

**REPORT OF ADVERSE  
EXPERIENCES  
2003 CALENDAR YEAR**

**July 2004**

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## EXECUTIVE SUMMARY

The last two years have seen numerous changes and improvements to the operation of the Adverse Experience Reporting Program (AERP). These improvements have been very effective in enabling the APVMA to more quickly and accurately identify issues involving veterinary medicines that require corrective action to minimise future adverse experiences from occurring.

When the program began in 1995 it focussed mainly on veterinary medicines, and in 2002 it was renamed the 'AERP for veterinary medicines' (AERP *Vet*). In December 2003 a new program was introduced for agricultural chemicals and this is called the 'AERP for agricultural chemicals' (AERP *Ag*). These post-registration quality assurance programs 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. Prior to 1995, the Australian Veterinary Association operated a non-regulatory pharmacovigilance program.

This Annual Report contains a summary of all adverse experience reports assessed, evaluated and classified by the APVMA during the 2003 Calendar Year. It is important to note that some reports relate to previous years, but because the APVMA only received them in late 2002 or 2003 and they were classified in 2003, they are included in this report for completeness.

Throughout the 2003 calendar year changes were made to thirty-seven products. This represents a substantial increase in the number of corrective actions taken compared to previous years. For example in the 2002 calendar year changes were made to twenty-one products. The reason for this increase is primarily due to the more efficient operational aspects of the program resulting in better assessments of adverse experience reports and more targeted outcomes.

These changes include:

- additional warning, precautionary or restraint statements placed on twenty-five product labels,
- additional instructions placed on four product labels,
- changes to First Aid Instructions and Safety Directions for seven products, and
- a recall of one product.

More information is provided on each 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 available from veterinarians, the AVA, the APVMA or on the APVMA Website at <http://www.apvma.gov.au/forms/KP81F03.rtf>, or via the online reporting system at <https://services.apvma.gov.au/AerpWebApp>.

### 1.5 Evaluation of adverse experience reports

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 (ie ‘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 (ie 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<sup>1</sup>. This report also recommends that if the reporting incidence is greater than one per 10,000 in two out of three consecutive years or an exceptional incidence of three 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 (ie 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;
- 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:

- associating clinical signs with a particular product or active constituent,
- assessing the safety and efficacy of a product or active constituent,

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

- 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 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.
- 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 in the following summaries of adverse experience reports that in one report a number of different clinical signs may have been observed. 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.

**ABAMECTIN****Equine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Lack of effect	2
Colic	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**ALPHA-CYPERMETHRIN****Ovine**

Number of reports	Probable	Possible
11	0	11

Presenting Signs	Number of reports
Lack of effect	11
Rubbing	1

Based on assessment of adverse experience reports for alpha-cypermethrin, the APVMA (in conjunction with its official governmental advisory agencies) is re-considering the First Aid Instructions and Safety Directions for these products.

**ALPHADOLONE****Feline**

Number of reports	Probable	Possible
13	1	12

Presenting Signs	Number of reports
Death	4
Respiratory problems	3
Swollen feet	2
Coughing	2
Slow recovery	2
Dyspnoea	1
Injection site reaction	1
Anaesthesia (deep)	1
Seizure	1
Anaesthesia (long)	1
Rales	1
Blindness	1
Swelling (local)	1
Blisters	1
Facial oedema	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.

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**ALPHAXALONE****Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Death	2
Cardiac Arrest	2

**ALPHAXALONE****Feline**

Number of reports	Probable	Possible
34	11	23

Presenting Signs	Number of reports
Death	8
Injection site reaction	6
Respiratory problems	6
Pain	5
Coughing	4
Facial oedema	3
Swelling (local)	2
Rales	2
Slow recovery	2
Swollen feet	2
Dyspnoea	1
Pulmonary oedema	1
Blisters	1
Disorientation	1
Recovery (poor)	1
Cardiac Arrest	1
Blindness	1
Laryngospasm	1
Ataxia	1
Paddling	1
Bronchial secretion	1
Seizure	1

Anaesthesia (long)	1
Anaesthesia (deep)	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.

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

### **AMITRAZ**

#### **Bovine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Lethargy	1
Lack of effect	1
Recumbency	1
Panting	1
Ataxia	1

An additional precautionary statement was included on labels for amitraz products for cattle to warn users not to treat animals in extremely hot weather (>40°C) or if under heat stress, and to ensure that adequate shade is available post-treatment. Since this change was made no further reports have been received where animals have been treated under extreme conditions.

### **AMITRAZ**

#### **Canine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Lack of effect	3

An additional precautionary statement was included on labels for amitraz products for dogs to warn users not to treat dogs under heat stress. Since this change was made no further reports have been received where dogs suffering heat stress were treated.

**AMOXYCILLIN AS AMOXYCILLIN TRIHYDRATE****Unknown**

Number of reports	Probable	Possible
5	5	0

Presenting Signs	Number of reports
Injection site reaction	5

**AMOXYCILLIN AS AMOXYCILLIN TRIHYDRATE****Canine**

Number of reports	Probable	Possible
26	24	2

Presenting Signs	Number of reports
Injection site reaction	24
Melaena	1
Thrombocytopenia	1
Depression	1
Hyperactivity	1
Ocular damage	1
Death	1
Haemorrhage	1

**AMOXYCILLIN AS AMOXYCILLIN TRIHYDRATE****Feline**

Number of reports	Probable	Possible
10	9	1

Presenting Signs	Number of reports
Injection site reaction	9
Death	1
Anaphylaxis	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**BENAZEPRIL HYDROCHLORIDE****Canine**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Dermatitis	2
Alopecia	2
Polydipsia	1
Vomiting	1
Anorexia	1

**BENAZEPRIL HYDROCHLORIDE****Feline**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Lethargy	2
Depression	1
Anorexia	1
Dehydration	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**BETAMETHASONE****Canine**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Deafness	2
Pain	1
Distress	1
Inflammation	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**BORDETELLA BRONCHISEPTICA****Canine**

Number of reports	Probable	Possible
15	5	10

Presenting Signs	Number of reports
Coughing	9
Respiratory problems	4
Swelling (local)	2
Pyrexia	2
Injection site reaction	2
Frothing at the mouth	1
Pharyngitis	1
Depression	1
Anorexia	1
Oedema	1
Distress	1
Collapse	1
Sore throat	1
Inflammation	1
Sneezing	1
Bradycardia	1

**BORDETELLA BRONCHISEPTICA (KILLED)****Canine**

Number of reports	Probable	Possible
17	4	13

Presenting Signs	Number of reports
Facial oedema	7
Swelling (local)	3
Vomiting	3
Respiratory problems	2
Urticaria	2
Pruritis	2
Injection site reaction	2
Swollen lips and face	2
Hives	2
Pale mucous membranes	1
Death	1
Ataxia	1
Lethargy	1
Shock	1
Collapse	1
Oedema	1
Tachycardia	1
Erythema	1
Cyanosis	1
Blepharitis	1
Periorbital swelling	1
Pain	1
Bradycardia	1

**BORDETELLA BRONCHISEPTICA (INACTIVATED)****Canine**

Number of reports	Probable	Possible
85	45	40

Presenting Signs	Number of reports
Facial oedema	44
Urticaria	23
Vomiting	11
Pale mucous membranes	9
Injection site reaction	8
Collapse	8
Swelling (local)	8
Depression	7
Diarrhoea	6
Lethargy	5
Swollen feet	4
Pruritis	4
Pain	3
Weakness	3
Tachycardia	2
Rubbing	2
Pyrexia	2
Hypersensitivity reaction	2
Periorbital swelling	2
Hives	2
Death	2
Inflammation	2
Swollen lips and face	2
Hypersalivation	1
Ocular pathology	1
Shock	1
Welts	1
Pawing at ground	1
Hypothermia	1
Gastroenteritis	1
Coughing	1
Sedation	1
Anaphylactoid reaction	1

Rectal prolapse	1
Tachypnoea	1
Anaphylaxis	1
Shaking	1
Paddling	1
Anorexia	1
Lack of effect	1
Hyperexcitable	1
Dyspnoea	1
Pupillary dilation	1
Respiratory problems	1
Agitation	1
Wheals	1
Listless	1

There are numerous vaccines that contain *Bordetella bronchiseptica* virus 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 very 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.

