

NOTICE OF FILING

This document was lodged electronically in the FEDERAL COURT OF AUSTRALIA (FCA) on 11/10/2019 8:54:52 AM AEDT and has been accepted for filing under the Court's Rules. Details of filing follow and important additional information about these are set out below.

Details of Filing

Document Lodged: Defence - Form 33 - Rule 16.32
File Number: NSD406/2018
File Title: RACHAEL ABBOTT v ZOETIS AUSTRALIA PTY LTD
Registry: NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA



A handwritten signature in blue ink that reads 'Warwick Soden'.

Dated: 11/10/2019 8:54:57 AM AEDT

Registrar

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.

The date and time of lodgment also shown above are the date and time that the document was received by the Court. Under the Court's Rules the date of filing of the document is the day it was lodged (if that is a business day for the Registry which accepts it and the document was received by 4.30 pm local time at that Registry) or otherwise the next working day for that Registry.



Defence to the Second Further Amended Statement of Claim

No. NSD 406 of 2018

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

Rachael Abbott

Applicant

Zoetis Australia Pty Ltd (ACN 156 476 425)

Respondent

In response to the Second Further Amended Statement of Claim filed on 18 September~~4 June~~ 2019 (SFASOC), the Respondent (**Zoetis**) pleads as follows:

1. Zoetis does not plead in response to paragraph 1 which makes no allegation of fact.
2. Zoetis does not know and therefore cannot admit the matters alleged in paragraph 2.
3. Zoetis does not know and therefore cannot admit the matters alleged in paragraph 3.
4. Zoetis:
 - a. admits the matters alleged in paragraph 4(a)-(c); ~~and~~
 - b. says that at the material times, it carried on the business of distributing and marketing veterinary medicines and products in Australia;
 - c. says that at the material times, Zoetis Australia Research & Manufacturing Pty Limited carried on the business of designing and manufacturing veterinary medicines and products in Australia; and
 - d. otherwise denies the matters alleged in paragraph 4(d).
5. Zoetis admits the matters alleged in paragraph 5.

Filed on behalf of (name & role of party)	Zoetis Australia Pty Ltd, Respondent		
Prepared by (name of person/lawyer)	Anne Freeman		
Law firm (if applicable)	Piper Alderman		
Tel	+61 2 9253 9999	Fax	+61 9253 9900
Email	afreeman@piperalderman.com.au		
Address for service (include state and postcode)	Level 23, Governor Macquarie Tower, 1 Farrer Place, Sydney NSW 2000 DX 10216 Sydney Stock Exchange		

6. Zoetis:
 - a. says that there are three kinds of permits, namely emergency permits, research permits and minor use permits, which allow the sale or use of chemical products within the meaning of section 5 of the Agricultural and Veterinary Chemicals Code (**Agvet Code**) without registration; and
 - b. otherwise denies the matters alleged in paragraph 6.
7. Zoetis:
 - a. relies upon the terms of Part 7 of the Agvet Code and Part 6 of the *Agricultural and Veterinary Chemicals Code Regulations, 1995* (Cth) to their meaning and effect; and
 - b. otherwise denies the matters alleged in paragraph 7.
8. Zoetis:
 - a. says that the first outbreak of the Hendra virus (**HeV**) of which it is aware occurred in Mackay, Queensland in August 1994;
 - b. admits that there was an outbreak of HeV at a racing stable in Hendra, Queensland a month later; and
 - c. otherwise admits the matters alleged in paragraph 8.
9. Zoetis:
 - a. says that the development of a vaccine against HeV in horses was a collaboration between the Commonwealth Scientific and Industrial Research Organisation (**CSIRO**), the Henry M Jackson Foundation, the Uniformed Services University, and Pfizer Animal Health, a division of Pfizer Australia Pty Limited (**PAH**), with each collaborator making varying contributions at varying times in the period from 2005 to 2012; and
 - b. otherwise denies the matters alleged in paragraph 9.
10. Zoetis:
 - a. says that PAH, together with the CSIRO, was involved in testing of a vaccine against HeV in horses from 2010, and that Zoetis was involved in the testing of a vaccine against HeV in horses from 2012;
 - b. says that PAH produced vaccines against HeV in horses for testing purposes from 2010;

