

**REPORT OF ADVERSE
EXPERIENCES
JANUARY 1995 TO
MAY 2003**

JULY 2003

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EXECUTIVE SUMMARY

A major review was conducted of the Adverse Experience Reporting Program for veterinary chemical products (AERP Vet) during 2001 and 2002 and as a result a number of significant changes were made to the operation of the program. These changes were aimed at ensuring that the Australian Pesticides and Veterinary Medicines Authority (APVMA) meets international best practice for assessing and classifying adverse experience reports and determining what, if any, corrective action is required. The changes have resulted in improved efficiency of the program and more targeted outcomes. As a direct result of this improvement in efficiency, the APVMA has been able to conduct a retrospective analysis of all adverse experience reports that we have received since 1995.

In previous annual reports of the AERP Vet, only adverse experience reports submitted voluntarily to the APVMA by veterinarians, farmers, animal owners and other users of veterinary chemical products (*Voluntary Reports*), and reports sent to the APVMA by product registrants under the requirements of section 161 of the Agvet Code that were considered to have been serious in nature (*Serious Registrant Reports*) were included. This year however, **all** adverse experience reports involving veterinary chemical products, including *Voluntary Reports* (submitted by the public), *Serious Registrant Reports* and *Non-Serious Registrant Reports* (ie reports submitted to the APVMA by product registrants) are included in this annual report. Since *Non-Serious Registrant Reports* had not been previously included in annual reports, this report covers all adverse experience reports in our database that have been assessed, evaluated and classified as ‘probable’ or ‘possible’ by the APVMA since 1995. For each report listed the main clinical signs that were observed are included.

The format of this annual report is different to previous years due to the large volume of information that is contained in it. There are two main sections in the report:

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

At the end of each list of adverse experiences for each active constituent there is a narrative summary on the assessment and analysis of the reports and whether any regulatory action was taken and why. For each active constituent, the APVMA conducts a trend analysis to determine whether there are any potential or emerging issues that need addressing. The APVMA uses international best practice standards for conducting trend analyses and this is covered in more detail in the Introduction.

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,
- Establishing acceptable frequency of occurrence of an adverse experience, or
- Comparing one product or active constituent with another product or active constituent.

1. INTRODUCTION

1.1 Program Outline

The APVMA is the Australian agency responsible for regulating agricultural and veterinary chemicals up to and including the point of retail sale. 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 Chemical Products (AERP Vet) is a post-registration quality assurance program established by the APVMA to facilitate responsible management of veterinary chemical products throughout their lifecycle. The program provides a means for identifying corrective actions necessary to assure the continued safety, quality and effectiveness of registered veterinary chemical products. Recording and investigating reports of adverse experiences is an important step in detecting unusual or rare conditions that were not evident in clinical or field trials and as a result, could not be assessed during the product registration process. The AERP 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 may be defined 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 chemical products 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 chemicals 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 chemical products.

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

1.4 Reporting an adverse experience

Adverse experiences with veterinary chemicals may be reported using the Adverse Experience Reporting Form for Veterinary Chemical Products available from veterinarians, the APVMA or on the APVMA Website at <http://www.apvma.gov.au/qa/aerp.shtml>

1.5 Evaluation of adverse experience reports

Procedures for dealing with adverse experience reports are as follows:

- The APVMA receives adverse experience reports from registrants, veterinarians, farmers, and other users of veterinary chemical products. In the first instance, each *Voluntary Report* is referred to the product registrant for investigation and comment.
- Registrants are required to report their investigation findings and comments to the AERP Coordinator.
- In considering the submitted reports, the AERP Coordinator also:
 - a. researches the available scientific literature (eg. worldwide veterinary, medical and toxicological databases); and
 - b. examines published information from pharmacovigilance agencies in other countries (eg. the Food and Drug Administration website).
- A decision on whether the adverse experience is product-related or not (see below) is made by an in-house panel of veterinary clinicians and pharmacologists.

1.6 Classification of adverse experience reports

The relationship between the use of the veterinary chemical product 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).

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).

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 chemical product, 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 sold¹. 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 chemical under the APVMA's Chemical Review Program;
- education of the veterinary profession, farming community or wider public on issues relating to use of products.

¹ Final Report to the VPC (2001) Department for Environment, Food & Rural Affairs.

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.

(S)-METHOPRENE**Feline**

Number of reports	Probable	Possible
8	8	0

Presenting Signs	Number of reports
Vomiting	3
Hypersalivation	3
Ataxia	2
Lack of effect	2
Irritation (skin)	1
Mouth Irritation	1
Dermatitis	1
Tremor	1
Cystitis	1
Irritation (eye)	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.

4-AMINO PYRIDINE**Bovine**

Number of reports	Probable	Possible
1	1	0

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

Only a single report of a severe reaction in a cow after treatment with this product, probably due to a hypersensitivity or anaphylactoid (shock) reaction. Based on this very low reporting incidence no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

4-AMINO PYRIDINE**Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Tachycardia	1
Pyrexia	1
Seizure	1
Vomiting	1
Hyperactivity	1
Agitation	1
Death	1
Cardiac Arrest	1
Unconscious	1

4-AMINO PYRIDINE**Feline**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Agitation	2
Vocalisation	2
Hypersalivation	2
Tachycardia	2
Vomiting	2

There have only been four reports of adverse experiences to these products in small animals. In one report, a dog died after experiencing seizures, however this was only considered to have been possibly related to the use of the product as no definitive diagnosis had been made by the attending veterinarian as to the cause of death.

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.

ABAMECTIN**Bovine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Depression	1
Ataxia	1
Death	1

ABAMECTIN**Equine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Lack of effect	2
Colic	1

On assessment of these reports it was found that very young cattle are more susceptible to abamectin toxicity, and although this is explained in the label directions for these products, the variation in weights for very young animals is being considered further.

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.

ACEPROMAZINE MALEATE**Canine**

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Pale mucous membranes	2
Abdominal pain	1
Haematuria	1
Vomiting	1
Swelling (local)	1
Diarrhoea	1
Bradycardia	1
Anorexia	1

ACEPROMAZINE MALEATE**Feline**

Number of reports	Probable	Possible
6	5	1

Presenting Signs	Number of reports
Death	4
Convulsions	2
Histamine Reaction	2
Respiratory problems	2
Seizure	1
Cyanosis	1
Bradycardia	1
Delayed Recovery	1
CNS dysfunction	1

Sedatives containing acepromazine maleate are potent vasodilators and therefore can cause side effects associated with hypotension, including pale mucous membranes. Bradycardia may also occur due to the CNS depressive effects on the autonomic nervous system. These side effects are listed in the product literature.

Acepromazine maleate products are often used as a pre-medication for general anaesthesia. Most of the adverse experiences listed above were considered to have been associated with the sedation/anaesthetic combination than solely to the use of the acepromazine maleate.

It is well recognised that all general anaesthetics are associated with a certain level of risk and 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.

ACRIFLAVINE

Other

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Respiratory problems	1
Irritation (skin)	1
Death	1

On assessment of adverse experience reports involving an aquaculture product containing this active constituent, it was found that one batch of this product was inadvertently over-formulated and was therefore recalled from the marketplace.

ADENOSINE TRIPHOSPHATE

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
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.

ADENOSINE-5-MONOPHOSPHATE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1

Injection site reactions such as pain and swelling can occur from any injectable product. 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.

ALBENDAZOLE**Ovine**

Number of reports	Probable	Possible
8	5	3

Presenting Signs	Number of reports
Death	6
Lack of effect	2
Diarrhoea	1
Lethargy	1
Weight loss	1
Bottle jaw	1
Anaemia	1
Hypersalivation	1
Frothing at the mouth	1
Tremor	1
Recumbency	1
Ataxia	1

Albendazole is a benzimidazole-derivative, and it is known that in Australia there is the possibility of resistance to some of these types of worm drenches. In some of these reports it was considered that due to a possible resistance problem some sheep succumbed to worm burdens and in some cases died. Label instructions for these and other worm drenches have been changed to ensure that

they contain information for the user about the potential for resistance to occur and how to manage it. Veterinary advisors are aware of these issues and routinely provide information to farmers on how to avoid and manage potential resistance.

Again, due to the very low number of reports of these types of incidents when compared to the very large number of sheep treated each year no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

ALPHA-CYPERMETHRIN

Ovine

Number of reports	Probable	Possible
99	64	35

Presenting Signs	Number of reports
Lack of effect	99
Rubbing	1

Alpha-cypermethrin is a synthetic pyrethroid, and it is known that in Australia there is the possibility of resistance to some of these types of lice control products. Veterinary advisors are aware of these issues and routinely provide information to farmers on how to avoid and manage potential resistance.

Again, due to the very low number of reports of these types of incidents when compared to the very large number of sheep treated each year no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

ALPHADOLONE

Canine

Number of reports	Probable	Possible
3	2	1

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

Apnoea	1
Anaesthesia (long)	1

ALPHADOLONE**Feline**

Number of reports	Probable	Possible
55	20	35

Presenting Signs	Number of reports
Death	17
Respiratory problems	9
Lack of effect	6
Cardiac Arrest	5
Histamine Reaction	5
Blindness	4
Cyanosis	3
Swelling (local)	3
Slow recovery	3
Coughing	3
Convulsions	2
Swollen feet	2
Dyspnoea	2
Seizure	2
Oedema	2
Delayed Recovery	2
Anaesthesia (deep)	1
Injection site reaction	1
Laryngitis	1
Bradycardia	1
CNS dysfunction	1
Pyrexia	1
Rales	1
Renal failure	1
Irritation (skin)	1
Anaesthesia (long)	1
Apnoea	1
Facial oedema	1
Circling	1

Blisters	1
Weakness	1
Paralysis	1

It is well recognised that all general anaesthetics are associated with a certain level of risk and 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
3	2	1

Presenting Signs	Number of reports
Death	3
Cardiac arrest	2
Cyanosis	1
Respiratory problems	1
Apnoea	1
Dyspnoea	1
Anaesthesia (long)	1

ALPHAXALONE**Feline**

Number of reports	Probable	Possible
75	30	45

Presenting Signs	Number of reports
Death	15
Respiratory problems	8
Injection site reaction	6
Pain	5
Cardiac Arrest	5
Histamine Reaction	4
Swelling (local)	4
Slow recovery	3
Cyanosis	3
Coughing	2
Facial oedema	2
Convulsions	2
Oedema	2
Delayed Recovery	2
Weakness	1
Rales	1

Anaesthesia (deep)	1
Ataxia	1
Pyrexia	1
Irritation (skin)	1
Seizure	1
Renal failure	1
Dyspnoea	1
Blindness	1
Bradycardia	1
Lack of effect	1
Pulmonary oedema	1
Blisters	1
Swollen feet	1
Bronchial secretion	1
CNS dysfunction	1
Laryngitis	1
Paralysis	1

It is well recognised that all general anaesthetics are associated with a certain level of risk and 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
5	2	3

Presenting Signs	Number of reports
Lethargy	2
Milk production decrease	2
Lack of effect	1
Panting	1
Anorexia	1
Depression	1
CNS dysfunction	1
Ataxia	1
Recumbency	1

AMITRAZ**Canine**

Number of reports	Probable	Possible
5	2	3

Presenting Signs	Number of reports
Lack of effect	3
Rash	1
Tick paralysis	1

After assessment of adverse experience reports for products containing amitraz it was found that animals treated in extremely hot weather may be more susceptible to toxicity. Therefore a label change was made to these products to warn the user to treat animals in accordance with good agricultural practice, avoid treating in extremely hot weather (>40°C) or if under heat stress and to ensure that adequate shade is available post-treatment.

AMMONIUM FERRIC CITRATE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1

AMMONIUM FERRIC CITRATE**Equine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Pain	2
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.

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**Camelid**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Injection site reaction	2

AMOXYCILLIN AS AMOXYCILLIN TRIHYDRATE**Canine**

Number of reports	Probable	Possible
55	34	21

Presenting Signs	Number of reports
Injection site reaction	22
Site Reaction	17
Dermatitis	3
Depression	3
Oedema	2
Pyrexia	2
Death	2
Urticaria	2
Pruritis	2
Haemorrhage	2
Respiratory problems	2
Skin slough	2
Uraemia	1
Hypoproteinaemia	1
Hepatopathy	1
Coughing	1
Vesicles	1
Inflammation	1
Melaena	1
Pain	1
Swelling (local)	1
Ulceration	1

Convulsions	1
Tremor	1
Ocular damage	1
Masticatory myositis	1
Dyspnoea	1
Thrombocytopenia	1
Irritation (skin)	1

AMOXYCILLIN AS AMOXYCILLIN TRIHYDRATE

Feline

Number of reports	Probable	Possible
15	13	2

Presenting Signs	Number of reports
Injection site reaction	9
Irritation (skin)	2
Respiratory problems	1
Convulsions	1
Death	1
Ptyalism	1
Cyanosis	1
Lethargy	1
Vaginitis	1
Anaphylaxis	1
Pruritis	1
Lacrimation	1
Scabs	1
Oedema	1

After assessment of adverse experience reports concerning one product containing this active constituent a batch problem was identified, which was resulting in an increased level of injection site reactions and the batch was recalled from the market place.

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.

AMPICILLIN AS THE SODIUM SALT**Bovine**

Number of reports	Probable	Possible
5	0	5

Presenting Signs	Number of reports
Residue violation in milk	5

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.

ANAPLASMA CENTRALE**Bovine**

Number of reports	Probable	Possible
22	12	10

Presenting Signs	Number of reports
Lack of effect	22

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.

ANTIGEN BM86**Bovine**

Number of reports	Probable	Possible
7	7	0

Presenting Signs	Number of reports
Lame	3
Injection site reaction	3
Lack of effect	2
Depression	1
Pyrexia	1
Swelling (local)	1
Milk production decrease	1
Abortion	1
Hair loss	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.

ATIPAMEZOLE HYDROCHLORIDE**Feline**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Oedema	2
Shock	2
Death	2
Respiratory problems	1
Somnolence	1

It is well recognised that all anaesthetics and reversing agents are associated with a certain level of risk and 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.

ATROPINE SULFATE**Feline**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Dyspnoea	2
Pulmonary oedema	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.

AVIAN ENCEPHALOMYELITIS VIRUS**Avian**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Antibody response (slow)	2
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.

BABESIA BOVIS**Bovine**

Number of reports	Probable	Possible
22	12	10

Presenting Signs	Number of reports
Lack of effect	22

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.

BACITRACIN ZINC**Feline**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Vomiting	1
Diarrhoea	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.

BENAZEPRIL HYDROCHLORIDE**Canine**

Number of reports	Probable	Possible
6	2	4

Presenting Signs	Number of reports
Diarrhoea	2
Alopecia	2
Dermatitis	2
Melaena	1
Electrolyte changes	1
Anorexia	1
Vomiting	1
Uraemia	1
Polydipsia	1

BENAZEPRIL HYDROCHLORIDE**Feline**

Number of reports	Probable	Possible
11	2	9

Presenting Signs	Number of reports
Anorexia	6
Lethargy	5
Dehydration	4
Uraemia	3
Renal failure	1
Death	1
Constipation	1
Kalaemia	1
Vomiting	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.

BENZATHINE PENICILLIN**Bovine**

Number of reports	Probable	Possible
6	5	1

Presenting Signs	Number of reports
Death	4
Behavioural change	1
Pruritis	1
Hypersalivation	1
Distress	1
Agitation	1
Bloat	1
Weight loss	1
Ataxia	1

BENZATHINE PENICILLIN**Canine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Injection site reaction	2
Swelling (local)	1

BENZATHINE PENICILLIN**Equine**

Number of reports	Probable	Possible
4	3	1

Presenting Signs	Number of reports
Death	3

Ataxia	2
Convulsions	1
Respiratory problems	1
Dyspnoea	1
Cardiac Arrest	1
Collapse	1

Penicillin reactions are well recognised in both the veterinary and human medical literature². However, it is important for the APVMA to monitor the reporting incidence of such reactions to identify any increasing level of incidence or unusual trends. The APVMA is satisfied that 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.

BENZOIC ACID

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lethargy	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.

² Adams, H.R. (2001) *Veterinary Pharmacology and Therapeutics* p61.

BETAMETHASONE**Canine**

Number of reports	Probable	Possible
12	7	5

Presenting Signs	Number of reports
Pain	2
Lack of effect	2
Horner's Syndrome	1
Ulceration	1
Pupillary constriction	1
Prolapse third eyelid	1
Vocalisation	1
Agitation	1
Pruritis	1
Inflammation	1
Irritation (ear)	1
Distress	1

Betamethasone is used in a number of different preparations including ear treatments. Many of the side effects listed above are already listed in the warnings on the product labels of these products. It is important for users of all veterinary products to take particular note of the warnings on products labels and take appropriate precautions as needed.

BIOTIN**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1

BIOTIN**Equine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Injection site reaction	2
Pain	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.

BISMUTH SUBSALICYLATE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Mouth ulcers	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.

BLACKLEG = CLOSTRIDIUM CHAUVOEI**Bovine**

Number of reports	Probable	Possible
2	0	2

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.

BORDETELLA BRONCHISEPTICA**Canine**

Number of reports	Probable	Possible
39	13	26

Presenting Signs	Number of reports
Coughing	15
Nasal discharge	8
Sneezing	6
Urticaria	6
Pyrexia	4
Injection site reaction	3
Respiratory problems	3
Gastroenteritis	2
Vomiting	2
Depression	2
Swelling (local)	2
Lethargy	2
Collapse	2
Death	2
Oedema	2
Ataxia	2
Diarrhoea	1
Facial oedema	1
Agitation	1
Anorexia	1
Stiffness	1
Anaemia	1
Inflammation	1
Bradycardia	1
Weakness	1
Panting	1
Pain	1
Tachycardia	1
Rash	1
Dyspnoea	1
Anaphylaxis	1
Lymphadenopathy	1
Shock	1

Auto-immune haemolytic anaemia	1
Polyarthritis	1

BORDETELLA BRONCHISEPTICA INACTIVATED VACCINE

Canine

Number of reports	Probable	Possible
242	138	104

Presenting Signs	Number of reports
Facial oedema	133
Urticaria	55
Vomiting	33
Pruritis	23
Pain	23
Injection site reaction	21
Swollen lips and face	19
Swelling (local)	14
Anaphylaxis	13
Pale mucous membranes	11
Collapse	10
Depression	9
Lethargy	8
Diarrhoea	7
Swollen feet	6
Erythema	6
Weakness	6
Periorbital swelling	5
Tachycardia	4
Inflammation	4
Hypersalivation	4
Panting	4
Shaking	4
Illness	3
Hives	3
Pyrexia	3
Oedema	3
Death	3
Vocalisation	3

Welts	2
Hyperexcitable	2
Site Reaction	2
Paddling	2
Dyspnoea	2
Distress	2
Agitation	2
Convulsions	2
Malaise	2
Anaphylactoid reaction	2
Pawing at ground	1
Coughing	1
Respiratory problems	1
Sneezing	1
Ocular pathology	1
Hypothermia	1
Irritation (skin)	1
Anorexia	1
Rectal prolapse	1
Ataxia	1
Tremor	1
Rubbing	1
Arthropathy	1
Lack of effect	1
Tachypnoea	1
Wheals	1
Shock	1
Pupillary dilation	1
Seizure	1
Vulval swelling	1
Listless	1
Defecation	1
Hypersensitivity reaction	1

BORDETELLA BRONCHISEPTICA KILLED VACCINE**Canine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Pale mucous membranes	1
Oedema	1
Death	1
Shock	1
Respiratory problems	1
Urticaria	1
Vomiting	1
Erythema	1
Pain	1

There are numerous vaccines that contain *Bordetella bronchiseptica* virus in live, attenuated, inactivated and killed forms. The most frequently reported side effects reported, such as facial oedema, urticaria, vomiting, pruritis and injection site reactions occur fairly commonly with most vaccines. Other common adverse experiences reported after use of these types of vaccines include coughing, nasal discharge and sneezing. In some cases this is probably related to the formulation of the vaccine (ie some preparations are a nasal droplet) which can cause some minor local irritation and hence the coughing and sneezing. 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.