**BROMHEXINE HYDROCHLORIDE****Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Swelling (local)	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**BUTORPHANOL TARTRATE****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1
Renal failure	1
Haematemesis	1
Weakness	1

**BUTORPHANOL TARTRATE****Feline**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Death	2
Anaphylaxis	1
Seizure	1
Dyspnoea	1
Tachycardia	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CALCIUM GLUCONATE****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Haematuria	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CAMPYLOBACTER FELIS (VIBRO FETUS) VENEREALIS BIOTYPE 1****Bovine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Injection site reaction	2

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CANINE ADENO VIRUS TYPE 2****Canine**

Number of reports	Probable	Possible
29	11	18

Presenting Signs	Number of reports
Coughing	7
Diarrhoea	7
Vomiting	6
Depression	6
Lethargy	5
Facial oedema	4
Urticaria	4
Respiratory problems	4
Injection site reaction	3
Collapse	3
Swelling (local)	3
Anorexia	2
Hypersensitivity reaction	2
Pale mucous membranes	2
Hypothermia	2
Distress	1
Hives	1
Rubbing	1
Haematuria	1
Thrombocytopenia	1
Pruritis	1
Listless	1
Agitation	1
Gastroenteritis	1
Haemorrhage	1
Sedation	1
Wheals	1
Sneezing	1
Rectal prolapse	1
Bradycardia	1
Pharyngitis	1
Frothing at the mouth	1
Sore throat	1

Anaphylaxis	1
Pain	1
Welts	1
Pyrexia	1
Tachycardia	1
Dyspnoea	1

**CANINE ADENO VIRUS TYPE 2****Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Swelling (local)	1

**CANINE ADENOVIRUS TYPE 2****Canine**

Number of reports	Probable	Possible
32	6	26

Presenting Signs	Number of reports
Vomiting	8
Lethargy	6
Pruritis	6
Diarrhoea	5
Depression	4
Collapse	4
Swelling (local)	4
Facial oedema	4
Pyrexia	3
Weakness	3
Death	3
Anorexia	3
Hives	3
Ataxia	3
Pale mucous membranes	3
Injection site reaction	2

Hypersalivation	2
Malaise	2
Anaemia	2
Tachycardia	2
Nystagmus	1
Blepharitis	1
Lack of effect	1
Prolapse third eyelid	1
Polydipsia	1
Uveitis	1
Welts	1
Corneal oedema	1
Pain	1
Conjunctivitis	1
Seizure	1
Swollen lips and face	1
Cardiac Arrest	1
Agitation	1
Parvovirus	1
Urticaria	1
Stiffness	1
Pupillary dilation	1
Corneal ulcer	1
Blepharospasm	1
Walking - difficult	1
Tremor	1
Haematemesis	1
Dyspnoea	1
Incoordination	1
Nasal discharge	1
Shaking	1
Haematuria	1
Panting	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.

Due to the very 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 CORONAVIRUS VACCINE - ANTIGEN****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Rectal prolapse	1
Vomiting	1
Diarrhoea	1
Facial oedema	1
Swelling (local)	1
Lethargy	1
Listless	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CANINE DISTEMPER VIRUS****Canine**

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Lethargy	2
Weight loss	1
Tachycardia	1
Thrombocytopenia	1
Diarrhoea	1
Haematuria	1
Vomiting	1
Injection site reaction	1
Haemorrhage	1
Hypothermia	1
Malaise	1

**CANINE DISTEMPER VIRUS****Canine**

Number of reports	Probable	Possible
34	6	28

Presenting Signs	Number of reports
Vomiting	8
Lethargy	7
Pruritis	7
Diarrhoea	5
Facial oedema	5
Anorexia	4
Depression	4
Hives	4
Swelling (local)	4
Collapse	4
Pyrexia	3
Ataxia	3
Death	3
Weakness	3
Pale mucous membranes	3
Injection site reaction	2
Tachycardia	2
Malaise	2
Hypersalivation	2
Anaemia	2
Haematemesis	1
Uveitis	1
Parvovirus	1
Panting	1
Nasal discharge	1
Swollen lips and face	1
Stiffness	1
Blepharitis	1
Agitation	1
Walking - difficult	1
Blepharospasm	1
Pupillary dilation	1
Prolapse third eyelid	1

Seizure	1
Urticaria	1
Corneal ulcer	1
Polydipsia	1
Haematuria	1
Corneal oedema	1
Nystagmus	1
Dyspnoea	1
Pain	1
Incoordination	1
Shaking	1
Cardiac Arrest	1
Conjunctivitis	1
Tremor	1
Lack of effect	1
Welts	1

### **CANINE DISTEMPER VIRUS - LIVING**

#### **Canine**

Number of reports	Probable	Possible
17	9	8

Presenting Signs	Number of reports
Diarrhoea	6
Vomiting	5
Depression	5
Urticaria	4
Facial oedema	4
Lethargy	4
Swelling (local)	3
Collapse	3
Hypersensitivity reaction	2
Pale mucous membranes	2
Injection site reaction	2
Gastroenteritis	1
Agitation	1
Dyspnoea	1
Anorexia	1
Pruritis	1

Listless	1
Rubbing	1
Anaphylaxis	1
Bradycardia	1
Hypothermia	1
Wheals	1
Rectal prolapse	1
Sedation	1
Hives	1
Welts	1
Pain	1

### **CANINE DISTEMPER VIRUS**

#### **Canine**

Number of reports	Probable	Possible
2	1	1

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

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.