- c. says that production of the Equivac HeV product (**Equivac HeV**) for commercial purposes commenced in 2012 and was conducted by Zoetis Australia Research & Manufacturing Pty Limited, which continues to manufacture Equivac HeV; and
 - d. otherwise denies the matters alleged in paragraph 10.
11. Zoetis:
 - a. says that PAH applied to the Australian Pesticides and Veterinary Medicines Authority (APVMA) ~~APVMA~~ for a minor use permit in respect of Equivac HeV as a veterinary chemical product within the meaning of s 5 of the AgvetGVET Code in May 2012; and
 - b. otherwise denies the matters alleged in ~~paragraph in~~ paragraph 11.
12. Zoetis:
 - a. says that:
 - i. initially PAH was issued minor use permit PER13510, which came into force from 10 August 2012 and was to remain in force until 3 August 2014;
 - ii. a version of minor use permit PER13150 was issued to Zoetis in about August 2013, which was to remain in force until 3 August 2014;
 - iii. Zoetis was issued with minor use permit PER14876, which came into force from 4 August 2014 and was to remain in force until 4 August 2015;
 - iv. Zoetis was issued with minor use permit PER14887, which came into force from 31 March 2015 and was to remain in force until 4 August 2015;
 - v. minor use permit PER14876 was superseded by minor use permit PER14887 and had no force on and from 31 March 2015;
 - b. relies on the terms of the Permits as if pleaded fully herein; and
 - c. otherwise denies the matters alleged ~~in paragraph~~ in paragraph 12.
13. Zoetis admits the matters alleged in paragraph 13.
14. Zoetis:
 - a. repeats paragraphs 10(~~-c~~) and 12 above;
 - b. says that Equivac HeV was not available for sale until 1 November 2012;
 - c. says that Zoetis sold Equivac HeV in accordance with the Permits and the registration from the APVMA referred to in paragraphs 12 and 13 above; and
 - d. otherwise denies the matters alleged ~~in paragraph~~ in paragraph 14.

15. ~~In response to paragraph 15,~~ Zoetis:
- a. admits that the Permits required, among~~st~~ other requirements, that Equivac HeV only be supplied and used by registered veterinary surgeons who were accredited through the completion of the Equivac HeV e-learning module provided by Zoetis; and
- ~~a.b. otherwise denies the matters alleged in paragraph 15.~~
16. Zoetis:
- a. says that the first version of the Registration Module was made available to veterinarians in or about October 2012;
- b. says that further versions of the Registration Module were made available in or about April 2013, July 2014, March 2015 and May 2016;
- c. says that the quoted material in paragraph 16 is an extract from a version of the Registration Module made available from April 2013 to veterinarians who had, by that date, been accredited;
- d. relies on the content of the Registration Module Materials as if pleaded fully herein; and
- e. otherwise ~~does not~~ admits the matters alleged in paragraph 16.
17. Zoetis:
- a. repeats paragraph 16(a)-(b) and (d) above;
- b. says that the quoted material in paragraph 17 is an extract from a version of the Registration Module made available from April 2013 to veterinarians who had not, prior to that time, been accredited; and
- c. otherwise ~~does not~~ admits the matters alleged in paragraph 17.
18. Zoetis:
- a. repeats paragraph 14(b) above;
- b. says that the quoted material in paragraph 18 is extracted from permit PER14876 but not permit PER13510;
- ~~b.c.~~ relies on the content of the First and Second Permit Disclosures as if pleaded fully herein; and
- ~~c.d.~~ otherwise ~~does not~~ admits the matters alleged in paragraph 18.
19. Zoetis:
- a. admits that the Third Permit Disclosure was distributed from 31 March 2015;

