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Details of Filing

Document Lodged:	Statement of Claim - Form 17 - Rule 8.06(1)(a)
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File Title:	RACHAEL ABBOTT v ZOETIS AUSTRALIA PTY LTD
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA

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Important Information

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abAForm 17
Rule 8.05(1)(a)

Amended Statement of Claim

No. 406 of 2018

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

Rachael Abbott
Applicant

Zoetis Australia Pty Ltd
Respondent

Details of claim

REPRESENTATIVE PROCEEDINGS

1. This is a representative proceeding brought under Part IVA of the *Federal Court of Australia Act*, 1976 by the applicant on her own behalf and on behalf of other horse owners whose horses have died or suffered adverse side-effects from being administered the product as defined herein.

DEFINITIONS

2. **AGVET CODE** means Agricultural and Veterinary Chemicals Act 1994.
3. **APVMA** means Australian Pesticides and Veterinary Medicines Authority.
4. **AVA** means Australian Veterinarians Association.
5. **EA** means Equestrian Australia, a non-profit organisation whose objects are to control equestrian sport in Australia and international competition as a member of Federation Equestre Internationale.
6. **EVA** means Equine Veterinarians (Association) Australia.
7. **ENSW** means Equestrian New South Wales, non-profit organisation whose objects are to control equestrian sport in New South Wales and is a part of EA.
8. **Product** means the vaccine developed and sold by the respondent ~~RESPONDENT~~ to treat the Hendra virus.

Filed on behalf of Rachael Abbott, Lead Applicant
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9. **Side effects** means the side effects reported to the APVMA and contained in Attachment "A" hereto together with other side effects that may be proven.
10. **VETERINARIANS** includes veterinarians trained and authorised to administer the product for the purpose provided by the minor use permits issued by APVMA.
11. **INTERMEDIARIES** means AVA, EA, EVA, ENSW and VETERINARIANS.

THE RESPONDENT

12. The respondent is a company incorporated in Australia and liable to be sued in its corporate name and style.
13. The respondent carries on the business of designing, manufacturing, distributing and marketing veterinary medicines and products.

~~**The Hendra Virus**~~

~~14. The Hendra Virus ("HeV") was first discovered in 1994 in the Brisbane suburb of Hendra.~~

~~15. Between 1994 and 2010 there were 14 cases of horses diagnosed as suffering from the Hendra Virus.~~

~~16. The affected horses were located in coastal Queensland or the north east corner of NSW.~~

~~17. The disease is known to be endemic to bats found near the seaboard of Queensland and North Eastern New South Wales. The mechanism of transmission from bats to horses is hypothesised to be by bat urine or faeces.~~

~~18. During 2011 and 2012 there were 26 HeV incidents in horses and one in a dog.~~

~~19. The following year there were eight incidents in horses and another dog.~~

~~20. In the past twenty four years there have been seven known human infections.~~

~~21. Five were veterinarians or their staff who did intrusive procedures on dying or dead horses without the use of Personal Protective Equipment (PPE). One other was a horse trainer who slept with his dying horse and one was his employee, a groom, who survived. Bodily fluid from the diseased animals was found on the floor and there was no use by these victims of PPE. Four of the humans infected are alleged to have died but it is doubtful whether two alleged deaths were caused by Hendra.~~

~~**PARTICULARS**~~

~~a) Mark Preston, had been infected but recovered and a year later he contracted an infection from a piggery and died. An Autopsy found Hendra in his body and his death was attributed to this condition.~~

~~b) Vic Rail died of heart attack although he was infected with Hendra.~~

~~22. The 2004 vet infected only had flu like symptoms only and recovered in weeks.~~

~~23. There has never been an incident of a private horse owner on any property being infected by their horse with HeV or racetrack staff, grooms or public gatherings.~~

~~24. There has never been an incident of any horse at an event having HeV.~~

~~25. Hendra is not an endemic disease in horses. Vaccination is a tool to manage endemic diseases in production animals.~~

~~26. HeV is not a common or endemic disease in horses.~~

~~27. There is no herd immunity benefit for horses from vaccination.~~

The Vaccine and application to APVMA

14. The respondent developed the product.

15. The respondent ~~and~~ made application to the APVMA for ~~a~~ minor use permits.

~~28.~~ **Particulars:**

~~29.~~ (i) On 1 November 2012 APVMA first released the product on minor use permit number PER13510 which was in force from 10 August 2012 to 3 August 2014.

(ii) On application by respondent the APVMA issued a second minor use permit number PER14876 which was in force from 4 August 2014 to 4 August 2015.

~~30.~~ (iii) The directions for use on permits PER13510 and PER14876 was ~~for the purpose~~ as "An aid in the prevention of clinical disease caused by Hendra virus."

~~31.~~ (iv) On application by respondent the APVMA issued a third minor use permit number PER14887 which was in force from 31 March 2015 to 4 August 2015.

(v) The directions for use on permit PER14887 was as "An aid in the prevention of clinical symptoms of the disease caused by Hendra virus."

~~(vi) which was in force from 4 August 2014 to 4 August 2015.~~

~~32.~~ (vii) The directions for use on permits PER13510 and PER14876 was as "an aid in~~l~~ the prevention of clinical disease caused by Hendra virus".

~~**Respondent application to APVMA in breach of Agvet Code**~~

~~33. In making its application to APVMA for issue of minor use permits respondent was in breach of the Agricultural and Veterinary Chemicals Code section 26(3) in that it:~~

~~a) Failed to provide relevant data as to safety criteria;~~

~~b) Failed to provide relevant data as to efficacy criteria;~~

~~c) Failed to provide relevant data as to labelling criteria;~~

~~20A The applicant pleads the respondent's applications for issue of minor use permits dated day of as if same were fully set out herein.~~

20B By reason of the matters alleged in paragraph 20 and 20A the respondent caused minor use permits to be issued for the vaccine which had the side effects which were deleterious to the health of horses when administered.

20C The effect of achieving registration was that a representation was thereby made to intermediaries that the product was safe to use which representation was misleading or deceptive.

Respondent in breach of minor use permits.

34. Respondent was in breach of the minor use permits in that it:

a) Failed to keep detailed records of the manufacture, use and adverse reactions;

b) Failed to advise APVMA of breaches of the manufacture, use and adverse reactions of which it was aware in a timely manner:

c) Failed to advise APVMA that in breach of the minor use permits the product was being distributed generally in breach of the Agvet Code.

d) Failed to advise APVMA that in breach of the minor use permits respondent was enabling and encouraging the intermediaries to market, advertise and press the use of the product in contravention to the use permitted by the minor use permits;

Failed to advise APVMA that in breach of the minor use permits respondent enabled and encouraged its ENSW to pass a By Law to use the product in contravention of the use permitted by the minor use permits.

e)

21A The facts and matters relied upon in support of the allegation in paragraph 21(a)-(e) are as follows:

21B The failure of the respondent to do the things pleaded in paragraph 21(a) to 21(e) had the effect that the minor use permits remained in force and the vaccine continued to be used on horses whose owners were unaware of the side effects.

Respondent in breach of Section 79 of Agvet Code.

35. At all material times the respondent was a person who was authorised by a permit to supply, or cause or permit to supply a registered chemical in accordance with conditions in Minor Use Permits referred to above.

36. In breach of Section 79 of the Agvet Code it knowingly advertised, provided and distributed the product for use other than provided for in the Minor Use Permits.

