

Dr. Tony Doherty MVB. MANZCVS..

[REDACTED]  
Caloundra Old 4551  
[REDACTED]



18 April 2016

The Agriculture and Environment Committee Hendra Vaccine Inquiry  
C/O Mr Rob Hansen  
Parliament House  
Brisbane  
Queensland 4000  
Phone: 07 3553 6660  
By email: [robert.hansen@parliament.qld.gov.au](mailto:robert.hansen@parliament.qld.gov.au)

Dear Mr Hansen,

**RE: Veterinarian Submission to Hendra virus Vaccine Inquiry**

### **Introduction.**

My name is **Dr. Anthony G Doherty MVB. MANZCVS**, and I am an equine veterinarian with over 25 years experience both here in Australia and overseas. I am the owner of the largest equine veterinary practice on the Sunshine Coast servicing an area from Burpengary in the south as far as Eumundi in the north and extending inland to Woodford. As well as providing a full ambulatory service we have the only equine surgical facility on the north side of Brisbane.

I am making this submission in an effort to dispel a lot of the misinformation which seems to abound regarding the Hendra vaccine, and the difficulties we as veterinarians face not only in treating horses once a daily basis and how the Hendra virus is impacting on recruiting and retaining veterinarians, our daily working life and on our families.

The first key points that need to be established are as follows:

1. The Hendra virus is endemic in Queensland and is a serious zoonosis
2. Hendra virus infection in horses is usually fatal
3. The main route of infection for horse is from the fly fox fruit bat
4. Infected horse shed large amounts of virus and can infect other horses, humans and other domestic animals
5. Hendra infection in humans is a serious zoonosis and is often fatal.
6. Currently there is only one commercially available Hendra vaccine namely Equivac HeV

The above points are a given, thus based on these facts it seems incredulous the amount of adverse public sentiment that has developed since the launch of the Hendra vaccine in November 2012, how or why has this occurred.

At its launch the product was over whelming welcomed by veterinary profession and the equestrian fraternity, and though I did welcome its arrival and immediately start to promote it to my clients I did as a scientist have some reservations namely, when I am promoting any product I like to have as much information as possible about it, and regardless of what animal one is vaccinating there are 2 common questions that any pet or animal owner will invariably ask:

- “How much is the vaccination going to cost

- and how often will I have to do it.

Often they will then ask about adverse reactions or side effects and the exact vaccination protocol that is, after the initial vaccination how many boosters will be required”

As to the first part of the question how much will it cost, that is a matter of professional judgement on how one values the service they provide.

The second part of the question how often will I have to do it( vaccination interval), this was where I felt somewhat compromised, as a scientist and a professional I like to have all the relevant data when endorsing a product, otherwise there is little to separate you from the snake oil salesmen and other charlatans. When this was raised with Zoetis we were told at the product launch that the limited registration had been granted “to save lives” and at the product launch the debate was quite heated and those who raised reservation on this matter were silenced by the use of the emotive excuse of saving lives. We're we also lead to believe that the duration of immunity studies and increasing the vaccine booster interval to annual was imminent. Thus based on this I and many of my colleagues embraced and promoted the product and continue to do so.

In making this submission I will address the following Terms of Reference in the Qld Parliament's Hendra virus Vaccine Inquiry as well as provide some personal experiences from administering this vaccine:

- The incidence and impact of adverse reactions by horses following vaccination and the reporting of adverse reactions and economic impacts of the Hendra vaccine.
- The development, trials and approval processes of the vaccine
- Who bears the risks of HeV infection and who incurs the costs and receives the benefits from each risk mitigation option.

#### **The incidence and impact of adverse reactions**

To date in our practice we have vaccinated several thousand horses and I can say without reservation that we have not have had any serious adverse reactions, certainly none that we have been aware off. Perhaps this is a combination of “good luck and good fortune but I think not, and I think it is impart due to the strict protocol we observe not only in vaccinating the horse but also in the handling of the vaccine.

In regard to these large number of supposed adverse reactions as far as I am aware **they have never been truly investigated and categorised in terms of what type of reaction they really are:**

- true adverse reactions to the actual vaccine that is immune mediated
- severe anaphylactic reaction of type 1 to 4
- reactions to the carrier that the antigen is compounded in
- bacterial infections due to contamination at the time of injection
- or a localised reaction to been injected at the wrong site

When considering these possibilities it should be borne in mind that if one gives enough injections over the course of your career you, will at some point be unfortunate enough to encounter at least one of these type of reactions, with a a bacterial contamination been the most common. I have discussed this matter on several occasions with my local Zoetis representative and their veterinary officer Dr. Richard L'estrange and have tried to impress on them the need to fully investigate and categorise these reactions.