Due to the very 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 PARAINFLUENZA TYPE 2****Canine**

Number of reports	Probable	Possible
29	6	23

Presenting Signs	Number of reports
Vomiting	7
Lethargy	6
Pruritis	6
Swelling (local)	4
Diarrhoea	4
Collapse	4
Facial oedema	4
Pale mucous membranes	3
Pyrexia	3
Weakness	3
Depression	3
Hives	3
Anorexia	3
Tachycardia	2
Injection site reaction	2
Anaemia	2
Ataxia	2
Malaise	2
Death	2
Haematuria	1
Swollen lips and face	1
Polydipsia	1
Shaking	1
Cardiac Arrest	1
Panting	1
Parvovirus	1
Hypersalivation	1
Lack of effect	1
Tremor	1
Pupillary dilation	1
Pain	1
Haematemesis	1
Incoordination	1

Nasal discharge	1
Welts	1
Dyspnoea	1
Prolapse third eyelid	1
Agitation	1
Stiffness	1
Seizure	1
Walking - difficult	1
Blepharitis	1
Blepharospasm	1
Urticaria	1

### **CANINE PARAINFLUENZA VIRUS**

#### **Canine**

Number of reports	Probable	Possible
31	13	18

Presenting Signs	Number of reports
Coughing	7
Diarrhoea	6
Vomiting	5
Lethargy	5
Facial oedema	5
Depression	5
Swelling (local)	5
Urticaria	4
Injection site reaction	4
Respiratory problems	4
Anorexia	3
Pale mucous membranes	2
Pruritis	2
Hives	2
Hypersensitivity reaction	2
Collapse	2
Pyrexia	2
Anaphylaxis	1
Frothing at the mouth	1
Pharyngitis	1
Rectal prolapse	1

Weight loss	1
Malaise	1
Sneezing	1
Gastroenteritis	1
Sore throat	1
Wheals	1
Distress	1
Rubbing	1
Hypothermia	1
Listless	1
Agitation	1
Welts	1
Inflammation	1
Pain	1
Sedation	1
Dyspnoea	1

## **CANINE PARAINFLUENZA VIRUS TYPE 2**

### **Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Swelling (local)	1

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 very 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****Canine**

Number of reports	Probable	Possible
36	6	30

Presenting Signs	Number of reports
Vomiting	9
Lethargy	8
Pruritis	6
Diarrhoea	6
Depression	4
Swelling (local)	4
Collapse	4
Facial oedema	4
Malaise	3
Tachycardia	3
Pyrexia	3
Injection site reaction	3
Weakness	3
Anorexia	3
Pale mucous membranes	3
Death	3
Ataxia	3
Hives	3
Hypersalivation	2
Haematuria	2
Anaemia	2
Stiffness	1
Nasal discharge	1
Haemorrhage	1
Seizure	1
Cardiac Arrest	1
Parvovirus	1
Polydipsia	1
Corneal ulcer	1
Welts	1
Weight loss	1
Nystagmus	1
Panting	1

Swollen lips and face	1
Tremor	1
Dyspnoea	1
Thrombocytopenia	1
Shaking	1
Blepharitis	1
Prolapse third eyelid	1
Incoordination	1
Corneal oedema	1
Walking - difficult	1
Lack of effect	1
Pupillary dilation	1
Pain	1
Uveitis	1
Hypothermia	1
Agitation	1
Blepharospasm	1
Urticaria	1
Haematemesis	1
Conjunctivitis	1

### **CANINE PARVO VIRUS TYPE 2**

#### **Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Collapse	1
Depression	1
Bradycardia	1
Lethargy	1

**CANINE PARVO VIRUS TYPE 2****Canine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Death	1
Swelling (local)	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. Due to the very 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.

**CARPROFEN****Canine**

Number of reports	Probable	Possible
8	1	7

Presenting Signs	Number of reports
Vomiting	4
Hepatopathy	3
Depression	2
Thrombocytopenia	1
Haemorrhage	1
Death	1
Ocular damage	1
Oedema	1
Inflammation	1
Pain	1
Tremor	1
Anaemia	1
Melaena	1
Pyrexia	1
Anorexia	1
Jaundice	1

**CARPROFEN****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Anorexia	1
Death	1
Vomiting	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CEFTIOFUR AS CEFTIOFUR SODIUM****Equine**

Number of reports	Probable	Possible
3	3	0

Presenting Signs	Number of reports
Diarrhoea	3
Pyrexia	2

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CEPHALEXIN****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Dehydration	1
Anorexia	1
Lethargy	1

**CEPHALEXIN****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Auto-immune haemolytic anaemia	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CETRIMIDE****Canine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Alopecia	2
Dermatitis	2

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CLAVULANIC ACID AS POTASSIUM CLAVULANATE****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Depression	1
Hyperactivity	1

**CLAVULANIC ACID AS POTASSIUM CLAVULANATE****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Anaphylaxis	1
Death	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CLINDAMYCIN HYDROCHLORIDE****Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Depression	1
Lethargy	1
Pustules	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CLOMIPRAMINE HYDROCHLORIDE****Canine**

Number of reports	Probable	Possible
7	3	4

Presenting Signs	Number of reports
Ataxia	2
Seizure	2
Death	1
Anorexia	1
Diarrhoea	1
Haematology (Abnormal)	1
Lethargy	1

**CLOMIPRAMINE HYDROCHLORIDE****Feline**

Number of reports	Probable	Possible
4	1	3

Presenting Signs	Number of reports
Circling	1
Head tilt	1
Sedation	1
Polydipsia	1
Constipation	1
Urinary retention	1
Tachycardia	1
Depression	1
Haematology (Abnormal)	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CLOPROSTENOL AS THE SODIUM SALT****Bovine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Lack of effect	3

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CLOSTRIDIUM BOTULINUM TYPE C TOXOID****Bovine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Injection site reaction	1
Lack of effect	1
Death	1

**CLOSTRIDIUM BOTULINUM TYPE D TOXOID****Bovine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Injection site reaction	1
Death	1
Lack of effect	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CLOSTRIDIUM CHAUVOEI - FORMOL CULTURE****Bovine**

Number of reports	Probable	Possible
9	6	3

Presenting Signs	Number of reports
Death	3
Recumbency	3
Hypersalivation	3
Lack of effect	2
Injection site reaction	2
Periorbital swelling	2
Blackleg	2
Swelling (local)	2
Wheals	1
Dyspnoea	1
Agitation	1
Facial oedema	1

**CLOSTRIDIUM CHAUVOEI - FORMOL CULTURE****Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Respiratory problems	1
Cyanosis	1

**CLOSTRIDIUM CHAUVOEI - KILLED****Bovine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Injection site reaction	3
Death	2
Stiffness	1

**CLOSTRIDIUM CHAUVOEI - TOXOID****Bovine**

Number of reports	Probable	Possible
5	0	5

Presenting Signs	Number of reports
Injection site reaction	4
Death	2
Stiffness	1
Swelling (local)	1
Lack of effect	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CLOSTRIDIUM NOVYI TYPE B****Bovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Swelling (local)	1
Injection site reaction	1

**CLOSTRIDIUM NOVYI TYPE B - KILLED****Bovine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Injection site reaction	3
Death	2
Stiffness	1

**CLOSTRIDIUM NOVYI TYPE B - TOXOID****Bovine**

Number of reports	Probable	Possible
13	6	7

Presenting Signs	Number of reports
Death	5
Injection site reaction	5
Lack of effect	3
Recumbency	3
Hypersalivation	3
Periorbital swelling	2
Blackleg	2
Swelling (local)	2
Agitation	1
Wheals	1
Stiffness	1
Dyspnoea	1
Facial oedema	1

**CLOSTRIDIUM NOVYI TYPE B - TOXOID****Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Cyanosis	1
Respiratory problems	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CLOSTRIDIUM PERFRINGENS TYPE D TOXOID****Bovine**

Number of reports	Probable	Possible
14	6	8

Presenting Signs	Number of reports
Injection site reaction	6
Death	5
Swelling (local)	3
Recumbency	3
Lack of effect	3
Hypersalivation	3
Blackleg	2
Periorbital swelling	2
Agitation	1
Facial oedema	1
Stiffness	1
Dyspnoea	1
Wheals	1

**CLOSTRIDIUM PERFRINGENS TYPE D TOXOID****Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Cyanosis	1
Respiratory problems	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CLOSTRIDIUM SEPTICUM - TOXOID****Bovine**

