Australian Government

Australian Pesticides and Veterinary Medicines Authority

REPORT OF ADVERSE EXPERIENCES

for Veterinary Medicines and Agricultural Chemicals

Calendar Year 2009

DECEMBER 2010

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EXECUTIVE SUMMARY

The Adverse Experience Reporting Program (AERP) is the main mechanism for the Australian Pesticides and Veterinary Medicines Authority (APVMA) to receive and consider stakeholder feedback on adverse experiences relating to the use of registered agricultural and veterinary chemicals (AERP *Ag* for registered agricultural chemicals and AERP *Vet* for registered veterinary medicines). These two programs provide post-registration monitoring loops that help facilitate responsible marketing and management of registered agricultural and veterinary chemicals throughout their lifecycle.

This report contains information on adverse experience reports for veterinary medicines (Chapter 2 and 3) and agricultural chemicals (Chapter 4 and 5). This report is also available online from the APVMA website at www.apvma.gov.au.

AERP *Vet* - During the calendar year 2009, a total of 1901 adverse experience reports involving veterinary products were processed and classified. These adverse experience reports were submitted by veterinary surgeons, pet owners, farmers, members of the public and product registrants. Of these adverse experience reports, 76 per cent involved animal safety, 20 per cent involved lack of efficacy and 4 per cent involved human health issues (Figure 1).

Of the 1901 adverse experiences reports processed and classified, 1413 were classified as either *probable* or *possible*.

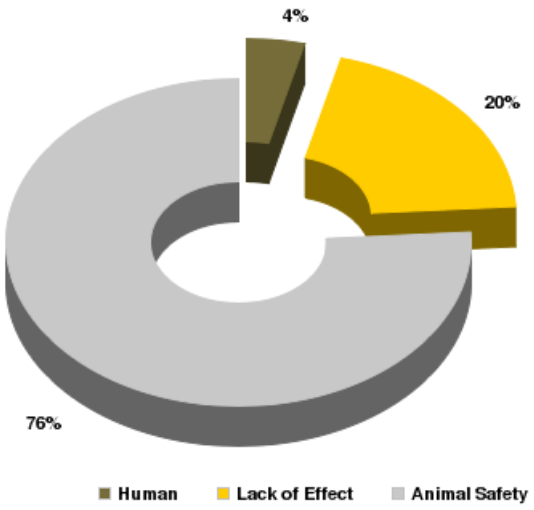

Figure 1. Adverse experience reports involving veterinary medicines - processed and finalised in 2009.

AERP *Ag* - During the calendar year 2009, a total of 115 adverse experience reports involving agricultural products were processed and classified. Nineteen of these reports were classified as *probable* or *possible*. Of the 115 adverse experience reports processed and classified, 30 per cent involved effects on crops or animals, 3 per cent involved lack of efficacy, 26 per cent involved human health issues and 41 percent involved effects on environment (Figure 2). In addition, numerous enquiries about agricultural and veterinary chemicals were received from members of the public.

When comparing the number of AERP *Ag* and AERP *Vet* reports, a likely under-reporting of adverse experiences involving agricultural products is notable. Therefore, the APVMA encourages members of the public, agronomists, farmers, product registrants and other stakeholders to report adverse events involving the use of agricultural products.

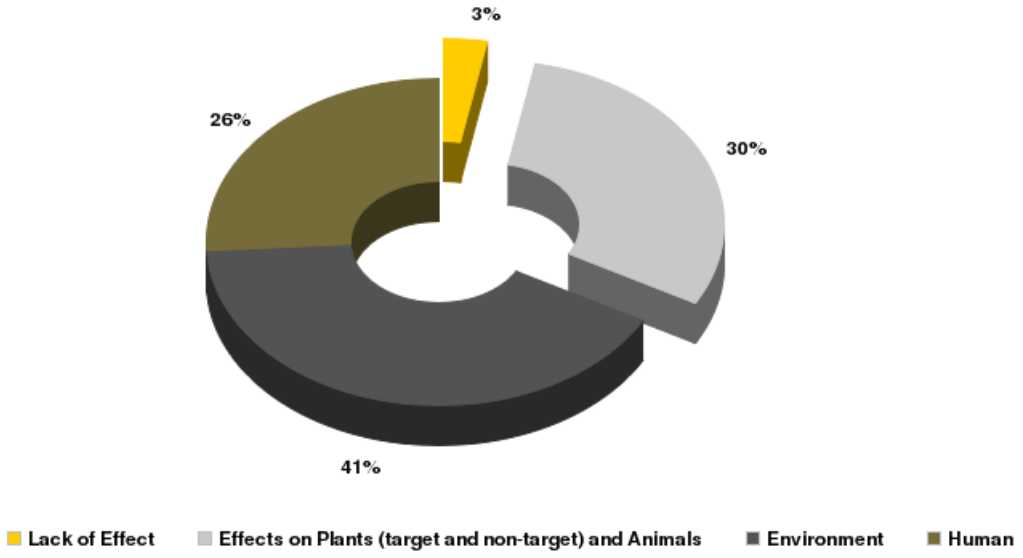

Figure 2. Adverse experience reports involving agriculture chemicals - processed and finalised in 2009.

Several suspected environmental, human and animal health adverse events were investigated with the assistance from State and Territory authorities. Specific chemicals could not be identified in a number of off-target spray cases. The environmental and off-target reports are being considered by the Chemical Review team as part of a project to consider regulatory controls for a number of chemicals that are applied by spray e.g., 2,4-dichlorophenoxyacetic acid (2,4-D) and 2-methyl-4-chlorophenoxyacetic acid (MCPA).

The AERP continued to provide surveillance feedback and data support to a range of core activities undertaken by the APVMA including veterinary and pesticide registration, chemical review, compliance and manufacturing quality and licensing, etc. The adverse experiences reported in 2009 did not lead to a major regulatory action against any registered product. A percentage of reports, however, warranted actions to mitigate potential risks, including updating product labels.

Off-label incidents are not included in this report. However, the AERP considers it valuable to report off-label adverse experiences as these can alert the APVMA to potential problems with products e.g.:

- Treatment protocols involving the administration of production animal products to companion animals resulting in illness or death, with some instances of treatment protocols clearly contradicting the label.
- The use of dog products on cats, resulting in serious adverse effects. This action is clearly off-label and the public should be aware that certain ingredients (e.g. permethrin) are toxic to cats.
- Spray drift issues involving environmental damage or human exposure as a result of chemical application contrary to label instructions

- Human exposure to veterinary medicines including injectable products (such as vaccines). Needle stick injuries continue to cause concern. Of particular concern is the accidental self-injection of oil-based preparations. Individuals involved in animal husbandry should take appropriate preventative action when injecting animals in order to avoid self-harm.

There were a total of 97 human reports received in 2009 across AERP *Ag* and *Vet*. The reports were classified as follows: 23 '*probable or possible*', 58 '*off-label*', and 16 '*unlikely or unknown*'.

Other than processing and classifying veterinary and agricultural adverse reports and responding to the queries from a number of stakeholders, the activities undertaken by the AERP during 2009 also included:

- A single more consistent reporting form aimed at simplifying the reporting of adverse experiences was introduced in 2009. Interactive, printable and hardcopy versions of the form were introduced to offer convenient reporting options for stakeholders.
- A Review of the registrant-reporting component of AERP *Ag*. The review's recommendations will not be implemented until after the Council of Australian Governments (COAG) considers and makes recommendations on the Primary Industries Ministerial Council (PIMC) proposal for a single, national framework to improve the efficiency and effectiveness of the regulation of agricultural and veterinary chemicals.
- Participation in the pharmacovigilence expert working group as part of the APVMA's commitment to the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).
- Participation in international pharmacovigilence efforts, including liaison with the US Environmental Protection Agency on issues relating to the prevalence of heartworm disease (Dirofilariasis).
- Participation in a multi-stakeholder steering committee to develop new labelling guidelines for permethrin-containing products. The APVMA has formally requested product registrants to vary their labels according to this new guideline. This strategy is aimed at mitigating and minimising the number of feline poisoning events.

AERP also undertook promotional initiatives during 2009 to improve awareness and visibility of the program. These included:

- Publishing the Report of Adverse Experiences for Veterinary Medicines and Agricultural Chemicals 2008
- Promoting the AERP through staff attendance at the Orange and Henty Field Days.
- Presenting a training session for agricultural workforce trainers at the first ever SMARTtrain® multilink video conference broadcast from Orange.
- An AERP article and banner advertising in Farm Guide magazine 2009.
- Encouraging adverse reporting and enhancing public awareness through the networks of members of the APVMA's Community Consultative Committee.

In an effort to augment available skills and knowledge, AERP staff successfully undertook courses in data management and processing.

1 INTRODUCTION

1.1 Program outline

The APVMA is the Australian government authority that manages the National Registration Scheme for Agricultural and Veterinary Chemicals. It is responsible for the assessment, evaluation and registration (marketing authorisation) of pesticides and veterinary medicines prior to sale, and their regulation up to and including the point of retail sale. The APVMA also manages quality assurance programs that monitor the safety and performance of registered products.

'Veterinary Medicines' include all veterinary chemical products such as vaccines, antibiotics, parasiticides for worms, lice, fleas and ticks, anti-inflammatory and anti-arthritic agents, nutritional supplements, therapeutic pet foods and diets for both companion and production animals.

'Pesticides' and 'Agricultural Chemicals' include agricultural and household chemicals such as insecticides, herbicides and fungicides, water treatment products including swimming pool products, products for treating algae and mould and products for preventing rot and infestation in marine structures.

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

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

1.2 What is an adverse experience?

The APVMA defines an ***AERP Vet adverse experience*** as:

An unintended or unexpected (deleterious) 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 when used according to label instructions.

A number of veterinary medicines have known side effects when used as directed and it is useful to maintain a record of these to be able to assess their true incidence. Furthermore, because of the enormous diversity amongst animal species and the relatively small number of veterinary medicines in the marketplace, it is occasionally necessary to use products in circumstances where there is limited information available on the dose rates or adverse reactions in off-label species. Such products may have originally been intended for

use in humans or other animal species. For this reason it is important that all adverse experiences, whether associated with recommended label use or not, are reported.

The APVMA defines an ***AERP Ag adverse experience*** as:

An unintended or unexpected effect (deleterious) on plants, plant products, animals, human beings or the environment, including injury, sensitivity reactions or lack of efficacy associated with the use of an agricultural chemical product when used according to label directions.

It is possible that some agricultural chemicals may cause effects when used according to the label and it is useful to maintain a record so that the true incidence of any unwanted effects can be assessed. Thus it is important to report all adverse experiences.

Adverse Experiences - Serious and Minor

The APVMA defines a ***serious adverse experience*** as one that involves:

- widespread and significant crop and plant damage (eg. crop death, severe stunting or significant yield loss)
- life-threatening or other significant effects in a human, including death
- farm, domestic and native animal deaths or
- significant environmental damage, including fish kills and water quality issues.