Particulars of Knowledge

37. At all material times the respondent knew or ought to have known that the product was being marketed by claiming a level of efficacy in excess of the Minor Use Permits by:

a) Correspondence between it and the intermediaries;

~~b) Statements in newspapers and journals attributed to representatives of the intermediaries;~~

~~Publications by AVA and EVA;~~

~~24A Facts and matters relied upon in support of the particulars in paragraph 24(a) above.~~

~~[*Insert dates, identities and the effect of correspondence between the respondent and intermediaries.*]~~

~~24B Particulars of the facts and matters relied upon in support of the allegation in paragraph 24(b) hereof.]~~

~~[*Here insert dates, names of publications etc. and what are said to be the representations made as to the level of efficacy and the facts demonstrastingdemonstrating that the representation is false.*]~~

~~24C Particulars of the facts and matters relied upon in support of the allegation in paragraph 24(c) hereof.~~

~~[*Here insert the date and description of the publications relied upon.*]~~

~~c) 24D By reason of the matters alleged in paragraph 24 to paragraph 24C the conduct therein alleged represented to the intermediaries and horse owners that the product was safe to use when this was not so because it caused the side-effects.~~

~~d)~~

Breach of Statutory Duty

16. Section 89(1)(a) of the Agvet Code imposed upon the respondent a duty not to publish or communicate any false or misleading information about the product.

17. In contravention of s.89(1)(a) of the Agvet Code the respondent published the following false or misleading information about the product:

Particulars:

~~That there was a risk to horses and humans of contracting the Hendra virus to horses and humans who were not located in the eastern seaboard of Queensland or the north-eastern corner of New South Wales;~~

(i) That there was a risk to humans of contracting the Hendra virus in areas outside the eastern seaboard of Queensland and the north-eastern corner of New South Wales.

~~That there was a risk to humans of contracting the Hendra virus in areas outside the eastern seaboard of Queensland and the north-eastern corner of New South;~~

~~Walesthe risk of contracting the Hendra virus was disproportionate to the actual risk of the contraction of the virus by horses;~~

~~That the risk of contracting the Hendra virus was disproportionate to the actual risk of the contraction of the virus by humans;~~

(ii) That horses that were outside the area of the eastern seaboard of Queensland or north-eastern New South Wales were exposed to the risk of contracting the Hendra virus;

(iii) That it was ~~desirable~~[A1]necessary for the owners of horses outside the area of the eastern seaboard of Queensland or the north-eastern corner of New South Wales to have their horses inoculated with the product to prevent ~~the owners or any other~~ humans from contracting the Hendra virus;

(iv) That the Hendra virus could be transferred from horses to humans in circumstances other than being exposed to fluids from horses alive or dead which horses had the Hendra virus;

(v) That the Hendra virus could be transmitted from horse to horse otherwise than by an exchange of bodily fluids from a horse infected with the Hendra virus to another horse;

(vi) That the side-effects from inoculation with the product were minor;

(vii) That it was necessary for owners of horses to have their horses inoculated with the product to protect their families from the risk of contracting the Hendra virus;

(viii) That it was necessary for veterinarians practising outside the area of the Queensland seaboard and the north-eastern corner of New South Wales to inoculate horses with the product to prevent them from catching the Hendra virus;

~~(i)~~(ix) That horses inoculated with the product could not contract the Hendra virus.

~~(ii)~~(x) That the effect of the product on horses was the same as any inoculation to humans;

~~(iii)~~(xi) That the product was 100% effective;

~~(iv)~~(xii) That Hendra kills more veterinarians than any other cause.

~~(v)~~(xiii) That Hendra was deadly to veterinarians.

~~38.~~ 18. Further, or in the alternative, in contravention of Section 89(1)(c) of the Agvet Code the respondent impliedly claimed that the use of the product was safe when this was untrue by reason of the side-effects contained in Attachment A hereto.

19. The applicant and group members for the reasons alleged in paragraphs 17 and 18 ~~and 19~~ hereof have a cause of action for breach of statutory duty in that they were persons within the contemplation of the Parliament as classes of persons specifically in need of the protection against the publishing or communicating of false or misleading information in contravention of Section 89 of the Agvet Code.

~~**Particulars of use other than permitted by Permits**~~

~~**39.** The permits refer to the product as being used as "An aid in the prevention of clinical disease caused by Hendra virus" or "An aid in the prevention of clinical symptoms of the disease caused by Hendra virus" the respondent, in breach of the permit use, advertised and promoted the product as being an authorised product for:~~

~~a) Preventing the~~

~~i. The cContracting of the Hendra virus;~~

~~ii. Infection by the Hendra virus;~~

~~iii. Viral shedding of the Hendra virus by horses;~~

~~iv. Transmission of the Hendra virus from horse to horse;~~

~~v. Transmission of the Hendra virus from horse to humans;~~

~~b) Protecting humans from contracting the infection;~~

~~c) Suitable and appropriate for use in cControlling an endemic or outbreak of the Hendra virus in Queensland and New South Wales;~~

~~Being as close to 100% effective as a vaccine can be;~~

~~When the publication of such representations were misleading or deceptive because they were not the subject of authorisation under the permit use.~~

~~25A Particulars of the advertisements and promotions.~~

~~[*Here insert where and when the advertisements were placed. Set out what the permit use was and the occasions upon which the advertising and the promotion occurred.*]~~

~~25B Further or in the alternative, the conduct of the respondent as alleged in paragraphs 25 and paragraph 25A represented to the intermediaries that it was safe to use the product when this was not so by reason of its causing the side-effects.~~

d)

40. Further, or in the alternative, the respondent:

e) Failed to include any reference to the vaccine only being an aid in the prevention of clinical disease or symptoms of Hendra.

f) Failed to report a no vaccination/no treatment policy of EA, EVA, AVA and veterinarians to the APVMA as being based on inflated claims of the efficacy of the vaccine and thereby in breach of the Minor Use Permits issued to it. ???

Particulars of advertising

41. The respondent permitted and encouraged the advertising of breaches of its permits and the efficacy of the product that was not permitted by the permits or justified by its data on many occasions by the intermediaries through different media including:

a) AVA and EVA "Notification of Veterinary Advice for Equestrian Events" undated; ???

b) ENSW Hendra Vaccination By Law;

c) ENSW Policy;

d) EA By-Law

Newspapers, journals, television and notices.

27A Particulars of the facts and matters relied upon in support of the allegation under paragraph 27(a).

27B Particulars of the facts and matters relied upon in support of the allegation under paragraph 27(b).

27C Particulars of the facts and matters relied upon in support of the allegation under paragraph 27(c).

27D Particulars of the facts and matters relied upon in support of the allegation under paragraph 27(d).

e) 27E By reason of the matters alleged in paragraph 27 to paragraph 27D the respondent represented that it was safe for the product to be used when this was misleading or deceptive by reason of the fact that it caused the side-effects.

Breach Agvet Code Section 88

42. The respondent did publish or cause or permit to be published a notice that offered to sell the product that was not a registered product.

The respondent published or caused or permitted to be published a notice that offered to sell the product. ???

28A Particulars of publication of the notice pleaded in paragraph 28.

42. 28B By reason of the facts and matters alleged in paragraph 27 to paragraph 28A the respondent engaged in misleading and deceptive conduct in that it represented that the product was a registered product and thereby was safe to use when such representation was misleading or deceptive because the product caused the side-effects.