Number of reports	Probable	Possible
14	6	8

Presenting Signs	Number of reports
Injection site reaction	6
Death	5
Hypersalivation	3
Lack of effect	3
Recumbency	3
Swelling (local)	3
Periorbital swelling	2
Blackleg	2
Dyspnoea	1
Facial oedema	1
Agitation	1
Stiffness	1
Wheals	1

**CLOSTRIDIUM SEPTICUM - TOXOID****Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Cyanosis	1
Respiratory problems	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CLOSTRIDIUM TETANI - TOXOID****Bovine**

Number of reports	Probable	Possible
13	6	7

Presenting Signs	Number of reports
Injection site reaction	5
Death	5
Hypersalivation	3
Lack of effect	3
Recumbency	3
Swelling (local)	2
Blackleg	2
Periorbital swelling	2
Wheals	1
Dyspnoea	1
Agitation	1
Facial oedema	1
Stiffness	1

**CLOSTRIDIUM TETANI - TOXOID****Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Respiratory problems	1
Cyanosis	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CLOSTRIDIUM TETANI UF TOXOID****Equine**

Number of reports	Probable	Possible
8	0	8

Presenting Signs	Number of reports
Swelling (local)	3
Injection site reaction	3
Stiffness	3
Strangles	2
Lack of effect	2
Pain	2
Site Reaction	1
Anorexia	1
Oedema	1

**CLOSTRIDIUM TETANI UF TOXOID****Wildlife**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Site Reaction	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CLOTRIMAZOLE****Canine**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Deafness	2
Pain	1
Distress	1
Inflammation	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**COBALT****Ovine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Pharyngitis	1
Convulsions	1
Death	1

In response to adverse experience reports for ovine capsule products containing cobalt and other vitamins and minerals, an additional warning statement is to be included to warn users not to use excessive force in order to avoid trauma and damage to the throat of the animals.

**CONTAGIOUS PUSTULAR DERMATITIS VIRUS, LIVING****Ovine**

Number of reports	Probable	Possible
5	1	4

Presenting Signs	Number of reports
Lack of effect	2
Blisters	1
Scabby mouth	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CORONAVIRUS****Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Anorexia	1
Hives	1
Pruritis	1
Facial oedema	1
Lethargy	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CORYNEBACTERIUM PSEUDOTUBERCULOSIS (OVIS) - TOXOID****Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Cyanosis	1
Respiratory problems	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**COUMAPHOS****Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Coughing	1
Listless	1
Ocular damage	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**CYCLOSPORIN****Canine**

Number of reports	Probable	Possible
7	4	3

Presenting Signs	Number of reports
Lethargy	3
Collapse	2
Pale mucous membranes	2
Erythema	1
Somnolence	1
Pruritis	1
Rubbing	1
Panting	1
Alopecia	1
Hypersalivation	1
Recumbency	1
Tremor	1
Anorexia	1
Capillary refill time - slow	1
Weakness	1
Periorbital swelling	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**DELMADINONE ACETATE****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Polydipsia	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**DELTAMETHRIN****Bovine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Burning sensation	1
Lack of effect	1

**DELTAMETHRIN****Unknown**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Death	2

**DELTAMETHRIN****Ovine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Lack of effect	3

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**DEXAMETHASONE PHENPROPIONATE****Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Depression	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**DEXPANTHENOL****Rabbit**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1
Seizure	1
Death	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**DI-ISOPROPYLAMINE DICHLOROACETATE****Rabbit**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1
Seizure	1
Death	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**DIAZINON****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**DIFLUBENZURON****Bovine**

Number of reports	Probable	Possible
8	0	8

Presenting Signs	Number of reports
Lack of effect	6
Alopecia	2

**DIFLUBENZURON****Ovine**

Number of reports	Probable	Possible
52	16	36

Presenting Signs	Number of reports
Lack of effect	51
Lesions	1
Skin slough	1
Site Reaction	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**DISODIC ADENOSINE MONOPHOSPHATE****Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Anorexia	1
Muscle twitching	1
Depression	1
Colic	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**DORAMECTIN****Bovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Excitation	1
Recumbency	1
Hyperactivity	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**DOXYCYCLINE MONOHYDRATE****Bovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Vomiting	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**ENROFLOXACIN****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Vomiting	1
Death	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**ENZOGENOL****Canine**

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Vomiting	3
Diarrhoea	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**ERYSIPELOTHRIX RHUSIOPATHIAE****Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Distress	1
Respiratory problems	1
Cyanosis	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**ESCHERICHIA COLI 987P PILUS ANTIGENS****Porcine**

Number of reports	Probable	Possible
4	2	2

Presenting Signs	Number of reports
Injection site reaction	4
Recumbency	1
Abortion	1
Abscess	1
Anorexia	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**ESCHERICHIA COLI K88AB PILUS ANTIGENS****Porcine**

Number of reports	Probable	Possible
4	2	2

Presenting Signs	Number of reports
Injection site reaction	4
Anorexia	1
Recumbency	1
Abortion	1
Abscess	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**ESCHERICHIA COLI K88AC PILUS ANTIGENS****Porcine**

Number of reports	Probable	Possible
4	2	2

Presenting Signs	Number of reports
Injection site reaction	4
Anorexia	1
Abscess	1
Abortion	1
Recumbency	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**ESCHERICHIA COLI K99 PILUS ANTIGENS****Porcine**

Number of reports	Probable	Possible
4	2	2

Presenting Signs	Number of reports
Injection site reaction	4
Recumbency	1
Abortion	1
Anorexia	1
Abscess	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**ETODOLAC****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Dry eye	1
Corneal ulcer	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**FEBANTEL****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**FELINE CALICIVIRUS - INACTIVATED****Feline**

Number of reports	Probable	Possible
83	58	25

Presenting Signs	Number of reports
Lethargy	47
Anorexia	41
Pyrexia	41
Depression	20
Pain	18
Injection site reaction	18
Behavioural change	4
Alopecia	4
Ataxia	4
Malaise	2
Hyperaesthesia	2
Site Reaction	2
Pruritis	2
Dehydration	2
Tachycardia	2
Vocalisation	2
Fibrosarcoma	2
Vomiting	2
Recumbency	2
Weakness	1
Blisters	1
Prolapse third eyelid	1
Dyspnoea	1
Distress	1
Lame	1
Cyanosis	1
Panting	1
Erythema	1
Ulceration	1
Agitation	1
Anaphylaxis	1
Listless	1
Illness	1

Inflammation	1
Diarrhoea	1
Swelling (local)	1
Unknown	1
Cat flu	1

**FELINE CALICIVIRUS - LIVE****Feline**

Number of reports	Probable	Possible
7	2	5

Presenting Signs	Number of reports
Fibrosarcoma	2
Lethargy	2
Anorexia	2
Behavioural change	1
Pyrexia	1
Recumbency	1
Vomiting	1
Injection site reaction	1
Death	1
Anaphylaxis	1
Nasal discharge	1

**FELINE CALICIVIRUS****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Fibrosarcoma	1

**FELINE CALICIVIRUS****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Fibrosarcoma	1

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. Due to the very low number of reports when 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
37	29	8

Presenting Signs	Number of reports
Lethargy	20
Anorexia	17
Pyrexia	16
Injection site reaction	8
Depression	8
Pain	7
Behavioural change	3
Vomiting	2
Vocalisation	2
Ataxia	2
Dehydration	2
Dyspnoea	1
Hyperaesthesia	1
Listless	1
Erythema	1
Tachycardia	1
Malaise	1
Alopecia	1
Fibrosarcoma	1
Cyanosis	1
Unknown	1
Panting	1
Pruritis	1
Ulceration	1
Blisters	1
Recumbency	1
Diarrhoea	1

