REPORT OF ADVERSE EXPERIENCES 2004 CALENDAR YEAR

Veterinary Medicines

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EXECUTIVE SUMMARY

The 2004 calendar year was essentially a year of stabilisation and consolidation of the new procedures that were put into place during 2002 and 2003. Risk management and communication strategies were further developed to ensure that the outcomes of the program were effective and relevant for veterinarians and animal owners. These improvements have been very effective in enabling the APVMA to more quickly and accurately identify issues involving veterinary medicines that require corrective action to minimise future adverse experiences from occurring.

Some of the activities undertaken during 2004 include:

- Publishing a peer-reviewed scientific paper on the AERP *Vet* for publication in *Aust Veterinary Journal* **83**(1&2): 32.
- Giving two presentations at the Australian Veterinary Association (AVA) Conference in Canberra, 5-6 May 2004.
- Publishing two scientific papers in the AVA Annual Conference Proceedings.
- Giving a presentation at the Australian College of Veterinary Scientists' annual conference in the first week of July 2004. This presentation was also circulated to the College members on CDROM.
- Sending an article to all 8 Australian Veterinary Surgeons' Boards for inclusion in their newsletters.
- Various articles, letters and another scientific papers were also prepared based on analyses of adverse experience information and were submitted for publication in the *Australian Veterinary Journal*, and other national and international refereed journals in the first half of the 2004-2005 financial year.

This Annual Report contains a summary of all adverse experience reports assessed, evaluated and classified by the APVMA during the 2004 Calendar Year. It is important to note that some reports relate to previous years, but because the APVMA only received them in late 2003 and they were classified in 2004, they are included in this report for completeness.

Throughout the 2004 calendar year changes were made to seventeen veterinary products. These changes include:

- additional warning, precautionary or restraint statements placed on fourteen products;
- changes to First Aid Instructions and Safety Directions for one product; and
- a recall of two products.

More information is provided on some of these changes in the following report under each respective active constituent.

Entries for the active constituent 'fipronil' have not been included in this report as these products are currently under formal review by the APVMA. These entries will be published in a later report.

1. INTRODUCTION

1.1 Program Outline

The APVMA is the independent Australian government authority responsible for the assessment and registration (marketing authorisation) of pesticides and veterinary medicines prior to sale, and their regulation up to and including the point of retail sale. *'Pesticides'* include agricultural and many household chemicals such as insecticides, herbicides and fungicides; water treatment products including swimming pool products; products for treating algae and mould; products for preventing rot and infestation in marine structures and other similar products. *'Veterinary medicines'* include all veterinary chemical products such as vaccines, antibiotics, worming treatments, flea and tick washes and other parasiticides for both domestic and production animals. Under the National Registration Scheme, the APVMA evaluates and registers agricultural and veterinary chemicals and manages quality assurance programs that monitor the safety and performance of registered products.

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

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

1.2 What is an adverse experience?

An 'adverse experience' is defined by the APVMA as:

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

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

1.3 Who can report an adverse experience?

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

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

1.4 Reporting an adverse experience

Adverse experiences with veterinary medicines may be reported using the Adverse Experience Reporting Form for veterinary medicines available from veterinarians, the AVA, the APVMA or on the APVMA Website at http://www.apvma.gov.au/forms/KP81F03.rtf, or via the online reporting system at https://services.apvma.gov.au/AerpWebApp.

1.5 Evaluation of adverse experience reports

Procedures for dealing with adverse experience reports are as follows:

- Reports made directly to the APVMA (*Voluntary Reports*) are copied to the product registrant for investigation. The registrant may then contact either the reporting person or the attending veterinarian and discuss the matter to determine if any follow up laboratory, pathology or other veterinary work is required.
- The product registrant subsequently provides the APVMA with an investigation report into the incident. The APVMA assesses this information and determines whether any further investigative work is required. In some cases, additional expert opinion may be sought from the Australian Veterinary Association, relevant State/Territory government agencies, universities or other appropriate authorities. The APVMA also considers scientific information publicly available either on the Internet or from an international agency (such as in the UK, Canada or US).
- In all cases, a standard method of assessment is used to determine whether the adverse experience may have been related to the use of the veterinary medicine (ie 'classification' – see 1.6 below). The APVMA also considers whether the product was used according to the label directions.
- The person making the report of an adverse experience will be advised of the outcome of the investigations as soon as possible.
- If a report of an adverse experience is made directly to the product registrant, they will investigate the matter and provide a report to the APVMA (*Registrant Reports*). The APVMA will then assess this information and determine whether any further investigative or regulatory work is required.

1.6 Classification of adverse experience reports

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

Probable
For inclusion in the category 'probable' all of the following minimum criteria should be met:

- there should be a reasonable association between the administration of the product and onset and duration of the reported adverse experience,
- the description of the clinical signs should be consistent with or at least plausible given the known pharmacology and toxicology of the product, and
- there should be no other equally plausible explanation (or contributing factors) for the clinical signs.

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

Probable/Off-label
As per the classification of 'probable' and where there is obvious evidence of off-label use (including use in species not listed on the product label, over-dosing or under-dosing). It is acknowledged that depending on State and Territory legislation, veterinary prescribing privileges, APVMA Permits and other legal exemptions may allow off-label use in some situations.

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

Possible/Off-label
As per the classification 'possible' and where there is obvious evidence of off-label use (including use in species not listed on the product label, over-dosing or under-dosing). It is acknowledged that depending on State and Territory legislation, veterinary prescribing privileges, APVMA Permits and other legal exemptions may allow off-label use in some situations.

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

Unknown
All adverse experiences where reliable data is either unavailable or is insufficient to make an assessment should be categorised as 'unknown'.