Breach Agvet Code Section 89

43. The respondent did or caused or permitted

a) publishing or communicating false or misleading information about the product.(1)(a) ???

Expressly or impliedly claimed that the product had particular qualities that were not prescribed by the regulations for the purpose of this paragraph (1)(f) of section 89.

3029A Particulars of the facts and matters relied upon in support of the allegation in paragraph 30(a) hereof.

[***Here insert what was published and what was false about what was published and what was misleading about what was published.***]

3029B Particulars of the facts and matters relied upon in support of the allegation in paragraph 30(b) hereof.

b) [***Here insert what were the particular qualities that the product claimed to have and the regulations prescribed and the respect in which the claimed qualities were other than prescribed.***]

PARTICULARS

44. The permits refer to the product as being used as "An aid in the prevention of clinical disease caused by Hendra virus" or "An aid in the prevention of clinical symptoms of the disease caused by Hendra virus" the respondent, in breach of the permit use, advertised and promoted the product as:

a) Preventing the

vi. Contracting

vii. Infection

viii. Viral shedding of Hendra by horses;

ix. Transmission of Hendra from horse to horse;

x. Transmission of Hendra from horse to humans;

b) Protecting humans from contracting the infection;

c) Suitable and appropriate for use in controlling an endemic or outbreak of Hendra in Queensland, New South Wales and Australia;

d) Overstating the effectiveness as being as close to 100% effective as a vaccine can be;

e) Failed to include reference that the vaccine was only an aid in the prevention of clinical disease or symptoms of Hendra.

f) Failed to report a no vaccination/no treat policy of EA, EVA, AVA and veterinarians to the APVMA as being based on inflated claims of the efficacy of the vaccine and thereby in breach of the Minor Use Permits issued to it.

[*These facts and matters should be picked up and included in the particulars in the new paragraphs 29A and 29B identifying in precise terms where, when and the content of the advertising and promotion and what the permit permitted and what was advertised and promoted was not within the permit.*]

30A By reason of the facts and matters alleged in paragraphs 20 to 30 the respondent represented that it was safe to use the product when such representation was misleading or deceptive because the product caused the side-effects.

Section 18 of the Australian Consumer Law (ACL).

45.20. In supplying the product respondent was engaged in trade or commerce.

46. The respondent in contravening s.18 of the ACL engaged in conduct that was misleading or deceptive or likely to mislead or deceive in that it:

a) packaged and distributed the product without any warning as to all most of the side effects in Attachment A; and

21. The respondent in contravention of s.18 of ACL engaged in conduct that was misleading or deceptive or likely to mislead or deceive in that it distributed product information without any warning as to all of the side-effects in Attachment Aor insufficient warning as to the side effects.

22. The respondent engaged in conduct that was misleading or deceptive or likely to mislead or deceive in that it distributed product information with insufficient warning as to the side effects in Annexure A.

23. Further, or in the alternative, the applicant repeats the allegations contained in the particulars (i)-(x) in paragraph 1817 and paragraph 1918 hereof and says that the conduct therein alleged also contravened s.18 of ACL.

a) Further, the conduct referred to in in paragraphs 20 to 23 above was conduct which misled or deceived or was likely to mislead or deceive

~~47. Further , t~~The ~~conduct referred to in paragraphs 21 to 25 hereinabove was conduct which misled or deceived or was likely to mislead or deceive~~respondent's ~~failure to warn of the side effects misled and deceived:~~

~~a)~~24. veterinarians to~~responsible for the supply,~~ prescribe ~~ing, and~~supply and ~~administering the~~administer the product or the applicant and group members to purchase or permit the product to be administered to their horses thereby causing loss or damage to them from the horses suffering from the side-effects in Attachment A~~drug~~;

~~the applicant and group members who purchased or permitted the drug to be administered to their horses.~~

25. Further, or in the alternative, in contravention of s.18 of the ACL the conduct of the respondent in ~~administering or~~ permitting in excess of 300,000 doses of the product to be administered was misleading or deceptive in that such extensive use ~~it~~ was not permitted by the minor use permits.

26. Further, or in the alternative, the respondent in contravention of s.18 of the ACL represented by its conduct that the permits that it obtained authorised the administration of the product in an unrestricted manner.

~~Further, or in the alternative, of contravention of s.18 of the ACL the respondent promoted the use of the product beyond the scope of the permits that had been issued by the APVMA.~~

27. Further, or in the alternative, the respondent in contravention of s.18 of the ACL failed to correct by media or otherwise the widespread misuse of the product as a general vaccine against contraction of the Hendra virus.

28. Further, or in the alternative, the respondent in contravention of s.18 of the ACL cooperated and assisted the intermediaries in promoting the product as a general vaccine when it knew or ought to have known that the intermediaries were unaware of the side-effects.

29. The Respondent~~:~~ In contravention of s.18 of the ACL ~~the respondent~~ made the following representations which were misleading or deceptive or likely to mislead or deceive:

a) That the product was safe;
b) That the product was free of adverse reactions including death;
c) That Hendra virus could be transmitted between horses;
d) That Hendra virus was highly contagious between horses;

e) That people interacting amongst horses increases the likelihood of human exposure to the disease;

~~33.~~30. The respondent is liable to compensate the applicant and each group member for the amount of loss and damage suffered by them as a result of their horses having suffered one or more of the side effects and each group member under section 236 is entitled to recover compensation by this action from the respondent.

~~Negligence~~

31. ~~The respondent had a duty to exercise reasonable care to the applicant and group members in that it could reasonably be expected to have foreseen that the sale of the product to them through the intermediaries would cause the product to be administered to their horses who may develop the side-effects thereby causing loss and damage to the applicant and group members from the illness or death of their horses.not expose the applicant and class members to a risk of injury~~The respondent owed a duty of care to the applicant and the group members to exercise reasonable care in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, distribution and/or sale of the product.

~~53.~~

~~The respondent was negligent in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, distribution, and/or sale of the product.~~

~~54. 50A The applicant relies upon the particulars set out in paragraphs [ ] hereof.~~

~~55.~~32. ~~Injury to the applicant and group members was caused by the negligence of the defendant~~ The applicant and group members suffered loss and damage by reason of the breaches by the respondent of the duty of care that it owed to them.

PARTICULARS OF BREACH OF DUTY~~NEGLIGENCE~~

~~56.~~33. The respondent was negligent in that, by its servants ~~and~~or agents;

a) Knew or ought to~~should~~ have known that the ~~Product~~product caused ~~increased~~ the ~~risk of the~~ adverse side effects in Attachment A including death;

b) failed to take reasonable care to ensure ~~that~~ the product was not dangerous to horses;

c) failed to conduct appropriate testing to determine whether and to what extent the injection of the ~~Product~~product posed serious risks, including the death to horses;

d) failed to adequately test the product prior to placing it on the market;

e) failed to adequately test the ~~Product~~product in a manner that would fully disclose the side effects including death of horses;

f) failed to use care in developing, designing and manufacturing the product so as to avoid posing unnecessary health risks to horses;

g) failed to conduct adequate pre-clinical and clinical testing, post-marketing surveillance and follow-up studies to determine the safety of the product;

h) failed to advise that the injection of the ~~Product~~product could result in severe side effects, including but not limited to, death;

i) failed to advise the veterinary and scientific communities of the potential to cause ~~increase~~ the ~~risk of~~ side effects including death;

j) failed to provide adequate and timely warnings or sufficient indications about the increased potential health risks to horses associated with the use of the ~~Product~~product;

k) failed to provide ~~Class Members~~group members and their veterinarians with adequate warnings or sufficient indications of inherent risks associated with the ~~Product~~product;

l) failed to provide adequate warnings regarding the side effects of the ~~Product~~product;

m) failed to provide adequate updated and current information to the applicant and ~~Class~~ group ~~M~~members and their veterinarians respecting the risks of the ~~Product~~product as such information became available;

n) failed to provide prompt warnings of potential hazards of the ~~P~~product in the products' labelling;