In fact I think the general public is naïve in believing that there should be no reaction post vaccination, as slight swelling at the site or mild stiffness at the very least is not only acceptable but also highly desirable as an indicator of a good immune response. In fact overseas where Influenza vaccination is mandated by most equestrian disciplines for the last forty year or so, vaccination reactions were almost expected and as such most vaccinations were given in a dependent area of the body such as the pectoral muscle to facilitate dissipation the post vaccine swelling. Such reaction as now less of the norm due to improved vehicles in which the vaccines are compounded. Initial influenza vaccines were made up in a mercury based vehicle and later in a slight less reactive aluminium vehicle. **So in addition to actually classifying what type of adverse reaction has occurred it needs to be graded.**



As for the reason I believe our practice has had so few adverse is due to the protocol we have adopted a strict protocol which is as follows.

- A completed clinical examination including recording rectal temperature, respiratory rate, pulse and examination of the buccal mucosa and conjunctiva is performed on all horses prior to inoculation. Any horse with any of these parameters outside of the normal range is not vaccinated.
- Any horse that is still hot from been exercised, that is wet from been washed or hosed off or any horse that has sweated up, are not to be vaccinated until such time as they have cooled off and dried off
- The small volume of air that is the Equivac HeV vaccine syringe is to be expelled and not injected into the horses muscle
- Carefully placement of the vaccine in the correct location in the neck muscle mass, as placement either too far caudal or distal will result in a very painful response (which I have seen when asked to examine such horses that have been vaccinated by other veterinarians.)
- The horse is to be lightly exercised either later that day or the following day, by this I mean non strenuous exercise, but enough to promote movement and assist absorption and lymphatic drainage of any oedema or swelling that might develop as a result of the vaccination.
- Storage and handling of the vaccine. No vaccines are stored in vehicle fridges due to the fact that they are relatively unreliable. When we have a vaccination scheduled the vaccines are taken from our clinic vaccine fridge places in an Eskie on ice packs and the vet proceeds directly from the clinic to the scheduled vaccination. Only the predetermined number of vaccines is taken to the appointment. This somewhat fastidious cold chain logistics may seem somewhat of an over kill, and may have resulted in our practice missing out on potential revenue in that as we do not routinely carry the vaccines in our practice vehicles we are not able to vaccinate the "oh by the way while you're here can you Hendra vaccinate this horse", but we have implemented this protocol to try minimise potential adverse reactions but more importantly to ensure that the vaccines we are administering are as the manufacturer intended and have not been damaged or deactivated by a break in the cold chain and have been inactivated by over heating. Denaturing of the vaccine by over heating in a vehicle or fridge that is not working properly may account from some of the adverse reaction a fact that Zoetis again needs to investigate. But more importantly creates a serious zoonotic risk in that the owner will be unaware that the vaccine given to their horse was ineffective due to heat damage, and will be under a false sense of security that their horse is immune when it is not, and should the horse at sometime in the future become infected with Hendra, both the owner and attending veterinarian would be at a serious risk of exposure to the virus (I will come back to this matter later and a simple and cost effective solution).

Despite the fact that we have not experienced any severe adverse reactions, it is a matter I encounter virtually on a daily basis when I ask people why their horse is not vaccinated or why they are no doing their booster vaccinations. Any despite very few or any of them actually witnessing an adverse reaction, they all seem to be au fait with them usually through social media or through a friend of a friend. Of those who have either experienced an adverse reaction or have seen one it always strikes me as amazing that despite how sick and painful the horse was, and how concerned they were about its welfare, and how much the horse means to them no veterinarian or in particular the veterinarian who did the vaccination was called to see the horse. There in lies two key factors:

1. It is very hard to quantify or subjectively assess these reaction and draw meaningful scientific data and explanations from them, and **their very existence has to be questioned** like " the tree that fell in the woods but nobody saw it so did it really happen.
2. On asking why a reaction which they deem to be so severe and significant did not warrant veterinary attention a **common response is cost** and I feel that much of the hype

and **negativity to the vaccination program is cost driven**, and part of a mind set I believe is due to the fact that during the Equine Influenza outbreak in 2007 prophylactic vaccination of horses was free.