BORIC ACID**Feline**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Prolapse third eyelid	2
Depression	1
Lethargy	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.

BOVINE EPHEMERAL FEVER VIRUS**Bovine**

Number of reports	Probable	Possible
8	1	7

Presenting Signs	Number of reports
Lack of efficacy	5
Lame	3
Recumbency	2
Depression	1
Milk production decrease	1
Swelling (local)	1
Anaphylaxis	1

A change to the formulation of Bovine Ephemeral Fever vaccines was made due to traces of Quil A being present in the finished product during the manufacturing process. It was found that cattle previously treated with certain antibiotics containing Quil A could have severe anaphylactic reactions.

Clinical signs typical of ephemeral fever are vague and may be confused with other conditions. Due to the vagueness of clinical signs, in instances where product efficacy is challenged it is imperative that a correct diagnosis of the presenting condition is made. Taking into account the number of doses of these products sold each year, the APVMA considers that the overall reporting

incidence is very low by international standards and no further regulatory action is required other than continued monitoring for future adverse experience reports.

BUTORPHANOL

Canine

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Haematemesis	1
Hallucinating	1
Pale mucous membranes	1
Vocalisation	1
Renal failure	1
Bradycardia	1
Death	1
Weakness	1

BUTORPHANOL

Feline

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Death	1
Dyspnoea	1
Hallucinating	1
Seizure	1
Vocalisation	1
Tachycardia	1

It is well recognised that all anaesthetics and sedatives are associated with a certain level of risk and 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 AS CALCIUM BOROGLUCONATE**Bovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Bradycardia	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.

CALCIUM AS CALCIUM GLUCONATE**Bovine**

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.

CALCIUM PENTOSAN POLYSULFATE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
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.

CAMPHOR**Equine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Irritation (skin)	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.

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
113	55	58

Presenting Signs	Number of reports
Facial oedema	32
Vomiting	20
Urticaria	18
Injection site reaction	16
Parvovirus	11
Depression	10
Death	9
Lack of effect	9
Pruritis	9
Lethargy	8
Diarrhoea	8
Swelling (local)	7
Pain	7
Collapse	6
Erythema	5
Pyrexia	5
Anaphylaxis	5
Swollen lips and face	5

Panting	5
Weakness	4
Anorexia	4
Swollen feet	3
Shaking	3
Malaise	3
Cyanosis	3
Distress	3
Agitation	3
Pale mucous membranes	3
Periorbital swelling	3
Welts	3
Gastroenteritis	3
Bradycardia	2
Hives	2
Ataxia	2
Rash	2
Hypothermia	2
Abdominal pain	2
Haemorrhage	2
Vocalisation	2
Hypersalivation	2
Rectal prolapse	1
Listless	1
Dyspnoea	1
Oedema	1
Sneezing	1
Hypotension	1
Irritation (skin)	1
Inflammation	1
Arthropathy	1
Thrombocytopenia	1
Haematuria	1
Lymphadenopathy	1
Somnolence	1
Non-ambulatory	1
Eosinophilia	1
Tachycardia	1
Anaemia	1
Convulsions	1
Vulval swelling	1
Wheals	1

Irritation (ear)	1
Defecation	1
Respiratory problems	1
Tremor	1
Fibrosarcoma	1

CANINE ADENO VIRUS TYPE 2 STRAIN V197

Unknown

Number of reports	Probable	Possible
24	21	3

Presenting Signs	Number of reports
Urticaria	11
Pain	10
Ataxia	5
Tremor	5
Vomiting	4
Lethargy	4
Injection site reaction	3
Depression	2
Diarrhoea	2
Death	2
Swelling (local)	2
Defecated	1
Weakness	1
hypersensitivity	1
Collapse	1
Paresis	1
Fasciculation	1
Pyrexia	1

CANINE ADENO VIRUS TYPE 2 STRAIN V197**Canine**

Number of reports	Probable	Possible
294	236	58

Presenting Signs	Number of reports
Urticaria	108
Pain	39
Vomiting	35
Anaphylaxis	31
Depression	28
Lethargy	27
Diarrhoea	17
Death	15
Injection site reaction	15
Ataxia	12
Gastroenteritis	11
Site Reaction	11
Collapse	10
Tremor	10
Anorexia	9
Respiratory problems	7
Convulsions	6
Oedema	5
Swelling (local)	5
Cyanosis	4
Polyarthritis	4
Weakness	4
Pyrexia	4
Abdominal pain	3
Seizure	3
Pruritis	2
Lame	2
Facial oedema	2
Hypersensitivity	2
Distress	2
hypersensitivity	2
CNS dysfunction	2
Malaise	2

Hyperaesthesia	2
Frothing at the mouth	2
Ocular damage	2
Swollen lips and face	2
Jaundice	1
Fasciculation	1
Lack of effect	1
Irritation (ear)	1
facial swelling	1
Vasoconstriction	1
Dermatitis	1
Paresis	1
Polydipsia	1
Disorientation	1
Arthropathy	1
Proprioception Deficit	1
Vocalisation	1
Dyspnoea	1
Defecated	1
Sneezing	1
Anaemia	1
Non-ambulatory	1
Deafness	1
Neutrophilia	1
Dehydration	1
Lymphadenopathy	1
Aggression	1
Defaecation	1
Restless	1
Nystagmus	1
Auto-immune haemolytic anaemia	1
Haemorrhagic Gastroenteritis	1
Salivating	1

CANINE ADENOVIRUS TYPE 2 (CAV2)**Canine**

Number of reports	Probable	Possible
21	11	10

Presenting Signs	Number of reports
Collapse	7
Pale mucous membranes	5
Facial oedema	4
Vomiting	4
Pruritis	3
Tachycardia	3
Lethargy	3
Death	3
Pain	3
Ataxia	2
Weakness	2
Pyrexia	2
Swelling (local)	2
Site Reaction	1
Stiffness	1
Recumbency	1
Urticaria	1
Hypersalivation	1
Anaphylaxis	1
Abscess	1
Diarrhoea	1
Pupillary dilation	1
Agitation	1
Paddling	1
Welts	1
Oedema	1
Erythema	1
Hives	1
Cardiac Arrest	1
Shock	1
Lymphadenopathy	1
Seizure	1
Hyperaesthesia	1

Bradycardia	1
Injection site reaction	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, such as facial oedema, urticaria, vomiting, pruritis and injection site reactions occur fairly commonly 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 CORONAVIRUS VACCINE - ANTIGEN

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Rectal prolapse	1
Diarrhoea	1
Vomiting	1
Listless	1
Swelling (local)	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.

CANINE DISTEMPER**Canine**

Number of reports	Probable	Possible
7	1	6

Presenting Signs	Number of reports
Injection site reaction	2
Vomiting	2
Lethargy	1
Urticaria	1
Anorexia	1
Fibrosarcoma	1
Depression	1
Hypothermia	1
Haemorrhage	1
Diarrhoea	1
Ataxia	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.

CANINE DISTEMPER VIRUS**Canine**

Number of reports	Probable	Possible
28	16	12

Presenting Signs	Number of reports
Collapse	7
Vomiting	5
Pale mucous membranes	5
Facial oedema	5
Lethargy	4
Swelling (local)	3
Tachycardia	3

Pruritis	3
Weakness	3
Urticaria	3
Pain	3
Death	3
Pyrexia	2
Ataxia	2
Welts	2
Diarrhoea	2
Anaphylaxis	1
Anaphylaxis	1
Anaemia	1
Cardiac Arrest	1
Depression	1
Abscess	1
Hypersalivation	1
Lymphadenopathy	1
Cyanosis	1
Bradycardia	1
Sneezing	1
Swollen lips and face	1
Anorexia	1
Hyperaesthesia	1
Agitation	1
Erythema	1
Stiffness	1
Rash	1
Hives	1
Pupillary dilation	1
Paddling	1
Gastroenteritis	1
Seizure	1
Shock	1
Injection site reaction	1
Oedema	1
Panting	1
Dyspnoea	1
Recumbency	1
Site Reaction	1

CANINE DISTEMPER VIRUS - LIVING**Unknown**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1
Depression	1
Parvovirus	1
Abdominal pain	1

CANINE DISTEMPER VIRUS - LIVING**Canine**

Number of reports	Probable	Possible
99	49	50

Presenting Signs	Number of reports
Facial oedema	31
Vomiting	17
Urticaria	15
Injection site reaction	14
Parvovirus	11
Death	9
Lack of effect	9
Pruritis	9
Depression	8
Pain	7
Swelling (local)	6
Collapse	6
Diarrhoea	6
Lethargy	6
Pyrexia	5
Erythema	5
Swollen lips and face	4
Anaphylaxis	4
Panting	4

Periorbital swelling	3
Pale mucous membranes	3
Shaking	3
Malaise	3
Weakness	3
Agitation	3
Distress	3
Swollen feet	3
Welts	2
Vocalisation	2
Hives	2
Abdominal pain	2
Hypersalivation	2
Gastroenteritis	2
Bradycardia	2
Anorexia	2
Cyanosis	2
Ataxia	1
Respiratory problems	1
Non-ambulatory	1
Hypothermia	1
Inflammation	1
Defecation	1
Hypotension	1
Tachycardia	1
Haemorrhage	1
Rash	1
Eosinophilia	1
Rectal prolapse	1
Somnolence	1
Listless	1
Oedema	1
Arthropathy	1
Tremor	1
Vulval swelling	1
Irritation (ear)	1
Irritation (skin)	1
Thrombocytopenia	1
Convulsions	1
Wheals	1
Lymphadenopathy	1

CANINE DISTEMPER VIRUS STRAIN ONDERSTEPOORT**Unknown**

Number of reports	Probable	Possible
24	21	3

Presenting Signs	Number of reports
Urticaria	11
Pain	10
Tremor	5
Ataxia	5
Lethargy	4
Vomiting	4
Injection site reaction	3
Death	2
Swelling (local)	2
Diarrhoea	2
Depression	2
Pyrexia	1
Weakness	1
Collapse	1
Hypersensitivity	1
Defecated	1
Fasciculation	1
Paresis	1

CANINE DISTEMPER VIRUS STRAIN ONDERSTEPOORT**Canine**

Number of reports	Probable	Possible
306	242	64

Presenting Signs	Number of reports
Urticaria	109
Pain	42
Vomiting	37
Anaphylaxis	31
Depression	30

Lethargy	29
Diarrhoea	18
Injection site reaction	16
Death	16
Ataxia	13
Gastroenteritis	12
Site Reaction	11
Tremor	11
Collapse	10
Anorexia	9
Respiratory problems	7
Convulsions	6
Swelling (local)	6
Oedema	5
Cyanosis	5
Seizure	4
Pyrexia	4
Polyarthrititis	4
Weakness	4
Abdominal pain	3
CNS dysfunction	3
Hyperaesthesia	2
Frothing at the mouth	2
Ocular damage	2
Pruritis	2
Hypersensitivity	2
Proprioception Deficit	2
Lame	2
Distress	2
Dehydration	2
Swollen lips and face	2
Malaise	2
hypersensitivity	2
Lymphadenopathy	2
Facial oedema	2
Auto-immune haemolytic anaemia	1
Defaecation	1
Paresis	1
Haemorrhagic Gastroenteritis	1
Ulceration	1
Sneezing	1
Hypotension	1

Pulmonary oedema	1
Anaemia	1
Anaphylaxis	1
Vocalisation	1
Non-ambulatory	1
Salivating	1
Listless	1
Fasciculation	1
Dyspnoea	1
Irritation (ear)	1
Arthropathy	1
Neutrophilia	1
Polydipsia	1
Dermatitis	1
Jaundice	1
Aggression	1
Disorientation	1
Vasoconstriction	1
Defecated	1
Restless	1
Nystagmus	1
Deafness	1
Lack of effect	1
Shock	1

There are numerous vaccines that contain Canine Distemper Virus in live, attenuated, inactivated and killed forms. The most frequently reported side effects reported, such as facial oedema, urticaria, vomiting, pruritis and injection site reactions occur fairly commonly 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 PARAINFLUENZA TYPE 2**Canine**

Number of reports	Probable	Possible
15	7	8

Presenting Signs	Number of reports
Collapse	6
Pale mucous membranes	4
Vomiting	3
Pruritis	3
Tachycardia	3
Death	2
Facial oedema	2
Swelling (local)	2
Lethargy	2
Anaphylaxis	1
Shock	1
Urticaria	1
Pyrexia	1
Cardiac Arrest	1
Oedema	1
Welts	1
Abscess	1
Ataxia	1
Weakness	1
Hives	1
Erythema	1
Pain	1
Agitation	1
Paddling	1
Bradycardia	1
Diarrhoea	1
Pupillary dilation	1
Seizure	1
Hypersalivation	1

CANINE PARAINFLUENZA VIRUS**Unknown**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1
Parvovirus	1
Depression	1
Abdominal pain	1

CANINE PARAINFLUENZA VIRUS**Canine**

Number of reports	Probable	Possible
92	47	45

Presenting Signs	Number of reports
Facial oedema	30
Vomiting	17
Injection site reaction	16
Urticaria	15
Parvovirus	11
Lack of effect	9
Death	8
Depression	8
Swelling (local)	8
Pruritis	8
Lethargy	6
Diarrhoea	6
Pain	6
Panting	5
Erythema	5
Swollen lips and face	4
Pyrexia	4
Anaphylaxis	4
Gastroenteritis	3

Agitation	3
Periorbital swelling	3
Pale mucous membranes	3
Collapse	3
Weakness	3
Inflammation	2
Hypersalivation	2
Lymphadenopathy	2
Hives	2
Distress	2
Rash	2
Swollen feet	2
Anorexia	2
Shaking	2
Stiffness	1
Hypothermia	1
Rectal prolapse	1
Convulsions	1
Listless	1
Haemorrhage	1
Vulval swelling	1
Malaise	1
Irritation (ear)	1
Welts	1
Ataxia	1
Abdominal pain	1
Respiratory problems	1
Tremor	1
Defecation	1
Anaemia	1
Oedema	1
Somnolence	1
Vocalisation	1
Eosinophilia	1
Wheals	1

CANINE PARAINFLUENZA VIRUS TYPE 2 STRAIN CGF 2004/75**Unknown**

Number of reports	Probable	Possible
19	16	3

Presenting Signs	Number of reports
Urticaria	8
Pain	5
Vomiting	4
Lethargy	3
Ataxia	3
Diarrhoea	2
Injection site reaction	2
Swelling (local)	2
Tremor	2
Collapse	1
Defecated	1
Paresis	1
Fasciculation	1
Weakness	1
Pyrexia	1

CANINE PARAINFLUENZA VIRUS TYPE 2 STRAIN CGF 2004/75**Canine**

Number of reports	Probable	Possible
204	160	44

Presenting Signs	Number of reports
Urticaria	77
Vomiting	29
Pain	26
Anaphylaxis	20
Depression	17
Lethargy	14
Diarrhoea	13
Injection site reaction	12
Gastroenteritis	11
Collapse	8
Death	7
Respiratory problems	7
Site Reaction	6
Anorexia	6
Cyanosis	5
Tremor	5
Facial oedema	4
Weakness	4
Distress	4
Swelling (local)	4
Pyrexia	3
Oedema	3
Abdominal pain	3
Pale mucous membranes	3
Seizure	3
Swollen lips and face	3
Ataxia	3
Hypersensitivity	2
Malaise	2
Pruritis	2
Dyspnoea	2
Sneezing	2
Restless	1

Convulsions	1
Aggression	1
Paresis	1
Haemorrhagic Gastroenteritis	1
Fasciculation	1
Frothing at the mouth	1
Ocular damage	1
Anaphylaxis	1
Dehydration	1
Shaking	1
Disorientation	1
Salivating	1
Defecated	1
Arthropathy	1
Lack of effect	1
Non-ambulatory	1
Polyarthritis	1
Lame	1
Proprioception Deficit	1
Hyperaesthesia	1
hypersensitivity	1
Welts	1
Dermatitis	1

There are numerous vaccines that contain Canine Parainfluenza Virus in live, attenuated, inactivated and killed forms. The most frequently reported side effects reported, such as facial oedema, urticaria, vomiting, pruritis and injection site reactions occur fairly commonly 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
35	17	18

Presenting Signs	Number of reports
Collapse	7
Vomiting	7
Lethargy	5
Facial oedema	5
Pale mucous membranes	5
Urticaria	4
Tachycardia	3
Weakness	3
Injection site reaction	3
Ataxia	3
Pain	3
Swelling (local)	3
Pruritis	3
Death	3
Diarrhoea	3
Welts	2
Anorexia	2
Depression	2
Pyrexia	2
Haemorrhage	1
Anaphylaxis	1
Pupillary dilation	1
Anaemia	1
Agitation	1
Sneezing	1
Haematuria	1
Site Reaction	1
Hypersalivation	1
Fibrosarcoma	1
Lymphadenopathy	1
Cyanosis	1
Hyperaesthesia	1
Shock	1

Gastroenteritis	1
Oedema	1
Rash	1
Cardiac Arrest	1
Dyspnoea	1
Recumbency	1
Hypothermia	1
Paddling	1
Stiffness	1
Hives	1
Seizure	1
Swollen lips and face	1
Panting	1
Anaphylaxis	1
Bradycardia	1
Abscess	1
Erythema	1

CANINE PARVO VIRUS TYPE 2

Canine

Number of reports	Probable	Possible
29	12	17

Presenting Signs	Number of reports
Facial oedema	13
Urticaria	6
Pain	5
Vomiting	4
Collapse	3
Pyrexia	3
Swollen feet	3
Malaise	3
Lethargy	2
Bradycardia	2
Injection site reaction	2
Cyanosis	2
Shaking	2
Hypotension	1

Anorexia	1
Wheals	1
Anaphylaxis	1
Diarrhoea	1
Welts	1
Irritation (skin)	1
Weakness	1
Swollen lips and face	1
Convulsions	1
Tachycardia	1
Pruritis	1
Distress	1
Abdominal pain	1
Vocalisation	1
Swelling (local)	1
Death	1
Non-ambulatory	1
Arthropathy	1
Thrombocytopenia	1
Hives	1
Ataxia	1

CANINE PARVO VIRUS TYPE 2 STRAIN K31 PASSAGE 69

Unknown

Number of reports	Probable	Possible
24	21	3

Presenting Signs	Number of reports
Urticaria	11
Pain	10
Ataxia	5
Tremor	5
Vomiting	4
Lethargy	4
Injection site reaction	3
Death	2
Swelling (local)	2
Diarrhoea	2

Depression	2
hypersensitivity	1
Weakness	1
Fasciculation	1
Pyrexia	1
Defecated	1
Collapse	1
Paresis	1

CANINE PARVO VIRUS TYPE 2 STRAIN K3I PASSAGE 69

Canine

Number of reports	Probable	Possible
306	242	64

Presenting Signs	Number of reports
Urticaria	109
Pain	42
Vomiting	37
Anaphylaxis	31
Depression	30
Lethargy	29
Diarrhoea	18
Injection site reaction	16
Death	16
Ataxia	13
Gastroenteritis	12
Site Reaction	11
Tremor	11
Collapse	10
Anorexia	9
Respiratory problems	7
Convulsions	6
Swelling (local)	6
Cyanosis	5
Oedema	5
Weakness	4
Polyarthritis	4
Pyrexia	4

Seizure	4
Abdominal pain	3
CNS dys function	3
Distress	2
Lymphadenopathy	2
Hypersensitivity	2
Swollen lips and face	2
Proprioception Deficit	2
Malaise	2
Pruritis	2
Dehydration	2
Ocular damage	2
Facial oedema	2
Lame	2
Frothing at the mouth	2
Hyperaesthesia	2
Deafness	1
Paresis	1
Jaundice	1
Nystagmus	1
Ulceration	1
Auto-immune haemolytic anaemia	1
Hypotension	1
Anaemia	1
Defecated	1
Polydipsia	1
Listless	1
Vocalisation	1
Irritation (ear)	1
Aggression	1
Vasoconstriction	1
Haemorrhagic Gastroenteritis	1
Disorientation	1
Pulmonary oedema	1
Fasciculation	1
Dyspnoea	1
Arthropathy	1
Sneezing	1
Lack of effect	1
Non-ambulatory	1
Dermatitis	1
Shock	1

Anaphylaxis	1
Salivating	1
Defaecation	1
Neutrophilia	1
Restless	1

CANINE PARVOVIRUS (INACTIVATED)

Canine

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Depression	2
Injection site reaction	2
Hyperexcitable	1
Gastroenteritis	1
Urticaria	1

There are numerous vaccines that contain Canine Parvovirus in live, attenuated, inactivated and killed forms. The most frequently reported side effects reported, such as facial oedema, urticaria, vomiting, pruritis and injection site reactions occur fairly commonly 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.