The most frequently reported side effects, such as lethargy, anorexia and pyrexia occur fairly commonly with many feline vaccines. Due to the very low number of reports when 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 HERPES VIRUS****Feline**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Death	1
Lethargy	1
Pyrexia	1
Anaphylaxis	1
Vomiting	1
Anorexia	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**FELINE LEUKAEMIA VIRUS - INACTIVATED****Feline**

Number of reports	Probable	Possible
8	7	1

Presenting Signs	Number of reports
Lethargy	4
Pyrexia	4
Injection site reaction	3
Pain	1
Erythema	1
Anorexia	1
Pruritis	1
Hyperaesthesia	1
Depression	1
Alopecia	1
Vocalisation	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**FELINE PANLEUCOPENIA VIRUS - INACTIVATED****Feline**

Number of reports	Probable	Possible
83	58	25

Presenting Signs	Number of reports
Lethargy	47
Pyrexia	41
Anorexia	41
Depression	20
Pain	18
Injection site reaction	18
Behavioural change	4
Ataxia	4
Alopecia	4
Site Reaction	2
Hyperaesthesia	2
Fibrosarcoma	2
Vomiting	2
Malaise	2
Dehydration	2
Vocalisation	2
Pruritis	2
Tachycardia	2
Recumbency	2
Inflammation	1
Panting	1
Erythema	1
Cyanosis	1
Anaphylaxis	1
Ulceration	1
Weakness	1
Agitation	1
Listless	1
Distress	1
Cat flu	1
Prolapse third eyelid	1
Dyspnoea	1
Blisters	1

Lame	1
Illness	1
Diarrhoea	1
Swelling (local)	1

### **FELINE PANLEUCOPENIA VIRUS - LIVE**

#### **Feline**

Number of reports	Probable	Possible
7	2	5

Presenting Signs	Number of reports
Lethargy	2
Fibrosarcoma	2
Anorexia	2
Death	1
Nasal discharge	1
Injection site reaction	1
Behavioural change	1
Recumbency	1
Vomiting	1
Pyrexia	1
Anaphylaxis	1

**FELINE PANLEUCOPENIA VIRUS****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Fibrosarcoma	1

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. Due to the very low number of reports when 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****Feline**

Number of reports	Probable	Possible
5	2	3

Presenting Signs	Number of reports
Fibrosarcoma	2
Injection site reaction	1
Recumbency	1
Nasal discharge	1
Behavioural change	1
Anorexia	1
Lethargy	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**FELINE RHINOTRACHEITIS VIRUS - INACTIVATED****Feline**

Number of reports	Probable	Possible
83	58	25

Presenting Signs	Number of reports
Lethargy	47
Pyrexia	41
Anorexia	41
Depression	20
Pain	18
Injection site reaction	18
Ataxia	4
Behavioural change	4
Alopecia	4
Dehydration	2
Tachycardia	2
Malaise	2
Vomiting	2
Recumbency	2
Site Reaction	2
Vocalisation	2
Fibrosarcoma	2
Pruritis	2
Hyperaesthesia	2
Agitation	1
Distress	1
Blisters	1
Diarrhoea	1
Listless	1
Ulceration	1
Dyspnoea	1
Cyanosis	1
Inflammation	1
Cat flu	1
Unknown	1
Swelling (local)	1
Illness	1
Panting	1

Anaphylaxis	1
Erythema	1
Prolapse third eyelid	1
Weakness	1
Lame	1

### **FELINE RHINOTRACHEITIS VIRUS**

#### **Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Fibrosarcoma	1

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. Due to the very low number of reports when 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.

### **FENTHION**

#### **Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Site Reaction	1
Ulceration	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**FLUMETHRIN****Bovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Listless	1
Diarrhoea	1
Non-ambulatory	1

**FLUMETHRIN****Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Respiratory problems	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**FRUSEMIDE****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Polydipsia	1
Anorexia	1
Vomiting	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**GENTAMICIN****Canine**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Deafness	2
Inflammation	1
Distress	1
Pain	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**GNRF - PROTEIN CONJUGATE****Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**GONADOTROPHIN-CHORIONIC****Unknown**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**HALOTHANE****Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Ataxia	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**HEPATITIS CANINE = CANINE ADENOVIRUS****Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Hives	1
Pruritis	1
Anorexia	1
Lethargy	1
Facial oedema	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**HEPTAMINOL HYDROCHLORIDE****Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Colic	1
Muscle twitching	1
Depression	1
Anorexia	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**HERPES VIRUS OF TURKEYS (HVT)****Avian**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Marek's Disease	1
Lack of effect	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**HYDROCORTISONE AS THE ACETATE****Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Vomiting	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**HYDROXYPROGESTERONE HEXANOATE****Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**HYOSCINE HYDROBROMIDE****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Haematuria	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**IMIDACLOPRID****Canine**

Number of reports	Probable	Possible
42	17	25

Presenting Signs	Number of reports
Site Reaction	14
Alopecia	8
Irritation (skin)	8
Pruritis	4
Agitation	3
Erythema	3
Hives	2
Lethargy	2
Rash	2
Property damage (minor)	2
Behavioural change	2
Restless	2
Hyperexcitable	2
Shaking	2
Coat colour change	2
Vomiting	1
Inflammation	1
Diarrhoea	1
Depression	1
Paralysis	1
Blisters	1
Scabs	1
Frothing at the mouth	1
Anorexia	1
Aggression	1
Somnolence	1
Hypersalivation	1
Panting	1
Dermatitis	1
Odour	1
Distress	1
Periorbital swelling	1

**IMIDACLOPRID****Feline**

Number of reports	Probable	Possible
32	18	14

Presenting Signs	Number of reports
Site Reaction	9
Alopecia	9
Irritation (skin)	7
Lethargy	4
Hypersalivation	4
Frothing at the mouth	4
Vomiting	4
Behavioural change	2
Coat colour change	2
Ataxia	1
Illness	1
Agitation	1
Anorexia	1
Weakness	1
Diarrhoea	1
Hyperexcitable	1
Pruritis	1
Erythema	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**INACTIVATED RABBIT CALICIVIRUS DISEASE VIRUS****Rabbit**

Number of reports	Probable	Possible
13	9	4

Presenting Signs	Number of reports
Injection site reaction	6
Skin slough	4
Death	4
Lethargy	3
Seizure	1
Lack of effect	1
Anorexia	1
Pale mucous membranes	1
Lame	1
Malaise	1
Scabs	1
Swelling (local)	1
Alopecia	1
Self trauma	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**INACTIVATED SALMONELLA DUBLIN & TYPHIMURIUM ANTIGENS****Bovine**

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Lack of effect	2
Death	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**INSULIN****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**IODINE****Ovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Pharyngitis	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**ISOFLURANE****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Anaesthesia (long)	1
Bradycardia	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**IVERMECTIN****Bovine**

Number of reports	Probable	Possible
4	1	3

Presenting Signs	Number of reports
Lack of effect	3
Alopecia	1

**IVERMECTIN****Canine**

Number of reports	Probable	Possible
9	4	5

Presenting Signs	Number of reports
Vomiting	4
Diarrhoea	4
Lethargy	3
Malaise	1
Incontinence	1
Collapse	1
Depression	1
Frothing at the mouth	1

**IVERMECTIN****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Vomiting	1
Lethargy	1
Rectal prolapse	1
Diarrhoea	1
Depression	1

**IVERMECTIN****Ovine**

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Death	2
Lack of effect	2

After assessment of adverse experience reports involving human health issues for pour-on products containing ivermectin and consideration of the known moderate eye and skin irritancy potential of these products additional First Aid Instructions and Safety Directions were included on these product labels.