In fact when the vaccine was initially released under permit and not fully registered, one of the main conditions of the permit was that all adverse reactions were to be fully documented and reported back to Zoetis or the AVPMA. Our practice made a point of telling people at the time of vaccination that they were obliged to inform us of any adverse reactions and that we would investigate them at no cost to them, as I would seek remuneration from Zoetis for any costs incurred.

### **PPE and Prosecutions**

To compound the situation the recent prosecutions of 3 our colleagues has made a difficult and stressful situation even more untenable. If one sits down and analyses this situation and the resultant prosecutions the only rationale conclusion is that they are ludicrous. No one in an effort to do their job to the best of their ability will willingly expose themselves or those assisting them to the risk of contacting Hendra but this is basically what these prosecutions amount to. It is very easy for someone in WH&S in a nice air conditioned office several weeks or months after the event to sit down and go through it with a fine tooth comb to look for faults, bearing in mind that nobody in any of these situations was infected.

Working in PPE outfits is extremely difficult not to mention trying to deal with a fractious animal which is further frightened by the appearance of these people in alien looking PPE suits. Couple with this you are not in your normal controlled working environment despite WH&S claiming that once the veterinarian attends a property it is then their work environment even though you may never have been there before and it may be dark and the weather may be inclement.

Surely the logical approach, and that which legal justice is based on “that as long as one does what the reasonable person or your peers would do “ then you have no case to answer.”

Working in PPE suits is extremely difficult and in most cases not practical, and the decision to use it should be left to the veterinarian’s professional judgement not the fear of litigation. We must assume that Hendra has been endemic in Queensland even before the first confirmed case in 1994, and if you were to calculate the number of horses examined by all the equine vets in that time frame or even from 1994 onwards and ran a statistical analysis on it to justify the use of PPE when examining every single unvaccinated horse (all horses pre November 2012 were unvaccinated), I would think that the analysis would show that the use was totally unwarranted. From initial outbreak in 1994 until the outbreak in Redlands Veterinary Clinic in 2008 we both veterinarians and horse owners lived in blissful ignorance that Hendra would present as a severe respiratory condition with copious nasal discharge progressing rapidly to death. Only since 2008 have we been aware that the condition can present with a myriad of clinical signs from colic to neurological, to asymptotic shedders. With this increased knowledge of the clinical presentations and the unfortunate deaths of 2 of our colleagues one of whom I knew personally, means that we are now more acutely aware of the disease, and the occasions where we deem PPE is necessary should be left to our professional judgement not dictated to by the fear of legislation. In fact since 2008 the number of occasions where I personally done PPE has risen exponentially based on the increased awareness of the disease and its clinical manifestations.

### **Equivac HeV**

In light of the serious zoonotic implications of Hendra, the difficulty of diagnosing it from other conditions due to the vast array of clinical presentations, that working in PPE suits is impractical if not impossible in some cases due to the fractious nature of horses and more recently the omnipresent fear of been prosecute and facing either financial ruin or possible imprisonment, all in

the process of trying to do ones job something we studying many years to qualifying in and have dedicated our live to, **leads to only one logical conclusion, vaccination.**

Based on the data presented to date Equivac HeV seems to be an excellent product, one which has come to market a lot sooner than was previously expected or predicted. It's efficacy based on the data available so far is very impressive and this is borne out by the fact that the **regulatory authorities will allow horses that are fully vaccinated as per the current approved vaccination protocol to leave a venue where there has been a confirmed case of Hendra**, and will not be subjected to been quarantined in situ as would be mandated for the non vaccinated horses. This to me says more about the efficacy of the product than any scientific data, as I am unable to think of any other disease outbreak situation where vaccinated animals would be permitted to leave without further testing. It should be borne in mind that this decision is made by government departments not Zoetis, and thus is based on independent analysis and scrutiny.

The other key point regarding efficacy and safety in my opinion it that **this vaccine stops the transfer of the Hendra virus from horses to people.** To me this is the most important and poignant fact in the whole of this debate, and based on my experience to date with the product and the lack of adverse reactions or even if there is a low level of mild adverse reactions then that is within the acceptable limits when balanced against the fact that it stops transmission of Hendra to humans.