1.7 Corrective action determination

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

For each registered veterinary medicine, and more broadly for each active constituent, the APVMA conducts a trend analysis of all adverse experience reports received. All reports that have been classified as 'probable' or 'possible' are compared to the total number of doses sold within the relevant financial year and a 'reporting incidence' is calculated (ie the number of adverse experience reports per number of doses sold). A control limit or "warning line" for reporting incidence figures, which indicate that further action may be required (for vaccines) is one or more per 10,000 doses sold[1]. This report also recommends that if the reporting incidence is greater than one per 10,000 in two out of three consecutive years or an exceptional incidence of three or more per 10,000 occurs on any one occasion, or a consistent rising trend is seen over five years (irrespective of the reporting incidence) then action may be required.

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

1.8 Outcomes of the program

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

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

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

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

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

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

1.9 Report Structure

This report is arranged into the following sections:

- **Section 1** a summary of adverse experience reports for each species listed by active constituent, and

- **Section 2** a summary of all adverse experience reports involving human health.

1.10 For further information

For information about the Adverse Experience Reporting Program please contact:

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2. SECTION 1

2.1 A summary of adverse experience reports for each species listed by active constituent

The following information is contained in this section:

The active constituent name

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

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

The species

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

The number of reports

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

The presenting signs

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

- It is important to note in the following summaries of adverse experience reports that in one report a number of different clinical signs may have been observed. Therefore the list of clinical signs observed does not relate directly to the total number of reports received.

Summary of corrective action

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

ABAMECTIN

Bovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1

ABAMECTIN

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Welts	1

The APVMA has received a number of adverse experience reports over recent years involving toxicity resulting from overdosing in calves and lambs (use contrary to label use). Assessment of these reports showed that there is a potential link between the age of the animal, the development of the blood-brain barrier and abamectin toxicity. Although abamectin penetrates the blood-brain barrier poorly in mature animals, it has been postulated that much younger animals (eg calves and lambs) may have blood-brain barriers that are permeable to large molecules for some weeks after birth. In response to this assessment, additional warning statements are to be included on abamectin products to warn users not to use in very young animals (calves under 16 weeks of age, lambs under 6 weeks of age) or very small animals (calves under 50kg, lambs under 10kg).

ACEPROMAZINE

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Dyspnoea	1
Death	1
Cardiac arrhythmia	1

Based on the very low number of adverse experience reports for these products when 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
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.

ALBENDAZOLE

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Pale mucous membranes	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.

ALPHA-CYPERMETHRIN

Ovine

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Lack of effect	3

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

ALPHAXALONE

Canine

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Induction (poor)	1
Anaesthesia (light)	1
Vocalisation	1
Hyperaesthesia	1
Hyperexcitable	1
Respiratory problems	1
Periorbital swelling	1

ALPHAXALONE

Feline

Number of reports	Probable	Possible
11	1	10

Presenting Signs	Number of reports
Pulmonary oedema	3
Coughing	3
Blindness	1
Hypersalivation	1
Induction (poor)	1
Pale mucous membranes	1
Dyspnoea	1
Hyperexcitable	1
Swelling (local)	1
Anaphylactoid reaction	1
Oedema	1
Recovery (prolonged)	1

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

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

AMITRAZ

Bovine

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Incoordination	1
Hypersalivation	1
Lethargy	1
Recumbency	1
Panting	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.

AMOXYCILLIN AS AMOXYCILLIN TRIHYDRATE

Canine

Number of reports	Probable	Possible
4	4	0

Presenting Signs	Number of reports
Abscess	2
Injection site reaction	2
Haemorrhage	1
Vomiting	1
Aggression	1
Thrombocytopenia	1

AMOXYCILLIN AS AMOXYCILLIN TRIHYDRATE

Equine

Number of reports	Probable	Possible
1	0	1

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.

ATIPAMEZOLE HYDROCHLORIDE

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Ataxia	1
Vocalisation	1
Respiratory problems	1
Incoordination	1
Cardiac Arrest	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.

ATROPINE

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Dyspnoea	1
Cardiac arrhythmia	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
1	1	0

Presenting Signs	Number of reports
Disorientation	1
Dyspnoea	1
Stiffness	1
Panting	1

Based on the very low number of adverse experience reports for these products when 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

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Cardiac Arrest	1
CNS dysfunction	1
Anaphylactoid 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.

BETAMETHASONE

Canine

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Deafness	3
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.

BLACKLEG = CLOSTRIDIUM CHAUVOEI

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Recumbency	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.

BORDETELLA BRONCHISEPTICA

Canine

Number of reports	Probable	Possible
26	19	7

Presenting Signs	Number of reports
Coughing	11
Respiratory problems	11
Sneezing	10
Lethargy	4
Nasal discharge	3
Vaccination reaction	1
Anorexia	1

BORDETELLA BRONCHISEPTICA KILLED VACCINE

Canine

Number of reports	Probable	Possible
7	6	1

Presenting Signs	Number of reports
Facial oedema	4
Urticaria	2
Vaccination reaction	1
Anaphylactoid reaction	1
Dyspnoea	1
Swelling (local)	1
Tachypnoea	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.

BORDETELLA BRONCHISPETICA (INACTIVATED CELL FREE EXTRACT)

Canine

Number of reports	Probable	Possible
50	38	12

Presenting Signs	Number of reports
Facial oedema	27
Vomiting	9
Periorbital swelling	7
Pain	6
Urticaria	6
Swelling (local)	6
Injection site reaction	5
Hypersensitivity reaction	5
Swollen lips and face	3
Collapse	3
Pruritis	3
Depression	2
Lethargy	2

Shock	2
Pale mucous membranes	2
Tremor	2
Erythema	2
Oedema	1
Welts	1
Malaise	1
Restless	1
Bradycardia	1
Rubbing	1
Panting	1
Pyrexia	1
Sneezing	1
Vocalisation	1
Cyanosis	1
Agitation	1
Wheals	1
Coughing	1

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

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

BORIC ACID

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Hypersalivation	1
Horner's Syndrome	1

Based on the very low number of adverse experience reports for these products when 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 (BEFV)

Bovine

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.

