLORIDE

Canine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Distress	1
Panting	1
Vomiting	1

MELOXICAM

Canine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Anorexia	1
Lethargy	1
Melaena	1

METHIONINE-DL

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

MICONAZOLE NITRATE

Canine

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Collapse	1
Hypersalivation	1
Vasculitis	1
Vomiting	1
Wheals	1

MICONAZOLE NITRATE

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Respiratory problems	1

MILBEMYCIN OXIME

Canine

Number of reports	Probable	Possible
13	5	8

Presenting Signs	Number of reports
Abdominal pain	1
Anorexia	4
Ataxia	2
Depression	1
Diarrhoea	2
Distress	1
Erythema	1
Hypersalivation	1
Lethargy	5
Panting	1
Paresis	1
Pruritis	1
Somnolence	2
Tremor	1
Vocalisation	1
Vomiting	10

MILBEMYCIN OXIME

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Vomiting	1

MONENSIN AS MONENSIN SODIUM

Bovine

Number of reports	Probable	Possible
15	2	13

Presenting Signs	Number of reports
Death	4
Lack of effect	13
Nil	1
Poor performance	1
Scouring	1

MORANTEL TARTRATE

Equine

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Bloat	1
Colic	2
Death	1
Diarrhoea	1
Frothing at the mouth	1
Hyperexcitable	1
Pyrexia	1
Recumbency	1
Rolling	1
Sweating	1

MOXIDECTIN

Bovine

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Lack of effect	2
Photosensitization	1

MOXIDECTIN

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Sweating	1
Tremor	1

MOXIDECTIN

Feline

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Alopecia	2
Irritation (skin)	2

MOXIDECTIN

Ovine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Lack of effect	2
Scouring	1

MOXIDECTIN MICROSPHERES

Canine

Number of reports	Probable	Possible
37	21	16

Presenting Signs	Number of reports
Abscess	3
Agitation	1
Anaphylactoid reaction	1
Anaphylaxis	2
Anorexia	3
Ataxia	1
Auto-immune haemolytic anaemia	1
Collapse	3
Cyanosis	1
Diarrhoea	2
Distress	1
Dyspnoea	1
Erythema	1
Facial oedema	7
Haematology (abnormal)	1
Hives	2
Hyperactivity	1
Hypersalivation	1
Injection site reaction	9
Lethargy	3
Paddling	1
Pale mucous membranes	5
Panting	1
Periorbital swelling	2
Pyrexia	3
Renal failure	1
Restless	1
Shaking	2
Swelling (local)	8

Presenting Signs	Number of reports
Tremor	2
Urination	1
Urticaria	2
Vocalisation	1
Vomiting	13
Wheals	2

MYCOBACTERIUM CELL WALL FRACTION

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Convulsions	1
Death	1
Recumbency	1
Tremor	1

MYCOPLASMA HYOPNEUMONIAE — INACTIVATED ANTIGEN

Porcine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Coughing	1

N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE

Canine

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Lack of effect	3

N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Hyperexcitable	1
Hypersalivation	1
Vomiting	1

N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE

Guinea Pig

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1

NAPHTHALENE

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Coat discoloration	1

NEOMYCIN BASE (AS THE SULFATE)

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Agitation	1
Collapse	1
Death	**1**
Muscle twitching	**1**

NEOMYCIN SULFATE

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Irritation (eye)	1

NITENPYRAM

Canine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Hypersalivation	1
Hypertonia	1
Mydriasis	1
Vomiting	1

NITENPYRAM

Feline

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Agitation	1
Hyperactivity	1
Hypersalivation	1
Hypertonia	1
Mydriasis	1
Vomiting	1

OATMEAL EXTRACT

Canine

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Dermatitis	3
Pruritis	1
Scabs	3

OCTYL METHOXYCINNAMATE

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Unknown	1

OESTRADIOL

(Registered Name: OESTRADIOL)