The APVMA defines a ***minor adverse experience*** as one that involves:

- crop and plant damage that is not widespread or significant (e.g. minor wilting or yellowing of crops, minor yield loss)
- human health effects that require medical attention, but are not life-threatening
- injury to domestic and native animals that require veterinary attention or
- minor environmental damage.

1.3 Who can report an adverse experience?

Anyone can submit an adverse experience report for a veterinary medicine or agricultural chemical. The APVMA encourages voluntary reporting, particularly from veterinarians, animal owners, farmers, gardeners, agronomists, health workers, bystanders, State and Territory authorities and other users of veterinary medicines and agricultural chemicals.

Registrants of veterinary medicines and agricultural chemicals also have a legal obligation to report to the AERP. Under Section 161 of the *Agvet Code*, registrants must provide the APVMA with any new information that comes to their attention. This new information may include adverse experience information on human health issues, harm to animals, damage to plants, property or the environment, or lack of efficacy when the

products are used according to label directions. The registrant reporting component of AERP *Ag* is one method by which registrants can meet certain legislative obligations of Section 161 of the *Agvet Code*.

1.4 How to report an adverse experience?

Adverse experiences can be reported online at https://services.apvma.gov.au/AerpWebApp/ or by using the Adverse Experience Reporting Form, or by contacting the AERP directly.

1.5 Benefits of the AERP

The AER Program provides benefits to a wide range of stakeholders.

Benefits to the community

- helps ensure the safety and efficacy of registered products in the marketplace
- provides confidence in the regulatory system.
- provides up-to-date safety information on registered products
- ensures that the latest safety information is available on product labels
- provides information on modifications needed to work practices to ensure safe use of chemicals
- identifies and acts on emerging issues quickly.

Benefits to States and Territories

- provides a feedback channel for issues (e.g. events pertaining to *the control of use*) that cross over jurisdictional boundaries.

1.6 Evaluation of adverse experience reports

Reports received by the APVMA are assessed to determine whether the adverse experience is related to the use of, or exposure to, the product.

Procedures for dealing with adverse experience reports are as follows:

- Reports made directly to the APVMA (voluntary reports) are copied to the product registrant for investigation. The registrant may then contact either the reporting person or the attending veterinarian and discuss the matter to determine if any follow up laboratory, pathology or other veterinary work is required.
- The product registrant subsequently provides the APVMA with an investigation report into the incident. The APVMA assesses this information and determines whether any further investigative work is required. In some cases, additional expert opinion may be sought from relevant State or Territory government agencies like the Office of Chemical Safety and Environmental Health (OCSEH), the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC), universities, the Australian Veterinary Association, or other appropriate authorities.

- The APVMA will also consider published scientific information or information provided by an equivalent international organisation.
- 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 or agricultural chemical (i.e. 'classification'; see 1.7 below). The APVMA also considers whether the product was used according to the label directions.
- The person submitting making the report will be advised of the outcome of the investigations.
- If a report of an adverse experience is made directly to the product registrant, they will provide a report to the APVMA (Registrant report). The APVMA will then assess this information and determine whether any further investigative or regulatory action is required.

1.7 Classification of adverse experience reports

The relationship between the use of a product and the reported clinical signs is determined after the incident has been investigated. This relationship is expressed in terms of ***probable***, ***possible***, ***probable*** or ***possible off-label***, ***unlikely*** and ***unknown***.

Probable

For inclusion in the category *probable,* all of the following minimum criteria should be met:

- there should be a reasonable association between the administration of the product and onset and duration of the reported adverse experience,
- the description of the clinical signs should be consistent with or at least plausible given the known pharmacology and toxicology of the product, 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*.

Possible

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

Probable or Possible Off-label

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

Unlikely

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

Unknown

All adverse experiences for which reliable data are either unavailable or are insufficient to make an assessment should be categorised as *unknown*.

1.8 Corrective action determination

The APVMA takes into account a broad range of issues and options when deciding what, if any, corrective action is required to mitigate possible risks to humans, animals, or the environment that may have been identified as a result of adverse experience reports.

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

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 also considers the severity of clinical signs (i.e. more severe signs may trigger corrective action at a lower reporting incidence).

1.9 Outcomes of the program

Based on the assessment of adverse experience reports, certain risk mitigation strategies or corrective actions may be requested. These may include, but are not restricted to, the following:

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

- registration amendments, such as label changes, changes to the method of manufacture or the product's physical or chemical design, changes to container design, changes to production line processes, or suspension and/or cancellation of registration and approval
- review of the active constituent under the APVMA's Chemical Review Program
- referral for action, such as compliance action, including product and batch recalls, referral to state authorities for action, or nomination of products or active constituents for formal chemical review by the APVMA, (note that once the recommendation for review has been made by the AERP the review program will conduct consultation and scoping prior to determining whether a review is necessary or not)
- education and publicity, such as providing scientific papers or articles on issues identified for relevant journals, magazines or newspapers. When required, education can be directed toward the veterinary profession, the farming community or the wider public on issues relating to the use of products.

The conclusions drawn by the APVMA during the processing and evaluation of each adverse experience report will be provided to the reporting person. This will include an explanation of whether the APVMA considers that the observed adverse effects (including health symptoms) were related to the use of or exposure to the product. The APVMA will explain what these conclusions are and what corrective action, if any, needs to be taken in response to the information.

The information contained in this report is only a general reference to the type of adverse experiences that have been reported either to the APVMA or to product registrants. This report does not provide any correlation between the number of units of each product sold and the number of adverse experiences for each product reported. It must also be noted that each product may have more than one active constituent and hence the adverse experience reported may be related to any one or more of the active constituents present in the particular product reported to the AERP.

Therefore, this information should not be used for:

- associating adverse effects with a particular product or active constituent
- assessing the safety and efficacy of a product or active constituent
- establishing an acceptable frequency of occurrence of an adverse experience, or
- comparing one product or active constituent with another product or active constituent.

1.10 Report Structure

This report is arranged into the following sections:

Chapters 2 and 3 AERP *Vet*

- Chapter 2 is a summary of adverse experience reports for veterinary medicines other than human health effects (including farm, domestic and native animals, environmental damage and lack of efficacy) listed by active constituent.
- Chapter 3 is a summary of adverse experience reports involving human health.

Chapters 4 and 5 AERP *Ag*

- Chapter 4 is a summary of adverse experience reports for agricultural chemicals other than human health effects (including crop damage, environmental damage and lack of efficacy) listed by active constituent.
- Chapter 5 is a summary of adverse experience reports involving human health.

The reports presented in the Tables below are for each '***active constituent***' and are classified as '***probable***' and '***possible***'. The information for each active is divided into '***species affected***'. Several species tables may be present for each active constituent. For effects on humans the reports are presented in Tables 3.2 and 5.2. Multiple '***presenting signs***' may be present for any one report; these are listed under '***incidence***' in the second table.

ACTIVE CONSTITUENT

Species Affected

NUMBER OF REPORTS	PROBABLE	POSSIBLE
X+Y	X	Y

PRESENTING SIGN	INCIDENCE
Burn(s)	A
Scabs	B
Skin slough	C

1.11 For further information

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2 VETERINARY MEDICINES - SUMMARY OF ADVERSE EXPERIENCE REPORTS 2009 (ANIMAL)

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

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.

Number of reports

- Only adverse experience reports that were classified by the APVMA during the calendar year 2009 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.

Presenting signs

- All observed clinical signs for reports that were classified as probable and possible are listed in order of frequency.
- It is important to note that multiple clinical signs have been noted in some individual reports. Therefore the list of clinical signs observed does not relate directly to the total number of reports received.

Summary of corrective action

- No regulatory action was required for many of the active constituents as the frequency of adverse experience reports received was relatively low when compared with the total number of doses sold. A short narrative is provided on any corrective action taken as a result of assessment of the adverse experience information for an active constituent.
- In many instances, the potential for adverse reactions to many veterinary medicines was recognised at the time of product registration. When adverse experiences are reported for such medicines, the need for corrective action is considered against the data assessed at the time of product registration.

2.1.2 Veterinary Medicines - animal safety AERs

ACEPROMAZINE MALEATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Urination	1
Collapse	1
Pale mucous membranes	1

ACRIFLAVINE

Fish

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1

ALBENDAZOLE

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	3	2

PRESENTING SIGN	INCIDENCE
Death	4
Hypersalivation	2
Sneezing	1
Coughing	1

Ataxia	1
Frothing at the mouth	1
Blindness	1
Lethargy	1
Panting	1

ALBENDAZOLE AS ALBENDAZOLE OXIDE

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Death	2
Ataxia	1

ALPHA-CYPERMETHRIN

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

PRESENTING SIGN	INCIDENCE
Lack of effect	4

ALPHAXALONE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
10	3	7

PRESENTING SIGN	INCIDENCE
Recovery (prolonged)	3
Wheals	1
Death	1
Papules	1
Recovery (poor)	1
Cardiac arrest	1
Respiratory problems	1
Seizure	1
Tremor	1
Vasodilation	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
8	0	8

PRESENTING SIGN	INCIDENCE
Recovery (prolonged)	2
Death	2
Cardiac arrest	2
Respiratory problems	1
Hypersalivation	1
Nil	1
Rales	1
Apnoea	1

ALUMINIUM HYDROXIDE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
38	2	36

PRESENTING SIGN	INCIDENCE
Injection site reaction	26
Lump (local)	22
Swelling (local)	6
Anorexia	4
Pain	4
Lethargy	4
Vomiting	2
Death	2
Irritation (skin)	2
Site reaction (swelling)	2
Defaecation	2
Malaise	2
Weakness	1
Anaphylactoid reaction	1
Necrosis	1
Listless	1
Pyrexia	1
Seroma	1
Diarrhoea	1
Lame	1
Vasculitis	1
Vocalisation	1

PRESENTING SIGN	INCIDENCE
Agitation	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Pyrexia	1
Anorexia	1
Pain	1

AMITRAZ

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Sedation	1
Lack of effect	1
Scouring	1

AMOXYCILLIN AS AMOXYCILLIN TRIHYDRATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Oedema	1
Injection site reaction	1

ANAPLASMA CENTRALE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
9	4	5

PRESENTING SIGN	INCIDENCE
Lack of effect	9

ARGININE-L HYDROCHLORIDE

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Swelling (local)	1
Listless	1
Site reaction	1

BABESIA BIGEMINA

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
9	4	5

PRESENTING SIGN	INCIDENCE
Lack of effect	9

BABESIA BOVIS

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
9	4	5

PRESENTING SIGN	INCIDENCE
Lack of effect	9

BACILLUS ANTHRACIS (STERNE 34F2 STRAIN)

Other

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

BENAZEPRIL HYDROCHLORIDE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lethargy	1
Ataxia	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Pruritis	1
Dermatitis	1

BENZATHINE PENICILLIN

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Death	1
Agitation	1

BETAMETHASONE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	2	2

PRESENTING SIGN	INCIDENCE
Deafness	3
Otitis externa	1

BISMUTH SUBNITRATE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Residue violation	1

BLACK DISEASE = CLOSTRIDIUM OEDEMATIENS

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Shaking	1
Convulsions	1
Death	1
Head tilt	1