BUSERELIN ACETATE

Camelid

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Tachycardia	1
Collapse	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.

CANINE ADENO VIRUS TYPE 2

Canine

Number of reports	Probable	Possible
45	20	25

Presenting Signs	Number of reports
Coughing	12
Facial oedema	10
Sneezing	10
Respiratory problems	10
Vomiting	5
Lethargy	4
Urticaria	4
Hypersensitivity reaction	3
Pruritis	3
Collapse	3
Shock	2
Injection site reaction	2
Auto-immune haemolytic anaemia	2
Nasal discharge	2
Swollen lips and face	2
Pain	2
Pale mucous membranes	2
Swelling (local)	1

Agitation	1
Cyanosis	1
Bradycardia	1
Anorexia	1
Restless	1
Vaccination reaction	1

CANINE ADENO VIRUS TYPE 2 STRAIN V197

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Facial oedema	1
Vomiting	1
Tremor	1
Pruritis	1
Lethargy	1
Rubbing	1

CANINE ADENOVIRUS TYPE 2 (CAV2)

Canine

Number of reports	Probable	Possible
17	3	14

Presenting Signs	Number of reports
Lack of effect	5
Facial oedema	3
Vomiting	3
Diarrhoea	2
Depression	2
Pain	2
Polyarthritis	2
Anaphylactoid reaction	2
Periorbital swelling	2
Death	1
Jaundice	1
Injection site reaction	1
Respiratory problems	1

Lame	1
Swelling (local)	1
Anorexia	1
Collapse	1
Pyrexia	1
Hypersalivation	1
Lethargy	1
Malaise	1
Panting	1
Dyspnoea	1

CANINE CORONAVIRUS VACCINE - ANTIGEN

Canine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Facial oedema	1
Lethargy	1
Listless	1
Periorbital swelling	1

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

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

CANINE DISTEMPER

Canine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Vaccination reaction	1
Polyarthritis	1

CANINE DISTEMPER VIRUS

Canine

Number of reports	Probable	Possible
18	4	14

Presenting Signs	Number of reports
Lack of effect	5
Vomiting	3
Facial oedema	3
Anaphylactoid reaction	2
Injection site reaction	2
Depression	2
Periorbital swelling	2
Diarrhoea	2
Pain	2
Polyarthritis	2
Collapse	1
Panting	1
Lethargy	1
Anorexia	1
Pyrexia	1
Swelling (local)	1
Dyspnoea	1
Hypersalivation	1
Respiratory problems	1
Malaise	1
Lame	1
Jaundice	1
Death	1

CANINE DISTEMPER VIRUS - LIVING

Canine

Number of reports	Probable	Possible
21	13	8

Presenting Signs	Number of reports
Facial oedema	10
Vomiting	5
Urticaria	4
Pruritis	3
Collapse	3
Hypersensitivity reaction	3
Pain	2
Shock	2
Pale mucous membranes	2
Swollen lips and face	2
Injection site reaction	2
Auto-immune haemolytic anaemia	2
Coughing	1
Restless	1
Cyanosis	1
Bradycardia	1
Agitation	1
Swelling (local)	1

CANINE DISTEMPER VIRUS STRAIN ONDERSTEPOORT

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Rubbing	1
Pruritis	1
Facial oedema	1
Lethargy	1
Tremor	1
Vomiting	1

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

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

CANINE PARAINFLUENZA TYPE 2

Canine

Number of reports	Probable	Possible
10	3	7

Presenting Signs	Number of reports
Facial oedema	3
Vomiting	2
Periorbital swelling	2
Pain	2
Polyarthritis	2
Lack of effect	2
Lame	1
Malaise	1
Pyrexia	1
Anaphylactoid reaction	1
Lethargy	1
Injection site reaction	1
Panting	1
Anorexia	1
Jaundice	1
Diarrhoea	1
Swelling (local)	1
Dyspnoea	1
Death	1
Depression	1

CANINE PARAINFLUENZA VIRUS

Canine

Number of reports	Probable	Possible
43	19	24

Presenting Signs	Number of reports
Coughing	12
Respiratory problems	10
Sneezing	10
Facial oedema	8
Vomiting	5
Lethargy	4
Collapse	3
Urticaria	3
Hypersensitivity reaction	3
Pale mucous membranes	2
Swollen lips and face	2
Injection site reaction	2
Pruritis	2
Nasal discharge	2
Shock	2
Cyanosis	1
Vaccination reaction	1
Pain	1
Polyarthritis	1
Restless	1
Bradycardia	1
Anorexia	1
Agitation	1

CANINE PARAINFLUENZA VIRUS TYPE 2 STRAIN CGF 2004/75

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Rubbing	1
Facial oedema	1
Lethargy	1
Tremor	1
Pruritis	1
Vomiting	1

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

CANINE PARVO VIRUS

Canine

Number of reports	Probable	Possible
21	5	16

Presenting Signs	Number of reports
Facial oedema	5
Lack of effect	5
Pain	3
Polyarthritis	3
Vomiting	3
Injection site reaction	2
Swelling (local)	2
Diarrhoea	2
Depression	2
Periorbital swelling	2
Anaphylactoid reaction	2
Panting	1
Anorexia	1
Pruritis	1
Malaise	1
Urticaria	1
Lame	1
Auto-immune haemolytic anaemia	1
Lethargy	1
Pyrexia	1
Hypersalivation	1
Death	1
Jaundice	1
Dyspnoea	1
Respiratory problems	1
Collapse	1

CANINE PARVO VIRUS TYPE 2

Canine

Number of reports	Probable	Possible
17	11	6

Presenting Signs	Number of reports
Facial oedema	7
Vomiting	5
Hypersensitivity reaction	3
Urticaria	3
Collapse	3
Pale mucous membranes	2
Pruritis	2
Swollen lips and face	2
Shock	2
Cyanosis	1
Bradycardia	1
Pain	1
Coughing	1
Restless	1
Auto-immune haemolytic anaemia	1
Injection site reaction	1

CANINE PARVO VIRUS TYPE 2 STRAIN K3I PASSAGE 69

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Tremor	1
Vomiting	1
Lethargy	1
Rubbing	1
Facial oedema	1
Pruritis	1

CANINE PARVOVIRUS (INACTIVATED)

Canine

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Haemorrhage	1
Lethargy	1
Behavioural change	1
Swelling (local)	1
Hypersalivation	1
Coughing	1

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

CARBARYL

Canine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Dermatitis	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.