**IXODES HOLOCYCLUS (PARALYSIS TICK) ANTISERUM****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Facial oedema	1
Periorbital swelling	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**KETAMINE HYDROCHLORIDE****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1
Cardiac Arrest	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**LEPTOSPIRA BORGPETERSENI SEROVAR HARDJO****Bovine**

Number of reports	Probable	Possible
9	6	3

Presenting Signs	Number of reports
Death	3
Hypersalivation	3
Recumbency	3
Lack of effect	3
Periorbital swelling	2
Blackleg	2
Agitation	1
Dyspnoea	1
Injection site reaction	1
Wheals	1
Facial oedema	1
Swelling (local)	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**LEPTOSPIRA ICTEROHAEMORRHAGIAE ANTIGEN****Canine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Facial oedema	2
Lethargy	2
Swelling (local)	1
Anorexia	1
Rectal prolapse	1
Hives	1
Vomiting	1
Diarrhoea	1
Listless	1
Pruritis	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**LEPTOSPIRA INTERROGANS SEROVAR POMONA****Bovine**

Number of reports	Probable	Possible
9	6	3

Presenting Signs	Number of reports
Lack of effect	3
Recumbency	3
Hypersalivation	3
Death	3
Periorbital swelling	2
Blackleg	2
Agitation	1
Wheals	1
Facial oedema	1
Dyspnoea	1
Swelling (local)	1
Injection site reaction	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**LEVAMISOLE****Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Ataxia	1
Vomiting	1
Diarrhoea	1

**LEVAMISOLE****Feline**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Vomiting	1

**LEVAMISOLE****Ovine**

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Death	2
Convulsions	1
Pharyngitis	1
Recumbency	1

As a result of assessment of adverse experience reports for these products in previous years, appropriate label changes were recommended to ensure that yarding animals overnight without feed or water prior to drenching did not occur. It is recognised that cattle and sheep that are under stress or that are dehydrated may be more susceptible to levamisole toxicity therefore these label changes were deemed necessary. As can be seen from the lower number of reports in 2003 the label changes are already assisting in minimising adverse experiences.

**LIGNOCAINE HYDROCHLORIDE****Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Vomiting	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**LUFENURON****Canine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Vomiting	2
Diarrhoea	2

**LUFENURON****Feline**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Hyperaesthesia	1
Aggression	1
Anorexia	1
Lethargy	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**M. HYOPNEUMONIAE - INACTIVATED****Porcine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Dyspnoea	1
Death	1
Anaphylaxis	1
Tremor	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**MAGNESIUM SULFATE****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Haematuria	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**MAGNESIUM ASPARTATE****Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Depression	1
Muscle twitching	1
Colic	1
Anorexia	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**MALDISON****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Behavioural change	1
Conjunctivitis	1
Corneal oedema	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**MEASLES VIRUS****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**MEDETOMODINE HYDROCHLORIDE****Canine**

Number of reports	Probable	Possible
5	1	4

Presenting Signs	Number of reports
Death	2
Haematuria	1
Facial oedema	1
Depression	1
Weakness	1
Haemorrhage	1
Injection site reaction	1
Renal failure	1
Pruritis	1
Cardiac Arrest	1
Swelling (local)	1
Lethargy	1
Diarrhoea	1
Pyrexia	1
Lame	1
Haematemesis	1

**MEDETOMODINE HYDROCHLORIDE****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Hyperexcitable	1
Panting	1
Agitation	1
Weakness	1
Unconscious	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**MEGESTROL ACETATE****Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Lack of effect	1
Diabetes	1

**MEGESTROL ACETATE****Feline**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Diabetes	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**MELARSOMINE DIHYDROCHLORIDE****Canine**

Number of reports	Probable	Possible
7	3	4

Presenting Signs	Number of reports
Injection site reaction	5
Swelling (local)	5
Pain	2
Haematuria	1
Lack of effect	1
Lame	1
Respiratory problems	1
Death	1
Depression	1
Lethargy	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**METHADONE HCL****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Anaesthesia (long)	1
Bradycardia	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**MILBEMYCIN OXIME****Canine**

Number of reports	Probable	Possible
4	2	2

Presenting Signs	Number of reports
Diarrhoea	3
Vomiting	2
Anorexia	1
Lethargy	1
Lack of effect	1
Illness	1
Melaena	1

**MILBEMYCIN OXIME****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Anorexia	1
Lethargy	1
Weakness	1
Non-ambulatory	1
Depression	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**MONENSIN****Bovine**

Number of reports	Probable	Possible
7	3	4

Presenting Signs	Number of reports
Death	6
Lack of effect	2
Bloat	2
Coughing	1
Ataxia	1
Lethargy	1
Hypersalivation	1
Depression	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**MOXIDECTIN****Canine**

Number of reports	Probable	Possible
90	46	44

Presenting Signs	Number of reports
Vomiting	26
Injection site reaction	26
Facial oedema	17
Collapse	15
Pruritis	14
Lethargy	14
Pale mucous membranes	10
Urticaria	8
Anorexia	7
Shaking	5
Bradycardia	5
Erythema	5
Pyrexia	4
Ataxia	4
Agitation	4
Depression	4
Wheals	4
Weakness	4
Defecation	3
Tachycardia	3
Diarrhoea	3
Panting	3
Swollen lips and face	2
Death	2
Distress	2
Shock	2
Behavioural change	2
Cyanosis	2
Pain	2
Hives	2
Tachypnoea	2
Hypothermia	2
Anaemia	1

Convulsions	1
Urination	1
Dyspnoea	1
Lymphadenopathy	1
Periorbital swelling	1
Tremor	1
Recumbency	1
Haemorrhagic Gastroenteritis	1
Somnolence	1
Tonsillitis	1
Unconscious	1
Sedation	1
Abscess	1
Swelling (local)	1
Pupillary dilation	1
Rash	1
Polydipsia	1
Inflammation	1
Arthropathy	1
Oedema	1
Illness	1
Immune-mediated haemolytic anaemia	1
Hypersalivation	1
Malaise	1
Death	1

As a result of assessment of adverse experience reports in previous years a label change was recommended for these products to inform users that allergic-type reaction (such as vomiting and facial oedema) may occur.