BLACKLEG = CLOSTRIDIUM CHAUVOEI

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Pneumonia	1
Bloat	1
Death	1
Haemorrhage	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Shaking	1
Convulsions	1
Death	1
Head tilt	1

BORDETELLA BRONCHISEPTICA

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
81	2	79

PRESENTING SIGN	INCIDENCE
Coughing	33
Sneezing	21
Vomiting	9
Facial oedema	9
Respiratory problems	8
Lethargy	8
Pyrexia	7
Nasal discharge	6
URTI	3
Depression	3
Pruritis	3
Death	3
Malaise	3
Collapse	2
Lack of effect	2
Illness	2
Injection site reaction	2
Anaphylaxis	1
Pale mucous membranes	1
Panting	1
Polyarthritis	1
Hives	1

PRESENTING SIGN	INCIDENCE
Abdominal pain	1
Conjunctivitis	1
Shaking	1
Anaphylactoid reaction	1
Stiffness	1
Swelling (local)	1
Thrombocytopenia	1
Tonsillitis	1
Urination	1
Anorexia	1
Urticaria	1
Vaccination reaction	1
Vasculitis	1

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

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

BORDETELLA BRONCHISEPTICA (INACTIVATED CELL FREE EXTRACT)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
68	11	57

PRESENTING SIGN	INCIDENCE
Injection site reaction	27
Lump (local)	22
Lethargy	17
Vomiting	12

PRESENTING SIGN	INCIDENCE
Pain	8
Anorexia	6
Swelling (local)	6
Anaphylaxis	5
Death	4
Pyrexia	3
Oedema	3
Weakness	2
Vocalisation	2
Unconscious	2
Hyperactivity	2
Collapse	2
Site reaction (swelling)	2
Irritation (skin)	2
Site reaction	2
Defaecation	2
Diarrhoea	2
Malaise	2
Erythema	1
Necrosis	1
Anaphylactoid reaction	1
Ataxia	1
Pruritis	1
Listless	1
Seizure	1
Seroma	1
Cyanosis	1

PRESENTING SIGN	INCIDENCE
Lame	1
Stomatitis	1
Agitation	1
Tachypnoea	1
Hypersalivation	1
Urticaria	1
Vasculitis	1
Haemorrhagic gastroenteritis	1
Bradycardia	1

BORDETELLA BRONCHISEPTICA KILLED VACCINE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
145	13	132

PRESENTING SIGN	INCIDENCE
Facial oedema	67
Vomiting	40
Lethargy	22
Anaphylaxis	15
Collapse	14
Pruritis	12
Urticaria	11
Diarrhoea	11
Pale mucous membranes	7
Pyrexia	6
Injection site reaction	6

PRESENTING SIGN	INCIDENCE
Welts	5
Dyspnoea	4
Erythema	4
Oedema	4
Abscess	3
Hives	3
Anorexia	3
Irritation (skin)	3
Wheals	2
Hypoproteinaemia	2
Lack of effect	2
Anaphylactoid reaction	2
Swollen lips and face	2
Swollen (lips)	2
Pain	2
Death	2
Swelling (local)	2
Cyanosis	1
Red eyes	1
Respiratory problems	1
Rubbing	1
Shaking	1
Sneezing	1
Defaecation	1
Behavioural change	1
Swollen ears and face	1
Swollen feet	1

PRESENTING SIGN	INCIDENCE
Frothing at the mouth	1
Urination	1
Coughing	1
Lump (local)	1
Immune-mediated haemolytic anaemia	1

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) resulting in a higher incidence of reporting. These products also have a very high volume of sales. The listed symptoms occur very occasionally with most vaccines.

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

BOVINE EPHEMERAL FEVER VIRUS (BEFV)

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Illness	2
Lack of effect	1

CAMPYLOBACTER FELIS (VIBRO FETUS) VENEREALIS BIOTYPE 1

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Pyrexia	1
Oedema	1

CANINE ADENOVIRUS TYPE 2

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
259	20	239

PRESENTING SIGN	INCIDENCE
Facial oedema	78
Vomiting	49
Lethargy	38
Coughing	35
Sneezing	24
Lack of effect	20
Collapse	18
Pyrexia	17
Anaphylaxis	16
Pruritis	13
Diarrhoea	13
Urticaria	11
Injection site reaction	11
Pale mucous membranes	10
Nasal discharge	9
Anorexia	7
Depression	6
Respiratory problems	6
Death	6
Oedema	4
Illness	4
Erythema	4

PRESENTING SIGN	INCIDENCE
Malaise	4
Welts	3
Abscess	3
Anaphylactoid reaction	3
URTI	3
Hives	3
Irritation (skin)	3
Dyspnoea	3
Pain	3
Wheals	2
Weakness	2
Thrombocytopenia	2
Swollen (lips)	2
Hypoproteinaemia	2
Swelling (local)	2
Stiffness	2
Defaecation	2
Shaking	2
Immune-mediated haemolytic anaemia	1
Shock	1
Abdominal pain	1
Rubbing	1
Red eyes	1
Cyanosis	1
Swollen ears and face	1
Swollen feet	1
Swollen lips and face	1

PRESENTING SIGN	INCIDENCE
Polyarthritis	1
Tonsillitis	1
Urination	1
Lump (local)	1
Frothing at the mouth	1
Vaccination reaction	1
Vasculitis	1
Listless	1
Panting	1
Behavioural change	1

Canine Adenovirus Type 2 is a constituent of many standard canine vaccines and as such has a very high volume of sales each year. Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse effects.

CANINE ADENO VIRUS TYPE 2 STRAIN V197

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Immune-mediated haemolytic anaemia	1

CANINE ADENO VIRUS TYPE 2 – LIVE (INFECTIOUS HEPATITIS)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
40	1	39

PRESENTING SIGN	INCIDENCE
Injection site reaction	24
Lump (local)	20
Swelling (local)	6
Pain	4
Vomiting	3
Anorexia	3
Malaise	3
Lethargy	3
Defaecation	2
Anaphylactoid reaction	2
Facial oedema	2
Irritation (skin)	2
Weakness	1
Lame	1
Lack of effect	1
Listless	1
Agitation	1
Diarrhoea	1
Ataxia	1
Panting	1
Pruritis	1
Pyrexia	1
Rash	1
Seroma	1
Site reaction (swelling)	1
Incoordination	1
Vocalisation	1

PRESENTING SIGN	INCIDENCE
Death	1

CANINE ADENOVIRUS TYPE 2 LIVE (CAV II)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	1	4

PRESENTING SIGN	INCIDENCE
Vomiting	2
Anaphylaxis	2
Collapse	1
Death	1
Injection site reaction	1
Lethargy	1

CANINE ADENOVIRUS TYPE 2 STRAIN MANHATTAN - LIVE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
15	2	13

PRESENTING SIGN	INCIDENCE
Coughing	5
Vomiting	4
Lethargy	3
Lack of effect	3
Sneezing	2
Facial oedema	2
Ataxia	1

Injection site reaction	1
Death	1
Anorexia	1
Lump (local)	1
Necrosis	1
Polyarthritis	1
Pyrexia	1
Respiratory problems	1
Hypersensitivity reaction	1
Vaccination reaction	1
Vasculitis	1

CANINE CORONAVIRUS VACCINE - ANTIGEN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
8	2	6

PRESENTING SIGN	INCIDENCE
Vomiting	3
Facial oedema	3
Lethargy	2
Death	2
Weakness	1
Collapse	1
Irritation (skin)	1
Erythema	1
Listless	1
Shock	1

PRESENTING SIGN	INCIDENCE
Swollen feet	1
Vaccination reaction	1
Anaphylaxis	1

CANINE DISTEMPER

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Sneezing	1
Anaphylaxis	1
Coughing	1
Death	1
Lack of effect	1

CANINE DISTEMPER VIRUS

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
203	17	186

PRESENTING SIGN	INCIDENCE
Facial oedema	73
Vomiting	47
Lethargy	31
Lack of effect	18
Collapse	17
Anaphylaxis	15

PRESENTING SIGN	INCIDENCE
Pruritis	12
Diarrhoea	12
Urticaria	11
Coughing	11
Pyrexia	10
Pale mucous membranes	10
Injection site reaction	10
Sneezing	8
Welts	5
Erythema	4
Anorexia	4
Oedema	4
Nasal discharge	4
Death	4
Abscess	3
Dyspnoea	3
Depression	3
Irritation (skin)	3
Hives	3
Malaise	3
Wheals	2
Weakness	2
Swollen (lips)	2
Hypoproteinaemia	2
Anaphylactoid reaction	2
Pain	2
Swelling (local)	2

PRESENTING SIGN	INCIDENCE
Illness	2
Defaecation	2
Shaking	2
Respiratory problems	2
Lump (local)	1
Rubbing	1
Shock	1
Red eyes	1
Stiffness	1
Frothing at the mouth	1
Behavioural change	1
Swollen ears and face	1
Swollen feet	1
Swollen lips and face	1
Thrombocytopenia	1
Urination	1
Cyanosis	1
Vaccination reaction	1
Vasculitis	1
Immune-mediated haemolytic anaemia	1
Listless	1
Abdominal pain	1

Canine Distemper Virus is a constituent of many standard canine vaccines and as such has a very high volume of sales each year. Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experiences. The listed side effects, such as facial oedema, vomiting, and lethargy occur very occasionally with a number of vaccines.

CANINE DISTEMPER VIRUS - LIVING

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
49	3	46

PRESENTING SIGN	INCIDENCE
Injection site reaction	25
Lump (local)	20
Vomiting	6
Swelling (local)	6
Anorexia	5
Pain	5
Lethargy	5
Malaise	3
Anaphylaxis	2
Defaecation	2
Pyrexia	2
Diarrhoea	2
Facial oedema	2
Death	2
Anaphylactoid reaction	2
Irritation (skin)	2
Weakness	1
Lame	1
Coughing	1
Listless	1
Lack of effect	1
Agitation	1

PRESENTING SIGN	INCIDENCE
Collapse	1
Panting	1
Pruritis	1
Incoordination	1
Rash	1
Seroma	1
Site reaction (swelling)	1
Ataxia	1
Vocalisation	1
Depression	1

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

CANINE DISTEMPER VIRUS STRAIN ONDERSTEPOORT

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
16	2	14

PRESENTING SIGN	INCIDENCE
Coughing	5
Vomiting	4
Lethargy	3
Lack of effect	3
Sneezing	2
Facial oedema	2
Ataxia	1
Immune-mediated haemolytic anaemia	1

Injection site reaction	1
Death	1
Anorexia	1
Lump (local)	1
Necrosis	1
Polyarthritis	1
Pyrexia	1
Respiratory problems	1
Hypersensitivity reaction	1
Vaccination reaction	1
Vasculitis	1

CANINE PARAINFLUENZA

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
56	2	54

PRESENTING SIGN	INCIDENCE
Coughing	23
Sneezing	16
Pyrexia	6
Lethargy	6
Nasal discharge	5
Facial oedema	5
Respiratory problems	4
URTI	3
Welts	2
Illness	2