CAPSICUM OLEORESIN**Equine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Mouth Irritation	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.

CARBARYL**Canine**

Number of reports	Probable	Possible
6	3	3

Presenting Signs	Number of reports
Hypersalivation	2
Ataxia	2
Pruritis	1
Disorientation	1
Lymphadenopathy	1
Lethargy	1
Death	1
Lack of effect	1
Irritation (skin)	1
Hyperexcitable	1

After assessment of adverse experience reports for products containing carbaryl it was found that occasionally dogs became poisoned after drinking some of the diluted product. A label warning has been included on these products now to advise owners not to allow animals to ingest the diluted product.

CARNITINE - L**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Depression	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.

CARPROFEN**Canine**

Number of reports	Probable	Possible
42	15	27

Presenting Signs	Number of reports
Vomiting	10
Jaundice	7
Melaena	6
Diarrhoea	6
Anorexia	5
Pain	4
Lethargy	4
Death	3
Haemorrhage	3
Polydipsia	3
Thrombocytopenia	2
Anaphylaxis	2
Irritation (skin)	2
Convulsions	2
Hepatopathy	2
Seizure	2
Tachycardia	1

Anaemia	1
Haemoconcentration	1
Pruritis	1
Dyspnoea	1
Depression	1
Hepatitis	1
Anorexic	1
Respiratory problems	1
Tremor	1
Inflammation	1
Arthropathy	1
Injection site reaction	1
Ocular damage	1
Inflammation	1
Auto-immune haemolytic anaemia	1
Lack of effect	1
Malaise	1
Defaecation	1
Behavioural change	1
Abdominal pain	1
Lame	1
Lethargic	1
Pale mucous membranes	1
Pyrexia	1
Somnolence	1
Collapse	1
Lymphadenopathy	1

CARPROFEN

Feline

Number of reports	Probable	Possible
12	5	7

Presenting Signs	Number of reports
Anorexia	5
Vomiting	5
Depression	2
Melaena	2

Polydipsia	2
Death	2
Jaundice	1
Ulceration	1
Lethargy	1
Pain	1
Colitis	1
Renal failure	1
Haemorrhage	1
Anaphylaxis	1

The side effects of non-steroidal anti-inflammatory drugs such as carprofen are documented (gastro-intestinal, lethargy, renal, hepatic, neurological, haematological and dermatological) but these are known to occur only in rare instances. The benefits of effective pain relief provided by these types of products out-weigh the very low potential for adverse effects.

CEFTIOFUR AS CEFTIOFUR SODIUM

Bovine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Dyspnoea	1
Death	1

CEFTIOFUR AS CEFTIOFUR SODIUM

Equine

Number of reports	Probable	Possible
119	11	8

Presenting Signs	Number of reports
Diarrhoea	16
Pyrexia	11
Death	3
Panting	1

Sweating	1
Colitis	1
Distress	1
Swelling (local)	1
Tachycardia	1
Respiratory problems	1
Thrombophlebitis	1
Unknown	1
Septicaemia	1

Colitis in horses has been associated secondarily to the use of certain antibiotics, including both parenteral and oral preparations. The pathophysiology of the resulting colitis and diarrhoea may involve altered volatile fatty acid synthesis, colonisation and invasion of the colon by pathogenic bacteria, and the release of bacterial toxins. *Salmonella*, *Clostridium perfringens* and *Clostridium difficile* or its cytotoxin have been implicated in these cases³. These types of reactions appear to occur more frequently in highly condition horses and therefore the product labels for these products contain warnings about using them in horses in training for racing.

CEPHALONIUM DIHYDRATE

Bovine

Number of reports	Probable	Possible
5	3	2

Presenting Signs	Number of reports
Delvo test positive	3
Illness	1
Delvo test positive (individual cow)	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.

³ Murray, M.J. (1992) Acute Colitis In: *Current Therapy in Equine Medicine 3*. Robinson, N.E. (ed.) W.B. Saunders Company, Pennsylvania pp 244-250.

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.

CHLORFENVINPHOS**Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Ataxia	1
Frothing at the mouth	1
Death	1

CHLORFENVINPHOS**Bovine**

Number of reports	Probable	Possible
8	6	2

Presenting Signs	Number of reports
Lack of effect	6
Ataxia	1
Death	1

Frothing at the mouth	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.

CHLORHEXADINE GLUCONATE

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Blisters	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.

CHLOROTHYMOL

Feline

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Prolapse third eyelid	2
Ataxia	1
Lethargy	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.

CHLORPHENIRAMINE MALEATE**Canine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Site Reaction	2

CHLORPHENIRAMINE MALEATE**Feline**

Number of reports	Probable	Possible
8	6	2

Presenting Signs	Number of reports
Death	6
Histamine Reaction	4
Convulsions	2
CNS dysfunction	2
Respiratory problems	2
Bradycardia	2
Seizure	2
Delayed Recovery	2

Chlorpheniramine maleate products are often used as a pre-medication for general anaesthesia. Most of the adverse experiences listed above were considered to have been associated with the sedation/anaesthetic combination than solely to the use of the chlorpheniramine maleate.

It is well recognised that all general anaesthetics are associated with a certain level of risk and 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.

CHLORPYRIFOS**Canine**

Number of reports	Probable	Possible
11	10	1

Presenting Signs	Number of reports
Irritation (skin)	10
Alopecia	9
Inflammation	9
Lethargy	1

CHLORPYRIFOS**Feline**

Number of reports	Probable	Possible
1	1	0

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.

CHOLINE CHLORIDE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

CHOLINE CHLORIDE**Equine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Pain	2
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.

CITRONELLA OIL**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Ulceration	1
Irritation (skin)	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.

CLAVULANIC ACID AS POTASSIUM CLAVULANATE**Canine**

Number of reports	Probable	Possible
30	12	18

Presenting Signs	Number of reports
Site Reaction	17
Depression	3
Dermatitis	3
Pruritis	2
Pyrexia	2
Haemorrhage	1
Swelling (local)	1
Inflammation	1
Coughing	1
Masticatory myositis	1
Tremor	1
Ulceration	1
Dyspnoea	1
Pain	1
Uraemia	1
Respiratory problems	1

Hypoproteinaemia	1
Irritation (skin)	1
Convulsions	1
Death	1
Vesicles	1
Hepatopathy	1

CLAVULANIC ACID AS POTASSIUM CLAVULANATE

Feline

Number of reports	Probable	Possible
5	3	2

Presenting Signs	Number of reports
Irritation (skin)	2
Oedema	1
Ptyalism	1
Cyanosis	1
Death	1
Pruritis	1
Lacrimation	1
Scabs	1
Anaphylaxis	1
Vaginitis	1
Respiratory problems	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.

CLINDAMYCIN AS CLINDAMYCIN HYDROCHLORIDE**Canine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Dermatitis	1
Lethargy	1
Pustules	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.

CLOMIPRAMINE HYDROCHLORIDE**Canine**

Number of reports	Probable	Possible
11	5	6

Presenting Signs	Number of reports
Hepatopathy	2
Lethargy	2
Ataxia	2
Seizure	2
Vomiting	2
Mouth ulcers	1
Anorexia	1
Sedation	1
Vesicles	1
Death	1
Pustules	1
Diarrhoea	1
Haematology (Abnormal)	1

CLOMIPRAMINE HYDROCHLORIDE**Feline**

Number of reports	Probable	Possible
16	11	5

Presenting Signs	Number of reports
Urinary retention	6
Haematology (Abnormal)	2
Lethargy	2
Sedation	2
Depression	1
Death	1
Respiratory problems	1
Tenesmus	1
Diarrhoea	1
Cardiac Arrest	1
Constipation	1
Tachycardia	1
Head tilt	1
Circling	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 SODIUM**Bovine**

Number of reports	Probable	Possible
7	0	7

Presenting Signs	Number of reports
Lack of effect	7

CLOPROSTENOL AS SODIUM**Camelid**

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.

CLOSANTEL**Caprine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Blindness	1

CLOSANTEL**Ovine**

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Anaemia	3
Worms	2
Lack of effect	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.

CLOSANTEL AS THE SODIUM SALT**Ovine**

Number of reports	Probable	Possible
3	3	0

Presenting Signs	Number of reports
Lack of effect	1
Anaemia	1
Bottle jaw	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.

CLOSTRIDIUM BOTULINUM TYPE C TOXOID**Bovine**

Number of reports	Probable	Possible
1	0	1

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

CLOSTRIDIUM BOTULINUM TYPE D TOXOID**Bovine**

Number of reports	Probable	Possible
2	1	1

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

CLOSTRIDIUM CHAUVOEI - FORMOL CULTURE**Bovine**

Number of reports	Probable	Possible
9	6	3

Presenting Signs	Number of reports
Death	4
Recumbency	4
Hypersalivation	3
Periorbital swelling	2
Blackleg	2
Lack of effect	2
Wheals	1
Swelling (local)	1

Facial oedema	1
Agitation	1
Injection site reaction	1
Dyspnoea	1
Anaphylaxis	1

CLOSTRIDIUM CHAUVOEI - FORMOL CULTURE

Caprine

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Injection site reaction	2
Lame	1
Pain	1
Abscess	1
Lethargy	1

CLOSTRIDIUM CHAUVOEI - FORMOL CULTURE

Ovine

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Death	2
Lack of effect	2
Lame	1
Blackleg	1
Respiratory problems	1
Cyanosis	1

CLOSTRIDIUM CHAUVOEI - KILLED**Bovine**

Number of reports	Probable	Possible
7	1	6

Presenting Signs	Number of reports
Injection site reaction	6
Death	2
Stiffness	1
Abscess	1
Welts	1

CLOSTRIDIUM CHAUVOEI - KILLED**Caprine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Abscess	1
Injection site reaction	1

CLOSTRIDIUM CHAUVOEI - KILLED**Ovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

CLOSTRIDIUM CHAUVOEI - TOXOID**Bovine**

Number of reports	Probable	Possible
16	3	13

Presenting Signs	Number of reports
Injection site reaction	8
Death	6
Lack of effect	1
Stiffness	1
Welts	1
Abscess	1
Depression	1
Blackleg	1

CLOSTRIDIUM CHAUVOEI - TOXOID**Caprine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Abscess	1
Injection site reaction	2

CLOSTRIDIUM CHAUVOEI - TOXOID**Other**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1

CLOSTRIDIUM CHAUVOEI - TOXOID**Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Injection site reaction	1

CLOSTRIDIUM NOVYI TYPE B**Bovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1
Anaphylaxis	1
Recumbency	1

CLOSTRIDIUM NOVYI TYPE B - KILLED**Bovine**

Number of reports	Probable	Possible
7	1	6

Presenting Signs	Number of reports
Injection site reaction	6
Death	2
Abscess	1
Welts	1
Stiffness	1

CLOSTRIDIUM NOVYI TYPE B - KILLED**Caprine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Abscess	1
Injection site reaction	1

CLOSTRIDIUM NOVYI TYPE B - KILLED**Ovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

CLOSTRIDIUM NOVYI TYPE B - TOXOID**Bovine**

Number of reports	Probable	Possible
26	9	17

Presenting Signs	Number of reports
Injection site reaction	11
Death	9
Lack of effect	3
Blackleg	3
Hypersalivation	3
Recumbency	3
Periorbital swelling	2
Wheals	1
Stiffness	1
Agitation	1
Swelling (local)	1
Abscess	1
Facial oedema	1
Dyspnoea	1
Welts	1
Depression	1

CLOSTRIDIUM NOVYI TYPE B - TOXOID**Caprine**

Number of reports	Probable	Possible
5	3	2

Presenting Signs	Number of reports
Abscess	1
Injection site reaction	4
Pain	1
Lethargy	1
Abscess	1
Lame	1

CLOSTRIDIUM NOVYI TYPE B - TOXOID**Other**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1

CLOSTRIDIUM NOVYI TYPE B - TOXOID**Ovine**

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Lack of effect	2
Death	2
Respiratory problems	1
Blackleg	1
Injection site reaction	1
Lame	1
Cyanosis	1

CLOSTRIDIUM PERFRINGENS TYPE D TOXOID**Bovine**

Number of reports	Probable	Possible
30	10	20

Presenting Signs	Number of reports
Injection site reaction	14
Death	10
Recumbency	4
Hypersalivation	3

Blackleg	3
Lack of effect	3
Periorbital swelling	2
Dyspnoea	1
Anaphylaxis	1
Wheals	1
Agitation	1
Abscess	1
Swelling (local)	1
Stiffness	1
Facial oedema	1
Depression	1
Welts	1

CLOSTRIDIUM PERFRINGENS TYPE D TOXOID**Caprine**

Number of reports	Probable	Possible
5	3	2

Presenting Signs	Number of reports
Abscess	1
Injection site reaction	4
Lethargy	1
Lame	1
Pain	1
Abscess	1

CLOSTRIDIUM PERFRINGENS TYPE D TOXOID**Other**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1

CLOSTRIDIUM PERFRINGENS TYPE D TOXOID**Ovine**

Number of reports	Probable	Possible
5	1	4

Presenting Signs	Number of reports
Lack of effect	2
Injection site reaction	2
Death	2
Lame	1
Cyanosis	1
Respiratory problems	1
Blackleg	1

CLOSTRIDIUM SEPTICUM - TOXOID**Bovine**

Number of reports	Probable	Possible
28	10	18

Presenting Signs	Number of reports
Injection site reaction	12
Death	10
Recumbency	4
Lack of effect	3
Hypersalivation	3
Blackleg	3
Periorbital swelling	2
Wheals	1
Swelling (local)	1
Dyspnoea	1
Welts	1
Depression	1
Agitation	1
Stiffness	1
Anaphylaxis	1
Facial oedema	1

Abscess	1
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CLOSTRIDIUM SEPTICUM - TOXOID**Caprine**

Number of reports	Probable	Possible
5	3	2

Presenting Signs	Number of reports
Abscess	1
Injection site reaction	4
Lethargy	1
Abscess	1
Pain	1
Lame	1

CLOSTRIDIUM SEPTICUM - TOXOID**Other**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1

CLOSTRIDIUM SEPTICUM - TOXOID**Ovine**

Number of reports	Probable	Possible
5	1	4

Presenting Signs	Number of reports
Injection site reaction	2
Lack of effect	2
Death	2

Blackleg	1
Lame	1
Respiratory problems	1
Cyanosis	1

CLOSTRIDIUM TETANI - TOXOID

Bovine

Number of reports	Probable	Possible
27	10	17

Presenting Signs	Number of reports
Injection site reaction	12
Death	9
Lack of effect	3
Hypersalivation	3
Blackleg	3
Recumbency	3
Periorbital swelling	2
Swelling (local)	1
Abscess	1
Depression	1
Agitation	1
Facial oedema	1
Welts	1
Wheals	1
Dyspnoea	1
Stiffness	1

CLOSTRIDIUM TETANI - TOXOID**Caprine**

Number of reports	Probable	Possible
5	1	4

Presenting Signs	Number of reports
Abscess	1
Injection site reaction	4
Pain	1
Lethargy	1
Abscess	1
Lame	1

CLOSTRIDIUM TETANI - TOXOID**Other**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1

CLOSTRIDIUM TETANI - TOXOID**Ovine**

Number of reports	Probable	Possible
5	1	4

Presenting Signs	Number of reports
Lack of effect	2
Death	2
Injection site reaction	2
Respiratory problems	1
Cyanosis	1

Lame	1
Blackleg	1

Vaccinations for use in production animals such as goats, cattle and sheep are used extensively throughout Australia and many thousands of doses of vaccine are sold each year. Many vaccines are also a combination of the five 'clostridial' components listed above.

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
10	2	8

Presenting Signs	Number of reports
Strangles	3
Lack of effect	3
Pyrexia	3
Death	2
Tetanus	2
Lethargy	2
Stiffness	1
Frothing at the mouth	1
Ataxia	1
Weakness	1
Pain	1
Swelling (local)	1
Anorexia	1
Lame	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
12	7	5

Presenting Signs	Number of reports
Pain	2
Lack of effect	2
Vocalisation	1
Distress	1
Inflammation	1
Ulceration	1
Pruritis	1
Irritation (ear)	1
Agitation	1
Pupillary constriction	1
Horner's Syndrome	1
Prolapse third eyelid	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.

