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Details of Filing

Document Lodged:	Statement of Claim - Form 17 - Rule 8.06(1)(a)
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Important Information

As required by the Court's Rules, this Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

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Form 17
Rule 8.05(1)(a)

Second Further Amended Statement of Claim

No. NSD406 of 2018

Federal Court of Australia
District Registry: New South Wales
Division: General Division

RACHAEL ABBOTT
Applicant

ZOETIS AUSTRALIA PTY LTD ACN 156 476 425
Respondent

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Filed on behalf of Rachael Abbott, Lead Applicant
Prepared by (name of person/lawyer) G Donnellan with AH Edwards
Law firm (if applicable) LHD Lawyers
Tel 02 9264 6644 Fax 02 9246 6622
Email MHGroup@lhd.com.au
Address for service (include state and postcode) Level 8, 151 Castlereagh Street, Sydney NSW 2000

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A. INTRODUCTION

A.1. The Applicant and Group Members

1. This is a representative proceeding brought pursuant to Part IVA of the *Federal Court of Australia Act 1976* (Cth) (**FCAA**) on behalf of the Applicant and all persons who suffered:

   (a) loss or damage; and/or

   (b) personal injury,

   in the period 10 August 2012 to 20 March 2018 (**Relevant Period**) by reason of the conduct of Zoetis Australia Pty Ltd (**Zoetis**) pleaded in this Second Further Amended Statement of Claim (collectively, **Group Members**).

2. As at the commencement of this proceeding, seven or more Group Members have claims against Zoetis within the meaning of s 33C of the FCAA.

3. The Applicant:

(a) commenced employment as a stockperson with JBS Caroona Feed Lot (**JBS**) in June 2014; and

(b) in the Relevant Period:

(c) owned Primetime, an 11-year-old mare;

(d) had possession of and an interest in Ervines Jive, a five-year-old mare,

used in connection with her employment at JBS.

Particulars

In relation to Ervines Jive:

(a) The owners of Ervines Jive in the Relevant Period and until his sale were Ian and Rochelle Hengstberger.

(b) The Applicant entered into an agreement with the Hengstbergers by which she would take possession of Ervines Jive for two years and train him, after which time Ervines Jive would be sold and the Applicant would be entitled to half the sale proceeds as consideration.

A.2. Zoetis

4. Zoetis:

(a) on 26 March 2012, was incorporated in Australia under the name Pfizer Animal Health Australia Pty Ltd;

(b) on 11 February 2013, changed its entity name to Zoetis Australia Pty Ltd;

(c) is, and was from 26 March 2012:

(i) incorporated pursuant to the *Corporations Act 2001 (Cth)* and capable of being sued; and

(ii) a corporation within the meaning of the *Competition and Consumer Act 2010* (Cth); and

(d) at the material times, carried on the business of designing, manufacturing, distributing and marketing veterinary medicines and products in Australia.

B. THE "EQUIVAC HEV" VACCINE

B.1. Regulatory background

5. The Australian Pesticides and Veterinary Medicines Authority (**APVMA**) is a Commonwealth statutory authority established in 1993 to centralise the registration of all agricultural and veterinary chemical products into the Australian marketplace.

6. Subject to paragraph 7 below, "chemical products" within the meaning of s 5 of the Agricultural and Veterinary Chemicals Code (**AGVET Code**) (which include "veterinary chemical products") must be registered to be sold or used in Australia.

7. A "minor use permit" may be granted under Part 7 of the Code for the sale and use of unregistered chemical products where (relevantly) the APVMA is satisfied that the proposed use of the veterinary chemical product is a "minor use" within the meaning of r 3 of the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Cth) (**AGVET Code Regulations**).

B.2. Development and regulatory approval of Equivac HeV

8. In 1994, the Hendra virus (**HeV**) was first identified in horses at a racing stable in Hendra, Queensland.

9. In 2011, the Commonwealth Scientific and Industrial Research Organisation (**CSIRO**) developed a new vaccine against Hendra in horses.

10. From about 2012, Zoetis commenced production and testing of a vaccine against Hendra in horses (**Equivac HeV**).

Particulars

The Applicant does not know the precise date Zoetis commenced production and testing of Equivac HeV with her present state of knowledge. Further particulars may be provided following discovery.

11. In or about 2012, Zoetis applied to the APVMA for a minor use permit in respect of Equivac HeV as a veterinary chemical product within the meaning of s 5 of the AGVET Code.

Particulars

The Applicant does not know the precise date Zoetis applied to the APVMA for a minor use permit in respect of Equivac HeV with her present state of knowledge. Further particulars may be provided following discovery.

12. In the period from 10 August 2012 to 4 August 2015, Zoetis was granted the following minor use permits:

    (a) minor use permit number PER13510 in force from 10 August 2012 to 3 August 2014;

    (b) minor use permit number PER14876 in force from 4 August 2014 to 4 August 2015; and

    (c) minor use permit number PER14887 in force from 31 March 2015 to 4 August 2015,

    (together, **Permits**).

13. On 5 August 2015, Equivac HeV received full registration from the APVMA.

14. Zoetis produced and sold Equivac HeV:

    (a) under each of the respective periods of the Permits from 10 August 2012 until 4 August 2015; and

    (b) under its full registration from 5 August 2015 to the present.

15. The Permits required that Equivac HeV only be used by registered veterinary surgeons who were accredited through the completion of the Equivac HeV e-learning module provided by Zoetis (**Registration Module**).

C. ZOETIS DISCLOSURES AND PUBLICATIONS

C.1. Permit related publications

16. From on or about August 2012, Zoetis presented to each registered veterinary surgeons who undertook the Registration Module materials (**Registration Module Materials**), in which Zoetis stated:

    "Vaccine Safety Update

Analysis of the first 25,500 doses administered to horses have shown a low adverse reaction rate, with no serious or life threatening reactions involved.

... 0.22% adverse reaction rate to date

Approximately half of these reactions are site reactions that require little or no treatment. There have not been any serious or life threatening reactions."

Particulars

The Registration Module Materials were provided by Zoetis as part of the Registration Module (https://www.abc.net.au/news/rural/2015-01-29/concern-mounts-that-hendra-vaccine-has-health-risk-for-horses/6052344).

The Applicant does not know the full content or the precise date of publication of the Registration Materials with her present state of knowledge. Further particulars as to other statements made in the Registration Materials and the date of the publication may be provided following discovery.

17. In the Registration Module Materials, Zoetis further stated:

"Managing Equine Preventative Care

- *Ensure you keep vaccine in an esky in your car.*
    - *Every call is an opportunity to discuss the risk of Hendra virus. Carrying enough vaccine in your car for the visits you're making that day allows you to vaccinate during these calls, rather than need to make a separate visit.*
- *Utilise the resources Zoetis have available for you*
    - *Send a letter to your clients about the risk of Hendra.*
    - *Run an information night to educate your clients regarding Hendra.*
    - *Run a vaccination day to eliminate your travel costs and save time.*
    - *Run a newsletter article on the dangers of Hendra.*
    - *Send a press release to any local newspapers.*

All of these documents are available from vetsaustralia.com.au,"

(**Registration Module Materials Inducement**).