Death	2
Lack of effect	2
Depression	2
Injection site reaction	1
Anaphylactoid reaction	1
Panting	1
Polyarthritis	1
Pruritis	1
Anorexia	1
Malaise	1
Anaphylaxis	1
Stiffness	1
Thrombocytopenia	1
Tonsillitis	1
Collapse	1
Vomiting	1

CANINE PARAINFLUENZA TYPE 2

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
156	12	144

PRESENTING SIGN	INCIDENCE
Facial oedema	68
Vomiting	42
Lethargy	22
Anaphylaxis	15
Collapse	15

PRESENTING SIGN	INCIDENCE
Pruritis	12
Lack of effect	12
Urticaria	11
Diarrhoea	11
Pale mucous membranes	7
Pyrexia	6
Injection site reaction	5
Oedema	4
Erythema	4
Welts	3
Hives	3
Death	3
Dyspnoea	3
Abscess	3
Irritation (skin)	3
Anorexia	3
Wheals	2
Hypoproteinaemia	2
Weakness	2
Anaphylactoid reaction	2
Pain	2
Defaecation	2
Swollen lips and face	2
Swollen (lips)	2
Swelling (local)	2
Respiratory problems	2
Listless	1

PRESENTING SIGN	INCIDENCE
Shaking	1
Shock	1
Rubbing	1
Red eyes	1
Swollen ears and face	1
Swollen feet	1
Frothing at the mouth	1
Thrombocytopenia	1
Urination	1
Immune-mediated haemolytic anaemia	1
Vaccination reaction	1
Behavioural change	1
Cyanosis	1
Lump (local)	1

The APVMA notes that vaccines are often used in conjunction with other products (including other vaccines) resulting in a higher incidence of reporting. These products also have a very high volume of sales. The listed symptoms such as vomiting and lethargy occur very occasionally with most vaccines.

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

CANINE PARAINFLUENZA VIRUS

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
33	2	33

PRESENTING SIGN	INCIDENCE
Vomiting	11
Coughing	10

PRESENTING SIGN	INCIDENCE
Sneezing	5
Lethargy	4
Respiratory problems	3
Facial oedema	3
Pruritis	2
Death	2
Malaise	2
Collapse	2
Anaphylaxis	2
Injection site reaction	2
Abdominal pain	1
Hives	1
Diarrhoea	1
Nasal discharge	1
Pain	1
Pale mucous membranes	1
Depression	1
Pyrexia	1
Conjunctivitis	1
Shaking	1
Anorexia	1
Swelling (local)	1
Urination	1
Urticaria	1
Vaccination reaction	1
Vasculitis	1

CANINE PARAINFLUENZA VIRUS - INACTIVATED

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
38	2	36

PRESENTING SIGN	INCIDENCE
Injection site reaction	26
Lump (local)	22
Swelling (local)	6
Anorexia	4
Pain	4
Lethargy	4
Vomiting	2
Death	2
Irritation (skin)	2
Site reaction (swelling)	2
Defaecation	2
Malaise	2
Weakness	1
Anaphylactoid reaction	1
Necrosis	1
Listless	1
Pyrexia	1
Seroma	1
Diarrhoea	1
Lame	1
Vasculitis	1
Vocalisation	1

Agitation	1

CANINE PARAINFLUENZA VIRUS TYPE 2 STRAIN CGF 2004/75

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Immune-mediated haemolytic anaemia	1

CANINE PARVO VIRUS

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
201	17	184

PRESENTING SIGN	INCIDENCE
Facial oedema	73
Vomiting	47
Lethargy	31
Lack of effect	18
Collapse	17
Anaphylaxis	15
Pruritis	12
Diarrhoea	12
Urticaria	11
Coughing	11
Pyrexia	10
Pale mucous membranes	10
Injection site reaction	10

PRESENTING SIGN	INCIDENCE
Sneezing	8
Anorexia	4
Erythema	4
Oedema	4
Nasal discharge	4
Death	4
Welts	3
Abscess	3
Dyspnoea	3
Depression	3
Irritation (skin)	3
Hives	3
Malaise	3
Wheals	2
Illness	2
Weakness	2
Anaphylactoid reaction	2
Swollen (lips)	2
Pain	2
Swelling (local)	2
Hypoproteinaemia	2
Defaecation	2
Shaking	2
Respiratory problems	2
Lump (local)	1
Rubbing	1
Shock	1

PRESENTING SIGN	INCIDENCE
Red eyes	1
Stiffness	1
Abdominal pain	1
Behavioural change	1
Swollen ears and face	1
Swollen feet	1
Swollen lips and face	1
Thrombocytopenia	1
Urination	1
Cyanosis	1
Vaccination reaction	1
Vasculitis	1
Immune-mediated haemolytic anaemia	1
Frothing at the mouth	1
Listless	1

Canine Parvo Virus is a component of many standard canine vaccines and as such has a very high volume of sales each year. Due to the low number of reports when taking into consideration the large number of dogs vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experiences. The listed side effects, such as facial oedema, vomiting, and lethargy occur very occasionally with most vaccines.

CANINE PARVO VIRUS TYPE 2

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
9	2	7

PRESENTING SIGN	INCIDENCE
Vomiting	3
Anaphylaxis	2

PRESENTING SIGN	INCIDENCE
Anorexia	2
Lethargy	2
Collapse	1
Death	1
Depression	1
Diarrhoea	1
Injection site reaction	1
Coughing	1
Pain	1
Pyrexia	1

CANINE PARVO VIRUS TYPE 2 STRAIN K3I PASSAGE 69

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Immune-mediated haemolytic anaemia	1

CANINE PARVOVIRUS - LIVE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
40	1	39

PRESENTING SIGN	INCIDENCE
Injection site reaction	24
Lump (local)	20
Swelling (local)	6

Pain	4
Vomiting	3
Anorexia	3
Malaise	3
Lethargy	3
Defaecation	2
Anaphylactoid reaction	2
Facial oedema	2
Irritation (skin)	2
Weakness	1
Lame	1
Lack of effect	1
Listless	1
Agitation	1
Diarrhoea	1
Ataxia	1
Panting	1
Pruritis	1
Pyrexia	1
Rash	1
Seroma	1
Site reaction (swelling)	1
Incoordination	1
Vocalisation	1
Death	1

CANINE PARVO VIRUS STRAIN 154 - LIVE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
15	2	13

PRESENTING SIGN	INCIDENCE
Coughing	5
Vomiting	4
Lethargy	3
Lack of effect	3
Sneezing	2
Facial oedema	2
Ataxia	1
Injection site reaction	1
Death	1
Anorexia	1
Lump (local)	1
Necrosis	1
Polyarthritis	1
Pyrexia	1
Respiratory problems	1
Hypersensitivity reaction	1
Vaccination reaction	1
Vasculitis	1

CARPROFEN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Pyrexia	1
Lethargy	1
Polyarthritis	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Injection site reaction	1

CEFOVECIN AS SODIUM SALT

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Weakness	1
Abdominal pain	1
Ataxia	1
Bradycardia	1
Hypersalivation	1
Lethargy	1
Pale mucous membranes	1

Pyoderma	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Vomiting	1
Behavioural change	1
Hyperactivity	1
Injection site reaction	1
Jaundice	1
Moribund	1
Pale mucous membranes	1
Seizure	1

CEPHALEXIN AS CEPHALEXIN MONOHYDRATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Vomiting	1

CHLAMYDOPHILIA FELIS BAKER STRAIN - LIVE, ATTENUATED

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
48	16	32

PRESENTING SIGN	INCIDENCE
Lethargy	22
Pyrexia	20
Anorexia	19
Pain	11
Vomiting	6
Ataxia	5
Anaphylaxis	4
Injection site reaction	4
Diarrhoea	4
Malaise	3
Depression	3
Vocalisation	2
Respiratory problems	2
Pruritis	2
Alopecia (localised)	1
Lack of effect	1
Lame	1
Abscess	1
Listless	1
Death	1
Mydriasis	1
Collapse	1
Polydipsia	1
Coughing	1
Pulmonary oedema	1
Agitation	1
Hypersalivation	1

PRESENTING SIGN	INCIDENCE
Sneezing	1
Vaccination reaction	1
Vasculitis	1
Facial oedema	1

Side effects, such as lethargy, pyrexia and anorexia occur very occasionally with most vaccines.

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

CHLORFENVINPHOS

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Lack of effect	2
Low efficacy	1

CHLORHEXIDINE GLUCONATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

PRESENTING SIGN	INCIDENCE
Irritation (skin)	3
Alopecia	1

CHLORPYRIFOS

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

CHONDROITIN SULFATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

PRESENTING SIGN	INCIDENCE
Diarrhoea	2
Pigmentation	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Unpleasant taste	1

CLA = CORYNEBACTERIUM PSEUDOTUBERCULOSIS OVIS

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Death	3
Swelling (local)	1
Convulsions	1
Head tilt	1
Lame	1
Shaking	1

CLAVULANIC ACID AS POTASSIUM CLAVULANATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Oedema	1
Injection site reaction	1

CLINDAMYCIN AS CLINDAMYCIN HYDROCHLORIDE

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Oedema	1
Anorexia	1
Erythema	1
Necrosis	1

CLOMIPRAMINE HYDROCHLORIDE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Hepatopathy	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

PRESENTING SIGN	INCIDENCE
Urinary retention	1
Aggression	1
Ataxia	1
Lethargy	1
Miosis	1
Somnolence	1

CLOSANTEL

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Blindness	1

CLOSTRIDIUM BOTULINUM TYPE C TOXOID

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lump (local)	1

CLOSTRIDIUM BOTULINUM TYPE D TOXOID

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lump (local)	1

CLOSTRIDIUM CHAUVOEI - FORMOL CULTURE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Recumbency	1
Ataxia	1
Death	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Death	2
Swelling (local)	1
Lame	1

CLOSTRIDIUM CHAUVOEI - KILLED

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lump (local)	1
Injection site reaction	1

CLOSTRIDIUM CHAUVOEI - TOXOID

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Illness	1

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lump (local)	1
Injection site reaction	1

CLOSTRIDIUM CHAUVOEI TOXOID AND INACTIVATED CELLS

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

CLOSTRIDIUM NOVYI TYPE B TOXOID AND INACTIVATED CELLS

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

CLOSTRIDIUM NOVYI TYPE B

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Recumbency	1
Ataxia	1
Death	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Death	2
Swelling (local)	1
Lame	1

CLOSTRIDIUM NOVYI TYPE B – KILLED

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lump (local)	1
Injection site reaction	1

CLOSTRIDIUM NOVYI TYPE B - TOXOID

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Pneumonia	1
Bloat	1
Death	1
Haemorrhage	1
Illness	1

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lump (local)	1
Injection site reaction	1

CLOSTRIDIUM PERFRINGENS TYPE D TOXOID

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

PRESENTING SIGN	INCIDENCE
Death	2
Recumbency	1
Bloat	1
Ataxia	1
Haemorrhage	1
Illness	1
Pneumonia	1

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lump (local)	1
Injection site reaction	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