CLOXACILLIN AS THE BENZATHINE SALT**Bovine**

Number of reports	Probable	Possible
8	3	5

Presenting Signs	Number of reports
Residue violation	5
Persistent dye excretion	4
Mastitis	1
Lack of effect	1

CLOXACILLIN AS THE SODIUM SALT**Bovine**

Number of reports	Probable	Possible
5	0	5

Presenting Signs	Number of reports
Residue violation	5

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	2	0

Presenting Signs	Number of reports
Shaking	1
Death	1
Pharyngitis	1
Convulsions	1
Frothing at the mouth	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.

COBALT EDTA**Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	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.

COBALT GLUCONATE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

COBALT GLUCONATE**Equine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Injection site reaction	2
Pain	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.

CONTAGIOUS PUSTULAR DERMATITIS VIRUS, LIVING, CELL CULTURE

Ovine

Number of reports	Probable	Possible
5	1	4

Presenting Signs	Number of reports
Lack of effect	2
Scabby mouth	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.

COPPER

Ovine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Oedema	1
Depression	1
Death	1
Pharyngitis	1
Swelling (local)	1

A label change was made to a number of products containing minerals such as copper in which the product is administered as a 'pellet'. The pellets are administered orally by a special applicator gun. It was found that if farmers did not take appropriate precautions when administering these types of products and this could result in damage to the pharyngeal area of some sheep. As a result a label change was made to emphasise the need for operators to take precautions not to force the applicator gun into the mouth.

COPPER GLUCONATE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Injection site reaction	1
Swollen feet	1
Pain	1

COPPER GLUCONATE**Equine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Injection site reaction	2
Pain	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.

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

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Injection site reaction	2
Pain	1
Abscess	1

Lame	1
Lethargy	1

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

Number of reports	Probable	Possible
4	1	3

Presenting Signs	Number of reports
Death	2
Lack of effect	2
Respiratory problems	1
Blackleg	1
Cyanosis	1
Lame	1

CORYNEBACTERIUM PSEUDOTUBERCULOSIS - KILLED**Ovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1

CORYNEBACTERIUM PSEUDOTUBERCULOSIS - TOXOID**Caprine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Injection site reaction	1

CORYNEBACTERIUM PSEUDOTUBERCULOSIS - TOXOID**Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Injection site reaction	1

Vaccinations for use in production animals such as goats, cattle and sheep are used extensively throughout Australia and many thousands of doses of vaccine are sold each year.

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
3	1	2

Presenting Signs	Number of reports
Ataxia	1
Irritation (skin)	1
Recumbency	1
Coughing	1
Listless	1
Ocular damage	1

COUMAPHOS**Equine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Hyperaesthesia	1
Irritation (skin)	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.

CYCLOSPORIN**Canine**

Number of reports	Probable	Possible
14	6	8

Presenting Signs	Number of reports
Vomiting	4
Diarrhoea	2
Anorexia	2
Erythema	2
Weakness	2
Lethargy	2
Agitation	2
Melaena	2
Pruritis	2
Pale mucous membranes	1
Depression	1
Hypersalivation	1
Diabetes	1
Panting	1
Colic	1

Collapse	1
Somnolence	1
Capillary refill time - slow	1
Seizure	1
Irritation (eye)	3
Ocular damage	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.

CYPERMETHRIN

Unknown

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Frothing at the mouth	1
Ataxia	1
Death	1

CYPERMETHRIN

Bovine

Number of reports	Probable	Possible
7	6	1

Presenting Signs	Number of reports
Lack of effect	6
Death	1
Ataxia	1
Frothing at the mouth	1

CYPERMETHRIN**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Depression	1
Hypersalivation	1

CYPERMETHRIN**Ovine**

Number of reports	Probable	Possible
21	3	18

Presenting Signs	Number of reports
Lack of effect	20
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.

CYROMAZINE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Hepatitis	1
Irritation (paws)	1
Renal failure	1

CYROMAZINE**Ovine**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Lack of effect	3

A product containing cyromazine and diethylcarbamazine was subject to a voluntary recall procedure and subsequently the product label has changed to indicate that it may be used only on dogs previously treated and which showed no adverse reaction following that treatment. This information was reported in the 1996 Annual Report. Since then, 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.

CYTHIOATE**Canine**

Number of reports	Probable	Possible
15	2	13

Presenting Signs	Number of reports
Alopecia	3
Irritation (skin)	3
Seizure	2
Vomiting	2
Lethargy	1
Diarrhoea	1
Respiratory problems	1
Ataxia	1
Death	1
Convulsions	1
Panting	1
Agitation	1
Hyperexcitable	1
Dermatitis	1

CYTHIOATE**Feline**

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.

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
86	15	71

Presenting Signs	Number of reports
Lack of effect	60
Irritation (skin)	13
Behavioural change	8

Milk production decrease	7
Death	6
Pinkeye	5
Alopecia	5
Photosensitisation	2
Anaemia	1
hair loss	1
Convulsions	1
Agitation	1
Defaecation	1
Tremor	1
Hypersalivation	1
Abortion	1
Site Reaction	1
Diarrhoea	1
Burning sensation	1
Distress	1
Scabs	1
Ataxia	1
Blisters	1

DELTAMETHRIN**Caprine**

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Lack of effect	4

DELTAMETHRIN**Other**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Death	2

DELTAMETHRIN**Ovine**

Number of reports	Probable	Possible
146	4	142

Presenting Signs	Number of reports
Lack of effect	141
Scabs	3
Site Reaction	3
Lumpy wool	2
Irritation (skin)	1

Deltamethrin is a synthetic pyrethroid, and it is known that in Australia there is the possibility of resistance to some of these types of lice control products. Veterinary advisors are aware of these issues and routinely provide information to farmers on how to avoid and manage potential resistance.

Again, due to the very low number of reports of these types of incidents when compared to the very large number of sheep treated each year no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

DEXAMETHASONE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1

DEXAMETHASONE PHENPROPIONATE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Depression	1

DEXAMETHASONE SODIUM PHOSPHATE**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**Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

DEXPANTHENOL**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.

DI-ISOPROPYLAMINE DICHLOROACETATE**Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1

DI-ISOPROPYLAMINE DICHLOROACETATE**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Swelling (local)	1

DI-ISOPROPYLAMINE DICHLOROACETATE**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.

DI-N-PROPYL ISOCINCHOMERONATE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Irritation (skin)	1
Ulceration	1

DI-N-PROPYL ISOCINCHOMERONATE**Equine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Pain	1
Alopecia	1
Hair loss	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.

DIAZEPAM**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Skin slough	1
Urticaria	1
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.

DIAZINON**Bovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Abscess	1

DIAZINON**Canine**

Number of reports	Probable	Possible
10	5	5

Presenting Signs	Number of reports
Lack of effect	3
Urticaria	2
Dermatitis	2
Toxicity	2
Vomiting	1
Irritation (skin)	1
Ataxia	1
Lethargy	1
Anorexia	1

DIAZINON**Feline**

Number of reports	Probable	Possible
20	7	13

Presenting Signs	Number of reports
Irritation (skin)	8
Lack of effect	4

Anorexia	3
Alopecia	2
Depression	1
Anaphylaxis	1
Ataxia	1
Shaking	1
Erythema	1
Photophobia	1
Welts	1
Toxicity	1
Coughing	1

DIAZINON**Ovine**

Number of reports	Probable	Possible
30	11	19

Presenting Signs	Number of reports
Lack of effect	29
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.

DICHLOROPHEN**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Irritation (skin)	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.

DICHLORVOS**Equine**

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Abortion	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.

DIETHYLCARBAMAZINE CITRATE**Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Hepatitis	1
Vomiting	1
Renal failure	1
Irritation (paws)	1

A product containing cyromazine and diethylcarbamazine was subject to a voluntary recall procedure and subsequently the product label has changed to indicate that it may be used only on dogs previously treated and which showed no adverse reaction following that treatment. This information was reported in the 1996 Annual Report. Since then, 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.

DIETHYLTOLUAMIDE**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Alopecia	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.

DIFLUBENZURON**Unknown**

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Site Reaction	4

DIFLUBENZURON**Bovine**

Number of reports	Probable	Possible
17	0	17

Presenting Signs	Number of reports
Pruritis	9
Lack of effect	6
Alopecia	2

DIFLUBENZURON**Ovine**

Number of reports	Probable	Possible
92	27	65

Presenting Signs	Number of reports
Lack of effect	72
Site Reaction	10
Irritation (skin)	10
Wool damage	4
Scabs	2
Lumpy wool	1
Alopecia	1

In Australia, although there are no known cases of resistance to diflubenzuron by sheep lice, it is known there is the possibility of resistance to some of these types of lice control products.

Veterinary advisors are aware of these issues and routinely provide information to farmers on how to avoid and manage potential resistance.

Again, due to the very low number of reports of these types of incidents when compared to the very large number of sheep treated each year no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

DIMETHYL SULFOXIDE**Equine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Blisters	1
Irritation (skin)	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.

DINOPROST AS DINOPROST TROMETAMOL**Bovine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Death	1
Abscess	1

DINOPROST AS DINOPROST TROMETAMOL**Ovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Lack of effect	1

Due to adverse experience reports in which cattle developed abscesses at the site of injection of products containing dinoprost trometamol, an additional warning statement has been included on product label to advise users that the site of injection should be thoroughly cleaned and disinfected before injection and that aggressive antibiotic therapy should be employed at the first signs of infection at the injection sites.

DOCUSATE = DIOCTYL SODIUM SULFOSUCCINATE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Inflammation	1
Oedema	1
Head tilt	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
6	0	6

Presenting Signs	Number of reports
Lack of effect	2
Injection site reaction	2
Hyperaesthesia	1
Recumbency	1
Alopecia	1
Hyperactivity	1
Excitation	1

DORAMECTIN**Porcine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
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.

DOXYCYCLINE AS DOXYCYCLINE MONOHYDRATE**Canine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Excitation	1
Head tilt	1
Restless	1
Vomiting	1
Death	1
Rolling	1
Rales	1
Ataxia	1
Ocular damage	1
Pupillary dilation	1

DOXYCYCLINE AS DOXYCYCLINE MONOHYDRATE**Feline**

Number of reports	Probable	Possible
4	1	3

Presenting Signs	Number of reports
Vomiting	2
Haemorrhage	1
Oedema	1
Swelling (local)	1
Pruritis	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.

ENROFLOXACIN**Canine**

Number of reports	Probable	Possible
7	3	4

Presenting Signs	Number of reports
Injection site reaction	5
Hypoproteinaemia	1
Dermatitis	1
Vasculitis	1
Erythema	1
Collapse	1
Anorexia	1
Urticaria	1

ENROFLOXACIN**Feline**

Number of reports	Probable	Possible
11	6	5

Presenting Signs	Number of reports
Hypersalivation	3
Vomiting	3
Ataxia	3
Blindness	2
Collapse	1
Anaemia	1
Anorexia	1
Weakness	1
Diarrhoea	1
Swelling (local)	1
Distress	1
Injection site reaction	1
Death	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.

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

Equine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Lack of effect	1
URTI	1
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.

EQUINE HERPES VIRUS 4 (EHV-4) 405/76 STRAIN

Equine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Abortion	1
URTI	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.

ERYSIPELOTHRIX RHUSIOPATHIAE**Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Distress	1
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.

ERYTHROMYCIN**Bovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	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.

ESCHERICHIA COLI 987P PILUS ANTIGENS**Porcine**

Number of reports	Probable	Possible
4	2	2

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

ESCHERICHIA COLI K88AB PILUS ANTIGENS**Porcine**

Number of reports	Probable	Possible
4	2	2

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

ESCHERICHIA COLI K99 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.

ETHYL ALCOHOL**Equine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Irritation (skin)	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.

ETODOLAC**Canine**

Number of reports	Probable	Possible
15	11	4

Presenting Signs	Number of reports
Diarrhoea	12
Haemorrhage	9
Vomiting	4
Death	3
Melaena	2
Pyrexia	1
Pain	1
Lethargy	1
Arthropathy	1
Dyspnoea	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.

EUCALYPTUS OIL**Equine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Irritation (skin)	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.

FEBANTEL**Canine**

Number of reports	Probable	Possible
35	7	28

Presenting Signs	Number of reports
Vomiting	18
Worms	6
Shaking	5
Diarrhoea	4
Illness	4
Tremor	3
Lethargy	3
Death	3
Ataxia	2
Depression	2
Hyperexcitable	2
Recumbency	2
Scouring	2
Pupillary dilation	2
Tachycardia	1
Abdominal pain	1
Agitation	1
Polyarthritis	1
Pupillary constriction	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.

FELINE CALICIVIRUS - INACTIVATED**Unknown**

Number of reports	Probable	Possible
6	6	0

Presenting Signs	Number of reports
Listless	3
Vomiting	3
Anorexia	3

FELINE CALICIVIRUS - INACTIVATED**Feline**

Number of reports	Probable	Possible
244	167	77

Presenting Signs	Number of reports
Lethargy	141
Anorexia	130
Pyrexia	103
Pain	55
Depression	47
Injection site reaction	33
Vomiting	13
Ataxia	10
Illness	8
Vocalisation	8
Stiffness	8
Death	7
Collapse	7
Nil	5
Alopecia	5
Hyperaesthesia	5
Tachycardia	5
Swelling (local)	4
Respiratory problems	4
Agitation	3

Unknown	3
Malaise	3
Cat flu	3
Listless	3
Weight loss	3
Diarrhoea	3
Fibrosarcoma	3
Dyspnoea	3
Weakness	3
Inflammation	3
Site Reaction	3
Tiredness	3
Comatose	3
Cyanosis	2
Disorientation	2
Anaphylaxis	2
Facial oedema	2
Lame	2
Distress	2
Muscle stiffness	2
Shaking	2
Recumbency	1
Hypersalivation	1
Blisters	1
Lymphadenopathy	1
Behavioural change	1
Nasal discharge	1
Opisthotonos	1
Irritation (paws)	1
Pulmonary oedema	1
Pruritis	1
Non-ambulatory	1
Paddling	1
Irritation (skin)	1
Ulceration	1
Restless	1
Sneezing	1
Lack of effect	1
CNS dysfunction	1
Pupillary dilation	1
Frothing at the mouth	1
Abortion	1

Panting	1
Urination	1
lameness	1
Melaena	1
Erythema	1
Miosis	1

FELINE CALICIVIRUS - LIVE

Feline

Number of reports	Probable	Possible
38	15	23

Presenting Signs	Number of reports
Lethargy	11
Injection site reaction	7
Pain	5
Anorexia	5
Respiratory problems	4
Pyrexia	4
Swelling (local)	4
Vomiting	3
Sneezing	2
Nasal discharge	2
Necrosis	2
Death	2
Lame	2
Prolapse third eyelid	2
Depression	2
Ataxia	2
Dermatitis	2
Site Reaction	2
Abscess	1
Aggression	1
Hypersalivation	1
Anaphylaxis	1
Sarcoma formation	1
Urticaria	1
Collapse	1

lame	1
Facial oedema	1
Hyperaesthesia	1
Recumbency	1
Diarrhoea	1
Behavioural change	1
Conjunctivitis	1
Distress	1

FELINE CALICIVIRUS STRAIN 2112**Feline**

Number of reports	Probable	Possible
9	4	5

Presenting Signs	Number of reports
Injection site reaction	3
Pain	1
Lethargy	1
Hyperaesthesia	1
Shock	1
Prolapse third eyelid	1
Lacrimation	1
Paresis	1
Death	1
Agitation	1
Fibrosarcoma	1

FELINE CALICIVIRUS STRAIN RVS45**Feline**

Number of reports	Probable	Possible
9	4	5

Presenting Signs	Number of reports
Injection site reaction	3
Pain	1

Prolapse third eyelid	1
Hyperaesthesia	1
Agitation	1
Lacrimation	1
Fibrosarcoma	1
Shock	1
Death	1
Paresis	1
Lethargy	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 lethargy, anorexia, pyrexia, depression and injection site reactions 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
113	103	10

Presenting Signs	Number of reports
Lethargy	78
Anorexia	76
Pyrexia	43
Pain	28
Depression	17
Injection site reaction	14
Vomiting	10
Stiffness	8
Vocalisation	5
Collapse	4
Respiratory problems	4
Nil	3
Hyperaesthesia	3
Unknown	3
Swelling (local)	3
Ataxia	3

Tachycardia	3
Agitation	3
Alopecia	3
Tiredness	3
Site Reaction	2
Dyspnoea	2
Malaise	2
Death	2
Weakness	2
Cyanosis	2
Diarrhoea	2
Weight loss	2
Pruritis	1
Recumbency	1
Erythema	1
Panting	1
Listless	1
Restless	1
Behavioural change	1
Pulmonary oedema	1
Blisters	1
Pupillary dilation	1
Ulceration	1
Lame	1
Inflammation	1

There are numerous vaccines that contain Feline Chlamydia Psittaci virus in live, attenuated, inactivated and killed forms. The most frequently reported side effects reported, such as lethargy, anorexia, pyrexia, depression and injection site reactions 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 LEUKAEMIA**Feline**

Number of reports	Probable	Possible
8	6	2

Presenting Signs	Number of reports
Lethargy	7
Anorexia	5
Pyrexia	2
Pain	2
Depression	1
Anaphylaxis	1
Injection site reaction	1

FELINE LEUKAEMIA VIRUS - INACTIVATED**Feline**

Number of reports	Probable	Possible
18	15	3

Presenting Signs	Number of reports
Lethargy	10
Anorexia	9
Pyrexia	7
Pain	5
Injection site reaction	4
Vomiting	4
Agitation	2
Alopecia	2
Ataxia	1
Vocalisation	1
Stiffness	1
Inflammation	1
Hyperaesthesia	1
Death	1
Erythema	1
Pruritis	1

Depression	1
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There are numerous vaccines that contain Feline Calicivirus in live, attenuated, inactivated and killed forms. The most frequently reported side effects reported, such as lethargy, anorexia, pyrexia, depression and injection site reactions 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 PANLEUCOPENIA VIRUS - INACTIVATED

Unknown

Number of reports	Probable	Possible
6	6	0

Presenting Signs	Number of reports
Anorexia	3
Vomiting	3
Listless	3

FELINE PANLEUCOPENIA VIRUS - INACTIVATED

Feline

Number of reports	Probable	Possible
244	167	77

Presenting Signs	Number of reports
Lethargy	141
Anorexia	130
Pyrexia	103
Pain	55
Depression	47
Injection site reaction	33
Vomiting	13
Ataxia	10
Illness	8
Stiffness	8

Vocalisation	8
Collapse	7
Death	7
Alopecia	5
Tachycardia	5
Hyperaesthesia	5
Swelling (local)	4
Respiratory problems	4
Agitation	3
Weight loss	3
Inflammation	3
Listless	3
Fibrosarcoma	3
Site Reaction	3
Tiredness	3
Cat flu	3
Unknown	3
Diarrhoea	3
Weakness	3
Dyspnoea	3
Comatose	3
Malaise	3
Shaking	2
Muscle stiffness	2
Cyanosis	2
Distress	2
Lame	2
Anaphylaxis	2
Disorientation	2
Facial oedema	2
Lack of effect	1
Restless	1
Erythema	1
Non-ambulatory	1
Irritation (skin)	1
Melaena	1
Pupillary dilation	1
Abortion	1
Sneezing	1
Lymphadenopathy	1
Hypersalivation	1
Urination	1