18. On 10 August 2012, Zoetis commenced distributing a leaflet in connection with permits PER13510 and PER14876 (**First and Second Permit Disclosures**) in which Zoetis stated with respect to side effects:

"Transient swelling may develop at the site of vaccination in some horses but should resolve within one week without treatment. In some horses transient post-vaccination reactions including injection site reaction, pain, increase in body temperature, lethargy, inappetance, and muscle stiffness have also been observed. Rarely reported symptoms have included urticaria, mild peripheral

oedema and mild transient colic. Symptoms may vary in severity and on some occasions may require veterinary intervention. Systemic allergic reactions such as anaphylaxis are thought to occur rarely with all vaccines and may require parenteral treatment with adrenaline, corticosteroid and antihistamine as appropriate and should be followed with appropriate supportive therapy".

19. On 31 March 2015, Zoetis commenced distributing a leaflet in connection with permit PER14887 (**Third Permit Disclosure**) in which Zoetis stated with respect to side effects:

"Transient swelling may develop at the site of vaccination in some horses but should resolve within one week without treatment.

In some horses transient post-vaccination reactions including injection site reaction, pain, increase in body temperature, lethargy, inappetence, and muscle stiffness have also been observed. Additional reported clinical signs have included urticaria, sweating, mild peripheral oedema and mild transient colic. Clinical signs may vary in severity and occasionally may require veterinary intervention.

Systemic allergic reactions such as anaphylaxis may require parenteral treatment with adrenaline, corticosteroid and antihistamine as appropriate and should be followed by appropriate supportive therapy".

C.2. Other publications

20. On 2 March 2013, Zoetis published a document entitled "Hendra Virus Fact Sheet" (**2013 Fact Sheet**) in which Zoetis stated:

(a) *"The virus occurs naturally in flying fox populations across most Australian states and territories, with the potential for the disease to appear wherever there are flying fox colonies"*; and

(b) *"How can horse owners and vets protect themselves and others from infection?*

In keeping with the Australian Veterinary Association's policy briefing on the Hendra virus horse vaccine (Equivac HeV), it is strongly recommended that all horses in Australia are vaccinated against Hendra virus to protect humans from its potentially fatal outcome."

Particulars

The 2013 Fact Sheet was published on 2 March 2013 and was distributed to the public online and provided to, or reported upon by, media organisations (e.g. https://www.northernstar.com.au/news/hendra-vaccine-released/1605868/)

21. On 2 March 2013, Zoetis issued a media release entitled "Statement from Zoetis" (**March 2013 Media Release**) in which Zoetis stated:

(a) *"the latest safety data shows that Equivac HeV has exceptionally low incidence of adverse events, with 0.2% of horses displaying minor events"*; and

(b) *"As such, Zoetis remains committed to making the vaccine available in Australia and to supporting veterinarians in their efforts to control Hendra virus. Zoetis also supports the Australian Veterinary Association's position that all horses in Australia should be vaccinated against Hendra to reduce equine and human infection."*

Particulars

The March 2013 Media Release was published on 2 March 2013 as a media release made available online at https://www.zoetis.com.au/_locale-assets/pdf_s/zoetis_equivac-statement_20mar2013.pdf.

22. On or about 2013, Zoetis published a pamphlet entitled "Vaccinate Before It's Too Late: MYTHBUSTING Hendra Vaccine" (**Mythbusting Pamphlet**), in which Zoetis stated:

(a) *"VACCINATE Before It's Too Late"*;

(b) *"MYTH: There's no risk of Hendra virus in my area*

Hendra virus has been found in all four mainland species of flying foxes in Australia. These bats are found in all mainland states and territories of the country, making exposure possible. For example, bats have tested positive to the Hendra Virus in Melbourne and more recently in South Australia, indicating exposure is possible.

There are many unknowns about how Hendra virus is contracted and bats can fly hundreds of kilometres in a few days meaning that an apparent absence of bats on a property does not eliminate risk"; and

(c) *"MYTH: The vaccine isn't safe*

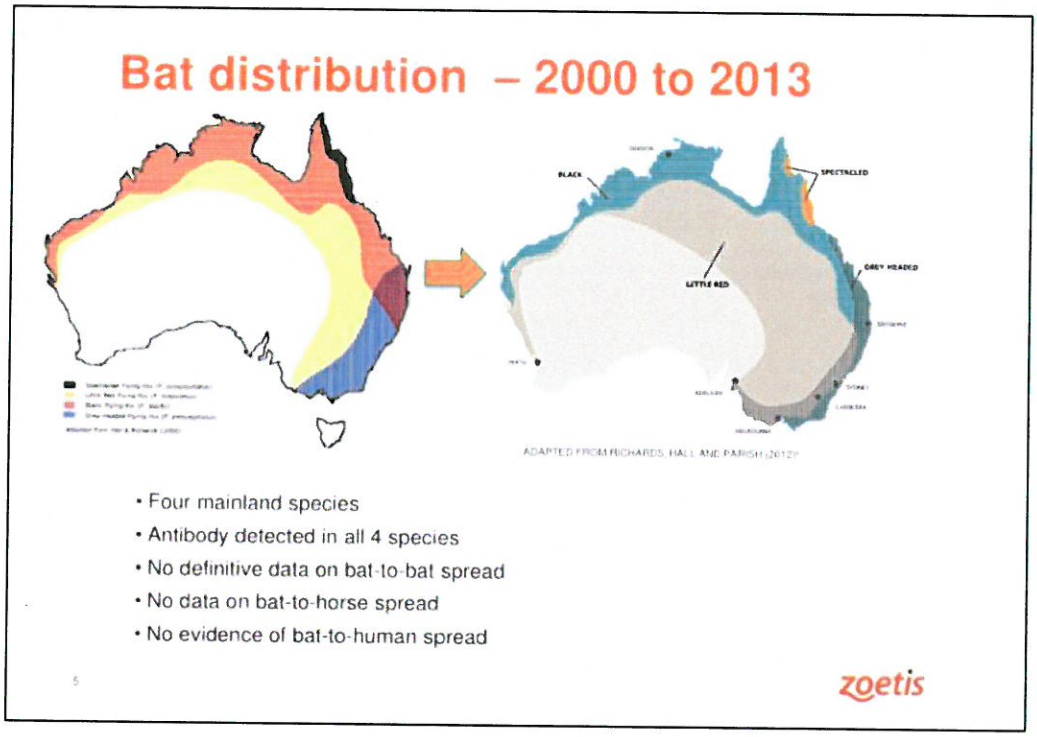
Data from the first 24,500 doses of the Hendra vaccine administered to horses resulted in only 58 reports from horse owners and veterinarians, with 53 horses categorised as having had a side-effect. The majority of these reports involved injection site swellings, which is not uncommon with any injection in a horse. The adverse event rate to date is approximately 0.22%, placing it in-line with the expected adverse event rate for most vaccines. None of the side-effects reported were serious, and all resolved."