PRESENTING SIGN	INCIDENCE
Death	3
Swelling (local)	1
Convulsions	1
Head tilt	1
Lack of effect	1
Lame	1
Shaking	1

CLOSTRIDIUM SEPTICUM - TOXOID

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Recumbency	1
Ataxia	1
Death	1
Illness	1

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lump (local)	1
Injection site reaction	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Death	2
Swelling (local)	1
Lack of effect	1
Lame	1

CLOSTRIDIUM TETANI - ANTITOXIN

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Hyperaesthesia	2
Urticaria	1
Injection site reaction	1
Muscle twitching	1
Oedema	1
Swelling (local)	1
Tremor	1

CLOSTRIDIUM TETANI - TOXOID

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Illness	1

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lump (local)	1
Injection site reaction	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

PRESENTING SIGN	INCIDENCE
Death	3
Swelling (local)	1
Convulsions	1
Head tilt	1
Lack of effect	1
Lame	1
Shaking	1

CLOSTRIDIUM TETANI UF TOXOID

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Injection site reaction	1

CLOTRIMAZOLE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	2	3

PRESENTING SIGN	INCIDENCE
Deafness	4
Otitis externa	1

COBALT OXIDE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

CONTAGIOUS PUSTULAR DERMATITIS VIRUS, LIVING, CELL CULTURE

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1
Dermatitis	1

CORONAVIRUS

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	0	5

PRESENTING SIGN	INCIDENCE
Welts	2
Anaphylaxis	1
Coughing	1
Death	1
Lack of effect	1
Sneezing	1

CORYNEBACTERIUM PSEUDOTUBERCULOSIS TOXIOD AND INACTIVATED CELLS

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

CYCLOSPORIN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
44	11	44

PRESENTING SIGN	INCIDENCE
Lack of effect	20
Vomiting	12

PRESENTING SIGN	INCIDENCE
Diarrhoea	4
Ataxia	3
Lethargy	3
Gingival hyperplasia	2
Coughing	1
Distress	1
Erythema	1
Atrophy	1
Haematemesis	1
Hyperactivity	1
Aggression	1
Dehydration	1
Pale mucous membranes	1
Pruritis	1
Tachypnoea	1

CYPERMETHRIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Lack of effect	1
Low efficacy	1

CYROMAZINE

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

CYTHIOATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

DELTAMETHRIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	0	4

PRESENTING SIGN	INCIDENCE
Lack of effect	2
Site reaction	1
Illness	1
Flystrike	1

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Hypersensitive to stimuli	1
Behavioural change	1
Distress	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lack of effect	1

DERACOXIB

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Vomiting	1
Ataxia	1
Blood in faeces	1
Collapse	1
Death	1
Lethargy	1

DESLORELIN AS DESLORELIN ACETATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
9	5	4

PRESENTING SIGN	INCIDENCE
Lack of effect	7
Recovery (prolonged)	1
Polyphagia	1
Polyuria	1

DEXAMETHASONE AS THE SODIUM PHOSPHATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Weakness	1
Ataxia	1

DIAZINON

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Lack of effect	3

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Hypersalivation	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

DICYCLANIL

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Vomiting	1
CNS dysfunction	1
Lethargy	1
Tremor	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

PRESENTING SIGN	INCIDENCE
Lack of effect	2
Dermatitis	1

DIFLUBENZURON

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
112	1	111

PRESENTING SIGN	INCIDENCE
Lack of effect	91
Low efficacy	20
Dermatitis	1

Diflubenzuron is an insect growth-regulating compound (IGR). An ***IGR*** is a chemical that controls the life cycle of pests such as roaches, fleas by inhibiting their maturation. The sheep and wool industry rely heavily on the use of the insect growth regulator (IGR) group of chemicals for treating lice. Unfortunately, there exist resistant insects with reduced susceptibility to IGR chemicals.

DI-ISOPROPYLAMINE DICHLOROACETATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Site reaction (swelling)	1

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Swelling (local)	1
Listless	1
Site reaction	1

DORAMECTIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lack of effect	1

EMODEPSIDE

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
22	21	1

PRESENTING SIGN	INCIDENCE
Alopecia (localised)	14
Self trauma	4
Inflammation	4
Alopecia	2
Irritation (skin)	2
Ataxia	2
Coat colour change	2
Weakness	1
Incoordination	1
Agitation	1
Erythema	1
Anorexia	1

ENROFLOXACIN

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Pupillary light reflex (abnormal)	1
Necrosis	1

ERYSIPELOTHRIX RHUSIOPATHIAE

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1

ESCHERICHIA COLI 987P PILUS ANTIGENS

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Injection site reaction	3
Anorexia	3
Lethargy	2

ESCHERICHIA COLI K88AB PILUS ANTIGENS

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Injection site reaction	3
Anorexia	3

PRESENTING SIGN	INCIDENCE
Lethargy	2

ESCHERICHIA COLI K88AC PILUS ANTIGENS

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Injection site reaction	3
Anorexia	3
Lethargy	2

ESCHERICHIA COLI K99 PILUS ANTIGENS

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Injection site reaction	3
Anorexia	3
Lethargy	2

FEBANTEL

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
12	10	2

PRESENTING SIGN	INCIDENCE
Hyperexcitable	5

PRESENTING SIGN	INCIDENCE
Vomiting	4
Lethargy	2
Lack of effect	2
Diarrhoea	1
Hypersensitivity reaction	1
Hypersalivation	1

FELINE CALICIVIRUS

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Sneezing	1
Pyrexia	1

FELINE CALICIVIRUS - INACTIVATED

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
78	36	42

PRESENTING SIGN	INCIDENCE
Lethargy	36
Pyrexia	30
Anorexia	26
Pain	17
Vomiting	11
Injection site reaction	10

PRESENTING SIGN	INCIDENCE
Diarrhoea	8
Ataxia	7
Anaphylaxis	6
Facial oedema	4
Collapse	4
Malaise	3
Depression	3
Alopecia (localised)	2
Death	2
Vocalisation	2
Unconscious	2
Erythema	2
Behavioural change	2
Haematemesis	2
Haemorrhage	2
Hypersalivation	2
Sneezing	2
Respiratory problems	2
Pruritis	2
Allergy	1
Listless	1
Lymphadenopathy	1
Coughing	1
Mydriasis	1
Alopecia	1
Polydipsia	1
Abscess	1

PRESENTING SIGN	INCIDENCE
Pulmonary oedema	1
Agitation	1
Lame	1
Lack of effect	1
Swollen lips and face	1
Tachycardia	1
Tremor	1
Arthropathy	1
Vaccination reaction	1
Vasculitis	1
Dyspnoea	1

The most reported side effects of vaccinations in cats include lethargy, anorexia and pyrexia. These occur very occasionally with most vaccines. Due to the low number of reports when taking into consideration the large number of cats vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

FELINE HERPES VIRUS

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Sneezing	1
Pyrexia	1

FELINE IMMUNODEFICIENCY VIRUS(PETALUMA STRAIN)INACTIVE

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
18	4	14

PRESENTING SIGN	INCIDENCE
Pyrexia	11
Lethargy	11
Anorexia	6
Pain	5
Injection site reaction	5
Behavioural change	2
Malaise	2
Tachycardia	1
Hypersalivation	1
Lymphadenopathy	1
Respiratory problems	1
Sneezing	1

FELINE LEUKAEMIA VIRUS – INACTIVATED

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
9	2	7

PRESENTING SIGN	INCIDENCE
Pyrexia	3
Lethargy	3
Anorexia	3
Depression	3
Vomiting	1
Diarrhoea	1
Injection site reaction	1
Ataxia	1

PRESENTING SIGN	INCIDENCE
Anaphylaxis	1
Respiratory problems	1

FELINE PANLEUCOPENIA

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Sneezing	1
Pyrexia	1

FELINE PANLEUCOPENIA VIRUS - INACTIVATED

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
78	36	42

PRESENTING SIGN	INCIDENCE
Lethargy	36
Pyrexia	30
Anorexia	26
Pain	17
Vomiting	11
Injection site reaction	10
Diarrhoea	8
Ataxia	7
Anaphylaxis	6
Facial oedema	4

PRESENTING SIGN	INCIDENCE
Collapse	4
Malaise	3
Depression	3
Alopecia (localised)	2
Death	2
Vocalisation	2
Unconscious	2
Erythema	2
Behavioural change	2
Haematemesis	2
Haemorrhage	2
Hypersalivation	2
Sneezing	2
Respiratory problems	2
Pruritis	2
Allergy	1
Listless	1
Lymphadenopathy	1
Coughing	1
Mydriasis	1
Alopecia	1
Polydipsia	1
Abscess	1
Pulmonary oedema	1
Agitation	1
Lame	1
Lack of effect	1

PRESENTING SIGN	INCIDENCE
Swollen lips and face	1
Tachycardia	1
Tremor	1
Arthropathy	1
Vaccination reaction	1
Vasculitis	1
Dyspnoea	1

The most reported side effects of vaccinations in cats include lethargy, anorexia and pyrexia. These occur very occasionally with most vaccines. Due to the low number of reports when taking into consideration the large number of cats vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

FELINE RHINOTRACHEITIS VIRUS - INACTIVATED

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
78	36	42

PRESENTING SIGN	INCIDENCE
Lethargy	36
Pyrexia	30
Anorexia	26
Pain	17
Vomiting	11
Injection site reaction	10
Diarrhoea	8
Ataxia	7
Anaphylaxis	6
Facial oedema	4

PRESENTING SIGN	INCIDENCE
Collapse	4
Malaise	3
Depression	3
Alopecia (localised)	2
Death	2
Vocalisation	2
Unconscious	2
Erythema	2
Behavioural change	2
Haematemesis	2
Haemorrhage	2
Hypersalivation	2
Sneezing	2
Respiratory problems	2
Pruritis	2
Allergy	1
Listless	1
Lymphadenopathy	1
Coughing	1
Mydriasis	1
Alopecia	1
Polydipsia	1
Abscess	1
Pulmonary oedema	1
Agitation	1
Lame	1
Lack of effect	1

PRESENTING SIGN	INCIDENCE
Swollen lips and face	1
Tachycardia	1
Tremor	1
Arthropathy	1
Vaccination reaction	1
Vasculitis	1
Dyspnoea	1

The most reported side effects of vaccinations in cats include lethargy, anorexia and pyrexia. These occur very occasionally with most vaccines. Due to the low number of reports when taking into consideration the large number of cats vaccinated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

FENBENDAZOLE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Shaking	1
Agitation	1
Paraesthesia	1

FENVALERATE

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Site reaction	1

FIPRONIL

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
42	4	38

PRESENTING SIGN	INCIDENCE
Irritation (skin)	15
Erythema	10
Alopecia (localised)	8
Site reaction	7
Pruritis	6
Vomiting	4
Lethargy	4
Swelling (local)	2
Scabs	2
Rash	2
Coat discoloration	2
Depression	1
Hypersalivation	1
Hypersensitive to stimuli	1
Inflammation	1
Irritation (eye)	1
Alopecia	1
Dermatitis	1
Pain	1
Papules	1
Hives	1
Blisters	1

PRESENTING SIGN	INCIDENCE
Distress	1
Blood in faeces	1
Diarrhoea	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
38	7	31

PRESENTING SIGN	INCIDENCE
Alopecia (localised)	26
Erythema	7
Lethargy	5
Anorexia	4
Scabs	3
Pyrexia	2
Ataxia	2
Irritation (skin)	2
Vomiting	1
Distress	1
Alopecia	1
Head tilt	1
Inflammation	1
Irritation (eye)	1
Dermatitis	1
Comatose	1
Muscle twitching	1
Nystagmus	1
Pruritis	1

PRESENTING SIGN	INCIDENCE
CNS dysfunction	1
Cellulitis	1
Site reaction	1
Tremor	1

Fipronil is a broad-spectrum phenyl pyrazole insecticide acting on the nervous system of insects by contact or ingestion. These are relatively new products in the market place and have a very high volume of sales. Fipronil is currently under review. The progress of the review can be monitored on the APVMA website (http://www.apvma.gov.au/products/review/index.php).