CARPROFEN

Canine

Number of reports	Probable	Possible
12	3	9

Presenting Signs	Number of reports
Pruritis	4
Depression	3
Pyrexia	3
Vomiting	3
Haematology (Abnormal)	2
Collapse	2
Haematemesis	1
Dermatitis	1
Erythema	1
Swelling (local)	1
Cardiac Arrest	1
Hepatopathy	1
CNS dysfunction	1
Polydipsia	1
Shaking	1
Tachypnoea	1
Death	1
Lethargy	1
Anaphylactoid reaction	1
Lesions	1

CARPROFEN

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
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.

CHLORFENVINPHOS

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Alopecia	1
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.

CHLOROTHYMOL

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Horner's Syndrome	1
Hypersalivation	1

In response to adverse experience reports for chlorothymol involving felines, the label claim for use in cats is to be removed.

CORYNEBACTERIUM PSEUDOTUBERCULOSIS OVIS

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Ataxia	1
Lethargy	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.

CLAVULANIC ACID AS POTASSIUM CLAVULANATE

Canine

Number of reports	Probable	Possible
4	4	0

Presenting Signs	Number of reports
Injection site reaction	2
Abscess	2
Aggression	1
Thrombocytopenia	1
Vomiting	1
Haemorrhage	1

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

CLENBUTEROL HYDROCHLORIDE

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Sweating	1

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

CLINDAMYCIN HYDROCHLORIDE

Canine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Dyspnoea	1
Death	1
Vomiting	1

CLINDAMYCIN HYDROCHLORIDE

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
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.

CLOMIPRAMINE HYDROCHLORIDE

Canine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Seizure	1
Lack of effect	1

CLOMIPRAMINE HYDROCHLORIDE

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Anorexia	1
Urinary retention	1
Death	1
Vomiting	1
Hypothermia	1
Urinary tract disease	1
Shock	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.

CLOSTRIDIUM BOTULINUM TYPE C TOXOID

Bovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1
Death	1

CLOSTRIDIUM BOTULINUM TYPE D TOXOID

Bovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lack of effect	1
Death	1

CLOSTRIDIUM CHAUVOEI - FORMOL CULTURE

Bovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Recumbency	1
Lethargy	1
Illthrift	1
Depression	1
Hypersalivation	1
Death	1

CLOSTRIDIUM NOVYI TYPE B

Bovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Depression	1
Illthrift	1
Recumbency	1
Hypersalivation	1
Death	1
Lethargy	1

CLOSTRIDIUM NOVYI TYPE B - ANTISERA/ANTIGEN

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Ataxia	1
Recumbency	1
Lethargy	1

CLOSTRIDIUM PERFRINGENS TYPE D - ANTISERA/ANTIGEN

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Ataxia	1
Lethargy	1
Recumbency	1

CLOSTRIDIUM PERFRINGENS TYPE D TOXOID

Bovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Depression	1
Hypersalivation	1
Recumbency	1
Death	1
Illthrift	1
Lethargy	1

CLOSTRIDIUM SEPTICUM - TOXOID

Bovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Hypersalivation	1
Death	1
Lethargy	1
Illthrift	1
Recumbency	1
Depression	1

CLOSTRIDIUM TETANI UF TOXOID

Equine

Number of reports	Probable	Possible
2	2	0

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

CLOTRIMAZOLE

Canine

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Deafness	3
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.

COBALT EDTA

Ovine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Death	2
Pain	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.

CORONAVIRUS

Canine

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Vaccination reaction	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.

COUMAPHOS

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Vomiting	1
Coughing	1

COUMAPHOS

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Rash	1
Hives	1
Shaking	1

Based on the very low number of adverse experience reports for these products when 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
3	1	2

Presenting Signs	Number of reports
Pruritis	2
Inflammation	1
Agitation	1
Disorientation	1
Spasm	1
Vocalisation	1
Erythema	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.

CYPERMETHRIN

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Alopecia	1
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.

CYROMAZINE

Ovine

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.

DELTAMETHRIN

Bovine

Number of reports	Probable	Possible
13	4	9

Presenting Signs	Number of reports
Lack of effect	8
Weight loss	1
Milk production decrease	1
Dermatitis	1
Depression	1
Irritation (skin)	1
Agitation	1
Lesions	1

DELTAMETHRIN

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Site Reaction	1
Excitation	1
Pain	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.

DIFLUBENZURON

Other

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Lack of effect	2

DIFLUBENZURON

Ovine

Number of reports	Probable	Possible
24	8	16

Presenting Signs	Number of reports
Lack of effect	18
Skin slough	3
Lesions	1
Site Reaction	1
Alopecia	1
Coat colour change	1
Scabs	1
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.

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.

DOXYCYCLINE MONOHYDRATE

Canine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Facial oedema	1

Blisters	1
Irritation (skin)	1

DOXYCYCLINE MONOHYDRATE

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Photosensitisation	1

Based on the very low number of adverse experience reports for these products when 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
1	0	1

Presenting Signs	Number of reports
Oedema	1
Urticaria	1

ENROFLOXACIN

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Seizure	1
Pupillary dilation	1

Based on assessment of national and international adverse experience information an additional warning statement is to be included on fluoroquinolone products to warn users that there is the rare potential to induce retinal degeneration in cats, especially when used at above label dose rates (ie contrary to label directions) or in elderly animals or animals suffering from renal or hepatic disease.