Recumbency	1
Nasal discharge	1
Miosis	1
Ulceration	1
Frothing at the mouth	1
Blisters	1
CNS dysfunction	1
Panting	1
Irritation (paws)	1
Pulmonary oedema	1
Behavioural change	1
Paddling	1
Opisthotonos	1
Pruritis	1

FELINE PANLEUCOPENIA VIRUS - LIVE

Feline

Number of reports	Probable	Possible
38	15	23

Presenting Signs	Number of reports
Lethargy	11
Injection site reaction	7
Pain	5
Anorexia	5
Respiratory problems	4
Swelling (local)	4
Pyrexia	4
Vomiting	3
Ataxia	2
Death	2
Depression	2
Sneezing	2
Necrosis	2
Nasal discharge	2
Lame	2
Site Reaction	2
Prolapse third eyelid	2

Dermatitis	2
Aggression	1
Sarcoma formation	1
Hypersalivation	1
Distress	1
Hyperaesthesia	1
Anaphylaxis	1
Recumbency	1
Diarrhoea	1
Urticaria	1
Collapse	1
Conjunctivitis	1
Abscess	1
Behavioural change	1
Facial oedema	1
lame	1

FELINE PANLEUCOPENIA VIRUS STRAIN LVH/71/FIE

Feline

Number of reports	Probable	Possible
9	4	5

Presenting Signs	Number of reports
Injection site reaction	3
Agitation	1
Pain	1
Shock	1
Prolapse third eyelid	1
Death	1
Fibrosarcoma	1
Paresis	1
Lethargy	1
Lacrimation	1
Hyperaesthesia	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, pyrexia, depression and injection site reactions 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
38	15	23

Presenting Signs	Number of reports
Lethargy	11
Injection site reaction	7
Pain	5
Anorexia	5
Pyrexia	4
Respiratory problems	4
Swelling (local)	4
Vomiting	3
Depression	2
Nasal discharge	2
Sneezing	2
Lame	2
Dermatitis	2
Necrosis	2
Prolapse third eyelid	2
Death	2
Site Reaction	2
Ataxia	2
Conjunctivitis	1
Distress	1
Facial oedema	1
lame	1
Behavioural change	1
Hyperaesthesia	1
Aggression	1
Abscess	1
Anaphylaxis	1
Diarrhoea	1
Sarcoma formation	1

Collapse	1
Hypersalivation	1
Recumbency	1
Urticaria	1

FELINE RHINOTRACHEITIS VIRUS - INACTIVATED**Unknown**

Number of reports	Probable	Possible
6	6	0

Presenting Signs	Number of reports
Listless	3
Vomiting	3
Anorexia	3

FELINE RHINOTRACHEITIS VIRUS - INACTIVATED**Feline**

Number of reports	Probable	Possible
244	167	77

Presenting Signs	Number of reports
Lethargy	141
Anorexia	130
Pyrexia	103
Pain	55
Depression	47
Injection site reaction	33
Vomiting	13
Ataxia	10
Illness	8
Stiffness	8
Vocalisation	8
Collapse	7
Death	7
Alopecia	5

Hyperaesthesia	5
Tachycardia	5
Swelling (local)	4
Respiratory problems	4
Unknown	3
Diarrhoea	3
Weakness	3
Agitation	3
Site Reaction	3
Cat flu	3
Fibrosarcoma	3
Malaise	3
Listless	3
Comatose	3
Inflammation	3
Weight loss	3
Tiredness	3
Dyspnoea	3
Muscle stiffness	2
Distress	2
Facial oedema	2
Cyanosis	2
Shaking	2
Anaphylaxis	2
Disorientation	2
Lame	2
Opisthotonos	1
Irritation (skin)	1
Urination	1
CNS dysfunction	1
Miosis	1
Lack of effect	1
Pulmonary oedema	1
Nasal discharge	1
Irritation (paws)	1
Pruritis	1
Melaena	1
Erythema	1
Hypersalivation	1
Lymphadenopathy	1
Blisters	1
Behavioural change	1

Paddling	1
Sneezing	1
Recumbency	1
lameness	1
Panting	1
Frothing at the mouth	1
Ulceration	1
Non-ambulatory	1
Pupillary dilation	1
Abortion	1
Restless	1

FELINE RHINOTRACHEITIS VIRUS STRAIN RVS34

Feline

Number of reports	Probable	Possible
9	4	5

Presenting Signs	Number of reports
Injection site reaction	3
Fibrosarcoma	1
Paresis	1
Hyperaesthesia	1
Lethargy	1
Prolapse third eyelid	1
Pain	1
Death	1
Agitation	1
Lacrimation	1
Shock	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, pyrexia, depression and injection site reactions 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.

FENBENDAZOLE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
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.

FENTHION**Canine**

Number of reports	Probable	Possible
7	2	5

Presenting Signs	Number of reports
Vomiting	2
Site Reaction	1
Shaking	1
Ulceration	1
Hyperexcitable	1
Panting	1
Malaise	1
Hypersalivation	1
listless	1
Swollen lips and face	1
Pruritis	1
Urticaria	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.

FERRIC CHLORIDE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Swollen feet	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.

FIPRONIL**Canine**

Number of reports	Probable	Possible
53	14	39

Presenting Signs	Number of reports
Lack of effect	20
Tick paralysis	18
Pruritis	9
Site Reaction	8
Irritation (skin)	6
Erythema	6
Alopecia	5
Scabs	5
Lethargy	4
Death	3
Papules	3
Respiratory problems	3
Anorexia	3
Abdominal pain	3
Depression	3
Vocalisation	2
Urticaria	2

Inflammation	2
Pain	2
Vomiting	2
Wheals	1
Self trauma	1
Diarrhoea	1
Ataxia	1
Inflammation	1
Pyoderma	1
Oedema	1
Dyspnoea	1
Pigmentation	1
Pyrexia	1
Hyperexcitable	1
Hives	1
Seizure	1
Vasculitis	1
Coat discoloration	1
Hypersalivation	1
Restless	1
Welts	1
Blisters	1
Aggression	1
Dermatitis	1

FIPRONIL**Feline**

Number of reports	Probable	Possible
24	7	17

Presenting Signs	Number of reports
Site Reaction	9
Anorexia	7
Lethargy	6
Irritation (skin)	4
Alopecia	4
Vomiting	3
Tremor	3

Ataxia	3
Dyspnoea	2
Lack of effect	2
Death	2
Pruritis	2
Seizure	1
Self trauma	1
Tick paralysis	1
Hypersalivation	1
Panting	1
Pyrexia	1
Dehydration	1
Coughing	1
leukaemia	1
Pyoderma	1

Based on assessment of adverse experience reports involving products containing fipronil used on animals, additional statements were included on the product labels to indicate that they should not be used if the owner or pet has a known hypersensitivity to insecticides or alcohol and not to use on rabbits.

FLUMETHASONE

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Blisters	1
Irritation (skin)	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
3	1	2

Presenting Signs	Number of reports
Lack of effect	2
Listless	1
Non-ambulatory	1
Diarrhoea	1

FLUMETHRIN**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Respiratory problems	1
Pruritis	1
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.

FLUNIXIN MEGLUMINE**Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Pale mucous membranes	1
Hepatopathy	1

Haemorrhage	1
Ataxia	1
Vocalisation	1
Recumbency	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.

FRAMYCETIN SULFATE

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.

FRUSEMIDE

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Anorexia	1
Vomiting	1
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.

GENTAMICIN**Canine**

Number of reports	Probable	Possible
12	7	5

Presenting Signs	Number of reports
Deafness	6
Pain	2
Lack of effect	2
Agitation	1
Inflammation	1
Vocalisation	1
Irritation (ear)	1
Prolapse third eyelid	1
Pupillary constriction	1
Pruritis	1
Horner's Syndrome	1
Distress	1
Ulceration	1

GENTAMICIN AS GENTAMICIN SULFATE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Polyuria	1
Polydipsia	1

GENTAMICIN AS GENTAMICIN SULFATE**Equine**

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.

GLYCERINE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

GLYCERINE**Equine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Injection site reaction	2
Pain	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.

GONADOTROPHIN-CHORIONIC**Aquatic**

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.

GRAMICIDIN**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.

GUAIPHENESIN**Equine**

Number of reports	Probable	Possible
3	3	0

Presenting Signs	Number of reports
Thrombophlebitis	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.

HALOTHANE**Canine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Seizure	1
Death	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.

HEPTAMINOL HYDROCHLORIDE**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
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.

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.

HYDROLYSED LINSEED FATTY ACIDS**Bovine**

Number of reports	Probable	Possible
7	4	3

Presenting Signs	Number of reports
Lack of effect	7

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 CAPROATE**Equine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	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.

HYOSCINE AS 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
32	12	20

Presenting Signs	Number of reports
Irritation (skin)	9
Site Reaction	8
Alopecia	5
Lack of effect	5
Depression	4
Anorexia	3
Rash	2
Hyperexcitable	2
Agitation	2
Shaking	2
Periorbital swelling	1
Dermatitis	1
Frothing at the mouth	1
Lethargy	1
Pruritis	1
Inflammation	1
Hypersalivation	1
Panting	1
Paralysis	1

IMIDACLOPRID**Feline**

Number of reports	Probable	Possible
13	6	7

Presenting Signs	Number of reports
Site Reaction	7
Alopecia	4
Lethargy	3
Ataxia	2

Frothing at the mouth	2
Hypersalivation	1
Weakness	1
Vomiting	1
Pyrexia	1
Diarrhoea	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.

IMIDOCARB DIPROPIONATE

Bovine

Number of reports	Probable	Possible
1	1	0

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.

INACTIVATED RABBIT CALICIVIRUS DISEASE VIRUS

Rabbit

Number of reports	Probable	Possible
63	44	19

Presenting Signs	Number of reports
Site Reaction	21
Alopecia	17
Death	9
Injection site reaction	9
Skin slough	4
Anorexia	3

Irritation (skin)	3
Scabs	2
Paralysis	2
Inflammation	2
Diarrhoea	2
Lame	2
Lethargy	2
Convulsions	1
Pyrexia	1
Necrosis	1
Pruritis	1
Anaphylaxis	1
Oedema	1
Depression	1
Reproduction Disorder	1
Self trauma	1
Erythema	1
Swelling (local)	1
Proprioception Deficit	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.

INOSITOL**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

INOSITOL**Equine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Pain	2
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.

INSULIN**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

INSULIN**Feline**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1
Renal failure	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
4	2	2

Presenting Signs	Number of reports
Death	2
Pharyngitis	2
Depression	1
Ataxia	1
Convulsions	1
Swelling (local)	1
Frothing at the mouth	1
Shaking	1
Oedema	1

A label change was made to a number of products containing minerals such as iodine in which the product is administered as a 'pellet'. The pellets are administered orally by a special drenching gun. It was found that in a number of cases farmers did not take appropriate precautions when administering these types of products and this resulted in damage to the pharyngeal area of some sheep. As a result a label change was made to emphasise the need for operators to take precautions not to force the drenching gun into the mouth

IRON AS AMMONIUM FERRIC CITRATE**Equine**

Number of reports	Probable	Possible
1	1	0

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.

ISOFLURANE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Shock	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
3	0	3

Presenting Signs	Number of reports
Lack of effect	3

IVERMECTIN**Canine**

Number of reports	Probable	Possible
15	6	9

Presenting Signs	Number of reports
Lack of effect	3
Irritation (skin)	2
Lethargy	2
Ataxia	1
Depression	1
Diarrhoea	1
Urticaria	1
Frothing at the mouth	1
Vomiting	1
Anaphylaxis	1
Tremor	1
Dermatitis	1
Site Reaction	1
Death	1
Vocalisation	1
Alopecia	1
Weakness	1
Seizure	1

IVERMECTIN**Caprine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1
Head tilt	1
Comatose	1
Blindness	1

IVERMECTIN**Ovine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Death	3
Coughing	1
Bottle jaw	1
Paddling	1
Lack of effect	1
Ataxia	1
Recumbency	1
Haemorrhage	1

A label change was made to a number of products containing ivermectin in which the product is administered as a 'pellet'. The pellets are administered orally by a special drenching gun. It was found that in a number of cases farmers did not take appropriate precautions when administering these types of products and this resulted in damage to the pharyngeal area of some sheep. As a result a label change was made to emphasise the need for operators to take precautions not to force the drenching gun into the mouth.

KETAMINE AS KETAMINE HYDROCHLORIDE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Vocalisation	1
Hallucinating	1
Disorientation	1
Hypersalivation	1

KETAMINE AS KETAMINE HYDROCHLORIDE**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1

KETAMINE AS KETAMINE HYDROCHLORIDE**Feline**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Lack of effect	1
Agitation	1
Behavioural change	1

KETAMINE HYDROCHLORIDE**Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Skin slough	1
Pale mucous membranes	1
Dyspnoea	1
Oedema	1
Urticaria	1
Bradycardia	1
Apnoea	1

KETAMINE HYDROCHLORIDE**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Haemorrhage	1
Distress	1
Death	1
Respiratory problems	1

KETAMINE HYDROCHLORIDE**Feline**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Respiratory problems	1

Oedema	1
Shock	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
12	6	6

Presenting Signs	Number of reports
Injection site reaction	4
Death	3
Hypersalivation	3
Lack of effect	3
Recumbency	3
Periorbital swelling	2
Blackleg	2
Facial oedema	1
Dyspnoea	1
Wheals	1
Swelling (local)	1
Agitation	1

LEPTOSPIRA INTERROGANS SEROVAR HARDJO

Bovine

Number of reports	Probable	Possible
6	3	3

Presenting Signs	Number of reports
Injection site reaction	4
Abortion	1
Death	1
Depression	1

LEPTOSPIRA INTERROGANS SEROVAR POMONA**Bovine**

Number of reports	Probable	Possible
15	8	7

Presenting Signs	Number of reports
Injection site reaction	5
Death	4
Lack of effect	3
Recumbency	3
Hypersalivation	3
Blackleg	2
Periorbital swelling	2
Facial oedema	1
Agitation	1
Dyspnoea	1
Abortion	1
Depression	1
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.

LEVAMISOLE**Bovine**

Number of reports	Probable	Possible
6	4	2

Presenting Signs	Number of reports
Death	2
Convulsions	1
Site Reaction	1
Abortion	1
Dermatitis	1

Hypersalivation	1
Alopecia	1
Irritation (skin)	1

LEVAMISOLE**Canine**

Number of reports	Probable	Possible
1	0	1

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

LEVAMISOLE AS LEVAMISOLE HYDROCHLORIDE**Canine**

Number of reports	Probable	Possible
4	3	1

Presenting Signs	Number of reports
Vocalisation	3
Agitation	2
Pain	2
Shaking	2
Diarrhoea	1
Irritation (skin)	1

LEVAMISOLE AS LEVAMISOLE HYDROCHLORIDE**Feline**

Number of reports	Probable	Possible
4	3	1

Presenting Signs	Number of reports
Vomiting	2
Gastroenteritis	1
Pain	1
Lethargy	1
Unknown	1

LEVAMISOLE AS LEVAMISOLE HYDROCHLORIDE**Ovine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Death	2
Tremor	1
Hypersalivation	1
Frothing at the mouth	1
Recumbency	1
Ataxia	1

LEVAMISOLE HYDROCHLORIDE**Avian**

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Death	4

Based on the assessment of adverse experience reports involving the use of levamisole in birds it was considered that parrots and finches may be less tolerant than other species such as pigeons to levamisole. Therefore a precautionary statement was added to the product labels to advise users to take precautions when treating parrots and finches.

LEVAMISOLE HYDROCHLORIDE**Bovine**

Number of reports	Probable	Possible
22	13	9

Presenting Signs	Number of reports
Death	13
Anorexia	7
Diarrhoea	7
Lethargy	3
Illthrift	3
Recumbency	2
Worms	2
Milk production decrease	2
Scouring	2
Rumen stasis	1
Fasciculation	1
Agitation	1
Fluke	1
Haemorrhage	1
Weakness	1
Tremor	1
Behavioural change	1

Pyrexia	1
Distress	1
Disorientation	1
Hypersalivation	1
Depression	1
Shaking	1

LEVAMISOLE HYDROCHLORIDE

Ovine

Number of reports	Probable	Possible
22	14	8

Presenting Signs	Number of reports
Death	17
Tremor	3
Frothing at the mouth	3
Ataxia	3
Shaking	3
Recumbency	2
Illthrift	2
Convulsions	2
Worms	2
Anorexia	2
Lethargy	1
Diarrhoea	1
Pharyngitis	1
Alopecia	1
Lame	1

Based on the assessment of adverse experience reports involving the use of levamisole in cattle and sheep it was identified that a number of users were yarding animals overnight without feed and in some cases without water prior to drenching. It is recognised that cattle and sheep that are under stress or that are dehydrated may be more susceptible to levamisole toxicity and as a result additional label warning statements to warn users to avoid these practices are being made.

LIGNOCAINE AS LIGNOCAINE HYDROCHLORIDE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Vomiting	1

LIGNOCAINE HYDROCHLORIDE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1

LIGNOCAINE HYDROCHLORIDE**Feline**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Lethargy	1
Irritation (ear)	1
Distress	1
Depression	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.

LUFENURON**Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Diarrhoea	1
Vomiting	1

LUFENURON**Canine**

Number of reports	Probable	Possible
142	13	129

Presenting Signs	Number of reports
Vomiting	54
Lethargy	36
Pruritis	21
Diarrhoea	19
Anorexia	16
Rash	12
Inflammation	5
Anaphylaxis	2
Ataxia	2
Alopecia	2
CNS dysfunction	2
Pulmonary oedema	1
Defaecation	1
Illness	1
Listless	1
Anaphylaxis	1
Pigmentation	1
Weight loss	1
Stiffness	1
Haematuria	1
Lack of effect	1
Coughing	1
Scabs	1

Site Reaction	1
Erythema	1
lethargic	1

LUFENURON

Feline

Number of reports	Probable	Possible
78	29	49

Presenting Signs	Number of reports
Lethargy	35
Injection site reaction	31
Anorexia	13
Vomiting	9
Abscess	8
Swelling (local)	6
Nil	6
Pain	5
Pyrexia	2
Necrosis	2
Aggression	1
Inflammation	1
Site Reaction	1
Anaphylaxis	1
Cyanosis	1
Sarcoma formation	1
Hyperaesthesia	1
Skin slough	1
Alopecia	1
Inflammation	1
Dehydration	1
Diarrhoea	1

The labels for the oral products containing lufenuron include a statement that the product should be administered with a full meal. This should be adhered to in order to prevent some of the most commonly reported clinical signs such as vomiting, lethargy and anorexia. Injection site reactions are sometimes seen with the injectable forms of these products.