Particulars

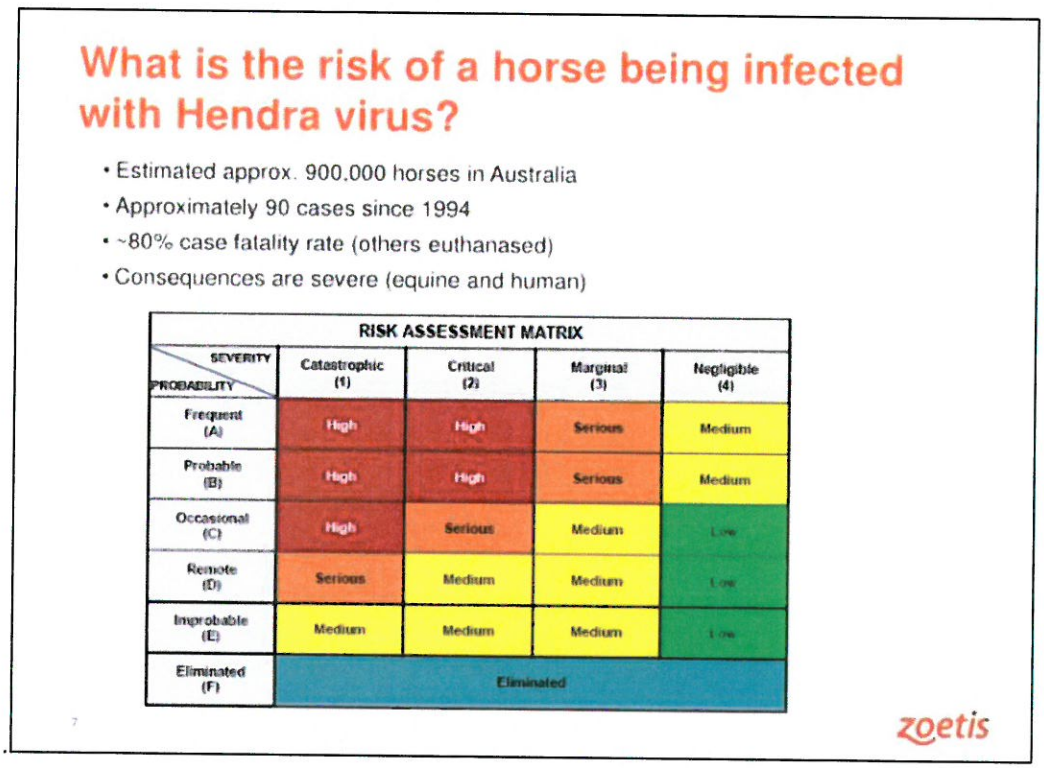
The Applicant does not know the precise date of publication of the Mythbusting Pamphlet with her present state of knowledge. Further particulars as to the date of the publication may be provided following discovery.

23. On or about September 2013, Zoetis presented a seminar and made publicly available slides entitled "Hendra virus and the Hendra virus vaccine" (**September 2013 Seminar**), in which Zoetis set out the following images with text:

(a)



(b)



Particulars

The Applicant does not know the precise date of publication of the September 2013 Seminar with her present state of knowledge. Further particulars as to the date of the publication may be provided following discovery.

24. On 3 September 2013, Zoetis made a submission to the Australian Competition and Consumer Commission entitled "N98410 – Equestrian Australia – Zoetis Australia submission" (**ACCC Letter**), in which Zoetis stated:

> *"It should be noted by the ACCC that the side effects of vaccination with Equivac HeV are minimal. Analysis of more than 380,000 doses administered shows that adverse events have been reported for less than 0.3% of doses administered. The majority of these symptoms are localised reactions such as pain or swelling at the site of the injection, as can be expected with any vaccine in animals or humans."*

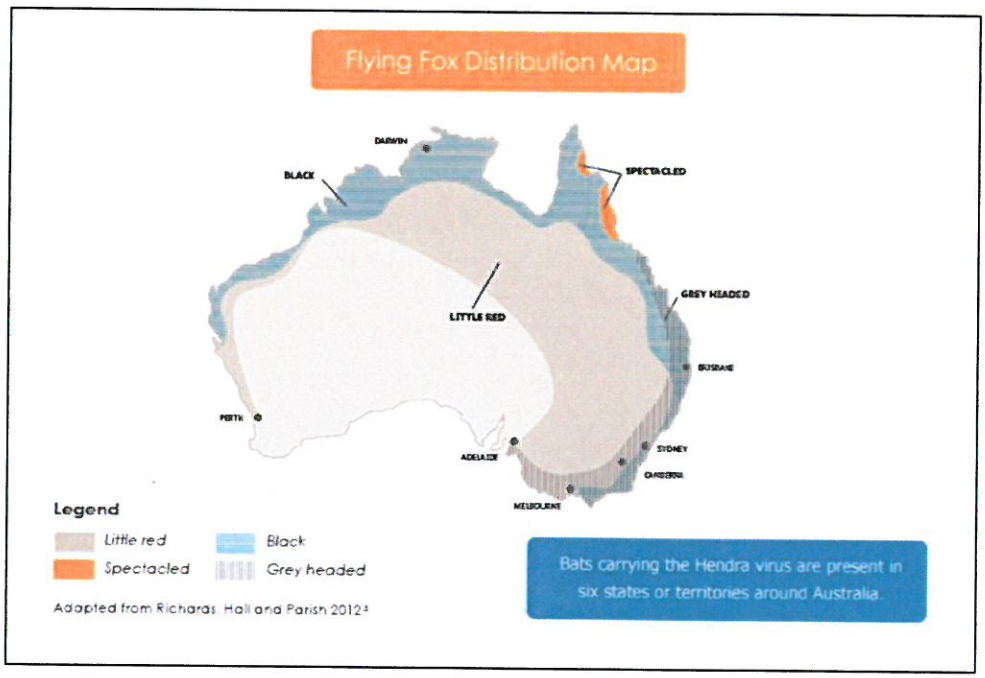
Particulars

The ACCC Letter was published on the ACCC's website.

25. On or about October 2013, Zoetis made available on the website Health4Horses a number of facts sheets in relation to HeV (**H4H Website Information**), in which Zoetis:

(a) *stated, "Widespread Risk … Hendra virus can occur wherever there is overlap of flying foxes and horses. Because of the large distances that flying foxes travel, Hendra virus outbreaks could occur across a large proportion of the country."*

(b) set out the following image and text immediately below the text set out in sub-paragraph (a) above:



(c) stated, "*Myth: There's no risk of Hendra virus in my area*

Hendra virus has been found in all four mainland species of flying foxes in Australia. These bats are found in all states and territories of the country, making

exposure possible. For example, bats have tested positive to the Hendra Virus in Melbourne and more recently in South Australia, indicating exposure is possible.

There are many unknowns about how Hendra is contracted and bats can fly hundreds of kilometres in a few days – meaning that an apparent absence of bats on a property does not eliminate risk"; and

(d) stated "*Myth: The vaccine isn't safe*

In doses administered to date, the adverse reaction rate is approximately 0.22%, placing it in-line with the expected adverse event rate for most vaccines. None of the side effects reported were serious, and all resolved. The majority of these reports involved injection site swellings, which is not uncommon with any injection in a horse."