~~o) failed to warn that Class Members and their veterinarians that the risks associated with the Product would exceed the risks of other available treatments and medications;~~

~~p)~~o) Failed, after receiving ~~actual or constructive~~ notice of the side-effects ~~problems~~ associated with the ~~Product~~product, to issue adequate warnings of the side-effects; ~~to publicize the problem and otherwise act properly and in a timely manner to alert the public, the Class Members and their veterinarians, of the products' inherent dangers;~~

~~q)~~p) failed to educate ~~stablish any adequate procedures to educate their~~ sales representatives and ~~prescribing~~ veterinarians of ~~respecting~~ the risks associated with the use of the product;

~~r)~~q) falsely stated and/or implied that the ~~Product~~product were safe when they knew or ought to have known that this representation was false;

r) disregarding ~~ed~~ reports of side effects;

s) failed to adequately investigate reports of adverse side effects caused by the product;

~~s)~~

t) failed to accurately and promptly disclose to APVMA information relating to the side effects associated with the ~~Product~~product;

~~t)~~u) failed ~~and~~ to modify the product data sheets and product labelling to record the side-effects~~accordingly in a timely manner~~;

~~u)~~v) failed to monitor and to initiate a timely review, evaluation and investigation of reports of side effects associated with the ~~Product~~product;

w) failed to properly investigate cases of side effects caused by the Product;

x) tfailing to properly and adequately test for effectiveness and side-effects of the product by:

i. conducting testing using inappropriate species as controls;

ii. applying insufficient test protocols;

iii. euthanazing test horses before the disease or side effects could manifest themselves;

iv. not reporting tests that disclosed side effects;

v. failing to follow the Veterinary Medicines Manual of Requirements and Guidelines ("MORAG") in that it;

a) failed to exercise good laboratory practice in its safety testing; and

b) failed to conduct non clinical health and environment safety studies that were properly;

i. planned;

ii. monitored;

iii. recorded;

iv. archived; and

v. reported.

y) further or in the alternative it failed to conduct adequate clinical trials to ascertain the safety, efficacy and potential harmful side effects of the product.

z) further or in the alternative it failed to adequately evaluate the safety of the product by:

a) testing on animals of minimum age that were likely to receive the product;

b) failing to test the product on horses that were sero-negative;

c) failing to justify test on horses that were sero-positive;

d) failing to test the product on a minimum of eight animals

e) failed to closely observe and examine the tested animals for signs of local and systemic reactions including post mortem macroscopic and microscopic examination of injections sites;

f) failing to ascertain the need and frequency of booster doses of the product;

g) failing to test the effect of an overdose of the product;

h) failing to ascertain the reproductive safety of the product on mares and stallions by conducting a dedicated laboratory trial in conjunction with supplemented field data;

i) failing to conduct appropriate tests to ascertain the effect of the product on immunological functions;

j) Failing to conduct adequate field safety trials.

aa) permitted the product to be administered to a greater number of horses than permitted by the permit;

bb) permitted the product to be promoted as a vaccine when it knew it had not been tested or authorised by the APVMA to do so;

cc) failed to correct by media or otherwise the widespread misuse of the product as a vaccine;

dd) cooperated and assisted the intermediaries in promoting the product as a vaccine when it knew or ought to have known that the intermediaries were unaware of the side-effects;

ee) failed to exercise veterinary pharmacovigilance in that it:

i. did not adequately collect information of adverse side effects;

ii. did not adequately conduct post market surveillance of adverse effects;

iii. did not ensure the continued safety and efficacy of the product in its use in the field;

iv. failed to properly and promptly investigate and report serious adverse reactions to the product;

v. failed to properly instruct and train veterinarians to promptly report adverse reactions to the product;

ff) Failed to advise and instruct veterinarians that the product was not permitted for use as a general vaccine;

~~v)~~gg) the applicant also relies upon the defendant's breaches of s.79(1)(a) and s.79(1)(b) and s.18 of the ACL as evidence of negligence.

~~w) deprived applicant and class members of a chance for safe, effective and/or successful alternative treatments; and~~

~~x) permitted the product to be used as a vaccine when it was not licensed for such use.~~

34. By reason of the negligence of the respondent ~~abovementioned~~ the applicant and group members have ~~were injured and~~ suffered and will ~~continue to~~ suffer loss and damage in that their horses became sick or died as a result of the side-effects caused by the administration of the product.

~~57.~~35. Except for the allegations made in paragraphs [~~41~~33(BB)]~~-~~, [~~41~~33(GG)~~-~~] ~~and [~~] hereof the applicant alleges that the causes of action set out herein and the particulars thereof as pleaded apply to those breaches before and after the registration of the product on 4 August 2015.

The Applicant

~~58.~~36. The applicant was born on 29 December 1968

~~59.~~37. The applicant is, by trade, a stockperson.

~~60.~~38. In June 2014 the applicant commenced employment as a stockperson with JBSS Caroona Feed Lot (the "employer").

~~61.~~39. In or about July 2014 the applicant was informed by Meg Wippell, the Livestock Manager of the employer that her horses had to be vaccinated for Hendra or her employment would be terminated and that the employer would pay for four horses for one year to be vaccinated.

~~62.~~40. At that time the applicant had two horses working in the feed lot and ~~all~~ both were in good health and did not have any symptoms of Hendra or any other illness.

~~63.~~41. On or about 29 July 2014 Dr Lisa Goodchild, a veterinarian from Quirindi ~~Veteranarian~~Veterinarian Clinic, 81 Pryor St, Quirindi NSW 2343, injected the applicant's two horses, Primetime and Ervines Jive, at the Caroona Feedlot with the HeV product. At the same time, Dr Goodchild administered the 2-in-1 vaccination for strangles and tetanus as well as an oral drench provided by the employer. ~~as well as a vaccination for tetanus and strangles.~~

~~64.~~42. The applicant was not advised by ~~Dr David Frith or~~ Dr Lisa Goodchild that:

(a) The product was not registered as a vaccine or for general use;
(b) There were side effects to the product;
(c) The product was being administered under a minor use permit;
(d) Use of the product as a general vaccine was not permitted under the minor use permit.
(e) ~~The Hendra vaccine compatibility studies with~~No studies had been conducted into the concurrent use of the HeV product with other veterinary products ~~have not yet been performed~~.
(f) The effect of this product on pregnant mares or on horses intended for breeding is not known.
(g) Administration of the second HeV injection ~~18~~ within 21 days after initial HeV injection is against permit ~~requirements~~restrictions.

~~65.~~43. Ms Jo Bromley, accompanied by Dr David Frith, administered a second dose to the applicant's horses on 20 August 2014.

~~66.~~44. Both horses were injected twice at the same site on the left side of the neck.

~~67.~~45. Primetime was an 11-year-old mare who was, prior to the HeV injection, fit and healthy according to the applicant. Primetime was a ~~well-educated~~well-educated camp drafting horse.