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.

LYSINE-L HYDROCHLORIDE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

LYSINE-L HYDROCHLORIDE**Equine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Injection site reaction	2
Pain	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.

M. HYOPNEUMONIAE - INACTIVATED WHOLE CELL CULTURE**Porcine**

Number of reports	Probable	Possible
6	4	2

Presenting Signs	Number of reports
Anaphylaxis	3
Vomiting	2
Frothing at the mouth	2
Collapse	2
Scouring	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.

MAGNESIUM**Ovine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Oedema	1
Depression	1
Swelling (local)	1
Pharyngitis	1
Death	1

A label change was made to a number of products containing minerals such as magnesium in which the product is administered as a 'pellet'. The pellets are administered orally by a special drenching gun. It was found that in a number of cases farmers did not take appropriate precautions when administering these types of products and this resulted in damage to the pharyngeal area of some sheep. As a result a label change was made to emphasise the need for operators to take precautions not to force the drenching gun into the mouth

MAGNESIUM AS MAGNESIUM HYPOPHOSPHITE**Bovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Bradycardia	1
Death	1

MAGNESIUM AS MAGNESIUM SULFATE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Haematuria	1

MAGNESIUM ASPARTATE**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Colic	1

There are many preparations on the market which contain minerals such as magnesium and 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.

MALACHITE GREEN**Aquatic**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Respiratory problems	1
Irritation (skin)	1
Death	1

On assessment of adverse experience reports involving an aquaculture product containing this active constituent, it was found that one batch of this product was inadvertently over-formulated and was therefore recalled from the marketplace.

MALDISON**Avian**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1

MALDISON**Canine**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Irritation (skin)	2
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.

MALIC ACID**Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
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.

MALIGNANT OEDEMA = CLOSTRIDIUM SEPTICUM**Bovine**

Number of reports	Probable	Possible
2	0	2

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.

MEASLES VIRUS STRAIN EDMONSTON**Canine**

Number of reports	Probable	Possible
12	6	6

Presenting Signs	Number of reports
Pain	3
Lethargy	2

Vomiting	2
Depression	2
Pulmonary oedema	1
Death	1
Tremor	1
Cyanosis	1
Seizure	1
Proprioception Deficit	1
Anaphylaxis	1
Swelling (local)	1
Diarrhoea	1
Gastroenteritis	1
Dehydration	1
Listless	1
Ataxia	1
Urticaria	1
Ulceration	1
Injection site reaction	1
Hypotension	1
CNS dysfunction	1
Shock	1
Lymphadenopathy	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.

MEBENDAZOLE

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Mouth Burn	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
19	7	12

Presenting Signs	Number of reports
Death	7
Respiratory problems	3
Seizure	3
Pulmonary oedema	2
Dyspnoea	2
Vomiting	1
Shock	1
Bloat	1
Pupillary dilation	1
Facial oedema	1
Weakness	1
Tachycardia	1
Pale mucous membranes	1
Comatose	1
Haematemesis	1
Hypersalivation	1
Pruritis	1
Paddling	1
Cardiac Arrest	1
Cyanosis	1
Hypotension	1
Renal failure	1
Diarrhoea	1
Haemorrhage	1
Apnoea	1
Bradycardia	1
Swelling (local)	1
Agitation	1
Pyrexia	1

MEDETOMODINE HYDROCHLORIDE**Feline**

Number of reports	Probable	Possible
7	2	5

Presenting Signs	Number of reports
Death	2
Oedema	2
Pulmonary oedema	2
Dyspnoea	2
Shock	2
Anorexia	1
Agitation	1
Somnolence	1
Unconscious	1
Hyperexcitable	1
Respiratory problems	1
Panting	1
Ataxia	1
Weakness	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.

MEGESTROL ACETATE**Canine**

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Oestrus (early)	1
Lack of effect	1
Vaginal discharge	1
Diabetes	1

MEGESTROL ACETATE**Feline**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Mammary hyperplasia	1
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
14	11	3

Presenting Signs	Number of reports
Injection site reaction	8
Swelling (local)	4
Death	3
Pain	1
Agitation	1
Respiratory problems	1
Diarrhoea	1
Depression	1
Panting	1
Cyanosis	1
Tremor	1
Lame	1
Lack of effect	1
Dyspnoea	1
Hypersalivation	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.

MELOXICAM**Canine**

Number of reports	Probable	Possible
13	0	13

Presenting Signs	Number of reports
Vomiting	6
Anorexia	5
Renal failure	3
Ataxia	2
Diarrhoea	2
Swelling (local)	1
Lethargy	1
Abdominal pain	1
Respiratory problems	1
Pancreatitis	1
Polydipsia	1
Hepatopathy	1
Death	1
Haematuria	1
Dehydration	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.

MENTHOL**Equine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Blisters	1
Irritation (skin)	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.

MENTHOL**Feline**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Prolapse third eyelid	2
Ataxia	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.

MEPIVACAINE HYDROCHLORIDE**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Arthropathy	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.

METHIONINE-DL**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1

METHIONINE-DL**Equine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Injection site reaction	2
Pain	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.

METHOCARBAMOL**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Masticatory myositis	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.

METHOPRENE**Canine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Inflammation	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.

METHYLENE BLUE DYE**Other**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Respiratory problems	1
Irritation (skin)	1

Death	1
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On assessment of adverse experience reports involving an aquaculture product containing this active constituent, it was found that one batch of this product was inadvertently over-formulated and was therefore recalled from the marketplace.

METHYLPREDNISOLONE ACETATE

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Inflammation	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.

METOCLOPRAMIDE HYDROCHLORIDE

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
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.

MICONAZOLE NITRATE**Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Lack of effect	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.

MILBEMYCIN OXIME**Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Vomiting	1
Diarrhoea	1

MILBEMYCIN OXIME**Canine**

Number of reports	Probable	Possible
111	16	95

Presenting Signs	Number of reports
Vomiting	45
Lethargy	34
Diarrhoea	22
Pruritis	18
Anorexia	12
Rash	6
Haemorrhage	4
CNS dysfunction	2

Anaphylaxis	2
Ataxia	2
Illness	2
Listless	1
Urticaria	1
Inflammation	1
Worms	1
Melaena	1
Scabs	1
Erythema	1
Muscle twitching	1
Pulmonary oedema	1
Site Reaction	1
Abdominal pain	1
Defaecation	1
Lack of effect	1
Tiredness	1
Pigmentation	1
Weight loss	1
Coughing	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.

MONENSIN

Bovine

Number of reports	Probable	Possible
21	11	10

Presenting Signs	Number of reports
Death	17
Bloat	2
Scouring	2
Depression	1
Lack of effect	1
Coughing	1
Hypersalivation	1
Ataxia	1

Frothing at the mouth	1
Lethargy	1
Malaise	1

Anti bloat capsules containing monensin have been the subject of a small number of reports. In most cases when the capsules were recovered from the rumen of the cattle at post mortem they were found to have fully paid out. The product should continue to pay out for at least 100 days. The reason for the increased rate of pay out of this product is unknown. Incidents similar to this have been published in previous APVMA publications however the incidence of these types of reports is very low when compared to the total number of doses sold and no regulatory action was required other than continued ongoing monitoring for any future adverse experience reports.

MONOSULFIRAM

Canine

Number of reports	Probable	Possible
1	1	0

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.

MORANTEL CITRATE

Equine

Number of reports	Probable	Possible
28	23	5

Presenting Signs	Number of reports
Mouth Burn	15
Colic	7
Death	4
Diarrhoea	3
Anorexia	3
Depression	3
Hypersalivation	3
Distress	2

Swelling (local)	1
Behavioural change	1
Stomatitis	1
Ptyalism	1
Lymphadenopathy	1
Abortion	1
Pyrexia	1
Ulceration	1
Pain	1
Lethargy	1

After assessment of adverse experience reports for products containing morantel citrate an additional warning statement was included on the product labels to advise users to take precautions to ensure that dogs do not ingest any unused product as it is toxic to dogs.

MORANTEL TARTRATE

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Mouth Burn	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

Unknown

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Vomiting	1
Urticaria	1
Lethargy	1
Oedema	1

MOXIDECTIN**Bovine**

Number of reports	Probable	Possible
24	2	22

Presenting Signs	Number of reports
Diarrhoea	8
Lack of effect	6
Site Reaction	5
Dermatitis	4
Anorexia	3
Ulceration	2
Colic	2
Alopecia	2
Pyrexia	2
Irritation (skin)	2
Illthrift	1
Erythema	1
Photosensitisation	1
Lame	1
Weight loss	1
Lymphadenopathy	1
Stiffness	1
Depression	1

MOXIDECTIN**Camelid**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Pulmonary oedema	1
Frothing at the mouth	1

MOXIDECTIN**Canine**

Number of reports	Probable	Possible
151	81	70

Presenting Signs	Number of reports
Vomiting	47
Injection site reaction	25
Lethargy	18
Pruritis	17
Urticaria	16
Collapse	16
Facial oedema	15
Depression	14
Anorexia	9
Diarrhoea	9
Bradycardia	7
Pale mucous membranes	6
Cyanosis	6
Anaphylaxis	5
Hypersalivation	5
Anaphylaxis	5
Oedema	4
Erythema	4
Shaking	4
Panting	4
Tachycardia	4
Wheals	4
Ataxia	4
Restless	4
Pyrexia	4
Agitation	3
Death	3
Dyspnoea	3
Recumbency	2
Weakness	2
CNS dysfunction	2
Respiratory problems	2
Hepatopathy	2

Swelling (local)	2
Behavioural change	2
Distress	2
Auto-immune haemolytic anaemia	2
Illness	2
Defaecation	1
Eosinophilia	1
Site Reaction	1
Spasm	1
Injected mucous membranes	1
Somnolence	1
Inflammation	1
Pupillary dilation	1
Alopecia	1
Unknown	1
Haemorrhage	1
Polydipsia	1
Irritation (skin)	1
Melaena	1
Inflammation	1
Deafness	1
Defecation	1
Disorientation	1
Head tilt	1
Myasthenia gravis	1
Pain	1
Anaphylactoid reaction	1
Convulsions	1
Vocalisation	1
Tremor	1
Anaemia	1
Abdominal pain	1
Hypotension	1
Rash	1
Arthropathy	1

MOXIDECTIN**Equine**

Number of reports	Probable	Possible
33	15	18

Presenting Signs	Number of reports
Colic	11
Swelling (local)	4
Anorexia	3
Death	3
Ataxia	3
Ulceration	2
Agitation	2
Depression	2
Diarrhoea	2
Urticaria	2
Oedema	1
Lethargy	1
Scouring	1
Irritation (skin)	1
Rolling	1
Unknown	1
Worms	1
Pawing at ground	1
Blisters	1
Inflammation	1
Tail rubbing	1

MOXIDECTIN**Ovine**

Number of reports	Probable	Possible
7	0	7

Presenting Signs	Number of reports
Death	6
Diarrhoea	2
Irritation (skin)	1

Lethargy	1
Scabs	1
Wool damage	1

MOXIDECTIN CONCENTRATE

Bovine

Number of reports	Probable	Possible
7	0	7

Presenting Signs	Number of reports
Lack of effect	4
Recumbency	2
Depression	2

After assessment of adverse experience reports for injectable products containing moxidectin for use in small animals, it was discovered that the incidence of allergic-type reactions (such as facial and aural swellings, urticaria, welts and vomiting) was higher than expected based on pre-registration trial work. The labels of these products were changed to include a warning statement for users of the products that these side effects may occur.

In other species, 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.

MYCOPLASMA HYOPNEUMONIDE BACTERIN

Porcine

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Death	1
CNS dysfunction	1
Dyspnoea	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
7	3	4

Presenting Signs	Number of reports
Inflammation	2
Lack of effect	2
Death	1
Hyperactivity	1
Ulceration	1
Vocalisation	1
Erythema	1
Pruritis	1
Hypersalivation	1
Pain	1
Irritation (skin)	1

N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE**Equine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Hair loss	1
Pain	1
Alopecia	1

N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE**Feline**

Number of reports	Probable	Possible
9	7	2

Presenting Signs	Number of reports
Hypersalivation	4
Vomiting	3
Ataxia	2
Death	2
Diarrhoea	2
Dyspnoea	1
Distress	1
Nystagmus	1
Head tilt	1
Anaphylaxis	1
Tremor	1
Collapse	1
Tachycardia	1
Mouth Irritation	1
Pyrexia	1
Hyperaesthesia	1
Seizure	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 AS THE SULFATE**Bovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1
Lethargy	1

NEOMYCIN AS THE SULFATE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Vomiting	1

NEOMYCIN SULFATE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Haematuria	1

NEOMYCIN SULFATE**Feline**

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Irritation (ear)	1
Vomiting	1
Death	1
Depression	1
Distress	1
Vocalisation	1
Diarrhoea	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.

NICLOSAMIDE**Canine**

Number of reports	Probable	Possible
6	3	3

Presenting Signs	Number of reports
Vocalisation	3
Agitation	2
Pain	2
Shaking	2
Dermatitis	1
Death	1
Oedema	1
Diarrhoea	1
Anorexia	1
Swelling (local)	1
Irritation (skin)	1
Conjunctivitis	1
Vomiting	1
Coughing	1

NICLOSAMIDE**Feline**

Number of reports	Probable	Possible
7	3	4

Presenting Signs	Number of reports
Vomiting	4
Pain	1
Gastroenteritis	1
Lethargy	1

NICLOSAMIDE MONOHYDRATE - MICRONISED**Feline**

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Vomiting	3
Vocalisation	1
Panting	1
Lethargy	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.

NITENPYRAM**Canine**

Number of reports	Probable	Possible
6	0	6

Presenting Signs	Number of reports
Pruritis	2
Erythema	1
Tremor	1
Pupillary dilation	1
Nil	1
Irritation (skin)	1
Lethargy	1

NITENPYRAM**Feline**

Number of reports	Probable	Possible
6	0	6

Presenting Signs	Number of reports
Hyperexcitable	3
Dyspnoea	2
Excitation	2
Pruritis	2
Panting	2
Nil	1
Agitation	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.

NITROFURAZONE**Feline**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Vocalisation	1
Distress	1
Depression	1
Irritation (ear)	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.

NONIVAMIDE**Equine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Mouth Irritation	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.

NOVOBIOCIN SODIUM**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Rash	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.

OCTYL METHOXYCINNAMATE**Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Self trauma	1
Erythema	1

Ulceration	1
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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 17 BETA

Bovine

Number of reports	Probable	Possible
3	3	0

Presenting Signs	Number of reports
Paraphimosis	2
Preputial prolapse	1

OESTRADIOL BENZOATE

Bovine

Number of reports	Probable	Possible
3	1	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

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.

OLEANDOMYCIN AS THE PHOSPHATE**Bovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Lethargy	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.

ORBIFLOXACIN**Canine**

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Anorexia	2
Erythema	1
Lethargy	1
Skin slough	1
Haemorrhage	1
Diarrhoea	1
Deafness	1
Depression	1

ORBIFLOXACIN**Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Blindness	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
33	10	23

Presenting Signs	Number of reports
Vomiting	12
Lack of effect	10
Diarrhoea	5
Death	4
Worms	2
Rash	2
Pruritis	2
Nil	2
Erythema	1
Lethargy	1
Collapse	1
Respiratory problems	1
Vocalisation	1
Anorexia	1
Urticaria	1
Paralysis	1
Weakness	1
Anaphylactoid reaction	1

listless	1
Distress	1
Haemorrhage	1
Melaena	1
Stiffness	1
Colic	1

OXANTEL EMBONATE**Feline**

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.

OXFENDAZOLE**Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Diarrhoea	1
Anorexia	1

OXFENDAZOLE**Bovine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Diarrhoea	2

OXFENDAZOLE**Equine**

Number of reports	Probable	Possible
20	13	7

Presenting Signs	Number of reports
Diarrhoea	7
Colic	7
Anorexia	3
Mouth Burn	3
Distress	3
Ulceration	2
Rolling	2
Colitis	2
Pawing at ground	2
Mouth ulcers	2
Death	1
Sweating	1
Blisters	1
Lethargy	1
Scouring	1
Depression	1
Mouth Irritation	1
Hypersalivation	1
Swelling (local)	1

OXFENDAZOLE**Ovine**

Number of reports	Probable	Possible
12	7	5

Presenting Signs	Number of reports
Death	9
Shaking	2
Worms	2
Ataxia	2
Tremor	2
Diarrhoea	1
Recumbency	1
Convulsions	1
Lethargy	1
Lame	1
Frothing at the 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.

OXIBENDAZOLE**Equine**

Number of reports	Probable	Possible
4	1	3

Presenting Signs	Number of reports
Abortion	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.

OXYBENZONE**Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Self trauma	1
Erythema	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.

OXYCLOZANIDE**Bovine**

Number of reports	Probable	Possible
24	13	9

Presenting Signs	Number of reports
Death	13
Anorexia	7
Diarrhoea	7
Lethargy	3
Illthrift	3
Worms	2
Recumbency	2
Milk production decrease	2
Scouring	2
Distress	1
Depression	1
Agitation	1
Hypersalivation	1
Weakness	1
Rumen stasis	1
Behavioural change	1

Pyrexia	1
Shaking	1
Tremor	1
Haemorrhage	1
Fluke	1
Disorientation	1
Fasciculation	1

OXYCLOZANIDE

Ovine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1
Illthrift	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

Bovine

Number of reports	Probable	Possible
5	4	1

Presenting Signs	Number of reports
Depression	3
Hypersalivation	3
Death	3
Recumbency	2
Respiratory problems	1
Dyspnoea	1
Frothing at the mouth	1
Collapse	1

Self trauma	1
Irritation (ear)	1
Pruritis	1
Oedema	1
Nasal discharge	1

OXYTETRACYCLINE**Equine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Urination	1
Death	1
Collapse	1
Defecation	1

OXYTETRACYCLINE AS OXYTETRACYCLINE HYDROCHLORIDE**Bovine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Delvo test positive (individual cow)	1
Death	1
Lethargy	1

OXYTETRACYCLINE HYDROCHLORIDE**Bovine**

Number of reports	Probable	Possible
9	7	2

Presenting Signs	Number of reports
Death	5
Recumbency	5
Hypersalivation	3
Frothing at the mouth	3
Anaphylaxis	2
Dyspnoea	2
Shaking	2
Ataxia	2
Swelling (local)	2
Respiratory problems	1
Nasal discharge	1
Tremor	1
Ocular discharge	1
Ptyalism	1
Agitation	1
Urination	1
Blindness	1

OXYTETRACYCLINE HYDROCHLORIDE**Canine**

Number of reports	Probable	Possible
1	0	1

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

OXYTETRACYCLINE HYDROCHLORIDE**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Colic	1
Pain	1
Death	1
Diarrhoea	1
Shock	1
Recumbency	1

Reactions to injectable formulations containing oxytetracycline are well recognised in production animals⁴. However, it is important for the APVMA to monitor the reporting incidence of such reactions to identify any increasing level of incidence or unusual trends. The APVMA is satisfied that 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.