FIROCOXIB

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Vomiting	1
Anorexia	1
Blood in faeces	1
Diarrhoea	1
Hypersalivation	1

FLUAZURON

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

FLUMETHRIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lack of effect	1

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Irritation (skin)	1
Inflammation	1

FORMALIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Pyrexia	1
Oedema	1

FRAMYCETIN SULFATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Deafness	1

FUCIDIC ACID DIETHANOLAMINE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Deafness	1

GENTAMICIN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	2	3

PRESENTING SIGN	INCIDENCE
Deafness	4
Otitis externa	1

GLUCOSAMINE HYDROCHLORIDE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

PRESENTING SIGN	INCIDENCE
Diarrhoea	2
Pigmentation	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Unpleasant taste	1

GLUCOSE

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Swelling (local)	1
Listless	1
Site reaction	1

GNRF - PROTEIN CONJUGATE

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Injection site reaction	4

HALOFUGINONE BASE AS THE LACTATE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Pain	1
Blood in faeces	1
Diarrhoea	1
Oral (lesions)	1

HEPATITIS CANINE = CANINE ADENOVIRUS

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	0	5

PRESENTING SIGN	INCIDENCE
Welts	2
Anaphylaxis	1
Coughing	1
Death	1
Lack of effect	1
Sneezing	1

HYDROXYPROGESTERONE CAPROATE

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Site reaction	1

IMIDACLOPRID

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
255	227	28

PRESENTING SIGN	INCIDENCE
Paraesthesia	149
Self trauma	22
Behavioural change	19
Site reaction	17
Irritation (skin)	15
Lethargy	14
Scabs	10
Lack of effect	9
Vomiting	8
Alopecia (localised)	8
Lump (local)	7
Walking (difficult)	5
Seizure	5
Restless	5
Anorexia	5
Rash	4
Agitation	4
Diarrhoea	3
Shaking	3
Distress	3
Pyoderma	3
Erythema	3

PRESENTING SIGN	INCIDENCE
Depression	3
Spasm	2
Rolling	2
Incoordination	2
Lesions	2
Panting	2
Hypertonia	1
Pain	1
Oral (irritation)	1
Hyperexcitable	1
Blisters	1
Frothing at the mouth	1
Red eyes	1
Respiratory problems	1
Nil	1
Listless	1
Rubbing	1
Alopecia	1
Disorientation	1
Allergy	1
Illness	1
Death	1
Ataxia	1
Tremor	1
Coat discoloration	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
67	58	9

PRESENTING SIGN	INCIDENCE
Alopecia (localised)	23
Lethargy	8
Hypersalivation	8
Self trauma	6
Anorexia	6
Behavioural change	6
Vomiting	5
Scabs	5
Oral (irritation)	5
Frothing at the mouth	5
Site reaction	4
Ataxia	2
Agitation	2
Diarrhoea	2
Restless	2
Panting	2
Lack of effect	2
Depression	1
Irritation (skin)	1
Alopecia	1
Nil	1
Distress	1
Oral (ulcers)	1

PRESENTING SIGN	INCIDENCE
Irritation (eye)	1
Inflammation	1
Illness	1
Hypothermia	1
Erythema	1
Toxicity	1

Rabbit

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Irritation (skin)	1

Imidacloprid is an insecticidal chemical. Given the very high sales volume, the incidence of adverse reactions is low. Therefore no further regulatory action is required other than continuing monitoring for future adverse experience reports.

INACTIVATED RABBIT CALICIVIRUS DISEASE VIRUS

Rabbit

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Injection site reaction	1

INACTIVATED SALMONELLA DUBLIN & TYPHIMURIUM ANTIGENS

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

INSULIN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Lack of effect	1
Abscess	1

ISOFLURANE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Recovery (prolonged)	2

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Recovery (prolonged)	1

IVERMECTIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Lack of effect	3

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Unpleasant taste	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	2	3

PRESENTING SIGN	INCIDENCE
Lack of effect	5

KETAMINE AS KETAMINE HYDROCHLORIDE

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Recovery (poor)	1
Hyperexcitable	1

KETOPROFEN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Collapse	1

LEPTOSPIRA ICTEROHAEMORRHAGIAE ANTIGEN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
10	2	8

PRESENTING SIGN	INCIDENCE
Vomiting	3
Facial oedema	3
Welts	2
Death	2
Lethargy	2
Erythema	1
Irritation (skin)	1
Collapse	1
Listless	1
Shock	1
Swollen feet	1
Vaccination reaction	1
Anaphylaxis	1
Weakness	1

LEPTOSPIRA INTERROGANS SEROVAR HARDJO

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Illness	1

LEPTOSPIRA INTERROGANS SEROVAR POMONA

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Illness	1

LEPTOSPIROSIS - DOG - LEPTOSPIRA ICTEROHAEMORRHAGIAE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Sneezing	1
Anaphylaxis	1
Coughing	1
Death	1
Lack of effect	1

LEVAMISOLE HYDROCHLORIDE

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Death	2
Ataxia	1

LUFENURON

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
13	4	9

PRESENTING SIGN	INCIDENCE
Vomiting	5
Diarrhoea	5
Lethargy	2
Anorexia	1
Haematemesis	1
Lack of effect	1
Convulsions	1
Pruritis	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

PRESENTING SIGN	INCIDENCE
Lethargy	2
Anorexia	2
Lump (local)	1
Depression	1
Alopecia (localised)	1

LYSINE HYDROCHLORIDE

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Swelling (local)	1
Listless	1

M.HYOPNEUMONIA – INACTIVATED WHOLE CELL CULTURE

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	1	3

PRESENTING SIGN	INCIDENCE
Death	4
Vomiting	2
Coughing	1
Convulsions	1
Dyspnoea	1

MAGNESIUM FLUOROSILICATE

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

MALACHITE GREEN

Fish

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1

MALIGNANT OEDEMA = CLOSTRIDIUM SEPTICUM

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Pneumonia	1
Bloat	1
Death	1
Haemorrhage	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Shaking	1
Convulsions	1
Death	1
Head tilt	1

MELOXICAM

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Vomiting	1
Abdominal pain	1
Anorexia	1
Blood in faeces	1
Melaena	1
Pain	1
Shaking	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Pyrexia	1
Anorexia	1
Azotaemia	1

PRESENTING SIGN	INCIDENCE
Blood in faeces	1
Depression	1
Diarrhoea	1
Melaena	1

METHOPRENE - RS

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Hypersalivation	1
Ataxia	1

METHYLENE BLUE

Fish

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1

MICONAZOLE NITRATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	1	2

PRESENTING SIGN	INCIDENCE
Irritation (skin)	3

PRESENTING SIGN	INCIDENCE
Alopecia	1

MILBEMYCIN OXIME

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
22	5	17

PRESENTING SIGN	INCIDENCE
Diarrhoea	10
Vomiting	9
Lethargy	6
Convulsions	2
Lack of effect	2
Anorexia	2
Blood in faeces	1
Haematemesis	1
Death	1
Pruritis	1
Renal failure	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	1	4

PRESENTING SIGN	INCIDENCE
Lethargy	3
Vomiting	2
Pyrexia	2

PRESENTING SIGN	INCIDENCE
Diarrhoea	2
Anorexia	1
Collapse	1
Erythema	1
Injected mucous membranes	1
Alopecia	1
Ataxia	1
Recumbency	1

MOMETASONE FUROATE MONOHYDRATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Deafness	1

MONENSIN AS MONENSIN SODIUM

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	2	2

PRESENTING SIGN	INCIDENCE
Lack of effect	2
Lesions	1
Death	1

MORAXELLA BOVIS

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
24	7	17

PRESENTING SIGN	INCIDENCE
Lack of effect	16
Lump (local)	6
Injection site reaction	6
Site reaction (swelling)	1
Distress	1
Death	1
Anaphylactoid reaction	1
Convulsions	1

MOXIDECTIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
34	6	28

PRESENTING SIGN	INCIDENCE
Lack of effect	11
Recumbency	10
Ataxia	9
Death	5
Incoordination	4
Hypersalivation	3
Swelling (local)	2
Allergy	2

PRESENTING SIGN	INCIDENCE
Illness	2
Walking (difficult)	1
Blurred vision	1
Depression	1
Lethargy	1
Muscle twitching	1
Nasal discharge	1
Nystagmus	1
Paddling	1
Panting	1
Pupillary light reflex (abnormal)	1
Blindness	1
Respiratory problems	1
Shaking	1
Stiffness	1
Head tilt	1
Rubbing	1

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
26	18	8

PRESENTING SIGN	INCIDENCE
Behavioural change	5
Lethargy	4
Site reaction	3
Alopecia (localised)	3
Lack of effect	3

PRESENTING SIGN	INCIDENCE
Anorexia	2
Seizure	2
Scabs	2
Vomiting	1
Irritation (skin)	1
Depression	1
Allergy	1
Rash	1
Erythema	1
Disorientation	1
Self trauma	1
Diarrhoea	1

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Lack of effect	2

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
43	35	8

PRESENTING SIGN	INCIDENCE
Alopecia (localised)	13
Self trauma	5
Anorexia	5
Vomiting	4

PRESENTING SIGN	INCIDENCE
Oral (irritation)	4
Lethargy	4
Behavioural change	4
Scabs	3
Hypersalivation	3
Frothing at the mouth	3
Site reaction	2
Diarrhoea	2
Restless	2
Lack of effect	2
Ataxia	2
Agitation	1
Nil	1
Panting	1
Depression	1
Inflammation	1
Alopecia	1
Illness	1
Toxicity	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
8	0	8

PRESENTING SIGN	INCIDENCE
Low efficacy	5
Lack of effect	2
Shaking	1

PRESENTING SIGN	INCIDENCE
Head tilt	1
Death	1
Convulsions	1

MOXIDECTIN CONCENTRATE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lethargy	1
Ataxia	1
Hypersalivation	1
Incoordination	1

MOXIDECTIN MICROSPHERES

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
71	9	62

PRESENTING SIGN	INCIDENCE
Facial oedema	19
Vomiting	18
Anaphylaxis	14
Collapse	10
Lethargy	9
Urticaria	6
Lump (local)	6

PRESENTING SIGN	INCIDENCE
Pale mucous membranes	5
Pruritis	4
Diarrhoea	3
Abscess	3
Weakness	2
Erythema	2
Pyrexia	2
Injection site reaction	2
Hives	1
Cyanosis	1
Listless	1
Defaecation	1
Depression	1
Dyspnoea	1
Irritation (skin)	1
Rash	1
Rubbing	1
Stiffness	1
Swelling (local)	1
Swollen (lips)	1
Thrombocytopenia	1
Urination	1
Death	1
Vasculitis	1
Anaphylactoid reaction	1

Moxidectin microspheres are often used in conjunction with other products, resulting in a higher incidence of reporting. Due to the low number of reports when taking into consideration the large number of animals treated each year, no further regulatory action is required other than continuing monitoring for future adverse experiences.