- b. relies on the content of the Third Permit Disclosure as if pleaded fully herein; and
 - c. otherwise ~~does not~~ admits the matters alleged in paragraph 19.
20. Zoetis:
- a. says that the Hendra Virus Fact Sheet was published by it in about November 2012;
 - b. relies on the content of the Hendra Virus Fact Sheet as if pleaded fully herein; and
 - c. otherwise ~~does not~~ admits the matters alleged in paragraph 20.
21. Zoetis:
- a. says that the Media Release is dated 20 March 2013;
 - b. relies on the content of the March 2013 Media Release as if pleaded fully herein; and
 - c. otherwise ~~does not~~ admits the matters alleged in paragraph 21.
22. Zoetis:
- a. says that the Mythbusting Pamphlet was first published in March 2013, and was updated in January 2014;
 - b. relies on the content of the Mythbusting Pamphlet as if pleaded fully herein; and
 - c. otherwise ~~does not~~ admits the matters alleged in paragraph 22.
23. Zoetis:
- a. says that the September 2013 Seminar was presented by sales representatives of Zoetis at various times to equine industry and equine sporting groups from October 2013;
 - b. relies on the content of the September 2013 Seminar as if pleaded fully herein; and
 - c. otherwise ~~does not~~ admits the matters alleged in paragraph 23.
24. Zoetis:
- a. says that the Zoetis made a submission to the Australian Consumer and Competition Commission titled "N98410 – Equestrian Australia – Zoetis Australia submission" on 3 September 2015;
 - b. relies on the content of the ACCC Letter as if pleaded fully herein; and
 - c. otherwise ~~does not~~ admits the matters alleged in paragraph 24.

25. Zoetis:
- a. admits that the H4H Website Information was made available in about October 2013;
 - b. relies on the content of the H4H Website Information as if pleaded fully herein; and
 - c. otherwise ~~does not~~ admits the matters alleged in paragraph 25.
26. Zoetis:
- a. admits that the Facts About HeV Pamphlet was made available in about December 2014;
 - b. relies on the content of the Facts About HeV Pamphlet as if pleaded fully herein; and
 - c. otherwise ~~does not~~ admits the matters alleged in paragraph 26.
27. Zoetis:
- a. says that the Every Horse Owner Pamphlet was first published in about January 2014 and was updated in June 2014;
 - b. relies on the content of the Every Horse Owner Pamphlet as if pleaded fully herein; and
 - c. otherwise ~~does not~~ admits the matters alleged in paragraph 27.
28. Zoetis:
- a. admits that the Equestrian Life article was published in about January 2016;
 - b. relies on the content of the Equestrian Life Article as if pleaded fully herein; and
 - c. otherwise ~~does not~~ admits the matters alleged in paragraph 28.
29. Zoetis:
- a. repeats paragraphs 17 to 28 above and says that ~~as pleaded therein~~ the Publications were published in different ways and reached particular audiences;
 - b. says whether any particular Publication was likely to reach or come to the attention of any particular person would need to be considered on an individual basis taking into account the nature, content and means of distribution of the Publication and the particular ~~circumstances characteristics~~ of the ~~person recipient thereof~~; and
 - c. otherwise denies the matters alleged in paragraph 29.

Particulars

- (a) The means of distribution of the Publications were:
- (i) for the Registration Module Materials, through the compulsory online training module that could only be accessed by registered veterinarians;
 - (ii) for the First and, Second Permit Disclosures, in the leaflet accompanying the product and, in addition:
 - a. through the recertification training module for veterinarians; and
 - b. by email sent to accredited veterinarians providing a copy of Second Permit;
 - (iii) for the Third Permit Disclosure, in the leaflet accompanying the product and, in addition:
 - a. through the recertification training module for veterinarians;
 - b. in hard copies distributed to veterinarians;
 - c. in hard copies distributed to wholesalers to be provided to veterinarians; and
 - d. by email sent to accredited veterinarians providing a copy of the Third Permit;
 - (iv) for the 2013 Fact Sheet:
 - a. -through the media as part of a package of information which also included, amongst other things:
 - i. a media release entitled "Vaccine arrives to boost the fight against deadly Hendra virus";
 - ii. a fact sheet entitled "Equivac HeV vaccine for horses";
 - iii. a fact sheet entitled "History of the Hendra Virus";
and
 - iv. a fact sheet entitled "Hendra virus horse vaccine development timeline";