### **Where to from here following this Enquiry.**

I would hope that this Enquiry will produce some clear findings and recommendations based on good scientific basis and that these can be implemented in a logical and practical manner. It is regrettable that an excellent product namely Equivac HeV has in such a short space of time developed such negativity and I believe all stakeholders in this debate Zoetis, horse owners, regulatory bodies such as the AVPMA and veterinarians have played a contributing role to varying degrees.

#### **Registration**

I believe that the product was rushed to the market based on emotive issues and the pretext of the possibility of saving lives, and that the complete data in particular the Duration of Immunity studies, which would have determined the vaccination booster interval from the start should been in place before its registration. This would have negated a major doubt either real or perceived. As a result of this lack of this data these supposed adverse reactions are difficult to determine if they are due possible over vaccination.

In addition this situation was compounded by the product then been given fully registration recently despite this information not been available.

If the product was to be allowed to come to market on limited registration under a permit this should have been done under the conditions that it was a for a limited time only say 24 months and that full registration would not be granted until all scientific testing data had been completed and approved.

This lack of information has given those apposed to the product or the principle of vaccination in general a golden opportunity to manipulate this major weakness in the registration process, and as a result the products image has been tarnished possibly irreparably.

#### **Adverse Reactions**

It must be made fundamentally clear to all horse owners that if they experience an adverse reaction of any kind then it must be reported back to a veterinarian ideally the one who vaccinated it, and must be fully investigated. As to the costs of this I feel that Zoetis must make a major contribution and state so publicly. The horse owners for their part must not publish and disseminate unfounded and unsubstantiated and sometimes down right scurrilous information be it by word of mouth or in particular on social media.

A systemic process must be established to report, confirm, categorise and grade severity all adverse reactions. Once this data has been collected it must be analysed to determine if there is a problem with adverse reactions. Then and only then can it be determined if there is a problem, and not on



rumours and hear say which is currently the case. This will involved all stakeholders and Zoetis I believe will have to bear the majority of the costs for it s expedience in getting its product to market in such a relatively short period of time.

**Adverse reactions are a scientific matter and their existence or otherwise must be determined by scientific means.**

### **Equivac HeV**

In light of the publics reaction to this product it is unlikely other manufacturers will be willing to enter the market, so it is more than like that Equivac HeV will remain the sole Hendra vaccine, thus it is essential that this Enquiry makes clear and accurate findings to help resolve the matters raised as we veterinarians as well as horse owners and the general public need to be protected against exposure to this disease.

In light to the serious zoonotic risk the Hendra vaccine must **always remain a Vet Only Product**. To further insure it efficacy and minimise potential failure I would suggest that each vaccine dose as part of it s packaging has a heat sensitive indicator adhered to it. This practice is common with other vaccines and I am sure is not a significant cost. Such indicators change colour is the product has not been kept at the required temperature, and the product denatured. I had mentioned this to Zoetis shortly after the product was launched and on several occasions subsequently only to be told that the product as expensive enough as it was and they did not want to add additional costs to it.

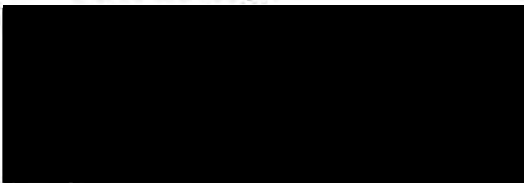
### **WH&S and Prosecution.**

I hope that during this course of this Enquiry it will become clear what a difficult and challenging environment we as veterinarians operate in, and this is further compounded when faced with a potential Hendra situation, and thus that the Enquiry's findings may direct WH&S to adopt a more practical and logical approach when examining many months after the event confirmed Hendra cases where veterinarians have been involved. They also need to be more proactive in informing horse owners of their responsibilities and duty of care in relation to Hendra if they are going to continue with prosecutions in the future.

The current situation where we as veterinarians are operating under the fear of litigation is seriously compromising our clinical judgement and as a result the welfare of the horses we are trying to treat.

In summary as stated earlier in light of this disease been endemic in Queensland and its ability to present with a myriad of clinical presentations the only no long term and viable option is routine vaccination based on sound scientific data in particular duration of immunity studies with a reasonable vaccination booster interval of at least one year. It is my professional opinion the Equivac HeV is an excellent when administered correctly but a booster interval of 6 months in unsustainable.

Yours sincerely,



**Dr Tony Doherty, MVB, MANZCVS (Equine Surgery)  
North Coast Equine Veterinary Services,**