~~68.~~46. Ervines Jive was a five-year-old mare who was, prior to the HeV injection fit and healthy according to the applicant. Ervines Jive was quiet and easy to handle.

~~69.~~47. A blood sample was collected from ~~each horse on 16~~Primetime and Ervines Jive on 24 September 2014. The sample was sent to Richard L'Estrange of Zoetis who confirmed receipt of the samples~~on 18 September 2014~~.

~~70.~~48. On 21 August 2014 the applicant ~~noted~~ observed ~~that~~ neither Primetime or Ervines Jive ate their previous nights' meal. The applicant further noted that both horses were suffering from runny stools and injection site swellings.

~~71. Primetime was removed from the stable as she was too unwell to work.~~

~~72.~~49. ~~Primetime~~ 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.

~~73.~~50. ~~Ervines Jive~~On or about 1 September 2014 the Applicant observed that Primteime 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, ~~Ervines Jive~~ Primetime required four months of veterinary care.

~~74.~~51. On 24 September 2014 the applicant met with Mr Richmond Nicholl regarding the use of the HeV injection and requested a full biochemistry blood test be done on each horse.

~~75.~~52. The applicant was required to continue to ride her horses between 25 September 2014 and 1 October 2014 in her employment notwithstanding they were unfit. Shortly thereafter Primetime was removed from the stable as she was too unwell to work.

53. The applicant refused to have any further injections in her horses and her employment was terminated on 20 March 2015.

~~76. 72A The termination of the plaintiff's employment occurred because her employer wrongly believed because of the misleading or deceptive conduct of the respondent as~~

~~pleaded herein that it was in its interest to require the product to be administered to all horses on properties owned by it to protect the safety of those horses.~~

54. Neither Primetime or Ervines Jive fully recovered from the effects of the injection.

55. As a result of the effect of the injection on both Primetime and Ervines Jive lost significant value.

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

57. Prior to the injection, Ervines Jive had a value of approximately $16,000. Since the injection and subsequent reaction, Ervines Jive cannot be sold.

58. In treating ~~Primteime~~Primetime and Ervines Jive, the Applicant incurred costs of $2,286.36.

59. Further, the Applicant claims loss of income from employment from 20 March 2015 to 19 September 2016 being an amount of $43,389.

~~77. 73A [Insert how much "Primetime" was worth prior to the injections and what it was worth after the injections and similarly with "Ervines Jive".]~~

~~**Registration**~~

~~78. Alternatively and in addition, on 4 August 2015 the APVMA permitted the respondent to register the product.~~

~~79. The product was registered as "an aid in the prevention of disease caused by the Hendra virus~~

~~80. The respondent thereafter manufactured, marketed, promoted and provided the product for general use.~~

~~81. At all material time the respondent knew or ought to have known that under the Minor Use Permit the product had been marketed, promoted and used as:~~

~~a. Preventing the~~

~~i. Contracting;~~

~~ii. Infection;~~

~~iii. Viral shedding of Hendra by horses;~~

~~iv. Transmission of Hendra from horse to horse;~~

~~v. Transmission of Hendra from horse to humans;~~

~~b. Protecting humans from contracting the infection;~~

c. Suitable and appropriate for use in controlling an endemic or outbreak of Hendra in Queensland and New South Wales;

d. Being as close to 100% effective as a vaccine can be;

Section 18 of the Australian Consumer Law (ACL).

82. After registration and contrary to the terms of the registration the product continued to be used for the same purposes under the Minor Use Permits which were also in contravention of the terms of registration.

83. In supplying the product respondent was engaged in trade or commerce.

84. The respondent engaged in conduct that was misleading or deceptive or likely to mislead or deceive in that it:

a. packaged and distributed the product without adequate warning as to the side effects; and

b. distributed product information without any warning or insufficient warning as to the side effects.

c. The respondent's failure to warn of the side effects misled and deceived:

i. veterinarians responsible for the supply, prescribing and administering the drug;

ii. the applicant and group members who purchased or permitted the drug to be administered to their horses.

85. Further in breach of the permits issued to it by the APVMA the respondent permitted and promoted the product to be used as a vaccine thereby misleading the users of the product that it was registered and suitable for that purpose and engaged in misleading conduct in failing to notify and inform veterinarians and horse owners that the continued use of the product in breach of registration restrictions and was not permitted.

Common issues of law and fact

86.60. The claims of the group members raise identical, similar or related issues of fact or law, namely:

a) Does the product cause, exacerbate or contribute to an increased risk of having the side effects in the manner alleged herein?

b) Did Was the respondent breach s.79 of the Agvet Code inCode in the manner alleged hereinnegligent and/or did they fail in their duty of safety and/or duty to warn/inform imposed upon them as developers, designers, researchers, manufacturers, testers, marketers, labellers, packagers, promoters, advertisers, distributers, and/or sellers of the product?

c) Did the respondent breach s.18 of the ACL in the manner alleged herein~~Was the product developed, designed, manufactured, tested, marketed, labelled, packaged, promoted, advertised, distributed, and/or sold with defects that increased the risk of a horse to which it was administered having the side effects~~?

d) Was ~~Did~~ the respondent negligent in the manner alleged or at all~~fail to adequately conduct, supervise and/or monitor clinical trials for the product~~ in the manner alleged herein?

e) Did the respondent fail to adequately and properly test the product before and/or after placing it on the market in the manner alleged herein?

f) Did the respondent know or should have known about the risks associated with the use of the product in the manner alleged herein?

g) Did the respondent knowingly, recklessly or negligently misrepresent to ~~Class Members~~Group Members, APVMA, and/or veterinarians the risks of harm from the use of the product in the manner alleged herein?

h) Did the respondent knowingly fail to disclose and warn of the product defects in the manner alleged herein?

i) Did the respondent adequately and sufficiently warn the applicant and ~~Class~~ Group Members and/or the veterinarians of the ~~Class~~ Group Members about the risks associated with the use of the product in the manner alleged herein?

j) Should the product have been sold with more appropriate warnings in the manner alleged herein?

k) Did the respondent engage in false advertising when it represented, through advertisements, promotions and other representations, that the product was safe or omitted to disclose material facts regarding the products' safety in the manner alleged herein?

l) Should the respondent have given written notification to all vets of the restrictive use of the product after registration in the manner alleged herein?

m) If the responsibility of the respondent is established, what is the nature and the extent of damages and other remedies to which the applicant members of the Class can claim from the respondent in the manner alleged herein?

n) Are the applicant and members of the Class entitled to general damages and damages for economic loss in the manner alleged herein?

THE APPLICANT AND GROUP MEMBERS CLAIM

~~1. Non economic~~Non-economic ~~loss~~ for the distress suffered by them caused by the ~~sickness and/or death of their horses from the side-effects.~~

1. Damages for economic loss caused by the death or sickness of their horses including veterinarian expenses, the loss or diminution in the value of the animals and any consequential losses occasioned as a result of the injury or death of the animals as income producing chattels caused by the product. ~~to be assessed~~.