NAPHTHALOPHOS

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	2	2

PRESENTING SIGN	INCIDENCE
Death	3
Lack of effect	1

NEOMYCIN BASE (AS THE SULFATE)

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Swelling (local)	1
Injection site reaction	1
Site reaction (swelling)	1

NITENPYRAM

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

PRESENTING SIGN	INCIDENCE
Hyperactivity	2

PRESENTING SIGN	INCIDENCE
Vomiting	1
Agitation	1
Irritation (ear)	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Tachycardia	1
Hyperactivity	1
Hypersalivation	1
Somnolence	1

N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Hypersalivation	1
Ataxia	1

NYSTATIN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Deafness	1

OATMEAL EXTRACT

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	2	2

PRESENTING SIGN	INCIDENCE
Welts	1
Allergy	1
Alopecia	1
Irritation (eye)	1
Irritation (skin)	1

OESTRADIOL 17-BETA

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Preputial prolapse	2

OESTRADIOL BENZOATE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Preputial prolapse	1

OESTRADIOL DIPROPIONATE

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Site reaction	1

OXANTEL EMBONATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	3	2

PRESENTING SIGN	INCIDENCE
Worms	2
Diarrhoea	2
Dehydration	1
Lack of effect	1
Lethargy	1
Poor performance	1

OXYTETRACYCLINE HYDROCHLORIDE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

PRESENTING SIGN	INCIDENCE
Death	3
Tachypnoea	2

PRESENTING SIGN	INCIDENCE
Tachycardia	2
Pyrexia	2
Dyspnoea	2
Cyanosis	1
Ataxia	1

PARVOVIRUS - LIVE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
5	0	5

PRESENTING SIGN	INCIDENCE
Welts	2
Anaphylaxis	1
Coughing	1
Death	1
Lack of effect	1
Sneezing	1

PERMETHRIN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
26	26	0

PRESENTING SIGN	INCIDENCE
Paraesthesia	13
Site reaction	4
Restless	3

PRESENTING SIGN	INCIDENCE
Irritation (skin)	3
Walking (difficult)	2
Rolling	2
Hypertonia	1
Oral (irritation)	1
Pain	1
Behavioural change	1
Depression	1
Distress	1
Rubbing	1
Self trauma	1
Shaking	1
Blisters	1
Vomiting	1

Permethrin is a common synthetic chemical, widely used as an insecticide, acaricide, and insect repellent. Permethrin is often used in conjunction with other products, resulting in a higher incidence of reporting. These products have a very high volume of sales. Off label permethrin cat toxicity is a serious issue and a multi-stakeholder steering committee is undertaking to address this matter arising from off label exposure of dog *spot-on* products.

PERMETHRIN (25:75 CIS:TRANS)

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Lack of effect	1
Hives	1

PERMETHRIN (40:60: :CIS:TRANS)

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
192	175	17

PRESENTING SIGN	INCIDENCE
Paraesthesia	136
Self trauma	17
Behavioural change	12
Lethargy	9
Irritation (skin)	9
Site reaction	8
Lump (local)	7
Vomiting	6
Scabs	6
Lack of effect	6
Seizure	3
Rash	3
Pyoderma	3
Alopecia (localised)	3
Walking (difficult)	2

PRESENTING SIGN	INCIDENCE
Lesions	2
Diarrhoea	2
Spasm	2
Shaking	2
Incoordination	2
Agitation	2
Anorexia	1
Frothing at the mouth	1
Respiratory problems	1
Distress	1
Illness	1
Alopecia	1
Panting	1
Coat discoloration	1
Nil	1
Death	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lethargy	1
Fasciculation	1

PHENOBARBITONE

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

PHENYLBUTAZONE

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Tachypnoea	1
Nystagmus	1
Paddling	1
Seizure	1
Sweating	1
Tachycardia	1

PIPERONYL BUTOXIDE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Rash	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

PRESENTING SIGN	INCIDENCE
Hypersalivation	2
Ataxia	2

POLYMYXIN B SULFATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Allergy	1

PRAZIQUANTEL

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
40	19	21

PRESENTING SIGN	INCIDENCE
Vomiting	13

PRESENTING SIGN	INCIDENCE
Diarrhoea	13
Lethargy	9
Lack of effect	5
Hyperexcitable	5
Worms	2
Convulsions	2
Anorexia	2
Dehydration	1
Death	1
Hypersalivation	1
Hypersensitivity reaction	1
Haematemesis	1
Blood in faeces	1
Paraesthesia	1
Poor performance	1
Pruritis	1
Renal failure	1
Shaking	1
Agitation	1

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Lack of effect	2

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
31	19	21

PRESENTING SIGN	INCIDENCE
Alopecia (localised)	14
Ataxia	6
Lethargy	5
Self trauma	4
Inflammation	4
Vomiting	3
Anorexia	3
Pyrexia	3
Alopecia	3
Coat colour change	2
Diarrhoea	2
Erythema	2
Irritation (skin)	2
Weakness	1
Agitation	1
Pain	1
Injected mucous membranes	1
Recumbency	1
Collapse	1
Incoordination	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

Rabbit

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Ataxia	1

Praziquantel is a systemic anthelmintic used primarily to treat worm infections. Due to the low number of reports when taking into consideration the large number of animals treated each year, no further regulatory action is required other than continuing monitoring for future adverse experience reports.

PREDNISALONE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Deafness	1

PROCAINE PENICILLIN

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	1	3

PRESENTING SIGN	INCIDENCE
Agitation	2
Swelling (local)	1
Death	1

PRESENTING SIGN	INCIDENCE
Injection site reaction	1
Restless	1
Site reaction (swelling)	1

PROGESTERONE

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Preputial prolapse	1

PROPENTOFYLLINE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Polyphagia	2
Restless	1

PROPOFOL

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	4	2

PRESENTING SIGN	INCIDENCE
Urticaria	2
Cardiac arrest	2

PRESENTING SIGN	INCIDENCE
Anaphylaxis	1
Death	1
Dyspnoea	1
Erythema	1
Facial oedema	1

PROPOXUR

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Irritation (skin)	1
Inflammation	1

PYRACLOFOS

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	3	1

PRESENTING SIGN	INCIDENCE
Death	4
Hypersalivation	2
Sneezing	1
Ataxia	1
Frothing at the mouth	1
Coughing	1
Lethargy	1

PRESENTING SIGN	INCIDENCE
Panting	1

PYRANTEL AS PYRANTEL EMBONATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
12	10	2

PRESENTING SIGN	INCIDENCE
Hyperexcitable	5
Vomiting	4
Lethargy	2
Lack of effect	2
Diarrhoea	1
Hypersensitivity reaction	1
Hypersalivation	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	3	0

PRESENTING SIGN	INCIDENCE
Ataxia	3
Vomiting	1
Lethargy	1

Rabbit

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Ataxia	3

PYRANTEL EMBONATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	4	2

PRESENTING SIGN	INCIDENCE
Worms	2
Diarrhoea	2
Agitation	1
Dehydration	1
Lack of effect	1
Lethargy	1
Paraesthesia	1
Poor performance	1
Shaking	1

PYRETHRINS

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Rash	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	2	1

PRESENTING SIGN	INCIDENCE
Hypersalivation	2
Ataxia	2

PYRIPROXYFEN

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lethargy	1
Fasciculation	1

QUIL

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Pyrexia	1
Anorexia	1
Pain	1

RECOMBINANT GP70 SUB-TYPE A

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Pyrexia	1
Anorexia	1
Pain	1

RESERPINE

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Tachycardia	1
Depression	1
Diarrhoea	1

ROTENONE FROM DERRIS

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

(S)-METHOPRENE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
37	2	35

PRESENTING SIGN	INCIDENCE
Irritation (skin)	15

PRESENTING SIGN	INCIDENCE
Erythema	10
Alopecia (localised)	8
Site reaction	7
Pruritis	5
Vomiting	3
Swelling (local)	2
Coat discoloration	2
Scabs	2
Lethargy	2
Dermatitis	1
Hypersensitive to stimuli	1
Inflammation	1
Irritation (eye)	1
Blood in faeces	1
Hypersalivation	1
Pain	1
Papules	1
Depression	1
Rash	1
Blisters	1
Distress	1
Diarrhoea	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
36	6	30

PRESENTING SIGN	INCIDENCE
Alopecia (localised)	25
Erythema	6
Lethargy	5
Anorexia	4
Scabs	3
Pyrexia	2
Ataxia	2
Irritation (skin)	2
Tremor	1
Alopecia	1
Head tilt	1
Inflammation	1
Distress	1
Dermatitis	1
Muscle twitching	1
Nystagmus	1
Pruritis	1
CNS dysfunction	1
Cellulitis	1
Site reaction	1

(S)-methoprene is often used in conjunction with other products, resulting in a higher incidence of reporting. (S)-methoprene is a pesticide that acts as a juvenile hormone mimic, disrupting the development of insects and preventing the larvae from emerging as adults.