Bovine

Number of reports	Probable	Possible
6	6	0

Presenting Signs	Number of reports
Pizzle drop	1
Preputial prolapse	6

(Registered Name: OESTRADIOL 17 BETA)

Bovine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Preputial prolapse	1

(Registered Name: OESTRADIOL BENZOATE)

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Alopecia	1
Papules	1
Pruritis	1
Tremor	1

(Registered Name: OESTRADIOL DIPROPIONATE)

Equine

Number of reports	Probable	Possible
5	5	0

Presenting Signs	Number of reports
Injection site reaction	5

(Registered Name: OESTRADIOL VALERATE)

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Alopecia	1
Papules	1
Pruritis	1
Tremor	1

OXYBENZONE

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Unknown	1

OXYCLOZANIDE

Bovine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Lack of effect	1

PANTOTHENOL-D = PANTHENOL-D

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

PERMETHRIN (25:75::CIS:TRANS)

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lethargy	1
Vomiting	1

PERMETHRIN (40:60::CIS:TRANS)

Canine

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Agitation	1
Alopecia	1
Dermatitis	2
Pruritis	1
Rolling	1
Site reaction	2

PETROLEUM OIL

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Coat discoloration	1

PHENYLBUTAZONE

Equine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Ataxia	1
Cardiac arrest	1
Collapse	2
Death	1
Dyspnoea	1
Pale mucous membranes	1
Respiratory problems	1
Rolling	1
Seizure	1
Shaking	1
Somnolence	1
Sweating	1
Tachycardia	1

PHENYLPROPANOLAMINE HYDROCHLORIDE

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Colic	1
Pyrexia	1
Tremor	1
Vomiting	1

PIPERONYL BUTOXIDE

Canine

Number of reports	Probable	Possible
4	2	2

Presenting Signs	Number of reports
Lack of effect	3
Rash	1

PIPERONYL BUTOXIDE

Feline

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Hyperexcitable	1
Hypersalivation	1
Lethargy	2
Vomiting	2

PIPERONYL BUTOXIDE

Guinea Pig

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1

POLYMYXIN B SULFATE

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Irritation (eye)	1

PRAZIQUANTEL

Avian

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1
Weakness	1

Based on the adverse experience report received for an avian product, a recommendation was made to change the label to restrict use in Gouldian finches.

PRAZIQUANTEL

Canine

Number of reports	Probable	Possible
13	5	8

Presenting Signs	Number of reports
Abdominal pain	1
Anorexia	3
Ataxia	2
Depression	1
Diarrhoea	2
Distress	1
Erythema	1
Hypersalivation	1
Lethargy	5
Panting	1
Paresis	1
Pruritis	1
Somnolence	1
Tremor	1
Vocalisation	1
Vomiting	10

PRAZIQUANTEL

Equine

Number of reports	Probable	Possible
5	4	1

Presenting Signs	Number of reports
Anorexia	1
Colic	1
Quality control	3
Sweating	2
Tremor	1

PRAZIQUANTEL

Feline

Number of reports	Probable	Possible
3	3	0

Presenting Signs	Number of reports
Ataxia	2
Behavioural change	1
Prolapsed third eyelid	1
Sedation	1
Vomiting	1

PRAZIQUANTEL

Other

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1

Based on the adverse experience reports received for these products in reptiles, the AERP recommended a change to labels to prevent damage to the oropharyngeal area of reptiles.

PREDNISOLONE

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Irritation (eye)	1

PROCAINE PENICILLIN

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lesions	1
Swelling (local)	1

PROCAINE PENICILLIN

Equine

Number of reports	Probable	Possible
6	6	0

Presenting Signs	Number of reports
Agitation	1
Collapse	2
Death	2
Muscle twitching	1
Pain	2
Seroma	1
Swelling (local)	4

PROCAINE PENICILLIN

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lesions	1
Swelling (local)	1