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

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Pyrexia	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.

ESCHERICHIA COLI 987P PILUS ANTIGENS

Porcine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Abortion	1
Anorexia	1

ESCHERICHIA COLI K88AB PILUS ANTIGENS

Porcine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Anorexia	1
Abortion	1
Anorexia	1
Abortion	1

ESCHERICHIA COLI K99 PILUS ANTIGENS

Porcine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Anorexia	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.

FEBANTEL

Canine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Hyperexcitable	1
Vomiting	1
Diarrhoea	1
Haemorrhage	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.

FELINE CALICIVIRUS - INACTIVATED

Feline

Number of reports	Probable	Possible
58	34	24

Presenting Signs	Number of reports
Lethargy	23
Anorexia	22
Pain	15
Pyrexia	14
Depression	13
Vomiting	11
Injection site reaction	8
Death	5
Vaccination reaction	3
Vocalisation	3
Respiratory problems	3
Diarrhoea	3
Cyanosis	2
Malaise	2
Site Reaction	2
Dehydration	2
Irritation (skin)	2
Anaphylactoid reaction	1
Arthropathy	1
Frothing at the mouth	1
Listless	1
Abscess	1
Colic	1
Irritation (eye)	1
Non-ambulatory	1
Recumbency	1
Collapse	1
Behavioural change	1
Urination	1
Pale mucous membranes	1
Dyspnoea	1
Anaphylaxis	1
Hypothermia	1

Coughing	1
Facial oedema	1

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

FELINE CHLAMYDIA PSITTACI (INACTIVATED)

Feline

Number of reports	Probable	Possible
17	10	7

Presenting Signs	Number of reports
Anorexia	8
Lethargy	6
Pain	5
Pyrexia	5
Vaccination reaction	3
Death	2
Injection site reaction	2
Depression	2
Malaise	1
Cyanosis	1
Arthropathy	1
Non-ambulatory	1
Dyspnoea	1
Colic	1
Vomiting	1

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

FELINE LEUKAEMIA VIRUS - INACTIVATED

Feline

Number of reports	Probable	Possible
5	1	4

Presenting Signs	Number of reports
Anorexia	3
Depression	2
Pyrexia	2
Lethargy	2
Pain	2
Malaise	1
Colic	1
Vomiting	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.

FELINE PANLEUCOPENIA VIRUS - INACTIVATED

Feline

Number of reports	Probable	Possible
58	34	24

Presenting Signs	Number of reports
Lethargy	23
Anorexia	22
Pain	15
Pyrexia	14
Depression	13
Vomiting	11
Injection site reaction	8
Death	5
Vaccination reaction	3
Vocalisation	3
Respiratory problems	3
Diarrhoea	3
Irritation (skin)	2
Cyanosis	2
Dehydration	2
Site Reaction	2
Malaise	2
Urination	1
Irritation (eye)	1
Pale mucous membranes	1
Facial oedema	1
Frothing at the mouth	1
Coughing	1
Listless	1
Collapse	1
Dyspnoea	1
Anaphylaxis	1
Behavioural change	1
Hypothermia	1
Non-ambulatory	1
Anaphylactoid reaction	1
Arthropathy	1
Abscess	1

Colic	1
Recumbency	1

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

FELINE RHINOTRACHEITIS VIRUS - INACTIVATED

Feline

Number of reports	Probable	Possible
58	34	24

Presenting Signs	Number of reports
Lethargy	23
Anorexia	22
Pain	15
Pyrexia	14
Depression	13
Vomiting	11
Injection site reaction	8
Death	5
Respiratory problems	3
Diarrhoea	3
Vocalisation	3
Vaccination reaction	3
Irritation (skin)	2
Malaise	2
Dehydration	2
Cyanosis	2
Site Reaction	2
Facial oedema	1
Behavioural change	1
Listless	1
Dyspnoea	1
Arthropathy	1
Abscess	1
Anaphylactoid reaction	1
Anaphylaxis	1
Non-ambulatory	1

Hypothermia	1
Frothing at the mouth	1
Urination	1
Coughing	1
Colic	1
Collapse	1
Pale mucous membranes	1
Irritation (eye)	1
Recumbency	1

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

FENBENDAZOLE

Ovine

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.

FLUMETHASONE

Equine

Number of reports	Probable	Possible
1	1	0

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.

FLUMETHRIN

Canine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Dermatitis	1
Alopecia	1
Site Reaction	1
Tick paralysis	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.

FLUNIXIN MEGLUMINE

Equine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Shaking	2
Ataxia	1
Tremor	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.

FRUSEMIDE

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Erythema	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.

GENTAMICIN

Canine

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Deafness	3
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.

GLUCOSAMINE HYDROCHLORIDE

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
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.

HAEMOPHILUS PARASUIS

Porcine

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Lack of effect	3

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

HALOTHANE

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Cardiac arrhythmia	1
Dyspnoea	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.

HEPATITIS CANINE = CANINE ADENOVIRUS

Canine

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Vaccination reaction	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.

HYDROXYPROGESTERONE HEXANOATE

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Feminisation	1

Based on the very low number of adverse experience reports for these products when 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
17	9	8

Presenting Signs	Number of reports
Site Reaction	7
Behavioural change	5
Alopecia	3
Lethargy	3
Pruritis	2
Anorexia	2
Depression	2
Dermatitis	2
Swelling (local)	1
Distress	1
Oedema	1
Irritation (eye)	1
Non-ambulatory	1
Welts	1
Erythema	1
Coat colour change	1
Rash	1
Hypersalivation	1
Vocalisation	1
Incoordination	1
Urticaria	1
Hallucinating	1
Rolling	1
Vomiting	1

IMIDACLOPRID

Feline

Number of reports	Probable	Possible
24	17	7

Presenting Signs	Number of reports
Site Reaction	12
Alopecia	11
Hypersalivation	7
Pruritis	3
Scabs	2
Erythema	2
Frothing at the mouth	1
Muscle stiffness	1
Coughing	1
Tachycardia	1
Lesions	1
Irritation (eye)	1
Anorexia	1
Behavioural change	1
Shaking	1
Colic	1
Mouth ulcers	1
Depression	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.