2. Interest.

3. Costs.

ATTACHMENT "A"

SIDE EFFECTS

1. Abdominal pain
2. abnormal breathing
3. Abortion
4. Adipsia
5. Aggression
6. Agitation
7. Allergy
8. Alopecia (general)
9. Alopecia (localised)
10. Anaphylaxis
11. Anorexia
12. Anuria
13. Ataxia
14. Atrophy
15. Azoturia
16. Behavioural change
17. Bradycardia
18. Coat colour change
19. Coat discoloration
20. Colic
21. Colitis
22. Confusion

23. Conjunctivitis

24. Constipation

25. Coughing

26. Death

27. Depression

28. Dermatitis

29. Diarrhoea

30. Disorientation

31. Distress

32. Dyspnoea

33. Eczema

34. Epistaxis

35. Facial oedema

36. Fasciculation

37. Haematoma

38. Hepatopathy

39. Hives

40. Hyperactivity

41. Hyperaesthesia

42. Hypersalivation

43. Hypersensitive to stimuli

44. Hypersensitivity reaction

45. Incoordination

46. Inflammation

47. Injection site reaction

48. Lame

49. Laminitis

50. Laryngitis

51. Lesions

52. Lethargy

53. Listless

54. Lump (local)

55. Lymphadenitis

56. Lymphadenopathy

57. Malaise

58. Muscle stiffness

59. Nasal discharge

60. Oedema

61. Pain

62. Pale mucous membranes

63. Panting

64. Paresis

65. Periorbital swelling

66. Polydipsia

67. Polymyositis

68. Preputial swelling

69. Pruritis

70. Pyrexia

71. Rash

72. Recumbency

73. Respiratory problems

74. Restlessness

75. Scrotitis

76. Shaking

77. Site reaction (swelling)

78. Stiffness

79. Stranguria

80. Sweating

81. Tachycardia

82. Tachypnoea

83. Tremor

84. Urticaria

85. Walking (difficult)

86. Weakness

87. Weight loss

88. Welts

Date: ~~15 March 2018~~24 May 2018

Signed by Matthew Berenger
Solicitor on behalf of the Applicant

This pleading was prepared by Matthew Berenger, lawyer

Pursuant to Rule 8.23(1)(b)(ii) - orders permitting the amendments of the Applicants statement of claim was made on 19 April 2018.

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: ~~15 March 2018~~24 May 2018

Signed by Matthew Berenger
Lawyer for the Applicant

abAForm 17
Rule 8.05(1)(a)

Amended Statement of Claim

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

No. 406 of 2018

Rachael Abbott
Applicant

Zoetis Australia Pty Ltd
Respondent

Details of claim

REPRESENTATIVE PROCEEDINGS

1. This is a representative proceeding brought under Part IVA of the *Federal Court of Australia Act*, 1976 by the applicant on her own behalf and on behalf of other horse owners whose horses have died or suffered adverse side-effects from being administered the product as defined herein.

DEFINITIONS

2. **AGVET CODE** means Agricultural and Veterinary Chemicals Act 1994.
3. **APVMA** means Australian Pesticides and Veterinary Medicines Authority.
4. **AVA** means Australian Veterinarians Association.
5. **EA** means Equestrian Australia, a non-profit organisation whose objects are to control equestrian sport in Australia and international competition as a member of Federation Equestre Internationale.
6. **EVA** means Equine Veterinarians (Association) Australia.
7. **ENSW** means Equestrian New South Wales, non-profit organisation whose objects are to control equestrian sport in New South Wales and is a part of EA.
8. **Product** means the vaccine developed and sold by the respondent to treat the Hendra virus.

Filed on behalf of Rachael Abbott, Lead Applicant
Prepared by (name of person/lawyer) Matthew Berenger
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

9. **Side effects** means the side effects reported to the APVMA and contained in Attachment "A" hereto together with other side effects that may be proven.
10. **VETERINARIANS** includes veterinarians trained and authorised to administer the product for the purpose provided by the minor use permits issued by APVMA.
11. **INTERMEDIARIES** means AVA, EA, EVA, ENSW and VETERINARIANS.

THE RESPONDENT

12. The respondent is a company incorporated in Australia and liable to be sued in its corporate name and style.
13. The respondent carries on the business of designing, manufacturing, distributing and marketing veterinary medicines and products.

The Vaccine and application to APVMA

14. The respondent developed the product.
15. The respondent made application to the APVMA for minor use permits.

Particulars:

(i) On 1 November 2012 APVMA first released the product on minor use permit number PER13510 which was in force from 10 August 2012 to 3 August 2014.

(ii) On application by respondent the APVMA issued a second minor use permit number PER14876 which was in force from 4 August 2014 to 4 August 2015.

(iii) The directions for use on permits PER13510 and PER14876 was as "An aid in the prevention of clinical disease caused by Hendra virus."

(iv) On application by respondent the APVMA issued a third minor use permit number PER14887 which was in force from 31 March 2015 to 4 August 2015.

(v) The directions for use on permit PER14887 was as "An aid in the prevention of clinical symptoms of the disease caused by Hendra virus."

(vi) The directions for use on permits PER13510 and PER14876 was as "an aid in the prevention of clinical disease caused by Hendra virus".

Breach of Statutory Duty

16. Section 89(1)(a) of the Agvet Code imposed upon the respondent a duty not to publish or communicate any false or misleading information about the product.
17. In contravention of s.89(1)(a) of the Agvet Code the respondent published the following false or misleading information about the product:

Particulars:

(i) That there was a risk to humans of contracting the Hendra virus in areas outside the eastern seaboard of Queensland and the north-eastern corner of New South Wales.

(ii) That horses that were outside the area of the eastern seaboard of Queensland or north-eastern New South Wales were exposed to the risk of contracting the Hendra virus;

(iii) That it was necessary for the owners of horses outside the area of the eastern seaboard of Queensland or the north-eastern corner of New South Wales to have their horses inoculated with the product to prevent humans from contracting the Hendra virus;

(iv) That the Hendra virus could be transferred from horses to humans in circumstances other than being exposed to fluids from horses alive or dead which horses had the Hendra virus;

(v) That the Hendra virus could be transmitted from horse to horse otherwise than by an exchange of bodily fluids from a horse infected with the Hendra virus to another horse;

(vi) That the side-effects from inoculation with the product were minor;

(vii) That it was necessary for owners of horses to have their horses inoculated with the product to protect their families from the risk of contracting the Hendra virus;

(viii) That it was necessary for veterinarians practising outside the area of the Queensland seaboard and the north-eastern corner of New South Wales to inoculate horses with the product to prevent them from catching the Hendra virus;

(ix) That horses inoculated with the product could not contract the Hendra virus.

(x) That the effect of the product on horses was the same as any inoculation to humans;

(xi) That the product was 100% effective;

(xii) That Hendra kills more veterinarians than any other cause.

(xiii) That Hendra was deadly to veterinarians.

18. Further, or in the alternative, in contravention of Section 89(1)(c) of the Agvet Code the respondent impliedly claimed that the use of the product was safe when this was untrue by reason of the side-effects contained in Attachment A hereto.

19. The applicant and group members for the reasons alleged in paragraphs 17 and 18 hereof have a cause of action for breach of statutory duty in that they were persons within the contemplation of the Parliament as classes of persons specifically in need of the protection against the publishing or communicating of false or misleading information in contravention of Section 89 of the Agvet Code.

Section 18 of the Australian Consumer Law (ACL).

20. In supplying the product respondent was engaged in trade or commerce.

21. The respondent in contravention of s.18 of ACL engaged in conduct that was misleading or deceptive or likely to mislead or deceive in that it distributed product information without any warning as to all of the side-effects in Attachment A.