PROPOFOL

Canine

Number of reports	Probable	Possible
131	124	7

Presenting Signs	Number of reports
Anaphylaxis	2
Anorexia	1
Apnoea	4
Bradycardia	7
Capillary refill time (slow)	1
Cardiac arrest	1
Cyanosis	4
Dermatitis	1
Dyspnoea	1
Erythema	27
Facial oedema	54
Hives	32
Hypersensitivity reaction	6
Hypotension	2
Hypothermia	1
Injected mucous membranes	2
Lesions	1
Muscle twitching	1
Oedema	1
Paddling	1
Pale mucous membranes	8
Papules	1
Periorbital swelling	32
Pulmonary oedema	1
Pyoderma	1
Rash	1
Recovery (prolonged)	1
Red eyes	1
Respiratory problems	1
Swelling (local)	16

Presenting Signs	Number of reports
Swollen feet	2
Tachycardia	1
Tremor	1
Urticaria	17
Welts	8
Wheals	22

PROPOFOL

Feline

Number of reports	Probable	Possible
4	4	0

Presenting Signs	Number of reports
Erythema	1
Facial oedema	2
Hives	1
Pain	1
Periorbital swelling	1
Swelling (local)	2

Assessment of adverse experience reports for a propofol anaesthetic revealed that anaphylactoid type skin hypersensitivity reactions may occur in dogs. The product label now includes warning statements to inform veterinarians of these potential adverse effects.

PYRANTEL

(Registered Name: PYRANTEL AS PYRANTEL EMBONATE)

Canine

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Anorexia	1
Jaundice	1
Lethargy	2
Vomiting	2

(Registered Name: PYRANTEL EMBONATE)

Feline

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Ataxia	2
Behavioural change	1
Prolapsed third eyelid	1
Sedation	1

PYRETHRIN

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lethargy	1
Vomiting	1

PYRETHRINS

Canine

Number of reports	Probable	Possible
4	2	2

Presenting Signs	Number of reports
Lack of effect	3
Rash	1

PYRETHRINS

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Hyperexcitable	1
Hypersalivation	1
Lethargy	1
Vomiting	1

PYRETHRINS

Guinea Pig

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1

PYRIPROXYFEN (10%)

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Hypersalivation	1

RACTOPAMINE HYDROCHLORIDE

Porcine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Behavioural change	1
Death	1
Hyperaesthesia	1
Rash	1
Shaking	1

SELAMECTIN

Canine

Number of reports	Probable	Possible
7	6	1

Presenting Signs	Number of reports
Abscess	1
Alopecia	1
Dermatitis	1
Erythema	1
Lethargy	1
Pruritis	3
Pyrexia	1
Self trauma	4
Tachycardia	1
Tachypnoea	1
Urticaria	1
Vomiting	1

SELAMECTIN

Feline

Number of reports	Probable	Possible
24	20	4

Presenting Signs	Number of reports
Agitation	1
Alopecia	20
Behavioural change	3
Depression	1
Dermatitis	7
Lethargy	1
Pruritis	1
Pyoderma	1
Self trauma	9
Site reaction	13
Vomiting	2

SELENIUM AS SODIUM SELENATE

Bovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Abortion	1
Injection site reaction	1
Lame	1

SELENIUM AS SODIUM SELENATE

Ovine

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Death	1
Dyspnoea	1
Frothing at the mouth	1
Lack of effect	1
Muscle twitching	1
Spasm	1

SHARK CARTILAGE

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Diarrhoea	1
Vomiting	1

SODIUM CALCIUM EDETATE

Canine

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Diarrhoea	1
Vomiting	2

SODIUM PENTOSAN POLYSULFATE

Canine

Number of reports	Probable	Possible
7	4	3

Presenting Signs	Number of reports
Behavioural change	1
Depression	1
Lame	1
Pain	1
Pale mucous membranes	1
Sedation	1
Tachycardia	1
Urticaria	1
Vomiting	5

SODIUM PENTOSAN POLYSULFATE

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Agitation	1
Rolling	1
Rubbing	1
Urticaria	1