INACTIVATED RABBIT CALICIVIRUS DISEASE VIRUS

Rabbit

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Lethargy	1
Lame	1
Anorexia	1
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.

IVERMECTIN

Bovine

Number of reports	Probable	Possible
6	4	2

Presenting Signs	Number of reports
Ataxia	2
Alopecia	2
Burning sensation	1
Skin slough	1
CNS dysfunction	1
Lack of effect	1
Inflammation	1
Stiffness	1

IVERMECTIN

Canine

Number of reports	Probable	Possible
5	3	2

Presenting Signs	Number of reports
Behavioural change	2
Lethargy	1
Irritation (eye)	1
Vocalisation	1
Hallucinating	1
Distress	1
Anorexia	1
Non-ambulatory	1
Welts	1
Vomiting	1
Incoordination	1
Depression	1
Pruritis	1

IVERMECTIN

Equine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Diarrhoea	1
Colic	1

IVERMECTIN

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Anorexia	1
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.

KETAMINE HYDROCHLORIDE

Equine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Induction (poor)	1
Anaesthesia (light)	1

KETAMINE HYDROCHLORIDE

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Cyanosis	1
Dyspnoea	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.

LEPTOSPIRA ICTEROHAEMORRHAGIAE ANTIGEN

Canine

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Facial oedema	1
Listless	1
Injection site reaction	1
Periorbital swelling	1
Lethargy	1
Vaccination reaction	1

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

LEVAMISOLE HYDROCHLORIDE

Avian

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Death	2
Dehydration	1

LEVAMISOLE HYDROCHLORIDE

Ovine

Number of reports	Probable	Possible
3	2	1

Presenting Signs	Number of reports
Death	3
Seizure	1
Pain	1

As a result of assessment of adverse experience reports for these products in previous years, appropriate label changes were recommended to ensure that yarding animals overnight without feed or water prior to drenching did not occur. It is recognised that cattle and sheep that are under stress or that are dehydrated may be more susceptible to levamisole toxicity therefore these labels changes

were deemed necessary. As can be seen from the lower number of reports in 2004 the label changes are already assisting in minimising adverse experiences.

LUFENURON

Canine

Number of reports	Probable	Possible
5	2	3

Presenting Signs	Number of reports
Diarrhoea	4
Vomiting	3
Seizure	1
Frothing at the mouth	1
Recumbency	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.

MALACHITE GREEN

Other

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.

MALIGNANT OEDEMA = CLOSTRIDIUM SEPTICUM

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Ataxia	1
Lethargy	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.

MEDETOMODINE HYDROCHLORIDE

Canine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Vomiting	2
Weakness	1
Haemorrhage	1
Seizure	1
Defecation	1

MEDETOMODINE HYDROCHLORIDE

Feline

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Respiratory problems	2
Pulmonary oedema	1
Death	1
Ataxia	1
Dyspnoea	1
Cardiac Arrest	1
Cyanosis	1
Incoordination	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.

MELARSOMINE DIHYDROCHLORIDE

Canine

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Death	2
Distress	1
Haemorrhage	1
Vomiting	1
Diarrhoea	1
Panting	1

Based on the very low number of adverse experience reports for these products when 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
1	1	0

Presenting Signs	Number of reports
Horner's Syndrome	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.

METHOPRENE

Feline

Number of reports	Probable	Possible
1	1	0

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.

METHYLENE BLUE DYE

Other

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.

MILBEMYCIN OXIME

Canine

Number of reports	Probable	Possible
6	2	4

Presenting Signs	Number of reports
Diarrhoea	4
Vomiting	3
CNS dysfunction	1
Recumbency	1
Depression	1
Abortion	1
Seizure	1
Ataxia	1
Hypersalivation	1
Bradycardia	1
Anorexia	1
Frothing at the mouth	1

MILBEMYCIN OXIME

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Pupillary dilation	1
Ataxia	1
Incoordination	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.

MOXIDECTIN

Canine

Number of reports	Probable	Possible
56	23	33

Presenting Signs	Number of reports
Anaphylaxis	16
Injection site reaction	13
Facial oedema	13
Vomiting	12
Pale mucous membranes	7
Swelling (local)	6
Bradycardia	5
Collapse	5
Urticaria	5
Diarrhoea	4
Abscess	3
Depression	3
Agitation	2
Anaphylactoid reaction	2
Lethargy	2
Pruritis	2
Hives	1
Cellulitis	1
Auto-immune haemolytic anaemia	1
Behavioural change	1
Walking - difficult	1
Capillary refill time - slow	1
Tremor	1
Recumbency	1
Oedema	1
Swollen lips and face	1
Hyperexcitable	1
Tachypnoea	1
Erythema	1
Apnoea	1
Weakness	1
Ataxia	1
Pyrexia	1

Cyanosis	1

MOXIDECTIN

Bovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Scabs	1
Alopecia	1

MOXIDECTIN

Equine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Hypersalivation	1
Urticaria	1
Pupillary dilation	1
Listless	1
Ataxia	1

MOXIDECTIN

Feline

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Scabs	1
Erythema	1
Hypersalivation	1

MOXIDECTIN

Ovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Ataxia	1
Recumbency	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.

MYCOPLASMA HYOPNEUMONIAE - INACTIVATED ANTIGEN

Porcine

Number of reports	Probable	Possible
4	1	3

Presenting Signs	Number of reports
Lack of effect	3
Diarrhoea	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.