Particulars

The H4H Website Information was published on or about October 2013 on the website www.health4horses.com.au.

The Applicant does not know the precise date of publication of the H4H Website Information with her present state of knowledge. Further particulars as to the date of the publication may be provided following discovery.

26. On or about December 2014, Zoetis released a pamphlet entitled "Facts About: The Hendra vaccine" (**Facts About HeV Pamphlet**), in which Zoetis stated:

(a) *When people get a vaccine from their doctor, it is expected that they will have a sore arm after the injection. Some horses may also respond with a mild injection site reaction after vaccination, and this is no reason for concern.*

With over 300,000 doses of Equivac HeV administered, reactions have only been reported for 0.28% of vaccinated horses, with the vast majority of these being injection site reactions, which resolve with little or no treatment.

Compare this with humans who get a vaccination: up to 80% of people who receive a tetanus vaccination will experience a minor reaction at the site of the injection.

The Hendra vaccine has not caused a single horse death.

While there have been rumours of this, they relate to horses that died of snake-bite, grain ingestion, twisted gut and other unrelated health issues"; and

(b) *"Facts About: The Hendra Vaccine*

- *Years of credible, Australian based research with the CSIRO*
- *Proven safety and immunity against the Hendra virus*
- *Most reactions are similar to those that people would expect when receiving a simple tetanus vaccine and are much less common*
- *Not one horse has died from administration of the Hendra vaccine*

• *The Hendra virus itself, not the vaccine, is a deadly threat to your horse*

• *Administering the Hendra vaccine offers peace of mind for the safety of your horse, family, friends and colleagues."*

Particulars

The Facts About HeV Pamplet was published on or about December 2014 on the website www.health4horses.com.au.

The Applicant does not know the precise date of publication of the Facts About HeV Pamplet with her present state of knowledge. Further particulars as to the date of the publication may be provided following discovery.

27. On or about 3 November 2013, Zoetis released a pamphlet entitled "Hendra Vaccination: What Every Horse Owner Needs to Know" (**Every Horse Owner Pamphlet**), in which Zoetis:

(a) stated,

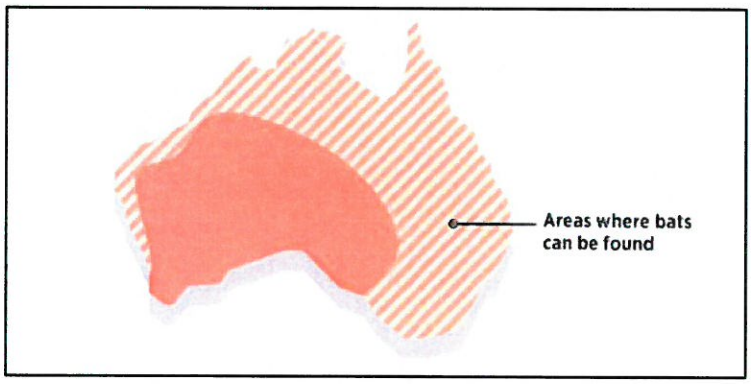
"*Spread of Hendra virus from fruit bats to horses is thought to occur via contamination of feed or water with fruit bat urine, faeces or bodily fluids.*

Fruit bats are found in every mainland state and territory in Australia, and bats containing either virus or evidence of viral exposure have now been detected in QLD, NSW. VIC, WA, NT and SA.

Hendra virus can be spread from horse to horse and from horse to humans through close contact with respiratory secretions and/or blood from an infected horse.

The movement of fruit bats may put horses at risk even if there are no fruit bats near a property"; and

(b) set out the following image and text immediately below the text set out in sub-



paragraph (b) above:

Particulars

The Every Horse Owner Pamphlet was published on 3 November 2013 as a printed and online booklet and distributed widely at seminars, in veterinary clinics, and to the general public.

28. On or about January 2016, Dr Richard L'Estrange, Veterinary Operations Manager for Zoetis, prepared for publication in Equestrian Life magazine an article entitled "Vaccine is safe and effective" (**Equestrian Life Article**), in which Dr L'Estrange stated:

(a) *"Veterinarians face a real threat to their health and now a legal threat to their livelihoods when diagnosing and treating unvaccinated horses. Veterinarians, of course, are not the only people with workplace health and safety obligations, which is why sporting bodies, event organisers and others often conclude that vaccination is an obvious, sensible precaution";*

(b) *"I have personally examined every adverse event report concerning the Hendra vaccine received by Zoetis. The majority are typical of the experiences many people have with human vaccines: temporary soreness or swelling around the injection site, sometimes a temperature, or being off colour for a day or so";*

(c) *"The vaccine is demonstrably safe and effective";*

(d) *"Everyone involved with horses in Australia is fortunate to have a safe, high quality vaccine to help protect against a deadly virus"*

Particulars

The Equestrian Life Article was published on or about January 2016 in issue 27 of Equestrian Life.

D. ZOETIS REPRESENTATIONS

D.1. Persons to whom representations made

29. Throughout the Relevant Period, Zoetis made the following public announcements and released the following publications:

(a) Registration Module Materials (paragraph 17);

(b) First and Second Permit Disclosures (paragraph 18);

(c) Third Permit Disclosure (paragraph 19);

(d) 2013 Fact Sheet (paragraph 20);

(e) March 2013 Media Release (paragraph 21);

(f) Mythbusting Pamphlet (paragraph 22);

(g) September 2013 Seminar (paragraph 23);

(h) ACCC Letter (paragraph 24);

(i) H4H Website Information (paragraph 25);

(j) Facts About HeV Pamphlet (paragraph 26);

(k) Every Horse Owner Pamphlet (paragraph 27); and

(l) Equestrian Life Article (paragraph 28); (particulars (a) to (l), the **Publications**).

in a manner which was likely to result in their publication to a class of persons comprising:

I. registered veterinary surgeons;

II. horse owners in Australia; and

III. equine organisations, veterinary bodies, governmental agencies, providers of equine services, and employers of persons requiring a horse to perform their employment (particulars (I) to (III), the **Class**).

30. Zoetis published the Publications in circumstances where:

(a) it was the manufacturer of Equivac HeV within the meaning s 7(1)(b) and or (c) of Schedule 2 of the *Competition and Consumer Act 2010 (Cth)* (**ACL**);

Particulars

(a) Zoetis caused its its name to be applied to the packaging of Equivac HeV.

(b) In the ACCC Letter, Zoetis stated "Zoetis is a leading animal health company and develops, manufactures and markets veterinary vaccines and medicines. It is also the developer, manufacturer and supplier of the Hendra virus horse vaccine, Equivac® HeV"

(b) it was required to accredit registered veterinary surgeons who wished to acquire and/or administer Equivac HeV;

(c) the supply of Equivac HeV to consumers was subject to certain of the guarantees in Part 3.2 Division 1 of Schedule 2 of the ACL including the guarantee of acceptable quality under s 54;

(d) the manufacture, sale and distribution of Equivac HeV was regulated by, inter alia, the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Cth), the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth), the AGVET Code, the *Agricultural and Veterinary Chemicals Act 1994* (Cth) and the AGVET Code Regulations; and

(e) the dissemination of misleading or deceptive information in connection with Equivac HeV by Zoetis was contrary to s 18 of the ACL.