- b. in hard copy for distribution at a press conference held in Brisbane on 1 November 2012;
- (v) for the March 2013 Media Release, through the media;
- (vi) for the Mythbusting Pamphlet online and in hardcopies;
- (vii) for the September 2013 Seminar, by distribution to attendees of the seminar conducted by Zoetis, including presentations to veterinarians, equine industry bodies, equine sporting groups and interested members of the public];
- (viii) for the ACCC Letter, by direct correspondence to the ACCC, which published the ACCC Letter, together with 162 other submissions in respect of Equestrian Australia Ltd proposal to offer equestrian sports event services to owners and/or riders on the condition that, in certain circumstances, horses had been vaccinated with Equivac HeV];
- (ix) for the H4H Website Information, online;
- (x) for the Facts About HeV Pamphlet, online at www.health4horses.com.au;
- (xi) for the Every Horse Owner Pamphlet, online and in hardcopy; and
- (xii) for the Equestrian Life Article, by online and hardcopy circulation of that publication , and in response to an article in a prior edition of the same publication which contained misinformation.
- (b) Further particulars will be provided by way of the Respondent's lay evidence.

30. Zoetis:

- a. repeats paragraphs 10(c) and 15 above, and paragraph 62 below;
- b. relies on the terms of section 7(1)(b) and Part 3.2 (including section 54) of Schedule 2 to the *Competition and Consumer Act 2010* (Cth) (**ACL**) to their meaning and effect;
- c. admits paragraph 30(d);
- d. does not plead to paragraph 30(e) which contains no allegation of material fact, is embarrassing and is liable to be struck out; and

d.e. otherwise denies the matters alleged in paragraph 30.

30.31. Zoetis:

- a. relies on the content of the Publications particularised in paragraph 31 of the SFASOC as if pleaded fully herein;
- b. says that the extent to which the ~~alleged representation~~Geographic Spread Representation was conveyed (if at all) would depend on the nature and content of the Publication, and the characteristics of the recipient thereof;
- ~~b.c.~~ says that, to the extent it was conveyed (if at all), the Geographic Spread Representation was a statement of opinion and/or as to a future matter; and
- d. otherwise denies the matters alleged in paragraph 31.

Particulars

- (a) During the Relevant Period, the characteristics of the recipients of the Publications included (but were not limited to):
 - (i) their education, experience and profession; and
 - (ii) their knowledge and/or experience of contagious disease in horses, in particular HeV.
- (b) Further particulars will be provided by way of the Respondent's lay evidence.

31.32. Zoetis:

- a. relies on the content of the Publications particularised in paragraph 32 of the SFASOC as if pleaded fully herein;
- b. says that the extent to which the ~~alleged r~~No Serious Side Effects Representation was conveyed (if at all) would depend on the nature and content of the Publication, and the characteristics of the recipient thereof;
- ~~b.c.~~ says that, to the extent it was conveyed (if at all), the No Serious Side Effects Representation was a statement of opinion and/or as to a future matter; and
- d. otherwise denies the matters alleged in paragraph 32.

Particulars

- (a) During the Relevant Period, the characteristics of the recipients of the Publications included (but were not limited to):
 - (i) their education, experience and profession;

(ii) their knowledge and/or experience of vaccines, including equine vaccines, and the possible or anticipated reactions to them;

(iii) their awareness of the state of technical and scientific knowledge about Equivac HeV and its side effects; and

(iv) their knowledge of the regulatory environment in which Equivac HeV was supplied, including the requirement for APVMA approval of the vaccine and its labels.

(b) Further particulars will be provided by way of the Respondent's lay evidence.

32.33. Zoetis:

a. relies on the content of the Publications particularised in paragraph 33 of the SFASOC as if pleaded fully herein;

b. says that the extent to which the Alleged-II Horses Rrepresentation was conveyed (if at all) would depend on the nature and content of the Publication, and the characteristics of the recipient thereof;

b.c. says that, to the extent it was conveyed (if at all), the All Horses Representation was a statement of opinion and/or as to a future matter; and

e.d. otherwise denies the matters alleged in paragraph 33.

Particulars

(a) During the Relevant Period, the characteristics of the recipients of the Publications included the matters set out in particular (a) to paragraph 31 above and particular (a) to paragraph 32 above.