N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE

Feline

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Hypersalivation	1
Tremor	1

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

NANDROLONE DECANOATE

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Feminisation	1

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

NAPHTHALOPHOS

Ovine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Death	2
Illness	1

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

NEOMYCIN SULFATE

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Pupillary dilation	1
Hypersalivation	1
Diarrhoea	1
Vomiting	1
Dyspnoea	1
Haemorrhage	1

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

OATMEAL EXTRACT

Canine

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Irritation (skin)	3
Pruritis	2
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.

OESTRADIOL BENZOATE

Bovine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Prolapsed uterus	2
Death	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.

OESTRADIOL DIPROPIONATE

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Feminisation	1

Based on the very low number of adverse experience reports for these products when 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
1	0	1

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.

OXFENDAZOLE

Equine

Number of reports	Probable	Possible
15	3	12

Presenting Signs	Number of reports
Diarrhoea	9
Anorexia	5
Colic	5
Hypersalivation	2
Depression	2
Abortion	1
Hypersensitivity reaction	1
Scouring	1
Colitis	1

OXFENDAZOLE

Ovine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Death	2
Seizure	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.

PARVOVIRUS LIVE

Canine

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Injection site reaction	1
Vaccination 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.

PERMETHRIN (40:60::CIS:TRANS)

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Coat colour change	1

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

PIPERONYL BUTOXIDE

Feline

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Tremor	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.

POLYMYXIN B SULFATE

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Dyspnoea	1
Pupillary dilation	1
Hypersalivation	1
Haemorrhage	1
Vomiting	1
Diarrhoea	1

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

PRAZIQUANTEL

Avian

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Death	2
Dehydration	1

PRAZIQUANTEL

Canine

Number of reports	Probable	Possible
6	2	4

Presenting Signs	Number of reports
Vomiting	5
Diarrhoea	3
Haemorrhage	1
Behavioural change	1
Depression	1
Hyperexcitable	1
Seizure	1
Frothing at the mouth	1
Recumbency	1

PRAZIQUANTEL

Equine

Number of reports	Probable	Possible
4	0	4

Presenting Signs	Number of reports
Diarrhoea	1
Urticaria	1
Colic	1
Welts	1

PRAZIQUANTEL

Feline

Number of reports	Probable	Possible
5	3	2

Presenting Signs	Number of reports
Ataxia	3
Incoordination	2
Death	1
Distress	1
Depression	1
Cyanosis	1
Pupillary dilation	1
Pain	1
Respiratory problems	1
Behavioural change	1
CNS dysfunction	1
Dyspnoea	1

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

In response to adverse experience reports for avian praziquantel, appropriate changes to the formulation were made in order to improve palatability for birds. It was recognized that birds may not drink treated water and thus may become dehydrated when alternate water sources are not available.

PREDNISOLONE

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Dyspnoea	1
Diarrhoea	1
Pupillary dilation	1
Vomiting	1
Hypersalivation	1
Haemorrhage	1

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

PROCAINE PENICILLIN

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Cardiac Arrest	1
Anaphylactoid reaction	1
CNS dysfunction	1

PROCAINE PENICILLIN

Equine

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Ataxia	2
Excitation	1
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.

PROPOFOL

Canine

Number of reports	Probable	Possible
52	45	7

Presenting Signs	Number of reports
Erythema	12
Periorbital swelling	12
Facial oedema	11
Urticaria	10
Wheals	10
Swelling (local)	10
Pale mucous membranes	6
Apnoea	6
Oedema	5
Capillary refill time - slow	4
Swollen lips and face	3
Hypersensitivity reaction	2
Hives	2
Tachycardia	2
Swollen feet	2
Vocalisation	2
Haemorrhage	1
Pruritis	1
Diarrhoea	1
Anaesthesia - unstable	1
Facial nerve paralysis	1
Respiratory problems	1
Recovery (prolonged)	1
Hypotension	1
Pain	1
Slow recovery	1
Death	1
Ocular pathology	1
Anaesthesia (long)	1
Cardiac arrhythmia	1
Dyspnoea	1
Paddling	1
Hyperexcitable	1

Papules	1
Welts	1

PROPOFOL

Feline

Number of reports	Probable	Possible
6	3	3

Presenting Signs	Number of reports
Facial oedema	2
Swollen feet	2
Hypotension	2
Recovery (prolonged)	2
Slow recovery	1
Capillary refill time - slow	1
Muscle twitching	1
Opisthotonos	1
Pain	1
Swelling (local)	1

Ongoing trend analysis and monitoring for future adverse experience reports for products containing propofol is continuing.

PROPOXUR

Canine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Alopecia	1
Lack of effect	1
Tick paralysis	1
Site Reaction	1
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.

PYRANTEL EMBONATE

Feline

Number of reports	Probable	Possible
4	2	2

Presenting Signs	Number of reports
Ataxia	2
CNS dysfunction	1
Incoordination	1
Dyspnoea	1
Depression	1
Pain	1
Death	1
Distress	1
Cyanosis	1
Respiratory problems	1

PYRANTEL EMBONATE

Canine

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Vomiting	2
Diarrhoea	1
Behavioural change	1
Hyperexcitable	1
Haemorrhage	1

PYRANTEL EMBONATE

Equine

Number of reports	Probable	Possible
11	0	11

Presenting Signs	Number of reports
Diarrhoea	9
Anorexia	4
Colic	3
Depression	2
Hypersensitivity reaction	1
Abortion	1
Colitis	1

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

PYRETHRINS

Feline

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Tremor	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.

PYRIPROXYFEN

Feline

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Lethargy	1
Pruritis	1
Alopecia	1
Agitation	1
Site Reaction	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.