22. The respondent engaged in conduct that was misleading or deceptive or likely to mislead or deceive in that it distributed product information with insufficient warning as to the side effects in Annexure A.

23. Further, or in the alternative, the applicant repeats the allegations contained in the particulars (i)-(x) in paragraph 17 and paragraph 18 hereof and says that the conduct therein alleged also contravened s.18 of ACL.

24. Further, the conduct referred to in in paragraphs 20 to 23 above was conduct which misled or deceived or was likely to mislead or deceive veterinarians to prescribe , supply and administer the product or the applicant and group members to purchase or permit the product to be administered to their horses thereby causing loss or damage to them from the horses suffering from the side-effects in Attachment A;

25. Further, or in the alternative, in contravention of s.18 of the ACL the conduct of the respondent in permitting in excess of 300,000 doses of the product to be administered was misleading or deceptive in that such extensive use was not permitted by the minor use permits.

26. Further, or in the alternative, the respondent in contravention of s.18 of the ACL represented by its conduct that the permits that it obtained authorised the administration of the product in an unrestricted manner.

27. Further, or in the alternative, the respondent in contravention of s.18 of the ACL failed to correct by media or otherwise the widespread misuse of the product as a general vaccine against contraction of the Hendra virus.

28. Further, or in the alternative, the respondent in contravention of s.18 of the ACL cooperated and assisted the intermediaries in promoting the product as a general vaccine when it knew or ought to have known that the intermediaries were unaware of the side-effects.

29. The Respondent In contravention of s.18 of the ACL made the following representations which were misleading or deceptive or likely to mislead or deceive:

a) That the product was safe;
b) That the product was free of adverse reactions including death;
c) That Hendra virus could be transmitted between horses;
d) That Hendra virus was highly contagious between horses;
e) That people interacting amongst horses increases the likelihood of human exposure to the disease;

30. The respondent is liable to compensate the applicant and each group member for the amount of loss and damage suffered by them as a result of their horses having suffered one or more of the side effects and each group member under section 236 is entitled to recover compensation by this action from the respondent.

Negligence

31. The respondent owed a duty of care to the applicant and the group members to exercise reasonable care in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, distribution and/or sale of the product.

32. The applicant and group members suffered loss and damage by reason of the breaches by the respondent of the duty of care that it owed to them.

PARTICULARS OF BREACH OF DUTY

33. The respondent was negligent in that, by its servants or agents;

a) Knew or ought to have known that the product caused the adverse side effects in Attachment A including death;

b) failed to take reasonable care to ensure the product was not dangerous to horses;

c) failed to conduct appropriate testing to determine whether and to what extent the injection of the product posed serious risks, including the death to horses;

d) failed to adequately test the product prior to placing it on the market;

e) failed to adequately test the product in a manner that would fully disclose the side effects including death of horses;

f) failed to use care in developing, designing and manufacturing the product so as to avoid posing unnecessary health risks to horses;

g) failed to conduct adequate pre-clinical and clinical testing, post-marketing surveillance and follow-up studies to determine the safety of the product;

h) failed to advise that the injection of the product could result in severe side effects, including but not limited to, death;

i) failed to advise the veterinary and scientific communities of the potential to cause the side effects including death;

j) failed to provide adequate and timely warnings or sufficient indications about the increased potential health risks to horses associated with the use of the product;

k) failed to provide group members and their veterinarians with adequate warnings or sufficient indications of inherent risks associated with the product;

l) failed to provide adequate warnings regarding the side effects of the product;

m) failed to provide adequate updated and current information to the applicant and group members and their veterinarians respecting the risks of the product as such information became available;

n) failed to provide prompt warnings of potential hazards of the product in the products' labelling;

o) Failed, after receiving notice of the side-effects associated with the product, to issue adequate warnings of the side-effects;

p) failed to educate sales representatives and veterinarians of the risks associated with the use of the product;

q) falsely stated and/or implied that the product were safe when they knew or ought to have known that this representation was false;

r) disregarding reports of side effects;

s) failed to adequately investigate reports of adverse side effects caused by the product;

t) failed to accurately and promptly disclose to APVMA information relating to the side effects associated with the product;

u) failed to modify the product data sheets and product labelling to record the side-effects;

v) failed to monitor and to initiate a timely review, evaluation and investigation of reports of side effects associated with the product;

w) failed to properly investigate cases of side effects caused by the Product;

x) failing to properly and adequately test for effectiveness and side-effects of the product by:

i. conducting testing using inappropriate species as controls;

ii. applying insufficient test protocols;

iii. euthanazing test horses before the disease or side effects could manifest themselves;

iv. not reporting tests that disclosed side effects;

v. failing to follow the Veterinary Medicines Manual of Requirements and Guidelines ("MORAG") in that it;

a) failed to exercise good laboratory practice in its safety testing; and

b) failed to conduct non clinical health and environment safety studies that were properly;

i. planned;

ii. monitored;

iii. recorded;

iv. archived; and

v. reported.

y) further or in the alternative it failed to conduct adequate clinical trials to ascertain the safety, efficacy and potential harmful side effects of the product.

z) further or in the alternative it failed to adequately evaluate the safety of the product by:

a) testing on animals of minimum age that were likely to receive the product;
b) failing to test the product on horses that were sero-negative;
c) failing to justify test on horses that were sero-positive;
d) failing to test the product on a minimum of eight animals
e) failed to closely observe and examine the tested animals for signs of local and systemic reactions including post mortem macroscopic and microscopic examination of injections sites;
f) failing to ascertain the need and frequency of booster doses of the product;
g) failing to test the effect of an overdose of the product;
h) failing to ascertain the reproductive safety of the product on mares and stallions by conducting a dedicated laboratory trial in conjunction with supplemented field data;
i) failing to conduct appropriate tests to ascertain the effect of the product on immunological functions;
j) Failing to conduct adequate field safety trials.

aa) permitted the product to be administered to a greater number of horses than permitted by the permit;

bb) permitted the product to be promoted as a vaccine when it knew it had not been tested or authorised by the APVMA to do so;

cc) failed to correct by media or otherwise the widespread misuse of the product as a vaccine;

dd) cooperated and assisted the intermediaries in promoting the product as a vaccine when it knew or ought to have known that the intermediaries were unaware of the side-effects;

ee) failed to exercise veterinary pharmacovigilance in that it:

i. did not adequately collect information of adverse side effects;
ii. did not adequately conduct post market surveillance of adverse effects;
iii. did not ensure the continued safety and efficacy of the product in its use in the field;

iv. failed to properly and promptly investigate and report serious adverse reactions to the product;

v. failed to properly instruct and train veterinarians to promptly report adverse reactions to the product;

ff) Failed to advise and instruct veterinarians that the product was not permitted for use as a general vaccine;

gg) the applicant also relies upon the defendant's breaches of s.79(1)(a) and s.79(1)(b) and s.18 of the ACL as evidence of negligence.

34. By reason of the negligence of the respondent the applicant and group members have suffered and will suffer loss and damage in that their horses became sick or died as a result of the side-effects caused by the administration of the product.

35. Except for the allegations made in paragraphs [33(BB)]-[33(GG)] hereof the applicant alleges that the causes of action set out herein and the particulars thereof as pleaded apply to those breaches before and after the registration of the product on 4 August 2015.