PANTOTHENOL-D = PANTHENOL-**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

⁴ Martindale *The ExtraPharmacopoeia* 28th Edition, edited by E.F. Reynolds (1982), The Pharmaceutical Press, 1197.

PANTOTHENOL-D = PANTHENOL-**Equine**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Injection site reaction	2
Pain	2
Collapse	1

PANTOTHENOL-D = PANTHENOL-**Ovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1
Shaking	1
Ataxia	1
Convulsions	1
Frothing at the 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.

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.

PENETHAMATE HYDRIODIDE**Equine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Recumbency	1
Tremor	1
Collapse	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**Equine**

Number of reports	Probable	Possible
6	0	6

Presenting Signs	Number of reports
Dermatitis	4
Erythema	1
Urticaria	1

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

Number of reports	Probable	Possible
12	1	11

Presenting Signs	Number of reports
Lack of effect	5
Swelling (local)	3
Pruritis	2
Inflammation	2
Irritation (skin)	1
Illness	1
Alopecia	1
Paralysis	1
Shaking	1

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

Number of reports	Probable	Possible
36	19	17

Presenting Signs	Number of reports
Lack of effect	8
Irritation (skin)	7
Pruritis	5
Site Reaction	4
Behavioural change	4
Ataxia	4
Shaking	3
Inflammation	3
Lethargy	3
Malaise	2
Vomiting	2
Distress	1
Dermatitis	1
Fainting	1
Erythema	1
Hyperexcitable	1
Tremor	1
Blisters	1
Rolling	1
Depression	1
Dyspnoea	1
Anorexia	1
Seizure	1
Panting	1

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

Number of reports	Probable	Possible
6	4	2

Presenting Signs	Number of reports
Dermatitis	3
Wheals	3
Hives	2
Coat colour change	1
Ocular damage	1
Erythema	1
Alopecia	1

Permethrin is contra-indicated in cats and therefore product labels for dogs contain adequate warnings. In some cases however owners have not heeded these label warnings and reports involving cats developing clinical signs of toxicity to permethrin have been received. As a result the contra-indication statement on these products has been highlighted to prevent such accidental treatment of cats.

PETHIDINE HYDROCHLORIDE**Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Oedema	1
Cardiac Arrest	1
Hyperexcitable	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.

PHENYLBUTAZONE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Masticatory myositis	1

PHENYLBUTAZONE**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Oedema	1

PHENYLBUTAZONE SODIUM**Equine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Collapse	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.

PHENYTOIN**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Dermatitis	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.

PHOSPHORUS (AS MAGNESIUM HYPOPHOSPHITE)**Bovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Bradycardia	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.

PIPERAZINE CITRATE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Diarrhoea	1
Vomiting	1
Distress	1
Hypothermia	1

PIPERAZINE CITRATE**Feline**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Bradycardia	1
Hypersalivation	1
Vomiting	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.

PIPERONYL BUTOXIDE**Avian**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1

PIPERONYL BUTOXIDE**Canine**

Number of reports	Probable	Possible
15	5	10

Presenting Signs	Number of reports
Pruritis	5
Irritation (skin)	3
Inflammation	2
Lack of effect	2
Hypersalivation	2
Illness	1
Death	1
Pain	1
Erythema	1
Vocalisation	1
Alopecia	1
Hyperactivity	1
Depression	1
Swelling (local)	1
Ulceration	1

PIPERONYL BUTOXIDE**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Alopecia	1
Pain	1

PIPERONYL BUTOXIDE**Feline**

Number of reports	Probable	Possible
9	6	3

Presenting Signs	Number of reports
Hypersalivation	4
Vomiting	3
Death	2
Ataxia	2
Anaphylaxis	1
Diarrhoea	1
Shaking	1
Pyrexia	1
Tremor	1
Head tilt	1
Collapse	1
Distress	1
Seizure	1
Nystagmus	1
Dyspnoea	1
Tachycardia	1
Mouth Irritation	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.

POLYMYXIN B SULFATE**Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Lack of effect	2

POLYMYXIN B SULFATE**Feline**

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Depression	1
Vomiting	1
Irritation (ear)	1
Distress	1
Death	1
Vocalisation	1
Diarrhoea	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.

PORCINE PARVO VIRUS - INACTIVATED**Porcine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Lack of effect	2
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.

PORCINE SOMATOTROPIN = PST**Porcine**

Number of reports	Probable	Possible
5	5	0

Presenting Signs	Number of reports
Injection site reaction	5

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**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Urticaria	1

POTASSIUM AS 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

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**Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Vomiting	1
Ataxia	1
Collapse	1
Hypersalivation	1
Weakness	1

PRAZIQUANTEL**Avian**

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Death	4

Based on the assessment of adverse experience reports involving the use of a product containing levamisole and praziquantel in birds it was considered that parrots and finches may be less tolerant than other species such as pigeons to levamisole. Therefore a precautionary statement was added to the product labels to advise users to take precautions when treating parrots and finches.

PRAZIQUANTEL**Canine**

Number of reports	Probable	Possible
67	19	48

Presenting Signs	Number of reports
Vomiting	31
Lack of effect	10
Diarrhoea	9
Worms	7
Death	6
Lethargy	5
Shaking	5
Illness	3
Ataxia	3
Tremor	3
Rash	2
Scouring	2
Depression	2
Pruritis	2
Nil	2
Recumbency	2
Hyperexcitable	2
Pupillary dilation	2
Distress	1

Vocalisation	1
Respiratory problems	1
Urticaria	1
Stiffness	1
Melaena	1
Erythema	1
Anorexia	1
Paralysis	1
listless	1
Colic	1
Pupillary constriction	1
Tachycardia	1
Collapse	1
Abdominal pain	1
Swelling (local)	1
Agitation	1
Haemorrhage	1
Weakness	1
Polyarthritis	1
Anaphylactoid reaction	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
49	25	24

Presenting Signs	Number of reports
Ataxia	36

Vomiting	18
Lethargy	7
Hypersalivation	7
Pupillary dilation	6
Depression	6
Diarrhoea	5
Prolapse third eyelid	4
Anorexia	4
Frothing at the mouth	3
Pyrexia	3
Weakness	2
Nil	2
Seizure	2
Dyspnoea	1
Respiratory problems	1
Behavioural change	1
Death	1
Hyperaesthesia	1
Abdominal pain	1
Colic	1
Restless	1
Vocalisation	1
Tachycardia	1
Collapse	1
Pain	1
Distress	1
Urination	1

Vomiting is one of the most commonly observed side effects of oral preparations containing praziquantel in small animals. The labels for these products include a warning statement that such reactions may occur. Also, one formulation of worming treatment for cats that contained a combination of praziquantel and pyrantel was changed to reduce the incidence of side effects such as lethargy, ataxia, hyperaesthesia and pupillary dilation. This was previously reported in the 1997/98 Annual Report⁵. 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.

⁵ The National Registration Authority for Agricultural and Veterinary Chemicals. *Report of Adverse Experiences 1997 and 1998*.

PREDNISOLONE**Canine**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Vomiting	2
Masticatory myositis	1
Rash	1

PREDNISOLONE ACETATE**Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Lack of effect	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.

PRILOCAINE HYDROCHLORIDE**Equine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Injection site reaction	1
Ataxia	1
Lame	1
Recumbency	1
Agitation	1

PRILOCAINE HYDROCHLORIDE**Bovine**

Number of reports	Probable	Possible
1	0	1

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.

PROCAINE HYDROCHLORIDE**Equine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Dyspnoea	1
Death	1
Convulsions	1
Ataxia	1

PROCAINE PENICILLIN**Bovine**

Number of reports	Probable	Possible
10	9	1

Presenting Signs	Number of reports
Death	5
Bloat	2
Ataxia	2
Collapse	2

Anaphylaxis	2
Respiratory problems	1
Distress	1
Pruritis	1
Weight loss	1
Hypersalivation	1
Agitation	1
Recumbency	1
Tachycardia	1
Behavioural change	1

PROCAINE PENICILLIN**Canine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Injection site reaction	2
Swelling (local)	1

PROCAINE PENICILLIN**Caprine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Weakness	1
Diarrhoea	1
Vomiting	1

PROCAINE PENICILLIN**Equine**

Number of reports	Probable	Possible
18	17	1

Presenting Signs	Number of reports
Excitation	5
Agitation	5
Death	4
Collapse	4
Ataxia	3
Hyperaesthesia	3
CNS dysfunction	2
Behavioural change	2
Tremor	1
Weakness	1
Apnoea	1
incoordination	1
Muscle twitching	1
Paddling	1
Oedema	1
Swelling (local)	1
Distress	1
Respiratory problems	1
Dyspnoea	1
Recumbency	1
Hyperactivity	1
Convulsions	1
Diarrhoea	1
Self trauma	1
Vomiting	1
Cardiac Arrest	1
Miosis	1

PROCAINE PENICILLIN**Porcine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Vomiting	1
Diarrhoea	1

Reactions to injectable formulations containing procaine penicillin are well recognised in production animals and horses⁶. However, it is important for the APVMA to monitor the reporting incidence of such reactions to identify any increasing level of incidence or unusual trends. The APVMA is satisfied that 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

⁶ Adams, HR *Veterinary Pharmacology and Therapeutics* (2001) p61.

PROGESTERONE**Feline**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Mouth Irritation	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.

PROPANTHELINE BROMIDE**Equine**

Number of reports	Probable	Possible
4	4	0

Presenting Signs	Number of reports
Colic	4

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
11	6	5

Presenting Signs	Number of reports
Erythema	3
Wheals	2
Pale mucous membranes	2

Facial oedema	2
Urticaria	1
Welts	1
Anaesthesia (long)	1
Stiffness	1
Bradycardia	1
Injected mucous membranes	1
Self trauma	1
Excitation	1
Anaesthesia - unstable	1
Cardiac Arrest	1
Swollen feet	1
Hives	1

PROPOFOL**Feline**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Self trauma	1
Cardiac Arrest	1
Vocalisation	1
Anaesthesia (long)	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.

PROPOXUR**Canine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Agitation	1
Respiratory problems	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.

PROPYLENE GLYCOL**Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
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.

PYRANTEL AS PYRANTEL EMBONATE**Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Vomiting	1
Collapse	1
Hypersalivation	1
Weakness	1
Ataxia	1

PYRANTEL AS PYRANTEL EMBONATE**Canine**

Number of reports	Probable	Possible
6	4	2

Presenting Signs	Number of reports
Ataxia	2
Weakness	1
Vomiting	1
Lethargy	1
Diarrhoea	1
Hyperexcitable	1
Seizure	1
Pupillary constriction	1
Tremor	1

PYRANTEL AS PYRANTEL EMBONATE**Feline**

Number of reports	Probable	Possible
48	24	24

Presenting Signs	Number of reports
Ataxia	35
Vomiting	18
Lethargy	7
Hypersalivation	7
Depression	6
Pupillary dilation	6
Diarrhoea	5
Anorexia	4
Prolapse third eyelid	4
Pyrexia	3
Frothing at the mouth	3
Weakness	2
Seizure	2
Collapse	1
Vocalisation	1
Colic	1
Tachycardia	1
Dyspnoea	1
Urination	1
Abdominal pain	1
Distress	1
Hyperaesthesia	1
Respiratory problems	1
Death	1
Behavioural change	1
Pain	1
Restless	1

PYRANTEL EMBONATE**Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Anorexia	1
Diarrhoea	1

PYRANTEL EMBONATE**Canine**

Number of reports	Probable	Possible
79	20	59

Presenting Signs	Number of reports
Vomiting	36
Diarrhoea	13
Lack of effect	11
Death	10
Worms	9
Lethargy	6
Shaking	5
Illness	4
Tremor	4
Depression	4
Anorexia	3
Pupillary dilation	2
Nil	2
Melaena	2
Vocalisation	2
Pruritis	2
Recumbency	2
Distress	2
Rash	2
Scouring	2
Ataxia	2

Colic	2
Dermatitis	1
Weakness	1
Collapse	1
Tachycardia	1
Polyarthritis	1
Hyperexcitable	1
Stiffness	1
Anaphylactoid reaction	1
Conjunctivitis	1
Bloat	1
listless	1
Agitation	1
Erythema	1
Pyrexia	1
Respiratory problems	1
Abdominal pain	1
Swelling (local)	1
Pain	1
Urticaria	1
Paralysis	1
Haemorrhage	1
Oedema	1
Coughing	1

PYRANTEL EMBONATE**Equine**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Diarrhoea	2
Mouth Irritation	1
Anorexia	1

PYRANTEL EMBONATE**Feline**

Number of reports	Probable	Possible
6	1	5

Presenting Signs	Number of reports
Vomiting	5
Ataxia	1
Lethargy	1

Vomiting is one of the most commonly observed side effects of oral preparations containing praziquantel in small animals. The labels for these products include a warning statement that such reactions may occur. Also, one formulation of worming treatment for cats that contained a combination of praziquantel and pyrantel was changed to reduce the incidence of side effects such as lethargy, ataxia, hyperaesthesia and pupillary dilation. This was previously reported in the 1997/98 Annual Report⁷. 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.

PYRETHRIN**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Pruritis	1

PYRETHRIN**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Pain	1
Alopecia	1

⁷ The National Registration Authority for Agricultural and Veterinary Chemicals. *Report of Adverse Experiences 1997 and 1998*.

PYRETHRINS**Avian**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1

PYRETHRINS**Canine**

Number of reports	Probable	Possible
10	4	6

Presenting Signs	Number of reports
Pruritis	2
Lack of effect	2
Irritation (skin)	2
Inflammation	2
Ulceration	1
Hyperactivity	1
Hypersalivation	1
Erythema	1
Vocalisation	1
Pain	1
Illness	1
Death	1

PYRETHRINS**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Hair loss	1

PYRETHRINS**Feline**

Number of reports	Probable	Possible
11	6	5

Presenting Signs	Number of reports
Hypersalivation	4
Vomiting	3
Ataxia	2
Death	2
Distress	2
Lethargy	1
Dyspnoea	1
Collapse	1
Anaphylaxis	1
Mouth Irritation	1
Irritation (ear)	1
Head tilt	1
Seizure	1
Vocalisation	1
Depression	1
Diarrhoea	1
Shaking	1
Pyrexia	1
Tachycardia	1
Tremor	1
Nystagmus	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.

PYRIPROXYFEN**Feline**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Anorexia	1
Coughing	1
Alopecia	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.

QUIL**Feline**

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Lethargy	2
Ataxia	1
Vomiting	1
Anorexia	1
Pyrexia	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.

RAMIFENAZONE**Equine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1
Collapse	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
3	1	2

Presenting Signs	Number of reports
Lethargy	2
Diarrhoea	1
Anorexia	1
Pyrexia	1
Vomiting	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.

RESERPINE**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.

ROMIFIDINE HYDROCHLORIDE**Equine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Lack of efficacy	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.

SALICYLIC ACID**Feline**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lethargy	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.

SALINOMYCIN SODIUM**Bovine**

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.

SELAMECTIN**Unknown**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Pruritis	1

SELAMECTIN**Canine**

Number of reports	Probable	Possible
79	32	47

Presenting Signs	Number of reports
Pruritis	19
Site Reaction	17
Vomiting	15
Lethargy	9
Alopecia	9
Erythema	7
Depression	6

Irritation (skin)	6
Anorexia	6
Diarrhoea	5
Behavioural change	4
Oedema	3
Hyperexcitable	3
Agitation	3
Tremor	2
Self trauma	2
Rubbing	2
Panting	2
Excitation	2
Distress	2
Hypersalivation	2
Hyperactivity	1
Pain	1
Swelling (local)	1
Somnolence	1
Listless	1
Pharyngitis	1
Sneezing	1
Vocalisation	1
Swollen ears and face	1
Malaise	1
Restless	1
Dermatitis	1
Ataxia	1
Tachycardia	1

SELAMECTIN**Feline**

Number of reports	Probable	Possible
62	34	28

Presenting Signs	Number of reports
Site Reaction	31
Alopecia	21
Irritation (skin)	7

Pruritis	6
Hyperexcitable	5
Vomiting	4
Diarrhoea	4
Lethargy	3
Anorexia	3
Dermatitis	3
Malaise	3
Self trauma	2
Vocalisation	2
Respiratory problems	2
Hypersalivation	2
Excitation	2
Behavioural change	1
Pyrexia	1
Hyperactive	1
Erythema	1
Lack of effect	1
Swelling (local)	1
Paralysis	1
Mydriasis	1
Depression	1
Renal failure	1
Inflammation	1
Hyperaesthesia	1
Dehydration	1
Weakness	1
Pyoderma	1
Pain	1

Based on assessment of all adverse experience reports for products containing selamectin, it was noted that the more frequent clinical signs observed included site reactions, including pruritis, coat colour change and alopecia. An additional warning statement on the labels of these products is being included to inform the user that such reactions might occur.

SELENIUM**Caprine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Blindness	1

SELENIUM**Ovine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Shaking	1
Pharyngitis	1
Death	1
Ataxia	1
Convulsions	1
Frothing at the 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.

SELENIUM AS SODIUM SELENATE**Caprine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Injection site reaction	1

SELENIUM AS SODIUM SELENATE**Ovine**

Number of reports	Probable	Possible
8	1	7

Presenting Signs	Number of reports
Death	4
Injection site reaction	2
Anaemia	2
Cyanosis	1
Lack of effect	1
Respiratory problems	1
Lethargy	1

SELENIUM SULFIDE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Irritation (skin)	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 ARSANILATE**Equine**

Number of reports	Probable	Possible
2	0	2

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.

SODIUM AS SODIUM CHLORIDE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Haematuria	1

SODIUM CACODYLATE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Swollen feet	1

SODIUM IODIDE**Bovine**

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.

SODIUM PENTOSAN POLYSULFATE**Canine**

Number of reports	Probable	Possible
38	26	12

Presenting Signs	Number of reports
Vomiting	17
Depression	10
Lethargy	10
Anorexia	3
Diarrhoea	3
Swelling (local)	2
Collapse	2
Tremor	2
Weakness	2
Haemorrhage	2
Death	2
Melaena	2
Shaking	1
Recumbency	1
Nystagmus	1
Head tilt	1
Hypersalivation	1
Lame	1

Vocalisation	1
Urticaria	1
Ataxia	1
Kyphosis	1
Distress	1
Thrombocytopenia	1
Pyrexia	1
Pale mucous membranes	1
Tachycardia	1
Abdominal pain	1
Dyspnoea	1
Stiffness	1
Ocular damage	1
Lack of effect	1
Bradycardia	1
Respiratory problems	1
Haematuria	1
Agitation	1
Restless	1
Wheals	1

SODIUM PENTOSAN POLYSULFATE

Equine

Number of reports	Probable	Possible
5	2	3

Presenting Signs	Number of reports
Injection site reaction	3
Haemorrhage	1
Ataxia	1

All adverse experience reports for products containing sodium pentosan polysulfate have been reported in a combined single entry, as is standard practice throughout this report and similar reports overseas. However, Australia is unusual in having three pentosan polysulfate products registered, and one registrant has raised concerns about these products being regarded as similar for regulatory purposes. This issue will be investigated further by the APVMA. The APVMA can provide information on adverse experiences for individual products on request if the product registrant agrees.

