

SUBMISSION TO:

Agriculture and Environment Committee
Parliament House
George Street
BRISBANE QLD 4000

Email: acc@parliament.qld.gov.au

HeV VACCINATION STATUS AND ADVERSE REACTIONS ON MY HORSES:

In November 2012 I received information about HeV Vaccine from my local Vet about HeV for my horses which included the following advice:

- The vaccine was fully tested, safe and available under minor use Permit for administration by Vets only until it became a Registered Vaccine through APVMA.
- That Annual Vaccination was the goal (with further testing already being conducted)
- That the horses needed to be micro-chipped so all Vaccines administered would be recorded on Zoetis Register.
- That Current Data stated there were only minor adverse reactions.
- That for the safety of my family and the protection of my horses from Hendra that I should vaccinate.

At no stage was I advised by my Vet or Zoetis that my horses were part of ongoing trials on HeV Vaccine.

None of my three (3) horses (two over the age of 18yrs) had any health issues prior to Vaccination.

Following Veterinary advice:

- Three (3) horses were started on the HeV regime
- First (1st) shot on November 2012
- Second (2nd) shot December 2012
- 6 month booster shot June 2013 (**see attached email notification from Zoetis)

I monitored the temperature, pulse and respiration of all three horses for three (3) days prior to and three (3) days after each vaccination

Adverse Reactions noticed within first 24 hrs following each Vaccination were:

- Swelling at injection site on all three horses but more noticeable on one (1) horse
- Elevated temps in all three (3) but High (up to 40C) temperature, inappetence and depression observed in one (1) horse for period of 24hrs after administration of HeV
- ***Notified Vet of High Temp Reaction in one (1) horse so he could make the appropriate report. He said he would report. I do not know if it was reported to Zoetis and/or APVMA.***
- All three (3) horses suffered malaise and lethargy for 3-4 days post Vaccination

In three (3) previously Healthy Horses where nothing had changed except being given HeV Vaccinations I observed Adverse Reactions/Horse Health Issues within one month of post HeV Vaccinations:

- Laminitis, loss of weight, hives, aggressive behaviour (normally placid animal), large lump on crest of neck and despite regular worming had dull and listless coats (normally glossy).

Process and Accuracy of Reporting Adverse Reactions after administration of HeV:

- Owner Reports to Vets, Vets report to Zoetis and Zoetis reports to APVMA
- APVMA started to accept HeV Adverse Reaction Reports direct from Horse Owners from early 2015
- ALL VACCINATED HORSES are micro-chipped and listed (with Owner Details) on Zoetis Register
- As an Owner of VACCINATED HORSES I was NOT contacted by Zoetis or APVMA to ask about possible Adverse Reactions
- APVMA categorize ALL Adverse Reaction Reports received
- APVMA Registered HeV in August 2015 presumably using Adverse Reactions to help confirm safety, duration and effectiveness of HeV

The HeV Vaccine was released on a limited Permit in November 2012 prior to Registration. For some horses the HeV Vaccine is not SAFE.

- Why weren't Owners, of ALL VACCINATED HORSES, who were at any time listed on the Zoetis Register, contacted by Zoetis or APVMA for comment on any possible Adverse Reactions prior to Registration of HeV in August 2015?

Only after doing the HeV Vaccinations did I become aware of HeV Labelling which includes the following:

- Vaccination is an aid in the prevention of Hendra Symptoms
- Is not 100% guaranteed against a horse contracting Hendra
- A vaccinated Hendra infected horse may still shed the Virus

When I asked my Vet at the 6 monthly booster (June 2013) when or if it would become an annual vaccination and whether there was any further information on side effects my Vet said "You know about as much as I do."

End of January early February 2014:

- My Vet advised me they had been notified by Zoetis that due to a problem with scientific testing my horses required another 6 monthly booster in December 2013. Zoetis did not advise me via email (as they did via email for 1st 6 monthly booster in June 2013 - see attached) that a 2nd 6 monthly booster was required in December 2013.
- By end of January early February 2014 all three (3) horses were more than 5wks past the due date to have this Second (2nd) 6 monthly booster due in December 2013 which meant all three (3) horses were classified as unvaccinated and no longer appeared on the Zoetis Register.
- My Vet stated that my horses needed to restart the HeV regime in February 2014 as per Information given to them by Zoetis.

What I did:

- Sent an email to Zoetis 13/2/2014 (see copy attached) requesting if there was any "scientific data" to support the need to restart the HeV Vaccination regime due to missing December 2013 6 monthly booster and to query the safety on doing so.