D.2. Geographic spread of HeV

31. From 2 March 2013 and throughout the Relevant Period, Zoetis represented to the Class that there was a serious risk of horses contracting Hendra in all areas of Australia in which flying foxes were present (**Geographic Spread Representation**).

Particulars

The representation was contained, separately and together, in:

(a) the 2013 Fact Sheet;

(b) the March 2013 Media Release;

(c) the Mythbusting Pamphlet;

(d) the September 2013 Seminar;

(e) the H4H Website Information; and

(f) the Every Horse Owner Pamphlet

D.3. Side effects of Equivac HeV

32. From 10 August 2012 and throughout the Relevant Period, Zoetis represented to the Class that Equivac HeV had no serious side effects (**No Serious Side Effects Representation**).

Particulars

The representation was contained, separately and together, in:

(a) the First and Second Permit Disclosures;

(b) the Registration Module Materials;

(d) the Third Permit Disclosure;

(c) the Mythbusting Pamphlet;

(e) the ACCC Letter;

(f) the H4H Website Information;

(g) the Facts About HeV Pamphlet; and

(h) the Equestrian Life Article.

D.4. Prudent to use Equivac HeV for all horses

33. From 2 March 2013 and throughout the Relevant Period, Zoetis represented to the Class that all horses in Australia should be treated with Equivac HeV (**All Horses Representation**).

Particulars

(a) The representation was made expressly in the 2013 Fact Sheet and March 2013 Media Release.

(b) Further to (a), the representation was contained in the Registration Module Materials and Equestrian Life Article.

D.5. Continuing conduct

34. Each of:

(a) the information contained in the Publications;

(b) the Geographic Spread Representation;

(c) the No Serious Side Effects Representation; and

(d) the All Horses Representation,

continued to be disseminated from the time of their first dissemination or publication to the end of the Relevant Period.

Particulars

The continuing nature of the dissemination of the information in subparagraphs (a) to (e) arises from:

(a) the publicly available nature of the Publications; and

(b) the omission by Zoetis to modify, qualify or contradict any of that information at any time.

E. THE TRUE POSITION

E.1. Infectivity of HeV between flying foxes and horses

35. Flying foxes (*Pteropus* spp.) are the natural reservoir for Hendra in Australia, in that Hendra or antibodies indicating past infection have been detected in each of the four mainland species:

    (a) black (*P. alecto*);

    (b) spectacled flying foxes (*P. conspicillatus*);

    (c) grey-headed (*P. poliocephalus*); and

    (d) little red (*P. scapulatus*).

36. Hendra is capable of passing from an infected flying fox to a horse by means that current scientific research suggests occurs via contamination of feed or water with the urine, faeces or bodily fluids of infected fruit bats.

Particulars

(a) Williamson et al, "Transmission studies of Hendra virus (equine morbillivirus) in fruit bats, horse and cats" 76 Aus Vet J 12 pp 812-818 (1998).

(b) Marsh et al, "Experimental Infection of Horses with Hendra Virus / Australia / Horse / 2008 / Redlands" 17 Emerging Infectious Diseases Journal 12 (2011).

(c) Hendra Virus: CDNA National Guidelines for Public Health Units (19 Jan 2012).

Further particulars as to paragraph 36 will be provided on service of the Applicant's expert evidence.

37. HeV has a low level of infectivity between infected flying foxes and horses.

Particulars

The Applicant repeats the particulars to paragraph 36.

Further particulars as to paragraph 37 will be provided on service of the applicant's expert evidence.

38. At the material times, there were approximately 900,000 domesticated horses in Australia.

Particulars

September 2013 Seminar (paragraph 23(b) above).

39. Between 1994 and 2011, there were:

(a) 23 incidents of Hendra in horses in Queensland affecting a total of 55 horses;

(b) 9 incidents of Hendra in horses in NSW affecting a total of 11 horses; and

(c) no other incidents of Hendra in horses in other parts of Australia.

Particulars

Hendra Virus: CDNA National Guidelines for Public Health Units (19 Jan 2012), Table: Summary of Hendra virus infection events with numbers of equine cases, and human cases and deaths, 1994-2011 (to October 2011), p 17.

40. As a result of the matters in paragraphs 35 to 39, at the material times the risk of a horse becoming infected with Hendra in:

(a) those parts of Queensland and NSW in the vicinity of the incidents identified in paragraph 39 was and is low; and

(b) in those parts of Australia where fruit bats are present outside the vicinity of the areas identified in paragraph (a) was and is extremely low.

Particulars

Further particulars will be provided on service of the applicant's expert evidence.

E.2. Infectivity of HeV between horses and humans

41. Hendra is capable of passing from a horse to a human via the bodily fluid of an infected horse or a horse that had died of an Hendra infection.

Particulars

(a) Selvey et al, "Infection of humans and horses by a newly described morbillivirus" 162 Med J Aus 12 pp 642-5 (1995).

(b) Playford et al, "Human Hendra virus encephalitis associated with equine outbreak, Australia, 2008" 16 Emerging Infectious Diseases Journal pp 219–23 (2010).

(c) Hendra Virus: CDNA National Guidelines for Public Health Units (19 Jan 2012).

Further particulars as to paragraph 41 will be provided on service of the Applicant's expert evidence.

42. Hendra has a low level of infectivity between infected horses and humans.

Particulars

The applicant repeats the particulars to paragraph 41.

Further particulars as to paragraph 42 will be provided on service of the applicant's expert evidence.

43. Between 1994 and 2008, 5 equine Hendra incidents have extended to humans, in which a total of 7 individuals were infected with Hendra.

Particulars

Marsh et al, "Experimental Infection of Horses with Hendra Virus / Australia / Horse / 2008 / Redlands" 17 Emerging Infectious Diseases Journal 12 (2011).

44. There has been no reported case of Hendra being transferred from horses to humans:

(a) other than by being exposed to the bodily fluid of an infected horse; or

(b) when exposed to the bodily fluid of an infected horse but appropriately using personal protective equipment.

Particulars

"Only seven human cases have been documented (as of September 2011). All seven had a high level of exposure to respiratory secretions and/or other body fluids of horses subsequently diagnosed with Hendra virus infection, or presumed to have Hendra virus infection through review of clinical/epidemiological evidence in the absence of samples for laboratory testing." (Hendra Virus: CDNA National Guidelines for Public Health Units… No cases have been documented in people with medium or lower exposure levels, including anyone appropriately using personal protective equipment, and not all people with high exposures have become infected." (19 Jan 2012), p 3).

45. As a result of the matters in paragraphs 41 to 44, at the material times the risk of a person becoming infected with Hendra as a result of interacting with an horse infected with Hendra was low.

Particulars

Further particulars to paragraph 45 will be provided on service of the Applicant's expert evidence.

E.3. Side effects of Equivac HeV

46. The side effects of Equivac HeV were not limited to site reactions and minor side effects but included serious and potentially debilitating adverse reactions (whether as a result of one side effect or more than one side effect acting in combination).