The Applicant

36. The applicant was born on 29 December 1968

37. The applicant is, by trade, a stockperson.

38. In June 2014 the applicant commenced employment as a stockperson with JBSS Caroona Feed Lot (the "employer").

39. In or about July 2014 the applicant was informed by Meg Wippell, the Livestock Manager of the employer that her horses had to be vaccinated for Hendra or her employment would be terminated and that the employer would pay for four horses for one year to be vaccinated.

40. At that time the applicant had two horses working in the feed lot and both were in good health and did not have any symptoms of Hendra or any other illness.

41. On or about 29 July 2014 Dr Lisa Goodchild, a veterinarian from Quirindi Veterinarian Clinic, 81 Pryor St, Quirindi NSW 2343, injected the applicant's two horses, Primetime and Ervines Jive, at the Caroona Feedlot with the HeV product. At the same time, Dr Goodchild administered the 2-in-1 vaccination for strangles and tetanus as well as an oral drench provided by the employer.

42. The applicant was not advised by Dr Lisa Goodchild that:

(a) The product was not registered as a vaccine or for general use;
(b) There were side effects to the product;
(c) The product was being administered under a minor use permit;
(d) Use of the product as a general vaccine was not permitted under the minor use permit.
(e) No studies had been conducted into the concurrent use of the HeV product with other veterinary products.
(f) The effect of this product on pregnant mares or on horses intended for breeding is not known.
(g) Administration of the second HeV injection within 21 days after initial HeV injection is against permit restrictions.

43. Ms Jo Bromley, accompanied by Dr David Frith, administered a second dose to the applicant's horses on 20 August 2014.

44. Both horses were injected twice at the same site on the left side of the neck.

45. Primetime was an 11-year-old mare who was, prior to the HeV injection, fit and healthy according to the applicant. Primetime was a well-educated camp drafting horse.

46. Ervines Jive was a five-year-old mare who was, prior to the HeV injection fit and healthy according to the applicant. Ervines Jive was quiet and easy to handle.

47. A blood sample was collected from Primetime and Ervines Jive on 24 September 2014. The sample was sent to Richard L'Estrange of Zoetis who confirmed receipt of the samples.

48. On 21 August 2014 the applicant observed neither Primetime or Ervines Jive ate their previous nights' meal. The applicant further noted that both horses were suffering from runny stools and injection site swellings.

49. 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.

50. On or about 1 September 2014 the Applicant observed that Primteime 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.

51. On 24 September 2014 the applicant met with Mr Richmond Nicholl regarding the use of the HeV injection and requested a full biochemistry blood test be done on each horse.

52. The applicant was required to continue to ride her horses between 25 September 2014 and 1 October 2014 in her employment notwithstanding they were unfit. Shortly thereafter Primetime was removed from the stable as she was too unwell to work.

53. The applicant refused to have any further injections in her horses and her employment was terminated on 20 March 2015.

54. Neither Primetime or Ervines Jive fully recovered from the effects of the injection.

55. As a result of the effect of the injection on both Primetime and Ervines Jive lost significant value.

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

57. Prior to the injection, Ervines Jive had a value of approximately $16,000. Since the injection and subsequent reaction, Ervines Jive cannot be sold.

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

59. Further, the Applicant claims loss of income from employment from 20 March 2015 to 19 September 2016 being an amount of $43,389.

Common issues of law and fact

60. The claims of the group members raise identical, similar or related issues of fact or law, namely:

a) Does the product cause, exacerbate or contribute to the side effects in the manner alleged herein?

b) Did the respondent breach s.79 of the Agvet Code in the manner alleged herein?

c) Did the respondent breach s.18 of the ACL in the manner alleged herein?

d) Was the respondent negligent in the manner alleged or at all in the manner alleged herein?

e) Did the respondent fail to adequately and properly test the product before and/or after placing it on the market in the manner alleged herein?

f) Did the respondent know or should have known about the risks associated with the use of the product in the manner alleged herein?

g) Did the respondent knowingly, recklessly or negligently misrepresent to Group Members, APVMA, and/or veterinarians the risks of harm from the use of the product in the manner alleged herein?

h) Did the respondent knowingly fail to disclose and warn of the product defects in the manner alleged herein?

i) Did the respondent adequately and sufficiently warn the applicant and Group Members and/or the veterinarians of the Group Members about the risks associated with the use of the product in the manner alleged herein?

j) Should the product have been sold with more appropriate warnings in the manner alleged herein?

k) Did the respondent engage in false advertising when it represented, through advertisements, promotions and other representations, that the product was safe or omitted to disclose material facts regarding the products' safety in the manner alleged herein?

l) Should the respondent have given written notification to all vets of the restrictive use of the product after registration in the manner alleged herein?

m) If the responsibility of the respondent is established, what is the nature and the extent of damages and other remedies to which the applicant members of the Class can claim from the respondent in the manner alleged herein?

n) Are the applicant and members of the Class entitled to general damages and damages for economic loss in the manner alleged herein?

THE APPLICANT AND GROUP MEMBERS CLAIM

1. Damages for economic loss caused by the death or sickness of their horses including veterinarian expenses, the loss or diminution in the value of the animals and any consequential losses occasioned as a result of the injury or death of the animals as income producing chattels caused by the product..

2. Interest.

3. Costs.

ATTACHMENT "A"

SIDE EFFECTS

1. Abdominal pain
2. abnormal breathing
3. Abortion
4. Adipsia
5. Aggression
6. Agitation
7. Allergy
8. Alopecia (general)
9. Alopecia (localised)
10. Anaphylaxis
11. Anorexia
12. Anuria
13. Ataxia
14. Atrophy
15. Azoturia
16. Behavioural change
17. Bradycardia
18. Coat colour change
19. Coat discoloration
20. Colic
21. Colitis
22. Confusion

23. Conjunctivitis

24. Constipation

25. Coughing

26. Death

27. Depression

28. Dermatitis

29. Diarrhoea

30. Disorientation

31. Distress

32. Dyspnoea

33. Eczema

34. Epistaxis

35. Facial oedema

36. Fasciculation

37. Haematoma

38. Hepatopathy

39. Hives

40. Hyperactivity

41. Hyperaesthesia

42. Hypersalivation

43. Hypersensitive to stimuli

44. Hypersensitivity reaction

45. Incoordination

46. Inflammation

47. Injection site reaction

48. Lame
49. Laminitis
50. Laryngitis
51. Lesions
52. Lethargy
53. Listless
54. Lump (local)
55. Lymphadenitis
56. Lymphadenopathy
57. Malaise
58. Muscle stiffness
59. Nasal discharge
60. Oedema
61. Pain
62. Pale mucous membranes
63. Panting
64. Paresis
65. Periorbital swelling
66. Polydipsia
67. Polymyositis
68. Preputial swelling
69. Pruritis
70. Pyrexia
71. Rash
72. Recumbency

73. Respiratory problems

74. Restlessness

75. Scrotitis

76. Shaking

77. Site reaction (swelling)

78. Stiffness

79. Stranguria

80. Sweating

81. Tachycardia

82. Tachypnoea

83. Tremor

84. Urticaria

85. Walking (difficult)

86. Weakness

87. Weight loss

88. Welts

Date: 24 May 2018

Signed by Matthew Berenger
Solicitor on behalf of the Applicant

This pleading was prepared by Matthew Berenger, lawyer

Pursuant to Rule 8.23(1)(b)(ii) - orders permitting the amendments of the Applicants statement of claim was made on 19 April 2018

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: 24 May 2018

Signed by Matthew Berenger
Lawyer for the Applicant