SODIUM PENTOSAN POLYSULFATE

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Vomiting	1

SODIUM SALICYLATE

Equine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Ataxia	1
Cardiac arrest	1
Collapse	2
Death	1
Dyspnoea	1
Pale mucous membranes	1
Respiratory problems	1
Rolling	1
Seizure	1
Shaking	1
Somnolence	1
Sweating	1
Tachycardia	1

SPINOSAD

Ovine

Number of reports	Probable	Possible
17	0	17

Presenting Signs	Number of reports
Death	1
Lack of effect	17

STABILISED GREEN-LIPPED MUSSEL POWDER

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Diarrhoea	1
Vomiting	1

STREPTOCOCCUS EQUI

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lymphadenopathy	1

STREPTOCOCCUS EQUI AS CELL FREE EXTRACT

Equine

Number of reports	Probable	Possible
4	2	2

Presenting Signs	Number of reports
Anorexia	1
Injection site reaction	4

SULFACETAMIDE SODIUM

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Irritation (eye)	1

SULFADIAZINE

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Collapse	1

SULFADIMIDINE AS SODIUM ETHANE SULPHONATE SALT

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Collapse	1
Hypersalivation	1
Lethargy	1
Pale mucous membranes	1
Recumbency	1
Shaking	1

TEPOXALIN

Canine

Number of reports	Probable	Possible
5	2	3

Presenting Signs	Number of reports
Abdominal pain	2
Diarrhoea	1
Melaena	2
Vomiting	2

THIOMERSAL

Canine

Number of reports	Probable	Possible
3	3	0

Presenting Signs	Number of reports
Collapse	1
Depression	1
Facial oedema	2
Pale mucous membranes	1
Periorbital swelling	2
Pruritis	1
Respiratory problems	1
Swelling (local)	1
Vomiting	2

TITANIUM DIOXIDE

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Alopecia	1
Dermatitis	1
Erythema	1

TRENBOLONE ACETATE

Bovine

Number of reports	Probable	Possible
6	6	0

Presenting Signs	Number of reports
Pizzle drop	1
Preputial prolapse	6

TRICHLORFON

Other

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Behavioural change	1
Respiratory problems	1

TRICLABENDAZOLE

Bovine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Abortion	1
Death	1
Lack of effect	1
Recumbency	1

TRIFLUMURON

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1

TRIMETHOPRIM

Equine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Collapse	2
Hypersalivation	1
Lethargy	1
Pale mucous membranes	1
Recumbency	1
Shaking	1

VITAMIN B12

(Registered Name: VITAMIN B12 = CYANOCOBALAMIN)

Bovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Abortion	1
Injection site reaction	1
Lame	1

(Registered Name: VITAMIN B12 = CYANOCOBALAMIN)

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

(Registered Name: VITAMIN B12A = HYDROXOCOBALAMIN)

Bovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Abortion	1
Injection site reaction	1
Lame	1

VITAMIN B2 = RIBOFLAVIN

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

VITAMIN B3 = NICOTINAMIDE

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

VITAMIN B6 HYDROCHLORIDE = PYRIDOXINE HYDROCHLORIDE

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

XYLAZINE AS THE HYDROCHLORIDE

Canine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Apnoea	1
Collapse	1
Death	1
Vomiting	1

ZETA-CYPERMETHRIN

Bovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Alopecia	1
Erythema	1
Swelling (local)	1

ZINC OXIDE

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Alopecia	1
Dermatitis	1
Erythema	1

3. SECTION 2

3.1 A summary of adverse experience reports in 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 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.

DIAZINON

Human

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Colic	1
Pancreatitis	1

DIMETHYL AZELATE

Human

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Nausea	1

DIMETHYL PIMELATE

Human

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Nausea	1

METHYL OLEATE

Human

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Nausea	1

METHYL PALMITATE

Human

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Nausea	1

PIPERONYL BUTOXIDE

Human

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Rash	1

PYRETHRINS

Human

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Rash	1

4. 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 agent	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 which 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 from the treatment of an animal before the animal or its products can be used for human food