Particulars

The side effects associated with the administration of Equivac HeV to horses are set out at Appendix A to this Second Further Amended Statement of Claim and are those recorded by the APVMA as probable and possible conditions in horses associated with the administration of Equivac HeV during the Relevant Period in the document "Summary of Adverse Experience Reports made to the APVMA about Hendra Virus Vaccine" published 31 August 2017 and available on the APVMA's website.

Further particulars as to paragraph 46 will be provided on service of the applicant's expert evidence.

E.4. Decisions to use Equivac HeV

47. As a result of the matters in paragraphs 35 to 46 above, the following matters were relevant to any person seeking to make a properly informed decision to administer Equivac HeV or to consent to its administration to a horse:

(a) the low risk of infection of horses outside specific areas of Australia;

(b) the low infectivity of Hendra between horses and humans; and

(c) the serious potential side effects of Equivac HeV.

F. MISLEADING AND DECEPTIVE CONDUCT

F.1. Geographic Spread Representation Contravention

48. By making the Geographic Spread Representation (see paragraph 31), Zoetis engaged in conduct in trade or commerce within the meaning of s 18 of the ACL.

49. The Geographic Spread Representation was misleading or deceptive, or likely to mislead or deceive within the meaning of s 18 of the ACL.

Particulars

By reason of the matters pleaded in paragraph 40, there was not a serious risk of horses contracting Hendra in all areas of Australia in which flying foxes were present.

50. By reason of the matters pleaded in paragraphs 48 and 49, during the Relevant Period, Zoetis engaged in conduct which was misleading or deceptive, or likely to mislead or deceive, in contravention of s 18 of the ACL (**Geographic Spread Representation Contravention**).

~~**F.2. Geographic Spread Statements Contravention**~~

~~51. Further and in the alternative to paragraphs 48 to 50 above, by publishing the Publications particularised in paragraph 31 above separately and/or together (**Geographic Spread Statements**), Zoetis engaged in conduct:~~

~~(a) in trade or commerce, within the meaning of s 18 of the ACL;~~

~~(b) that, from 2 March 2013 and throughout the Relevant Period was misleading or deceptive, or likely to mislead or deceive, in contravention of s 18 of the ACL,~~

~~(**Geographic Spread Statements Contravention**).~~

~~**Particulars**~~

~~*By reason of the matters pleaded in paragraph 40, there was not a serious risk of horses contracting HeV in all areas of Australia in which flying foxes were present.*~~

F.3. No Serious Side Effects Representation Contravention

52. By making the No Serious Side Effects Representation (paragraph 32), Zoetis engaged in conduct in the Relevant Period in trade or commerce within the meaning of s 18 of the ACL.

53. The No Serious Side Effects Representation was misleading or deceptive, or likely to mislead or deceive within the meaning of s 18 of the ACL.

Particulars

By reason of the matters pleaded in paragraph 46, there was a real and material risk of horses experiencing serious side effects as a result of the administration of Equivac HeV.

54. By reason of the matters pleaded in paragraphs 52 and 53, during the Relevant Period, Zoetis engaged in conduct which was misleading or deceptive, or likely to mislead or deceive, in contravention of s 18 of the ACL (**No Serious Side Effects Representation Contravention**).

~~**F.4. No Serious Side Effects Statements Contravention**~~

~~55. Further and in the alternative to paragraphs 52 to 54 above, by the Publications particularised to paragraph 32 above separately and/or together (**No Serious Side Effects Statements**), Zoetis engaged in conduct:~~

~~(a) in trade or commerce, within the meaning of s 18 of the ACL;~~

~~(b) that throughout the Relevant Period was misleading or deceptive, or likely to mislead or deceive, in contravention of s 18 of the ACL,~~

~~(**No Serious Side Effects Statements Contravention**).~~

~~**Particulars**~~

~~*By reason of the matters pleaded in paragraph 46, there was a material risk of horses experiencing serious side effects as a result of the administration of Equivac HeV.*~~

F.5. All Horses Representation Contravention

56. By making the All Horses Representation (paragraph 33), Zoetis engaged in conduct from 2 March 2013 and throughout the Relevant Period in trade or commerce within the meaning of s 18 of the ACL.

57. The All Horses Representation Contravention was misleading or deceptive, or likely to mislead or deceive within the meaning of s 18 of the ACL.

Particulars

By reason of the matters pleaded in paragraph 40, 45, 46, and/or 47 it was not prudent and/or necessary for all horses in Australia to be vaccinated having regard to:

(a) the low risk of infection of horses outside specific areas of Australia;

(b) the low infectivity of Hendra between horses and humans; and

(c) the serious potential side effects of Equivac HeV.

58. By reason of the matters pleaded in paragraphs 56 and 57, during the Relevant Period, Zoetis engaged in conduct which was misleading or deceptive, or likely to mislead or deceive, in contravention of s 18 of the ACL (**All Horses Representation Contravention**).

~~**F.6. All Horses Statements Contravention**~~

~~59. Further and in the alternative to paragraphs 56 to 58 above, by the Publications particularised to paragraph 33 above separately and/or together (**All Horses Statements**), Zoetis engaged in conduct:~~

~~(a) in trade or commerce, within the meaning of s 18 of the ACL;~~

~~(b) that throughout the Relevant Period was misleading or deceptive, or likely to mislead or deceive, in contravention of s 18 of the ACL,~~

~~(**All Horses Statements Contravention**).~~

~~**Particulars**~~

~~*By reason of the matters pleaded in paragraph 40, 45, 46, and/or 47 it was not prudent and/or necessary for all horses in Australia to be vaccinated having regard to*~~

~~*(a) the low risk of infection of horses outside specific areas of Australia;*~~

~~*(b) the low infectivity of Hendra between horses and humans; and*~~

~~*(c) the serious potential side effects of Equivac HeV.*~~

G. CONSUMER GUARANTEE CONTRAVENTION

60. In the Relevant Period, Zoetis supplied Equivac HeV to consumers in trade or commerce within the meaning of s 18 of the ACL.

61. From 10 August 2012 and throughout the Relevant Period, by operation of s 54(1) of the ACL, Zoetis guaranteed to consumers within the meaning of the ACL that Equivac HeV was of acceptable quality within the meaning of sub-s 54(2) (**Acceptable Quality Guarantee**).

62. Registered veterinary surgeons who acquired Equivac HeV from Zoetis during the Relevant Period were consumers of Equivac HeV within the meaning of s 3 of the ACL.

Particulars

The Applicant relies upon the statutory presumption in s 3(10) of the ACL.

63. By reason of the matters pleaded in paragraph 46, Equivac HeV was not of acceptable quality within the meaning of sub-s 54(2) of the ACL.

64. By reason of the matters pleaded in paragraphs 62 and 63, during the Relevant Period Zoetis breached the Acceptable Quality Guarantee in connection with its supply of Equivac HeV to registered veterinary surgeons (**Consumer Guarantee Contravention**).

H. CAUSATION, LOSS AND DAMAGE

H.1. Applicant

65. In or about July 2014, the Applicant was informed by Meg Wippell, the Livestock Manager of JBS, that JBS required all horses on JBS sites to be vaccinated with Equivac HeV.