(b) Further particulars will be provided by way of the Respondent's lay evidence

33.34. Zoetis denies the matters alleged in paragraph 34.:

a. repeats paragraphs 16 to 28 above;

b. does not admit that the information contained in any of the Publications continued to be disseminated to the end of the Relevant Period; and

c. otherwise denies the matters alleged in paragraph 34.

34.35. Zoetis admits the matters alleged in paragraph 35.

35.36. Zoetis admits the matters alleged in paragraph 36.

~~36.37.~~ Zoetis denies the matters alleged in paragraph 37.

~~37.38.~~ Zoetis ~~does not admits~~ the matters alleged in paragraph 38.

~~38.39.~~ Zoetis:

- a. admits the matters pleaded in ~~sub-paragraphs~~ 39(b) ~~and~~ (c) but says that between 1994 and 2011, 61 horses were affected by the 23 incidents of HeV occurring in Queensland; ~~and~~
- b. says further that as of the date of this pleading, there have been 62 outbreaks of HeV in Queensland and New South Wales, resulting in the death of 104 horses, seven infections of humans and the deaths of four humans; ~~and~~
- c. otherwise ~~does not admit~~denies the matters alleged in paragraph 39.

~~39.40.~~ Zoetis denies the matters alleged in paragraph 40.

~~40.41.~~ Zoetis admits the matters alleged in paragraph 41.

~~41.42.~~ Zoetis denies the matters alleged in paragraph 42.

~~42.43.~~ Zoetis:

- a. says that there were seven infections of HeV in humans, including four deaths, from five outbreaks of HeV between 1994 and 2009; and
- b. otherwise ~~does not admit~~denies the matters alleged in paragraph 43.

~~43.44.~~ Zoetis admits the matters alleged in paragraph 44.

~~44.45.~~ Zoetis denies the matters alleged in paragraph 45.

~~46.~~ Zoetis:

- a. to the extent that the "Summary of Adverse Experience Reports made to the APVMA about Hendra Virus Vaccine" published 31 August 2017 (Summary) is sought to be relied upon to prove that any reported side effect was in fact caused by Equivac HeV:
 - i. denies that any individual report of an incidence of a side effect proves that the reported side effect was in fact suffered or that it was caused by Equivac HeV;
 - ii. says that the Summary is hearsay and of no probative value of itself on the question of causation of any reported side effect; and
 - iii. shall object to the tender of the Summary as proof of the fact of the underlying reports or that the reported side effects were caused by Equivac HeV; and

a.b. otherwise denies the matters alleged in paragraph 46.

45-47. Zoetis:

- a. repeats paragraphs 35 to 46 above;
- b. says that matters relevant to any person seeking to make a properly informed decision to administer Equivac HeV or to consent to its administration to a horse included, in addition to the risk of infection and potential side effects:
 - i. the nature and effect of HeV;
 - ii. the consequences for a horse of contracting HeV;
 - iii. the consequences for a human of contracting HeV; and
 - iv. recommendations or advice from the horse's treating veterinarian; and
- c. otherwise denies the matters alleged in paragraph 47.

46-48. Zoetis:

- a. repeats paragraph 31 above; and
- b. otherwise admits that publication of the Publications particularised in paragraph 31 of the SFASOC was conduct in trade or commerce within the meaning of section 18 of ~~Schedule 2 to the Competition and Consumer Act 2010 (Cth)~~ (ACL) the ACL.

49. Zoetis:

- a. says that the Geographic Spread Representation (if made) was
 - i. a statement of opinion and/or as to a future matter made on reasonable grounds; or
 - ii. a statement of fact which was accurate at the time it was made;
- c.b. otherwise denies the matters alleged in paragraph 49.