- ***No reply or response was received from ZOETIS to my email.***

Without receiving a response to my email from Zoetis on evidence of necessity and safety I did not restart HeV Vaccination regime with my horses in February 2014:

- All three horses were given an "Annual" booster in July 2014 .
- Following this "Annual Booster" an email notice of when 2nd vaccinations were due was received from Zoetis therefore indicating that the stance of the requirement for my horses needing to restart the regime still existed, Zoetis were able to contact me to pass on this information in August 2014 therefore "I still wonder why my email of 13/2/2014 has not been responded to?"

My Vet advised they would accept Annual Vaccination to ensure Veterinary Care for my horses if needed.

Some Vets (and not ALL Vets) accepting Annual Vaccination is contradictory to how the Product has been Registered with APVMA i.e. 6 monthly boosters. Who is legally responsible and/or liable for any consequences arising due to not following APVMA 6 monthly protocol if an Annual Vaccinated horse contracts Hendra?

It is more than 3 years since the release of HeV in November 2012:

- Has Zoetis provided APPROPRIATE data to APVMA which demonstrates that HeV Vaccination Regime needs to restart (if Vaccinations have lapsed) due to being PROVEN that horses no longer have immunity from previous vaccinations?
- Has Zoetis provided APPROPRIATE data to APVMA which demonstrates it is not detrimental to the Horse Health if HeV Vaccination Regime is restarted?
- Has Zoetis provided NEW data to APVMA so HeV can be approved for Annual Vaccinations or maybe even longer Intervals?
- Has Zoetis provided NEW data to APVMA to give assurance that using the current protocol of 6 monthly Vaccinations Horses are not Over-Vaccinated or at any increased risk to their overall health?

HeV VACCINATION ISSUES OF "NO VAC NO TREATMENT":

With millions of people (Vets/Owners/Farriers/Equine Dentists/etc) handling millions of horses on a daily basis long before and after the introduction of HeV why is it that ALL reported horse to human infections have involved Vets or their Staff?

I am not qualified to be making decisions on the effectiveness of HeV. Neither the manufacturer Zoetis and/or Vet are able or willing to answer fair and reasonable questions on the duration/effectiveness/safety/likelihood of severe adverse reactions from the Product.

Vet/s give various reasons for their current "no vac no treatment" Policy for unvaccinated horses and whether valid or otherwise, it is extremely distressing to Horse Owners. Horses have and will suffer due to this Policy. Prior to availability of HeV in 2012 Vet/s were considerate to the welfare of horses and when required would attend, diagnose and give appropriate treatment. Whether horses were at home or away at Competition etc they could be diagnosed and receive appropriate treatment from ANY Vet/s for ANY situation without Hendra exclusion tests. Since the introduction of HeV unconditional attendance by Vet/s is no longer available and Hendra Exclusion tests seem to have become a mandatory part of diagnosis prior to treatment. Horses potentially could suffer for 1 – 4 days from a treatable illness awaiting results of these tests before receiving appropriate Veterinary treatment.

It seems that not ALL Horses are suitable to be HeV vaccinated. Despite Zoetis and APVMA Registration of the Product which supposedly means it is a safe and effective product the adverse side effects already seen on the health of my horses is extremely concerning. For this reason alone I have decided to cease HeV Vaccination of my horses.

Vet/s are within their rights to choose who and who they do not want as clients but what is my alternative when considering animal welfare? My horses suffer due to Adverse Reactions when administered with HeV. They may actually have a "life time" immunity from the 4 HeV Vaccinations they have already received and therefore safe for treatment by ALL Vets?

Since November 2012 there is no additional information available to Horse Owners from Zoetis (other than what appears on the Product Label) as to whether research has been ongoing which may advise the effectiveness of the Vaccine beyond 6 months, whether 6 monthly boosters is over vaccinating and/or whether as in my horses situation 4 vaccinations may provide them with a "life time" immunity and therefore Vet/s could attend them without concern of Hendra Virus Infection.

Such a difficult and compromising situation for Horses. Owner and the Vets all because of HeV.

The HeV Inquiry needs to investigate and include the following:

- 1) Identify the "real" risk to human life of Hendra Virus infection with everyday interaction with a horse
- 2) Identify the "real" level of adverse side effects occurring when horses are administered with HeV.
- 3) Identify the effects on horses and horse ownership of introduction of mandatory HeV vaccination
- 4) Identify the "real" reasons behind Veterinary Services Policy of "no vacs no treatments"
- 5) Identify Animal Welfare Concerns arising from Veterinary Services Policy of "no vacs no treatments"
- 6) Identify possible Economic ramifications for Businesses (e.g. farriers, produce stores, saddlers, horse flog makers) due to reduced Equine Ownership and Sport in Queensland

I request that during the Inquiry AEC use Zoetis and CSIRO HeV Research Data, Govt Dept Information (APVMA; BioSecurity Qld; WH&S) and Public Submissions to fully investigate all the aspects surrounding the use or non-use of HeV and finds answers to resolve the confusion faced daily by Competition/Recreational Horse Owners and the Veterinary Profession in Queensland.