66. On 29 July 2014, Dr. Lisa Goodchild, a registered veterinary surgeon, administered to Primetime and Ervines Jive at Quirindi Veterinary Clinic:

(a) the first treatment of Equivac HeV; and

(b) a vaccine for strangles and tetanus.

67. On 20 August 2014, Dr. David Frith, a registered veterinary surgeon, attended JBS to administer or cause to be administered to Primetime and Ervines Jive:

(a) the second treatment of Equivac HeV;

(b) a vaccine for strangles and tetanus.

68. Prior to each of the above treatments, both Primetime and Ervines showed no signs of ill-health.

69. In her decision to consent to the treatment of her horses with Equivac HeV, the Applicant:

(a) relied on~~, alone and/or in combination:~~

~~(i)~~ the No Serious Side Effects Representation (paragraph 32~~); and/or~~

~~(ii) the No Serious Side Effects Statements (paragraph 55);~~

(b) would not have caused or allowed her horse or horses to be treated with Equivac HeV had she had known some or all of the information pleaded and particularised in paragraph 46 above.

Particulars

(a) It may be inferred by reason of the matters in paragraphs 15, 29, 30 and 65 to 67 that JBS, Dr Goodchild and Dr Frith were aware of the Contravening Representations ~~and Statements~~ above and reasonably placed reliance upon some or all of them.

(b) In connection with its requirement that the Applicant's horses be treated with Equivac HeV, JBS repeated to the Applicant~~:~~

(i) the No Serious Side Effects Representation~~; and/or~~

~~(ii) the No Serious Side Effects Statements.~~

(c) Prior to each administration of Equivac HeV, each of Dr Goodchild and Dr Frith repeated to the Applicant:

(i) the No Serious Side Effects Representation~~; and/or~~

~~(ii) the No Serious Side Effects Statements.~~

(d) Each of JBS, Dr Goodchild, and/or Dr Frith repeated the representations and statements identified in particulars (b) and (c) to the Applicant by reason of Zoetis making the Contravening Representations ~~and Statements~~ and particular (a).

(e) The Applicant would not have had her horses treated with Equivac HeV if the representations ~~and statements~~ identified in particulars (b) and (c) had not been made to her.

70. Further, and in the alternative to paragraph 69, but for the:

(a) the Geographic Spread Representation (paragraph 31);

~~(b) the Geographic Spread Statements (paragraph 51);~~

(c) the No Serious Side Effects Representation (paragraph 32);

~~(d) the No Serious Side Effects Statements (paragraph 55);~~

(e) the All Horses Representation (paragraph 33)~~; and~~

~~(f) the All Horses Statements (paragraph 59),~~

(together, the **Contravening Representations ~~and Statements~~**) the horses of the Applicant would not have been treated with Equivac HeV.

Particulars

(a) It may be inferred by reason of the matters in paragraphs 15, 29, 30 and 65 to 67 that JBS, Dr Goodchild and Dr Frith were aware of the Contravening Representations ~~and Statements~~ above and reasonably placed reliance upon some or all of them in considering the treatment of the Applicant's horses with Equivac HeV.

(b) The making by Zoetis of the Contravening Representations ~~and Statements~~ (alone or in combination) induced and/or materially contributed to the decision of JBS to or require treatment of the Applicant's horses with Equivac HeV as a condition of employment.

(c) Further, making by Zoetis of the Contravening Representations ~~and Statements~~ (alone or in combination) induced and/or materially contributed to the decision Dr Goodchild and Dr Frith to recommend and/or provide the treatment of the Applicant's horses with Equivac HeV.

(d) As a result of particulars (b) and/or (c), the Applicant consented to the treatment of her horses with Equivac HeV and the horses were treated with the vaccine.

71. From 21 August 2014, Primetime and Ervines Jive developed serious adverse reactions to the Equivac HeV treatment.

Particulars

(a) On 21 August 2014 the Applicant observed that neither Primetime nor Ervines Jive ate their previous nights' meal. The Applicant further noted that both horses were suffering from runny stools and injection site swellings.

(b) On or about 1 September 2014 the Applicant observed that Ervines Jive had suffered a localised Alopecia lump at the site of the injection and suffered pain, pale mucous membranes and stiffness and these symptoms persisted into September 2014.

(c) On or about 1 September 2014 the Applicant observed that Primetime had suffered an injection site reaction, oedema, pain and Pyrexia and became depressed and touch sensitive after the administration of the HeV injection. She experienced swelling in her joints and over kidneys, pale or white gums, rapid breathing, weight loss, disorientation and was stiff in her movements. As a result of this, Primetime required four months of veterinary care.

H.2. Reliance – Group Members

72. In their decision to treat their horse or horses, or consent to the treatment of their horse or horses, with Equivac HeV, some Group Members:

(a) relied on, alone and/or in combination the Contravening Representations ~~and Statements~~; and

(b) would not have caused or allowed their horse or horses to be treated with Equivac HeV had they had known some or all of the information pleaded and particularised in in paragraphs 35 to 47 above.

Particulars

The identity of all those Group Members which or who relied directly on any or all of the Contravening Representations ~~and Statements~~ is not within the current state of the applicant's knowledge and cannot be ascertained unless

and until those advising the applicant take detailed instructions from all Group Members on individual issues relevant to the determination of those individual Group Member's claims; those instructions will be obtained (and particulars of the identity of those Group Members will be provided) following opt out, the determination of the Applicant's claim and identified common issues at an initial trial and if and when it is necessary for a determination to be made of the individual claims of those Group Members.

73. Further or in the alternative to paragraph 72, during the Relevant Period:

(a) the Contravening Representations ~~and Statements~~ (and each of them) materially contributed to the decision of some of the Group Members to treat their horse or horses or consent to the treatment of their horse or horses, with Equivac HeV; and

(b) those Group Members would not have caused or allowed their horse or horses to be treated with Equivac HeV had they had known some or all of the information pleaded and particularised in paragraphs 35 to 47 above.

Particulars

(a) It may be inferred by reason of the matters in paragraphs 15, 29 and 30 that registered veterinary surgeons, equine organisations, veterinary bodies, governmental agencies, and employers of persons requiring a horse to perform their employment were aware of the Contravening Representations ~~and Statements~~ and reasonably placed reliance upon some or all of them in considering the treatment of horses with Equivac HeV.

(b) The making by Zoetis of the Contravening Representations ~~and Statements~~ and each of them induced registered veterinary surgeons, equine organisations, veterinary bodies, governmental agencies, and/or employers of persons requiring a horse to perform their employment to repeat all or some of the Contravening Representations ~~and Statements~~ to some of the Group Members.

(c) Further, by the Registration Module Materials Inducement, registered veterinary surgeons were induced by Zoetis to repeat all or some of the Contravening Representations ~~and Statements~~ to some of the Group Members.

(d) The decision or consent of those Group Members pleaded in paragraph 73 to treat their horse or horses with Equivav HeV was materially contributed to by their reliance upon the matters in particulars (b) and/or (c) above.