Particulars

- (a) The basis on which Zoetis made statements concerning the risk of horses in Australia contracting HeV in all areas in which flying foxes were present included:
 - (i) the knowledge and understanding that HeV was spread from flying foxes to horses and from infected horses to other horses;
 - (ii) the fact that HeV or antibodies indicating infection with HeV have been detected in each of the four mainland species of flying foxes;

- (iii) the geographic distribution of flying fox species that carry HeV antibodies in Australia, including the movement of flying fox species;
 - (iv) the fact that the location of an outbreak cannot be predicted since, relevantly for transmission from horse to horse:
 - a. HeV is difficult to diagnose because its symptoms can vary significantly both in composition (resembling common equine diseases and/or presenting with non-specific clinical signs) and timing (an infected horse may take five to 16 days to show symptoms of HeV); and
 - b. viral shedding by an infected horse (which is excretion of infectious viral particles) can occur prior to the onset of symptoms; and
 - (v) the fact that HeV had, at the time of the release of Equivac HeV in November 2012, resulted in the deaths of 80 horses in areas of Australia in which flying foxes were present.
- (b) Further particulars will be provided by way of the Respondent's lay and/or expert evidence.

47.50. Zoetis denies the matters alleged in paragraph 50.

48.51. ~~[not used]~~Zoetis:

- a. ~~repeats paragraph 48 above; and~~
- b. ~~otherwise denies the matters alleged in paragraph 51.~~

49.52. Zoetis:

- a. repeats paragraph 32 above; and
- b. otherwise admits that publication of the Publications particularised in paragraph 32 of the SFASOC was conduct in trade or commerce within the meaning of section 18 of the ACL.

53. Zoetis:

- a. says that the No Serious Side Effects Representation (if made) was:
 - i. a statement of opinion and/or as to a future matter made on reasonable grounds; or
 - ii. a statement of fact which was accurate at the time it was made;

- b. says further that the No Serious Side Effects Representationalleged representation could not be misleading or deceptive based on the combined effect of side effects which were not each themselves serious; and
- c. otherwise denies the matters alleged in paragraph 53.

Particulars

- (a) The basis on which Zoetis made statements concerning the side effects of Equivac HeV included:
- (i) the state of technical and scientific knowledge about Equivac HeV and its side effects, including:
- a. the reactivity of vaccines generally;
- b. the composition of Equivac HeV and that its components have been used in other equine vaccines without issues;
- c. the results of trials prior to the release of Equivac HeV to the market; and
- d. the results of field and other studies following release of Equivac HeV to the market;
- (ii) its compliance with the regulatory regime applicable to the supply of veterinary chemical products under the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) and the *Aqvet Code*;
- (iii) the fact that the APVMA approved the supply of Equivac HeV under the Permits and then upon registration, including the identification of its side effects in the product label, which approval was not at any time cancelled or suspended; and
- (iv) its investigation of reported adverse effects of Equivac HeV and consideration of differential diagnoses.
- (b) Further particulars will be provided by way of the Respondent's lay and/or expert evidence.

~~50-54.~~ Zoetis denies the matters alleged in paragraph 54.

~~51-55.~~ [not used]Zoetis:

- a. ~~repeats paragraph 52 above; and~~
- b. ~~otherwise denies the matters alleged in paragraph 55.~~

52-56. Zoetis:

- a. repeats paragraph 33 above; and
- b. otherwise admits that publication of the Publications particularised in paragraph 33 of the SFASOC was conduct in trade or commerce within the meaning of section 18 of the ACL.

57. Zoetis:

- a. says that the All Horses Representation (if made) was:
 - i. a statement of opinion and/or as to a future matter made on reasonable grounds; or
 - ii. a statement of fact which was accurate at the time it was made;
- b. otherwise denies the matters alleged in paragraph 57.

Particulars

- (a) The basis on which Zoetis made statements concerning the appropriateness of vaccination of horses in Australia against HeV included:
 - (i) the fact that HeV is a significant biosafety threat classified as a biosafety level 4 pathogen (the same classification as the Ebola virus);
 - (ii) the fact that there is no treatment for HeV infection in horses, nor an approved fully tested specific treatment for HeV infection in humans;
 - (iii) the knowledge and understanding that HeV was spread from flying foxes to horses and from infected horses to other horses;
 - (iv) the fact that HeV or antibodies indicating infection with HeV have been detected in each of the four mainland species of flying foxes;
 - (v) the geographic distribution of flying fox species that carry HeV antibodies in Australia, including the movement of flying fox species;
 - (vi) the fact that horses routinely travel within Australia for reasons including competition, breeding and sale;

(vii) the fact that the location of an outbreak cannot be predicted since, relevantly for transmission from horse to horse:

- a. HeV is difficult to diagnose because its symptoms can vary significantly both in composition (resembling common equine diseases and/or presenting with non-specific clinical signs) and timing (an infected horse may take five to 16 days to show symptoms of HeV); and
- b. viral shedding by an infected horse (which is excretion of infectious viral particles) can occur prior to the onset of symptoms; and

(viii) the fact that HeV had, at the time of the release of Equivac HeV in November 2012, resulted in the infection of seven people and the death of four of those people, and the deaths of 80 horses in areas of Australia in which flying foxes were present;

(ix) the fact that the geographical territory in which HeV has fatally infected horses is uncertain because the symptoms of HeV can be mistaken for other diseases and not all horses that die are tested for HeV;

(x) the fact that vaccination confers immunity and if all horses were immune, there would be no known risk of contraction by horses or humans (and therefore no risk of horse or human deaths);

(xi) the recommendations of the Australian Veterinary Association, the Equine Veterinary Association, equestrian associations, State, Territory and Commonwealth governments and the CSIRO; and

(xii) animal welfare concerns associated with unvaccinated horses receiving inadequate veterinary care pending the results of HeV exclusion tests.

(b) Further particulars will be provided by way of the Respondent's lay and/or expert evidence.

53.58. Zoetis denies the matters alleged in paragraph 58.

54.59. ~~[not used]~~Zoetis:

- a. ~~repeats paragraph 56 above; and~~
- b. ~~otherwise denies the matters alleged in paragraph 59.~~

55.60. Zoetis denies the matters alleged in paragraph 60.

56.61. Zoetis:

- a. says that section 54(1) and (2) of the ACL applied on their terms; and
- b. otherwise denies the matters alleged in paragraph 61.

57.62. Zoetis denies the matters alleged in paragraph 62.

63. Zoetis:

- a. says that Equivac HeV was of acceptable quality because it was as safe as a reasonable consumer fully acquainted with the state of the vaccine would have regarded as acceptable having regard to:
 - i. the nature of the product, including that it was a veterinary chemical product approved by the APVMA; and
 - ii. the state of scientific or technical knowledge at the time it was supplied;
and
- b. otherwise denies the matters alleged in paragraph 63.

58.64. Zoetis denies the matters alleged in paragraph 64.

59.65. Zoetis does not know and therefore cannot admit the matters alleged in paragraph 65.

60.66. Zoetis does not know and therefore cannot admit the matters alleged in paragraph 66.

64.67. Zoetis does not know and therefore cannot admit the matters alleged in paragraph 67.

62.68. Zoetis does not know and therefore cannot admit the matters alleged in paragraph 68.

63.69. Zoetis denies the matters alleged in paragraph 69.

64.70. Zoetis denies the matters alleged in paragraph 70.

65.71. Zoetis denies the matters alleged in paragraph 71.

66.72. Zoetis denies the matters alleged in paragraph 72.

67.73. Zoetis denies the matters alleged in paragraph 73.

68.74. Zoetis denies the matters alleged in paragraph 74.

69.75. Zoetis denies the matters alleged in paragraph 75.

70.76. Zoetis denies the matters alleged in paragraph 76.

74.77. Zoetis denies the matters alleged in paragraph 77.

72.78. Zoetis denies the matters alleged in paragraph 78.

73.79. Zoetis denies the matters alleged in paragraph 79.

Date: ~~30-11 October~~ July 2019



Signed ~~on behalf of by~~ Anne Elizabeth Freeman
Lawyer for the Respondent, ~~by her Partner Florian Ammer~~

This pleading was prepared by Anne Freeman and Simon Fitzpatrick, of counsel, and settled by L.V. Gyles SC.

Certificate of lawyer

I Anne Elizabeth Freeman certify to the Court that, in relation to the defence filed on behalf of the Respondent, the factual and legal material available to me at present provides a proper basis for:

- (a) each allegation in the pleading; and
- (b) each denial in the pleading; and
- (c) each non admission in the pleading.

Date: ~~11-8 October~~ 30 July 2019



Signed ~~by on behalf of~~ Anne Elizabeth Freeman
Lawyer for the Respondent, ~~by her Partner Florian Ammer~~