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**Ovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	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.

SODIUM SELENITE**Equine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Swelling (local)	1
Distress	1
Respiratory problems	1
Rolling	1
Pain	1
Colic	1
Sweating	1
Recumbency	1
Stiffness	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.

SQUALANE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Oedema	1
Inflammation	1
Head tilt	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
2	1	1

Presenting Signs	Number of reports
Stiffness	1
Urticaria	1
Listless	1
Pruritis	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.

STREPTOCOCCUS EQUI AS CELL FREE EXTRACT**Equine**

Number of reports	Probable	Possible
8	2	6

Presenting Signs	Number of reports
Strangles	3
Pyrexia	3
Lack of effect	2
Lethargy	2
Pain	1
Anorexia	1
Swelling (local)	1
Stiffness	1
Ataxia	1
Weakness	1
Frothing at the mouth	1
Lame	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 AS 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.

SULFACETAMIDE SODIUM**Bovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Irritation (skin)	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
4	0	4

Presenting Signs	Number of reports
Pain	2
Hives	1
Skin slough	1
Recumbency	1
Pruritis	1
Haematuria	1
Swelling (local)	1

SULFADIAZINE**Equine**

Number of reports	Probable	Possible
8	6	2

Presenting Signs	Number of reports
Death	4
Collapse	2

Recumbency	2
Prolapse third eyelid	1
Tremor	1
Ataxia	1
Hyperaesthesia	1

Colitis in horses has been associated secondarily to the use of certain antibiotics, including both parenteral and oral preparations. The pathophysiology of the resulting colitis and diarrhoea may involve altered volatile fatty acid synthesis, colonisation and invasion of the colon by pathogenic bacteria, and the release of bacterial toxins. *Salmonella*, *Clostridium perfringens* and *Clostridium difficile* or its cytotoxin have been implicated in these cases⁸. These types of reactions appear to occur more frequently in highly condition horses and therefore the product labels for these products contain warnings about using them in horses in training for racing.

Also after assessment of adverse experience reports involving the use sulfadiazine, it was found that adverse interactions may occur if used with alpha-2 agonists. As a result a change was made to the product labels of products containing intravenously injected potentiated sulphonamides to warn users not to use alpha-2 agonists in combination.

SULFADIAZINE

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Somnolence	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.

⁸ Murray, M.J. (1992) Acute Colitis In: *Current Therapy in Equine Medicine 3*. Robinson, N.E. (ed.) W.B. Saunders Company, Pennsylvania pp 244-250.

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
Preputial swelling	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.

SULFADOXINE**Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1

SULFADOXINE**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1
Colic	1
Diarrhoea	1
Pain	1
Shock	1
Recumbency	1

SULFADOXINE**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.

SULFATROXAZOLE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Collapse	1
Pale mucous membranes	1

Urination	1
Defecation	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.

TALLOW FAT

Bovine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Irritation (skin)	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.

TEMEPHOS

Unknown

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Irritation (skin)	1

TEMEPHOS**Canine**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Tremor	1
Hypersalivation	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.

TESTOSTERONE**Canine**

Number of reports	Probable	Possible
2	1	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.

TETANUS = CLOSTRIDIUM TETANI**Bovine**

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Injection site reaction	2
Death	1
Recumbency	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.

TETRACYCLINE HYDROCHLORIDE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Vomiting	1
Rash	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
227	131	96

Presenting Signs	Number of reports
Facial oedema	122
Urticaria	49
Vomiting	30
Pruritis	23
Injection site reaction	20
Pain	19
Swollen lips and face	18
Swelling (local)	13
Anaphylaxis	12
Pale mucous membranes	11
Collapse	10
Depression	9
Lethargy	8
Diarrhoea	7
Erythema	6
Weakness	6
Periorbital swelling	5
Swollen feet	4
Tachycardia	4
Inflammation	4
Hypersalivation	4
Panting	4
Death	3
Vocalisation	3
Illness	3
Oedema	3
Pyrexia	3
Shaking	3
Distress	2
Hyperexcitable	2
Paddling	2
Dyspnoea	2
Hives	2
Anaphylactoid reaction	2

Site Reaction	2
Agitation	2
Welts	2
Malaise	1
Pawing at ground	1
Lack of effect	1
Tachypnoea	1
Rectal prolapse	1
Sneezing	1
Rubbing	1
Seizure	1
Vulval swelling	1
Coughing	1
Defecation	1
Ocular pathology	1
Respiratory problems	1
Tremor	1
Pupillary dilation	1
Ataxia	1
Hypersensitivity reaction	1
Listless	1
Convulsions	1
Arthropathy	1
Hypothermia	1
Shock	1
Irritation (skin)	1
Anorexia	1

THIOMERSAL

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Respiratory problems	1
Cyanosis	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
6	2	4

Presenting Signs	Number of reports
Death	3
Shock	1
Ataxia	1
Cardiac Arrest	1
Apnoea	1
Seizure	1
Hyperaesthesia	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.

TILETAMINE AS THE HYDROCHLORIDE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Weakness	1
Lethargy	1
Shock	1
Anaesthesia (long)	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.

TILETAMINE AS THE HYDROCHLORIDE**Feline**

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.

TITANIUM DIOXIDE**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.

TRIAMCINOLONE ACETONIDE**Canine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
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.

TRICHLORFON**Equine**

Number of reports	Probable	Possible
43	34	9

Presenting Signs	Number of reports
Mouth Burn	19
Colic	12
Diarrhoea	6
Anorexia	4
Distress	4
Death	4
Hypersalivation	4
Depression	4
Ulceration	3
Pawing at ground	2
Colitis	2
Mouth ulcers	2
Swelling (local)	2
Rolling	2
Behavioural change	1
Lethargy	1
Pain	1
Blisters	1

Lymphadenopathy	1
Sweating	1
Stomatitis	1
Ptyalism	1
Abortion	1
Scouring	1

The most common clinical signs observed in horses after use of products containing trichlorfon include mouth burn, colic and diarrhoea. Based on the assessment of adverse experience reports for these products additional label statements were included to inform the user to administer the product into an empty mouth, over the back of the tongue and not between the cheek and teeth and to avoid treating horses with oral abrasions.

TRICLABENDAZOLE

Bovine

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Photosensitisation	2
Erythema	1

TRICLABENDAZOLE

Ovine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Death	2
Bottle jaw	1
Coughing	1
Paddling	1
Lack of effect	1
Recumbency	1
Haemorrhage	1

Ataxia	1
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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.

TRICLOSAN

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Hair loss	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.

TRIFLUMURON

Ovine

Number of reports	Probable	Possible
31	12	19

Presenting Signs	Number of reports
Lack of effect	19
Site Reaction	6
Irritation (skin)	5
Wool damage	2
Frothing at the mouth	1
Ulceration	1
Welts	1
Anorexia	1
Alopecia	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
4	1	3

Presenting Signs	Number of reports
Pain	2
Defecation	1
Collapse	1
Recumbency	1
Urination	1
Hives	1
Pale mucous membranes	1
Pruritis	1
Swelling (local)	1
Skin slough	1

TRIMETHOPRIM**Equine**

Number of reports	Probable	Possible
10	6	4

Presenting Signs	Number of reports
Death	5
Recumbency	3
Collapse	2

Shock	1
Pain	1
Hives	1
Diarrhoea	1
Hyperaesthesia	1
Tremor	1
Prolapse third eyelid	1
Ataxia	1
Colic	1
Preputial swelling	1

TRIMETHOPRIM**Feline**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
CNS dysfunction	1
Somnolence	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.

TYLOSIN**Bovine**

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Death	1
Orange urine	1
Nasal discharge	1
Vaginal discharge	1

Collapse	1
Vulval swelling	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.

URIDINE TRIPHOSPHATE

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
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.

UROGASTRONE EPIDERMAL GROWTH FACTOR (URO-EGF)

Ovine

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.

VACCINE - EQUINE SALMONELLA TYPHIMURIUM**Equine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Wobbler	1
CNS dysfunction	1
Pain	1
Lame	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**Bovine**

Number of reports	Probable	Possible
4	1	3

Presenting Signs	Number of reports
Swelling (local)	1
Diarrhoea	1
Acidosis	1
Orange urine	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
4	0	4

Presenting Signs	Number of reports
Colic	4
Constipation	2
Pyrexia	1
Laminitis	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.

VITAMIN A = RETINYL**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Collapse	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 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**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Collapse	1

VITAMIN B1 HYDROCHLORIDE = THIAMINE HYDROCHLORIDE**Ovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Shaking	1
Death	1
Ataxia	1
Frothing at the mouth	1
Convulsions	1

VITAMIN B1 HYDROCHLORIDE = THIAMINE HYDROCHLORIDE**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 B12 = CYANOCOBALAMIN**Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

VITAMIN B12 = CYANOCOBALAMIN**Bovine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Injection site reaction	2

VITAMIN B12 = CYANOCOBALAMIN**Canine**

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
4	2	2

Presenting Signs	Number of reports
Pain	2
Injection site reaction	2
Collapse	1
Colic	1

VITAMIN B12 = CYANOCOBALAMIN**Ovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1
Frothing at the mouth	1
Ataxia	1
Convulsions	1
Shaking	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 = RIBOFLAVIN**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Pain	1
Injection site reaction	1

VITAMIN B2 = RIBOFLAVIN**Equine**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Pain	2
Injection site reaction	2
Collapse	1

VITAMIN B2 = RIBOFLAVIN**Ovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Frothing at the mouth	1
Shaking	1
Death	1
Convulsions	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.

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
Pain	1
Injection site reaction	1

VITAMIN B3 = NICOTINAMIDE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

VITAMIN B3 = NICOTINAMIDE**Equine**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Pain	2
Injection site reaction	2
Collapse	1

VITAMIN B3 = NICOTINAMIDE**Ovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Death	1
Ataxia	1
Shaking	1
Convulsions	1
Frothing at the mouth	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 = PYRIDOXINE**Equine**

Number of reports	Probable	Possible
1	0	1

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

VITAMIN B6 HYDROCHLORIDE = PYRIDOXINE HYDROCHLORIDE**Unknown**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Injection site reaction	1
Pain	1

VITAMIN B6 HYDROCHLORIDE = PYRIDOXINE HYDROCHLORIDE**Equine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Injection site reaction	2
Pain	2

VITAMIN B6 HYDROCHLORIDE = PYRIDOXINE HYDROCHLORIDE**Ovine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Shaking	1
Frothing at the mouth	1
Convulsions	1
Death	1
Ataxia	1

VITAMIN B6 HYDROCHLORIDE = PYRIDOXINE HYDROCHLORIDE**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 D3 = CHOLECALCIFEROL**Bovine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Death	1

VITAMIN D3 = CHOLECALCIFEROL**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Collapse	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 E-D = ALPHA TOCOPHEROL-D**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Collapse	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 E-DL ACETATE = ALPHA TOCOPHEROL ACETATE**Canine**

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Urticaria	1

VITAMIN E-DL ACETATE = ALPHA TOCOPHEROL ACETATE**Equine**

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Recumbency	1
Rolling	1
Sweating	1
Respiratory problems	1
Stiffness	1
Swelling (local)	1
Pain	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.

VITAMIN K1 = PHYTOMENADIONE**Canine**

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Distress	2
Shaking	2
Pruritis	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.

XYLAZINE AS THE HYDROCHLORIDE**Equine**

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Recumbency	2
Death	1
Haemorrhage	1

XYLAZINE AS THE HYDROCHLORIDE**Feline**

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Death	1
Cardiac Arrest	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.

YOHIMBINE HYDROCHLORIDE**Bovine**

Number of reports	Probable	Possible
1	1	0

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

YOHIMBINE HYDROCHLORIDE**Canine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Agitation	1
Tachycardia	1
Seizure	1

Pyrexia	1
Unconscious	1
Hyperactivity	1
Vomiting	1
Death	1
Cardiac Arrest	1

YOHIMBINE HYDROCHLORIDE

Feline

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Tachycardia	2
Vomiting	2
Vocalisation	2
Agitation	2
Hypersalivation	2
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.

ZERANOL

Bovine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Migration (subcutaneous)	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.

ZETA-CYPERMETHRIN**Bovine**

Number of reports	Probable	Possible
21	21	0

Presenting Signs	Number of reports
Irritation (skin)	21

Zeta-cypermethrin is a synthetic pyrethroid and are known to cause transient skin irritation. Based on assessment of the adverse experience reports in which skin irritations were observed in large numbers of animals, an additional statement was added to these product labels to warn users that cattle may become agitated, which may pose a occupational health and safety issue for dairy farmers when the cattle are in the milking shed.

ZINC**Ovine**

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Oedema	1
Death	1
Pharyngitis	1
Swelling (local)	1
Depression	1

A label change was made to a number of products containing minerals such as copper in which the product is administered as a 'pellet'. The pellets are administered orally by a special drenching gun. It was found that in a number of cases farmers did not take appropriate precautions when administering these types of products and this resulted in damage to the pharyngeal area of some sheep. As a result a label change was made to emphasise the need for operators to take precautions not to force the drenching gun into the mouth.

ZINC EDTA**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.

ZINC OXIDE**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.

ZOLAZEPAM AS THE HYDROCHLORIDE**Canine**

Number of reports	Probable	Possible
1	0	1

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

Lethargy	1
Weakness	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.

ZOLAZEPAM HYDROCHLORIDE

Feline

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.

3. SECTION 1

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.

(S)-METHOPRENE

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Hives	1
Disorientation	1
Dizziness	1
Swelling (local)	1

The clinical symptoms observed in these patients were considered to have been directly related to the product formulation and not solely the (S)-methoprene component, therefore regulatory action is listed under another active constituent (eg fipronil).

ALPHA-CYPERMETHRIN

Number of reports	Probable	Possible
4	1	3

Presenting Signs	Number of reports
Respiratory problems	2
Irritation (skin)	2
Irritation (eye)	1
Behavioural 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.

AMITRAZ

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Bradycardia	1
Dizziness	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.

BLACK DISEASE = CLOSTRIDIUM OEDEMATIENS

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Swelling (local)	1
Needle stick injury	1

Needle stick injuries are an inevitable part of using vaccines. Due to the low level of reporting and the lack of any serious symptoms, no regulatory action has been required in light of these types of reports.

BLACKLEG = CLOSTRIDIUM CHAUVOEI

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Swelling (local)	1
Needle stick injury	1

Needle stick injuries are an inevitable part of using vaccines. Due to the low level of reporting and the lack of any serious symptoms, no regulatory action has been required in light of these types of reports.

CLA = CORYNEBACTERIUM PSEUDOTUBERCULOSIS OVIS

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Needle stick injury	1
Swelling (local)	1

Needle stick injuries are an inevitable part of using vaccines. Due to the low level of reporting and the lack of any serious symptoms, no regulatory action has been required in light of these types of reports.

CLOSTRIDIUM PERFRINGENS TYPE D TOXOID

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Swelling (local)	1
Needle stick injury	1

Needle stick injuries are an inevitable part of using vaccines. Due to the low level of reporting and the lack of any serious symptoms, no regulatory action has been required in light of these types of reports.

CLOSTRIDIUM TETANI - TOXOID

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Needle stick injury	1
Swelling (local)	1

Needle stick injuries are an inevitable part of using vaccines. Due to the low level of reporting and the lack of any serious symptoms, no regulatory action has been required in light of these types of reports.

CRESYLIC ACID

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Numbness	1
Respiratory problems	1
Malaise	1
Dyspnoea	1
Coughing	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.

CYPERMETHRIN

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Anorexia	1
Irritation (skin)	1
Headache	1
Malaise	1
Rash	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

Number of reports	Probable	Possible
3	3	0

Presenting Signs	Number of reports
Irritation (skin)	2
Irritation (eye)	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.

DIAZINON

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Irritation (skin)	1
Anorexia	1
Malaise	1
Headache	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

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Irritation (skin)	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

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Odour	1
Paraesthesia	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.

FIPRONIL

Number of reports	Probable	Possible
37	8	29

Presenting Signs	Number of reports
Irritation (skin)	13
Rash	12
Pruritis	9
Swelling (local)	8
Welts	6
Irritation (eye)	4
Erythema	2
Hives	2
Headache	2
Dizziness	2
Disorientation	2
Inflammation	2
Odour	2
Respiratory problems	2
Dermatitis	1
Sneezing	1
Unpleasant taste	1
Reproduction Disorder	1
Papules	1

Ataxia	1
Hepatitis	1
Coughing	1

Based on assessment of adverse experience reports in humans involving exposure to products containing fipronil a label change was made to warn users not to use these products if they or their pets have a known hypersensitivity to pesticides or alcohol. Also due to the APVMA continuing to receive reports of human health issues involving the use of these products the APVMA has decided to review the registration particulars of these products.

FLUMETHRIN

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Headache	1
Irritation (skin)	1
Blurred vision	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
1	0	1

Presenting Signs	Number of reports
Rash	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
1	0	1

Presenting Signs	Number of reports
Swelling (local)	1
Vomiting	1
Colic	1

Based on assessment of adverse experiences for products containing ivermectin involving human health, additions were included to the first aid instructions and safety directions of these product labels.

LEVAMISOLE HYDROCHLORIDE

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Blisters	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.

MALIGNANT OEDEMA = CLOSTRIDIUM SEPTICUM

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Swelling (local)	1
Needle stick injury	1

Needle stick injuries are an inevitable part of using vaccines. Due to the low level of reporting and the lack of any serious symptoms, no regulatory action has been required in light of these types of reports.

MOXIDECTIN

Number of reports	Probable	Possible
8	4	4

Presenting Signs	Number of reports
Headache	3
Swelling (local)	3
Malaise	2
Numbness	1
Gastroenteritis	1
Needle stick injury	1
Diarrhoea	1
odour	1
Crusting skin	1
Peeling skin	1
Lethargy	1
Head cold	1

Based on assessment of adverse experiences for products containing ivermectin involving human health, additions were included to the first aid instructions and safety directions of these product labels.

NAPHTHALOPHOS

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Blisters	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.

OLAQUINDOX

Number of reports	Probable	Possible
8	8	0

Presenting Signs	Number of reports
Irritation (skin)	3
Rash	2
Photosensitisation	2
Dermatitis	2
Nil	1
Hypersensitivity reaction	1
Arthropathy	1
Erythema	1

Based on assessment of adverse experiences for products containing ivermectin involving human health, additions were included to the first aid instructions and safety directions of these product labels.

PICLORAM AS THE HEXYLOXYPROPLAMINE SALT

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Irritation (skin)	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

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Rash	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.

PROPOXUR

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Irritation (skin)	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.

TRICLOPYR AS THE BUTOXYETHYL ESTER

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Irritation (skin)	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.

TRIFLUMURON

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Headache	2
Seizure	1
Irritation (skin)	1
Haemorrhage	1
weak	1
Malaise	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.

4. REFERENCES

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5. GLOSSARY

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