Based on these low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**MYCOPLASMA HYOPNEUMONIDE****Porcine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Dyspnoea	1
CNS dysfunction	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE****Canine**

Number of reports	Probable	Possible
6	0	6

Presenting Signs	Number of reports
Lack of effect	3
Pruritis	2
Vomiting	1

**N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**NEOMYCIN SULFATE****Canine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Vomiting	1
Haematuria	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**NICLOSAMIDE****Canine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Vomiting	2
Diarrhoea	1
Oedema	1
Dermatitis	1
Ataxia	1
Anorexia	1
Conjunctivitis	1

**NICLOSAMIDE****Feline**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Vomiting	2

**NICLOSAMIDE****Feline**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Lethargy	1
Vomiting	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**NITENPYRAM****Feline**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Hyperexcitable	2
Dyspnoea	2
Excitation	2
Panting	2
Agitation	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**OESTRADIOL BENZOATE****Bovine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Pizzle drop	2

**OESTRADIOL BENZOATE****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Metritis	1

**OESTRADIOL BENZOATE****Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**ORBIFLOXACIN****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Erythema	1
Anorexia	1
Skin slough	1
Depression	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**OXANTEL EMBONATE****Canine**

Number of reports	Probable	Possible
5	2	3

Presenting Signs	Number of reports
Lack of effect	4
Vomiting	1
Diarrhoea	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**OXFENDAZOLE****Equine**

Number of reports	Probable	Possible
17	15	2

Presenting Signs	Number of reports
Mouth Burn	13
Colic	10
Anorexia	4
Blisters	1
Scouring	1

**OXFENDAZOLE****Ovine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Death	2
Illthrift	1
Convulsions	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**OXYTETRACYCLINE HYDROCHLORIDE****Canine**

Number of reports	Probable	Possible
1	0	1

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

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**PARVOVIRUS LIVE****Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Anorexia	1
Pruritis	1
Lethargy	1
Facial oedema	1
Hives	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**PECTIN****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Haematuria	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**PERMETHRIN (25:75::CIS:TRANS)****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Shaking	1
Paralysis	1

**PERMETHRIN (40:60::CIS:TRANS)****Canine**

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Lack of effect	2
Site Reaction	1

**PERMETHRIN (80:20::CIS:TRANS)****Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Coat colour change	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**PIPERONYL BUTOXIDE****Canine**

Number of reports	Probable	Possible
7	0	7

Presenting Signs	Number of reports
Lack of effect	3
Pruritis	3
Vomiting	1

**PIPERONYL BUTOXIDE****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**PORCINE PARVO VIRUS****Porcine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Lack of effect	3
Abortion	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**POTASSIUM CHLORIDE****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Haematuria	1

**POTASSIUM ASPARTATE****Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Colic	1
Muscle twitching	1
Depression	1
Anorexia	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**PRAZIQUANTEL****Canine**

Number of reports	Probable	Possible
6	2	4

Presenting Signs	Number of reports
Lack of effect	4
Death	1
Vomiting	1
Diarrhoea	1

**PRAZIQUANTEL****Equine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Lack of effect	2
Colic	1

**PRAZIQUANTEL****Feline**

Number of reports	Probable	Possible
8	1	7

Presenting Signs	Number of reports
Ataxia	6
Lethargy	3
Depression	2
Vomiting	1
Weakness	1
Anorexia	1
Non-ambulatory	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**PROCAINE PENICILLIN****Equine**

Number of reports	Probable	Possible
4	4	0

Presenting Signs	Number of reports
Agitation	3
Paddling	1
Anaphylactoid reaction	1
Tremor	1
Behavioural change	1
Collapse	1
Recumbency	1
Hyperaesthesia	1
Distress	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**PROGESTERONE****Bovine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Pizzle drop	2

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**PROPOFOL****Canine**

Number of reports	Probable	Possible
37	21	16

Presenting Signs	Number of reports
Facial oedema	8
Wheals	6
Erythema	5
Apnoea	4
Bradycardia	4
Periorbital swelling	4
Muscle twitching	3
Recovery (poor)	2
Swelling (local)	2
Opisthotonos	2
Excitation	2
Urticaria	2
Hypersensitive to noise	2
Recovery (prolonged)	2
Death	2
Induction (poor)	2
Listless	1
Ataxia	1
Cyanosis	1
Delayed Recovery	1
Hepatopathy	1
Hives	1
Depression	1
Hypersensitive to stimuli	1
Injected mucous membranes	1
Respiratory problems	1
Haemorrhage	1
Pawing at face	1
Pale mucous membranes	1
Injection site reaction	1
Anaesthesia (long)	1
Anaesthesia - unstable	1
Malaise	1
Cardiac Arrest	1

Cardiac arrhythmia	1
Welts	1
Vocalisation	1
Deafness	1
Defecation	1
Swollen feet	1
Pain	1
Vomiting	1
Shaking	1
Diarrhoea	1
Tremor	1

**PROPOFOL****Feline**

Number of reports	Probable	Possible
6	2	4

Presenting Signs	Number of reports
Pawing at face	2
Death	1
Defecation	1
Delayed Recovery	1
Facial oedema	1
Cardiac Arrest	1
Shaking	1
Swollen feet	1
Periorbital swelling	1
Apnoea	1
Dyspnoea	1
Hypersensitive to stimuli	1
Cardiac arrhythmia	1
Opisthotonos	1
Recovery (poor)	1
Vocalisation	1
Facial nerve paralysis	1
Respiratory problems	1

Assessment of adverse experience reports for a propofol anaesthetic revealed that transient swelling, urticaria and redness around the head, ventral abdomen or other body parts might be occasional side effects. The product label now includes a warning statement to inform veterinarians of these potential adverse effects.

**PYRANTEL EMBONATE****Canine**

Number of reports	Probable	Possible
9	2	7

Presenting Signs	Number of reports
Lack of effect	4
Vomiting	4
Diarrhoea	1
Death	1
Conjunctivitis	1
Oedema	1
Anorexia	1
Dermatitis	1
Vomiting	2
Lethargy	1
Nil	1

**PYRANTEL EMBONATE****Feline**

Number of reports	Probable	Possible
7	1	6

Presenting Signs	Number of reports
Ataxia	6
Lethargy	2
Depression	1
Vomiting	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**PYRETHRINS****Canine**

Number of reports	Probable	Possible
7	0	7

Presenting Signs	Number of reports
Lack of effect	3
Pruritis	3
Vomiting	1

**PYRETHRINS****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

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

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Anorexia	1
Lethargy	1
Pyrexia	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**SELAMECTIN****Canine**

Number of reports	Probable	Possible
21	9	12

Presenting Signs	Number of reports
Depression	6
Lethargy	5
Alopecia	4
Vomiting	3
Erythema	3
Site Reaction	3
Behavioural change	2
Anorexia	2
Ataxia	2
Pruritis	2
Agitation	2
Excitation	2
Rubbing	2
Self trauma	2
Irritation (skin)	2
Diarrhoea	1
Hyperactivity	1
Swelling (local)	1
Restless	1
Vocalisation	1
Tachycardia	1
Dermatitis	1
Panting	1
Pharyngitis	1

**SELAMECTIN****Feline**

Number of reports	Probable	Possible
18	9	9

Presenting Signs	Number of reports
Alopecia	6
Site Reaction	4
Dermatitis	3
Irritation (skin)	3
Lethargy	3
Vomiting	3
Diarrhoea	2
Depression	2
Excitation	2
Self trauma	2
Pyoderma	1
Renal failure	1
Mydriasis	1
Inflammation	1
Erythema	1
Hypersalivation	1
Dehydration	1
Vocalisation	1
Respiratory problems	1
Pruritis	1
Swelling (local)	1
Anorexia	1

A previous label change was made to selamectin products to warn users that occasional site reactions such as alopecia may occur.

Based on the continuing very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**SELENIUM****Ovine**

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Pharyngitis	1
Death	1
Cyanosis	1
Respiratory problems	1

In response to adverse experience reports for ovine capsule products containing selenium and other vitamins and minerals, an additional warning statement is to be included to warn users not to use excessive force in order to avoid trauma and damage to the throat of the animals.