SELAMECTIN

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Welts	1
Pruritis	1
Site reaction	1
Vomiting	1

Feline

NUMBER OF REPORTS	PROBABLE	POSSIBLE
8	7	1

PRESENTING SIGN	INCIDENCE
Site reaction	6
Alopecia (localised)	2
Pruritis	2
Erythema	1

SELENIUM

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Death	2
Swelling (local)	1

PRESENTING SIGN	INCIDENCE
Lame	1

SELENIUM AS SODIUM SELENATE

Caprine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lump (local)	1
Injection site reaction	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Death	1
Lack of effect	1

SODIUM PENTOSAN POLYSULFATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
6	0	6

PRESENTING SIGN	INCIDENCE
Facial oedema	2
Swelling (local)	1
Anaphylaxis	1
Diarrhoea	1

PRESENTING SIGN	INCIDENCE
Agitation	1
Hyperexcitable	1
Lethargy	1
Restless	1
Stiffness	1

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Site reaction	1
Injection site reaction	1
Pyrexia	1

SODIUM SALICYLATE

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Tachypnoea	1
Nystagmus	1
Paddling	1
Seizure	1
Sweating	1
Tachycardia	1

SPINOSAD

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Vomiting	1
Anorexia	1
Ataxia	1
Lethargy	1
Paralysis	1
Respiratory problems	1
Tachycardia	1

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
39	13	26

PRESENTING SIGN	INCIDENCE
Lack of effect	19
Low efficacy	18
Nil	1
Flystrike	1

STABILISED GREEN-LIPPED MUSSEL POWDER

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Pigmentation	1
Diarrhoea	1

STREPTOCOCCUS EQUI AS CELL FREE EXTRACT

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Injection site reaction	

SULFADOXINE

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Nystagmus	2
Agitation	2
Collapse	2
Tachycardia	1
Ataxia	1

SULFUR

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

TETANUS = CLOSTRIDIUM TETANI

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
3	0	3

PRESENTING SIGN	INCIDENCE
Death	2
Recumbency	1
Bloat	1
Ataxia	1
Haemorrhage	1
Pneumonia	1

TETRACHLORVINPHOS

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Lack of effect	2

THIOMERSAL

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Death	2
Swelling (local)	1
Lame	1

TOLTRAZURIL

Porcine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Scouring	1
Death	1
Lack of effect	1

TRIFLUMURON

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
10	6	4

PRESENTING SIGN	INCIDENCE
Lack of effect	9
Necrosis	1

TRIMETHOPRIM

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Nystagmus	2
Agitation	2
Collapse	2
Tachycardia	1
Ataxia	1

TULATHROMYCIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Dyspnoea	1

VITAMIN B12 – CYANOCOBALAMIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Pneumonia	1
Bloat	1
Death	1
Haemorrhage	1

VITAMIN B12A – HYDROXOCOBALAMIN

Ovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	0	2

PRESENTING SIGN	INCIDENCE
Death	2
Swelling (local)	1
Lame	1

VITAMIN K1 = PHYTOMENADIONE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Histamine reaction	1

XYLAZINE AS THE HYDROCHLORIDE

Equine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Hypothermia	1
Collapse	1
Head tilt	1

ZETA-CYPERMETHRIN

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Lack of effect	1

3 VETERINARY MEDICINES- SUMMARY OF ADVERSE EXPERIENCE REPORTS 2009 (HUMAN)

3.1 Adverse experience report summaries involving humans listed by active constituent

The following information is contained in this section:

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.

Number of reports

Only adverse experience reports that were classified by the APVMA during the calendar year 2009, 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.

Presenting signs

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

It is important to note that multiple clinical signs may have been noted in some individual reports. Therefore the list of clinical signs observed does not relate directly to the total number of reports received.

3.1.1 Veterinary Medicines – Human AERs

BLACK DISEASE = CLOSTRIDIUM OEDEMATIENS

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Needle stick injury	1
Swelling (local)	1

BLACKLEG = CLOSTRIDIUM CHAUVOEI

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Needle stick injury	1
Swelling (local)	1

CLA = CORYNEBACTERIUM PSEUDOTUBERCULOSIS OVIS

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Needle stick injury	2
Swelling (local)	1

CLOSTRIDIUM CHAUVOEI – FORMOL CULTURE

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Needle stick injury	1

CLOSTRIDIUM NOVYI TYBE B

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

Presenting sign	Incidence
Needle Stick	1

CLOSTRIDIUM PERFRINGES TYPE D TOXOID

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Needle stick injury	1
Swelling (local)	1

CLOSTRIDIUM TETANI - TOXOID

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Needle stick injury	1
Swelling (local)	1

ENROFLOXACIN

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Nil	1

ENTEROTOXAEMIA = PULPY KIDNEY = C PERFRINGENS

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Needle stick injury	1

FIPRONIL

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Rash	1

FLUAZURON

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Headache	2
Dizziness	1
Rash	1
Oral (irritation)	1
Nausea	1
Vomiting	1

IMIDACLOPRID

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
4	3	1

PRESENTING SIGN	INCIDENCE
Irritation (eye)	2
Headache	1
Nausea	1
Irritation (skin)	1
Numbness	1

MALIGNANT OEDEMA = CLOSTRIDIUM SEPTICUM

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Needle stick injury	2
Swelling (local)	1

MOXIDECTIN

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Needle stick injury	1
Swelling (local)	1

PERMETHRIN

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Numbness	1

PERMETHRIN (40:60 CIS:TRANS)

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Headache	1
Nausea	1

PRESENTING SIGN	INCIDENCE
Irritation (skin)	1
	1

TETANUS = CLOSTRIDIUM TETANI

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Needle stick injury	1

4 AGRICULTURAL CHEMICALS - SUMMARY OF ADVERSE EXPERIENCE REPORTS 2009 (STANDARD)

4.1 Adverse experience report summaries involving crop damage, domestic animal harm, environmental damage or lack of efficacy listed by active constituent (= 'standard' AERs)

The following information is contained in this section:

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.

Number of reports

- Only adverse experience reports that were classified by the APVMA during the calendar year 2009, 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.

Presenting signs

- All observed effects for reports that were classified as probable and possible are listed in order of frequency.
- It is important to note that multiple adverse effects have been noted in some individual reports. Therefore the list of observed effects does not relate directly to the total number of reports received.

4.1.1 Agricultural Chemicals – (not including human) AERs

FLAMPROP-M-METHYL

Wheat

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Lack of effect	1

METALDEHYDE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Collapse	1
Cyanosis	1
Muscle twitching	1
Unconscious	1

PERMETHRIN (25:75::CIS:TRANS)

Environmental

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Potential Hazard	1

PICLORAM PRESENT AS THE HEXYLOXYPROPYLAMINE SALT

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Anorexia	1
Hypersalivation	1

SODIUM FLUOROACETATE

Canine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Death	1

TRICLOPYR PRESENT AS THE BUTOXYETHYL ESTER

Bovine

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Anorexia	1
Hypersalivation	1

5 AGRICULTURAL CHEMICALS - SUMMARY OF ADVERSE EXPERIENCE REPORTS 2009 (HUMAN)

5.1 Adverse experience report summaries involving humans listed by active constituent

The following information is contained in this section:

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.

Number of reports

Only adverse experience reports that were classified by the APVMA during the calendar year 2009, 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.

Presenting signs

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

It is important to note that multiple adverse effects have been noted in some individual reports. Therefore the list of observed effects does not relate directly to the total number of reports received.

5.1.1 Agricultural Chemicals – Human AERs

ALCOHOL ALKOXYLATE

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	NUMBER OF REPORTS
Red eyes	1

ALPHA-CYPERMETHRIN

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Burning sensation	1
Erythema	1
Irritation (skin)	1

BIFENTHRIN

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Irritation (skin)	1

CHLORPYRIFOS

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Irritation (eye)	1
Respiratory problems	1
Sore throat	1

DIMETHOATE

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Red eyes	1

MCPA PRESENT AS THE DIMETHYLAMINE SALT

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Red eyes	1

MOXIDECTIN

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Irritation (skin)	1

PICARIDIN

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	0	1

PRESENTING SIGN	INCIDENCE
Unpleasant smell	1
Unpleasant taste	1

PICLORAM PRESENT AS THE HEXYLOXYPROPYLAMINE SALT

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Nil	1
Sensitivity to chemicals	1

PROPIONIC ACID

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Burning sensation	2
Irritation (eye)	1

PRESENTING SIGN	INCIDENCE
Red eyes	1

SELENIUM AS SODIUM SELENATE

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
1	1	0

PRESENTING SIGN	INCIDENCE
Irritation (skin)	1

SOYAL PHOSPHOLIPIDS

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	2	0

PRESENTING SIGN	INCIDENCE
Burning sensation	2
Irritation (eye)	1
Red eyes	1

TRICLOPYR PRESENT AS THE BUTOXYETHYL ESTER

Human

NUMBER OF REPORTS	PROBABLE	POSSIBLE
2	1	1

PRESENTING SIGN	INCIDENCE
Nil	1
Sensitivity to chemicals	1

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GLOSSARY

Adipsia	Absence of thirst or abnormal avoidance of drinking
Alopecia	Absence of hair from areas where it is normally present
Analgesic	Pain relieving treatment
Anaphylactoid	An anaphylactic-type reaction
Anaphylaxis/anaphylactic	An exaggerated allergic reaction of an animal to a foreign protein or other substances
Anorexia	Lack or loss of appetite
Anthelmintic	An agent destructive to worms
Antimicrobial	An agent that kills micro-organisms or suppresses their multiplication or growth
Ataxia	Unsteady walking action due to muscular incoordination
Bradycardia	Excessive slowness in the action of the heart
Coagulopathy	Any disorder of blood coagulation
Colic	A general term for abdominal pain
Conjunctivitis	Conjunctivitis is the inflammation of the conjunctiva, a thin, delicate membrane that covers the eyeball and lines the eyelid
Cyanosis	Cyanosis is a physical sign causing bluish discoloration of the skin and mucous membranes due to a lack of oxygen in the blood
Dermatitis	Inflammation of the skin
Dyspnoea	Laboured breathing
Epiphora	Diseases of the lacrimal apparatus
Epistaxis	Bleeding from the nose
Erythema	Abnormal redness of the skin due to local congestion, as in inflammation
Fasciculation	Involuntary contractions or twitchings of groups of muscle fibers
Folliculitis	Inflammation of the follicles
Haematemesis	Vomiting of blood
Haemorrhage	Bleeding
Hepatopathy	Disease or disorder of the liver
Hypersalivation	Excessive salivation
Hypersensitivity	An excessive reaction to an allergen

Intramammary	Within or into the mammary gland
Jaundice	Yellowish staining of the skin and mucous membranes
Melaena	The passage of dark stools due to haemorrhage in the stomach or small intestine
Mydriasis	Unusual state of dilatation of pupil of the eye
Nausea	Unpleasant sensation in the stomach with a tendancy to vomit
Necrosis	Pathological process associated with severe cellular trauma
Oedematous	Abnormal accumulation of fluid in body cavities and under the skin
Paraesthesia	An abnormal sensation
Parasiticide	An agent that is destructive to parasites
Periorbital	Surrounding the eyes
Petechiae	Purplish or brownish red discoloration, caused by hemorrhage into the tissues
Preputial	Of or pertaining to the prepuce
Prolapse	To fall or slip out of place
Pruritis	Irritation and intense itching
Pyrexia	High fever
Rales	Abnormal respiratory sound heard on auscultation, indicating some pathologic condition
Registrant	The commercial party that is responsible for the marketing of the product
Seizure	A sudden attack, as of disease or epilepsy
Seroma	A collection of serum in the body, producing a tumor-like mass
Somnolence	State of sleepiness or unnatural drowsiness
Tachycardia	Excessive rapidity in the action of the heart
Tachypnoea	Rapid shallow breaths
Tenesmus	Ineffectual and painful straining in an attempt to urinate or defecate
Thrombocytopenia	Decrease in the number of blood platelets
Urticaria	Vascular reaction of the skin as a result of contact with a chemical or may be immunologically based.
Wheals	A small swelling on the skin, as from an insect bite, that usually itches or burns
Withholding period	The time interval after the withdrawal of a drug or chemical use, to either the time of re-entry, harvesting or use of an animal or animal product for human consumption

LIST OF ACTIVE CONSTITUENTS