(e) The identity of all those Group Members identified in paragraph 73 is not within the current state of the applicant's knowledge. Further particulars of individual Group Member claims will be provided, if necessary after the initial trial of common issues.

H.3. Indirect causation – Group Members

74. Further, and in the alternative to paragraphs 72 and 73, but for the Contravening Representations ~~and Statements~~ (alone or in combination) the horses of some Group Members would not have been treated with Equivac HeV.

Particulars

(a) *It may be inferred by reason of the matters in paragraphs 15, 29 and 30 that registered veterinary surgeons, equine organisations, veterinary bodies, governmental agencies, and employers of persons requiring a horse to perform their employment were aware of the Contravening Representations ~~and Statements~~ and reasonably placed reliance upon some or all of them in considering the treatment of horses with Equivac HeV.*

(b) *The making by Zoetis of the Contravening Representations ~~and Statements~~ (alone or in combination) induced and/or materially contributed to the decision of registered veterinary surgeons, equine organisations, veterinary bodies, governmental agencies, and employers of persons requiring a horse to perform their employment to recommend or require treatment of some of the Group Member horses with Equivac HeV.*

(c) *Further, by the Registration Module Materials Inducement, registered veterinary surgeons were induced by Zoetis to encourage some Group Members to accept treatment of their horse or horses by Equivac HeV.*

(d) *As a result of the Contravening Representations ~~and Statements~~ (alone or in combination), some Group Members were required to vaccinate their horses as a condition of employment, membership of equine clubs, participation in equestrian events or competitions, or of the supply of equine services.*

(e) *The consent or decision of some Group Members to treat their horse or horses with Equivac HeV was a result of their reliance upon the advice, recommendation or decision as the case may be of the entities identified in particulars (a), (b) and/or (c) above, which advice, recommendation or decision was induced by the Contravening Representations ~~and Statements~~ and/or Registration Module Materials Inducement.*

(f) *The identity of all those Group Members identified in paragraph 74 is not within the current state of the applicant's knowledge. Further particulars of individual Group Member claims will be provided, if necessary after the initial trial of common issues.*

H.4. Loss and damage

75. As a result of the Contravening Representations ~~and Statements~~, the Applicant suffered loss and damage.

Particulars

(a) Neither Primetime nor Ervines Jive fully recovered from the effects of the Equivac HeV treatments.

(b) As a result of the effects of the injections of Equivac HeV, both Primetime and Ervines Jive lost significant value.

(c) Prior to the injection, Primetime had a value of approximately $30,000. Since the injection and subsequent reaction, Primetime cannot be sold.

(d) Prior to the injection, Ervines Jive had a value of approximately $25,000. Since the injection and subsequent reaction, Ervines Jive was sold for $17,000 which reflected its then market value and the Applicant's share in the sale proceeds was accordingly reduced.

(e) In treating Primetime and Ervines Jive, the Applicant incurred costs of $2,286.36.

(f) The Applicant was directed to allow but refused to have any further injections administered to her horses and as a result her employment was terminated on 20 March 2015.

(g) By reason of particular (f), the Applicant suffered a loss of income from employment from 20 March 2015 to 19 September 2016 being an amount of $43,389.

76. As a result of:

(a) the Contravening Representations ~~and Statements~~; and, or in the alternative

(b) the Consumer Guarantee Contravention,

the Group Members suffered loss and damage.

Particulars

To the extent it is within the Applicant's knowledge, the loss suffered by the Group Members will be calculated by reference to:

(a) the loss in value or any horse or horses damaged by the administration of Equivac HeV;

(b) the cost of administering Equivac HeV and associated veterinary expenses; or

(c) the cost of treating any horse or horses which experienced a serious adverse reaction to Equivac HeV;

(d) the replacement costs of any horse or horses damaged by the administration of Equivac HeV; and/or

(e) loss of income as a result of damage to a horse or horses damaged by the administration of Equivac HeV;

(f) loss of opportunity as a result of damage to a horse or horses damaged by the administration of Equivac HeV; and/or

(g) consequential economic loss or damage as a result of a horse or horses being damaged by the administration of Equivac HeV.

Further particulars will be provided following the determination of the Applicants' claim and identified common issues at an initial trial and if and when it is necessary for a determination to be made of the individual claims of those Group Members.

77. Further to paragraph 76, as a result of:

(a) the Contravening Representations ~~and Statements~~; and, or in the alternative

(b) the Consumer Guarantee Contravention,

some of the Group Members suffered a personal injury, being an injury within the meaning of s 13 of the ACL.

Particulars

Further particulars as to the personal injury suffered by some of the Group Members will be provided following the determination of the Applicants' claim and identified common issues at an initial trial and if and when it is necessary for a determination to be made of the individual claims of those Group Members.

H.5. Entitlement to relief

78. By reason of the matters pleaded in paragraphs 65 to 77 above, the Applicant may recover the amount of the loss and damage suffered by her from Zoetis pursuant to s 236 of the ACL.

79. By reason of the matters pleaded in paragraphs 30(a) and 60 to 77 above, each of the Group Members may recover the amount of the loss and damage, or compensation in respect of the personal injury, suffered by them from Zoetis pursuant to:

(a) s 236 of the ACL; and, or alternatively,

(b) ss 271 and 272 of the ACL.

Date: 17 September 2019

Signed by Matthew Berenger

Solicitor on behalf of the Applicant

This pleading was prepared by Guy Donnellan and Alexander H Edwards

CERTIFICATE OF LAWYER

I Matthew Berenger certify to the Court that, in relation to the statement of claim filed on behalf of the Applicant, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 17 September 2019

Signed by Matthew Berenger

Lawyer for the Applicant

APPENDIX A
SIDE EFFECTS

Abdominal pain

Abnormal breathing

Abortion

Adipsia

Aggression

Agitation

Allergy

Alopecia (general)

Alopecia (localised)

Anaphylaxis

Anorexia

Anuria

Ataxia

Atrophy

Azoturia

Behavioural change

Bradycardia

Coat colour change

Coat discoloration

Colic

Colitis

Confusion

Conjunctivitis

Constipation

Coughing

Death

Depression

Dermatitis

Diarrhoea

Disorientation

Distress

Dyspnoea

Eczema

Epistaxis

Facial oedema

Fasciculation

Haematoma

Hepatopathy

Hives

Hyperactivity

Hyperaesthesia

Hypersalivation

Hypersensitive to stimuli

Hypersensitivity reaction

Incoordination

Inflammation

Injection site reaction

Lame

Laminitis

Laryngitis

Lesions

Lethargy

Listless

Lump (local)

Lymphadenitis

Lymphadenopathy

Malaise

Muscle stiffness

Nasal discharge

Oedema

Pain

Pale mucous membranes

Panting

Paresis

Periorbital swelling

Polydipsia

Polymyositis

Preputial swelling

Pruritis

Pyrexia

Rash

Recumbency

Respiratory problems

Restlessness

Scrotitis

Shaking

Site reaction (swelling)

Stiffness

Stranguria

Sweating

Tachycardia

Tachypnoea

Tremor

Urticaria

Walking (difficult)

Weakness

Weight loss

Welts