**SODIUM CHLORIDE****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Haematuria	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**SODIUM SELENATE****Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Colic	1
Muscle twitching	1
Anorexia	1
Depression	1

**SODIUM SELENATE****Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Convulsions	1
Death	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**STREPTOCOCCUS EQUI****Equine**

Number of reports	Probable	Possible
11	1	10

Presenting Signs	Number of reports
Injection site reaction	3
Swelling (local)	3
Stiffness	3
Site Reaction	2
Urticaria	2
Pain	2
Lack of effect	2
Strangles	2
Oedema	1
Anorexia	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**STREPTOMYCIN SULFATE****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Haematuria	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**SULFADIAZINE****Canine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Hives	1
Haematuria	1
Pruritis	1
Pain	1
Recumbency	1
Skin slough	1

**SULFADIAZINE****Equine**

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Death	1
Collapse	1
Ataxia	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**SULFADIMIDINE****Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Haematuria	1

**SULFADIMIDINE****Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Swelling (local)	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**SULFADOXINE****Feline**

Number of reports	Probable	Possible
2	1	1

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

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**TEPOXALIN****Canine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Melaena	2
Vomiting	2
Haemorrhage	1
Diarrhoea	1
Haemoptysis	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**TETANUS = CLOSTRIDIUM TETANI****Bovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Swelling (local)	1
Injection site reaction	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**THIOMERSAL****Canine**

Number of reports	Probable	Possible
85	45	40

Presenting Signs	Number of reports
Facial oedema	44
Urticaria	23
Vomiting	11
Pale mucous membranes	9
Injection site reaction	8
Collapse	8
Swelling (local)	8
Depression	7
Diarrhoea	6
Lethargy	5
Swollen feet	4
Pruritis	4
Weakness	3
Pain	3
Swollen lips and face	2
Inflammation	2
Hypersensitivity reaction	2
Rubbing	2
Hives	2
Periorbital swelling	2
Death	2
Tachycardia	2
Pyrexia	2
Ocular pathology	1
Hyperexcitable	1
Shock	1
Welts	1
Hypersalivation	1
Pawing at ground	1
Anaphylactoid reaction	1
Hypothermia	1
Shaking	1
Tachypnoea	1

Anorexia	1
Coughing	1
Sedation	1
Respiratory problems	1
Listless	1
Dyspnoea	1
Lack of effect	1
Wheals	1
Anaphylaxis	1
Pupillary dilation	1
Rectal prolapse	1
Gastroenteritis	1
Paddling	1
Agitation	1

## **THIOMERSAL**

### **Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Cyanosis	1
Respiratory problems	1

Thiomersal is a component of many large and small animal vaccines and therefore is over-represented in this report. Assessment of each vaccine has been taken into account when assessing the safety of these products.

**THIOPENTONE SODIUM****Canine**

Number of reports	Probable	Possible
4	1	3

Presenting Signs	Number of reports
Ataxia	1
Death	1
Hyperaesthesia	1
Cardiac Arrest	1
Apnoea	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**TITANIUM DIOXIDE****Canine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Dermatitis	2
Alopecia	2

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**TOLFENAMIC ACID****Bovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Skin slough	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**TRICHLORFON****Equine**

Number of reports	Probable	Possible
16	15	1

Presenting Signs	Number of reports
Mouth Burn	13
Colic	10
Anorexia	3
Scouring	1
Blisters	1

Previous label changes were made to trichlorfon products to warn users not to allow dogs access to spilt product as it is highly toxic to dogs and to prevent damage to horses' mouths by administering the paste over the back of the tongue and not between the cheek and teeth.

Based on the continuing very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**TRICLABENDAZOLE****Ovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1
Lack of effect	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**TRIMETHOPRIM****Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1

**TRIMETHOPRIM****Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Hives	1
Skin slough	1
Pruritis	1
Pain	1
Recumbency	1

**TRIMETHOPRIM****Equine**

Number of reports	Probable	Possible
4	1	3

Presenting Signs	Number of reports
Swelling (local)	1
Collapse	1
Death	1
Ataxia	1

**TRIMETHOPRIM****Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Hypersalivation	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**VIRGINIAMYCIN****Equine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Colic	3
Constipation	2

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**VITAMIN B1 HYDROCHLORIDE = THIAMINE HYDROCHLORIDE****Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

**VITAMIN B1 HYDROCHLORIDE = THIAMINE HYDROCHLORIDE****Rabbit**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Spasm	1
Death	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**VITAMIN B12 = CYANOCOBALAMIN****Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1

**VITAMIN B12 = CYANOCOBALAMIN****Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Colic	1
Anorexia	1
Depression	1
Muscle twitching	1

**VITAMIN B12 = CYANOCOBALAMIN****Rabbit**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Spasm	1
Death	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**VITAMIN B2 PHOSPHATE SODIUM = RIBOFLAVIN PHOSPHATE SODIUM****Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

**VITAMIN B2 PHOSPHATE SODIUM = RIBOFLAVIN PHOSPHATE SODIUM****Rabbit**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Spasm	1
Death	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**VITAMIN B3 = NICOTINAMIDE****Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

**VITAMIN B3 = NICOTINAMIDE****Rabbit**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1
Spasm	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**VITAMIN B6 HYDROCHLORIDE = PYRIDOXINE HYDROCHLORIDE****Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1

**VITAMIN B6 HYDROCHLORIDE = PYRIDOXINE HYDROCHLORIDE****Rabbit**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Spasm	1
Death	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**ZINC EDTA****Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1
Convulsions	1

**ZINC OXIDE****Canine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Dermatitis	2
Alopecia	2

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

### **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 in the following summaries of adverse experience reports that in one report a number of different clinical signs may have been observed. 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.

**ALBENDAZOLE OXIDE**

Number of reports	Probable	Possible
1	0	1

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

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**ALPHA-CYPERMETHRIN**

Number of reports	Probable	Possible
2	1	1

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

Based on assessment of adverse experience reports for alpha-cypermethrin, the APVMA (in conjunction with its official governmental advisory agencies) is re-considering the First Aid Instructions and Safety Directions for these products.

**DELTAMETHRIN**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Irritation (skin)	2
Nausea	1
Burning sensation	1
Headache	1
Numbness	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**IMIDACLOPRID**

Number of reports	Probable	Possible
6	0	6

Presenting Signs	Number of reports
Rash	2
Headache	1
Swelling (local)	1
Pruritis	1
Welts	1
Odour	1
Respiratory problems	1
Burning sensation	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**IVERMECTIN**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Vomiting	1
Colic	1
Nil	1

After assessment of adverse experience reports involving human health issues for pour-on products containing ivermectin and consideration of the known moderate eye and skin irritancy potential of these products additional First Aid Instructions and Safety Directions were included on these product labels.

**LEVAMISOLE HYDROCHLORIDE**

Number of reports	Probable	Possible
1	0	1

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

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**NAPHTHALOPHOS**

Number of reports	Probable	Possible
1	0	1

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

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**OLAQUINDOX**

Number of reports	Probable	Possible
6	4	2

Presenting Signs	Number of reports
Rash	2
Irritation (skin)	2
Arthropathy	1
Nil	1
Dermatitis	1

A previous change was made to the First Aid Instructions and Safety Directions for olaquindox products to warn users that repeated exposure may cause allergic reactions and to avoid skin and eye contact.

Based on the continuing very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**SELENIUM**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Malaise	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

**TOLTRAZURIL**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Vocalisation	1

Based on the very low number of adverse experience reports for these products when compared to the total number of doses sold no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

## 4. GLOSSARY

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