SELAMECTIN

Canine

Number of reports	Probable	Possible
8	7	1

Presenting Signs	Number of reports
Dermatitis	3
Alopecia	2
Site Reaction	2
Self trauma	2
Distress	2
Vomiting	1
Depression	1
Diarrhoea	1
Behavioural change	1
Pruritis	1
Lethargy	1

SELAMECTIN

Feline

Number of reports	Probable	Possible
28	23	5

Presenting Signs	Number of reports
Site Reaction	15
Alopecia	15
Dermatitis	14
Depression	6
Self trauma	4
Anorexia	2
Pruritis	1
Irritation (eye)	1
Dyspnoea	1
Hypersalivation	1
Distress	1
Facial oedema	1
Epiphora	1
Pulmonary oedema	1
Ataxia	1
Vomiting	1
Pyrexia	1
Sneezing	1
Stroke	1

Based on the very low number of adverse experience reports for these products when 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 CHONDROITIN SULFATE

Canine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
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.

SODIUM PENTOSAN POLYSULFATE

Canine

Number of reports	Probable	Possible
4	3	1

Presenting Signs	Number of reports
Vomiting	4
Shaking	1
Lethargy	1
Weakness	1
Agitation	1
Diarrhoea	1
Disorientation	1
Defecation	1
Depression	1
Behavioural change	1

SODIUM PENTOSAN POLYSULFATE

Equine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Colic	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.

Australia is unusual in having three sodium pentosan polysulphate products registered, and one registrant has raised concerns about these products being regarded as similar for regulatory purposes. The APVMA can provide information on adverse experiences for individual products on request if the product registrant agrees.

SODIUM SELENATE

Ovine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Death	2
Pain	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.

STREPTOCOCCUS EQUI

Equine

Number of reports	Probable	Possible
1	0	1

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

STREPTOCOCCUS EQUI AS CELL FREE EXTRACT

Equine

Number of reports	Probable	Possible
2	2	0

Presenting Signs	Number of reports
Injection site reaction	2
Pain	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.

SULFACETAMIDE SODIUM

Feline

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Hypersalivation	1
Haemorrhage	1
Dyspnoea	1
Vomiting	1
Diarrhoea	1
Pupillary dilation	1

Based on the very low number of adverse experience reports for these products when 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

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Sweating	1

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

TEPOXALIN

Canine

Number of reports	Probable	Possible
17	9	8

Presenting Signs	Number of reports
Diarrhoea	10
Vomiting	7
Anorexia	3
Melaena	2
Haemorrhage	2
Lethargy	2
Ulceration	1
Depression	1
Hallucinating	1

Based on the very low number of adverse experience reports for these products when 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 PROPIONATE

Bovine

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Prolapsed uterus	2
Death	1
Swelling (local)	1

TESTOSTERONE PROPIONATE

Equine

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.

TETANUS = CLOSTRIDIUM TETANI

Bovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Illthrift	1
Lethargy	1
Recumbency	1
Hypersalivation	1
Depression	1
Death	1

TETANUS = CLOSTRIDIUM TETANI

Bovine

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Lethargy	1
Ataxia	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.

THIOMERSAL

Canine

Number of reports	Probable	Possible
34	27	7

Presenting Signs	Number of reports
Facial oedema	20
Periorbital swelling	7
Swelling (local)	6
Pain	5
Vomiting	4
Injection site reaction	4
Urticaria	3
Hypersensitivity reaction	2
Tremor	2
Erythema	2
Lethargy	2
Depression	2
Vocalisation	1
Wheals	1
Sneezing	1
Swollen lips and face	1
Agitation	1
Malaise	1
Pruritis	1
Welts	1
Panting	1
Oedema	1
Rubbing	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.

THIOPENTONE SODIUM

Canine

Number of reports	Probable	Possible
3	0	3

Presenting Signs	Number of reports
Anaesthesia (long)	1
Respiratory problems	1
Hyperaesthesia	1
Anaesthesia (deep)	1
Excitation	1

Based on the very low number of adverse experience reports for these products when 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
3	3	0

Presenting Signs	Number of reports
Colic	2
Hypersalivation	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.

TRIFLUMURON

Ovine

Number of reports	Probable	Possible
8	1	7

Presenting Signs	Number of reports
Lack of effect	5
Site Reaction	2
Persistent dye excretion	1
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.

TRIMETHOPRIM

Equine

Number of reports	Probable	Possible
1	1	0

Presenting Signs	Number of reports
Sweating	1

Based on the very low number of adverse experience reports for these products when 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
1	0	1

Presenting Signs	Number of reports
Colic	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.

XYLAZINE AS THE HYDROCHLORIDE

Equine

Number of reports	Probable	Possible
4	3	1

Presenting Signs	Number of reports
Hyperexcitable	3
Muscle twitching	3
Recumbency	3
Stiffness	1
Sedation (prolonged)	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.

ZINC EDTA

Ovine

Number of reports	Probable	Possible
2	1	1

Presenting Signs	Number of reports
Death	2
Seizure	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.

3. SECTION 2

3.1 A summary of adverse experience reports in humans listed by active constituent

The following information is contained in this section:

The active constituent name

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

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

The number of reports

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

The presenting signs

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

It is important to note in the following summaries of adverse experience reports that in one report a number of different clinical signs may have been observed. Therefore the list of clinical signs observed does not relate directly to the total number of reports received.

Summary of corrective action

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

ALPHA-CYPERMETHRIN

Human

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.

CARBARYL

Human

Number of reports	Probable	Possible
3	1	2

Presenting Signs	Number of reports
Rash	3
Irritation (eye)	1
Blisters	1
Nausea	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.

DELTAMETHRIN

Human

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.

IMIDACLOPRID

Human

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
Rash	1
Pruritis	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.

IVERMECTIN

Human

Number of reports	Probable	Possible
2	0	2

Presenting Signs	Number of reports
Lymphadenopathy	1
Pruritis	1
Periorbital swelling	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.

MYCOBACTERIUM PARATUBERCULOSIS

Human

Number of reports	Probable	Possible
7	7	0

Presenting Signs	Number of reports
Injection site reaction	7
Abscess	2
Osteomyelitis	1

Based on the very low number of adverse experience reports for these products when 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 EMBONATE SALT

Human

Number of reports	Probable	Possible
1	0	1

Presenting Signs	Number of reports
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.

4. GLOSSARY

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