Kind regards

[REDACTED]

Pauline Denise Fawcett

[REDACTED] Delaneys Creek Qld 4514

[REDACTED]

[REDACTED]

[REDACTED]

NOTE "my error" in said email in first line stating that commenced Nov/Dec 2013 but actually commenced vaccinating Nov/Dec 2012. ZOETIS records should have had correct information.***

----- Original Message -----

Subject: Re: Zoetis Hendra six month reminder

Date: 2014-02-13 16:36

From: [REDACTED]

To: support@vetsaustralia.com.au

To Whom It May Concern

I commenced my horses Hendra Virus Vaccines in November/December 2013. I received the email below from you advising the necessity for my horses to have a six monthly booster. They were vaccinated with that booster end of June 2013.

Let me state here that I am a very angry and dissatisfied customer!! I was one of only a few that took on the responsible role of vaccinating my horses in November/December 2012 when it was first released. Your Company followed up by notifying me through this attached email that my horses needed to receive a follow up vaccine of a 6 month booster end of June 2013. That booster was given end of June 2013. Why didn't your Company send me an email to notify me of the need for a second 6 monthly booster?

As part of the discussions with my Vet today I was told that because a second 6 monthly vaccine was not given at the end of December 2013 as per your Company's current protocol my horses are no longer classified as having Hendra Virus protection and that their vaccinations will need to start again....as though they had never had them in the first place!!

I am well aware that protection from Hendra Virus is vital for humans and horses and therefore to find a vaccine then trials are necessary. My initial response to the suggestion of Hendra Virus vaccination for my horses in November/December 2012 was that I was hesitant and concerned for the welfare of my horses as they may well become part of your Company's trial. After receiving this information today from my Vet I would be hard to convince that they were not part of your initial trial and due to lack of advice from your Company that they should have had a second 6 monthly booster they may well now part of your ongoing trials.

Like many other horse owners who commenced their horses Hendra Virus Vaccination in November/December 2012 I hoped to be given confirmation as to whether an Annual Booster will be all that is required. That information was expected to fall within the time frame of the initial vaccinations of my horses in November/December 2012 and a 6 month booster end of June 2013. I received notification that confirmation of an Annual Booster was compromised due to failure in testing. However I have not received ANY notification from your Company (as happened for the

first 6 monthly booster) that a second 6 monthly booster was required to maintain my horses status as having Hendra Virus protection. My horses did not receive a second 6 monthly booster at the end of December 2013 so now are no longer classified as having Hendra Virus protection and need to recommence the vaccination program.

Despite my concerns on whether the vaccine was safe for my horses both my family and my horses welfare was the reason I had the initial vaccines done in November/December 2012. With three horses to vaccinate this was not a cheap exercise and to be expected to recommence the program is just outrageous. Has any testing been done with horses recommencing the vaccinations? If so have any additional side effects been noticed? One of my horses has displayed an extremely high temperature as an adverse effect each time a vaccine has been administered (initial and booster) so aside from cost I do not want my horses to be exposed to further possible side effects should they be completely revaccinated.

How long will it be before trials are completed and it is proven or disproven whether my horses would actually still have Hendra Virus protection from the vaccines they have already received? If it is proven that a annual booster is all that is required (therefore with their current immunisations my horses would be due in June 2014) would my horses Hendra Virus protection status be reinstated?

My thoughts at this stage is that if I need to recommence the vaccinations (as suggested) I will wait until June 2014. My reasoning is that even if I were to commence them again now my horses Hendra Virus Protection will not be reinstated til a month or so prior to when their annual booster would have been due.

I want my horses and humans protected from Hendra Virus and would give another 6 monthly booster now if that will help keep up their protection. I am extremely disappointed that your Company did not notify me that they required a second 6 monthly booster and in not having it now deems them unprotected but I am not prepared to expose my horses to recommencing vaccinations if there is any possibility that a booster will continue their protection.

Thank you in advance for your response.

Regards
Pauline Fawcett

ATTACHED COPY OF EMAIL RECEIVED FROM ZOETIS FOR 1ST 6 MONTHLY HeV BOOSTER:

on May 17, 2013, **Vets Australia** <support@vetsaustralia.com.au> wrote:

If you are unable to see the message below, [click here to view](#).

Due to changes made to the Equivac[®] HeV label and minor use permit recently, your horses in November 2012 are almost due for a six month booster. Protocol requires a booster since the 2nd dose. This is a friendly reminder that it's nearly time for the booster dose.

Regards,

The team at Zoetis