

**Submission to the Agriculture & Environment Committee Hendra Vaccine Inquiry**  
c/o Research Director, Agriculture and Environment Committee  
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The announcement of a Hendra vaccine for horses in November 2012 was initially greeted with a sense of relief by horse owners in the mainly affected areas of Queensland and New South Wales. Since its early, limited introduction and later full registration though, a number of alarming issues have become apparent that were unforeseen at the time, which have ultimately led to this parliamentary inquiry.

The inquiry has the following terms of reference and the comments that I have are below each section.

**Terms of Reference no. 1 - The development, trials and approval processes**

The Hendra vaccine has been described as “...*the single most effective way of reducing the risk of Hendra virus infection in horses and provides a work health and safety and public health benefit by the vaccine's ability to not only protect horses from infection but also to break the cycle of virus transmission from horses to humans.*” <https://www.health.qld.gov.au/ph/documents/cdb/hev-inf-prev-adv.pdf> It has been heavily promoted by government health authorities and by veterinarians. Its effectiveness is emphasized and the side-effects are characterized as minor and rare. Owner's assertions regarding harmful reactions to the vaccine are dismissed as anecdotal and scarcely acknowledged.

So... let's look at the vaccine trials that have led to the proposed “One Health” solution for Hendra.

To test for vaccine efficacy, it is little appreciated that there have been only a few, very small sample-size horse studies performed and that in only one trial was a horse used as the control animal. All other trials used ferrets or guinea pigs. I understand the limitations imposed as a result of Hendra being classified as a Biosecurity Level 4 virus (the highest classification, for only the most dangerous pathogens) and having to do tests on a large animal, but the numbers remain minimal nevertheless and they preempt making sweeping declarations of how well the vaccine works based on such a small sample size and the failure to consistently use the same species as a control. In fact, in the second trial, prior to issuance of the minor use permit, only one of the four guinea pig controls died, illustrating the difficulty of matching up two very disparate species. Had another horse been the control and not died, the entire trial could have been invalidated under the same circumstances, so having multiple numbers of a small (completely different) animal allowed the trial to be considered good enough - apparently.

## **Terms of Reference no. 1 – (cont.)**

The minor use permit was released before the 6 month efficacy trial in horses was even done. When the 6 month trial was performed, perhaps its most significant findings was glossed over. Out of the 3 vaccinated horses, one had evidence of replicating virus in its nasal swabs on four sampling days. Why was this not flagged? This was an extraordinary finding as the incubation period for Hendra in a horse is 5-16 days, yet the animal was killed on Day 8, in the middle of that period. This was done before there was a chance to see whether it would have gone on to develop Hendra – which had it done so, would have had concerning implications for the efficacy of the vaccine. Again, it re-illustrates the limitations of drawing broad conclusions from such a small and limited dataset confounded by interspecies control animals. Any vet who thinks that such a vaccinated horse could pose little risk to them should carefully reconsider whether that is necessarily true in light of these results.

What little can be found on the 12 month efficacy study indicates that it failed completely, as neither the 2 control ferrets, nor the 3 vaccinated horses became infected from the Hendra virus challenge that they received.

There is also no mention of the mutability of the virus and the effect that this may have on vaccine efficacy as time goes on. Hendra is a relatively rare disease, given the number of horses in Australia, so it will be very hard to tell whether the vaccine is having an effect or not, although it will likely be given credit for any decline in spite of scant evidence.

### **Vaccine Safety Testing**

I have been unable to find details on the safety testing that was done on vaccinated horses. Pertinent questions that need to be answered include;

How many horses were tested?

What was the duration of testing?

What was used for the control, was it saline, was it adjuvant only or was it even another vaccine as done with some human vaccines?

Were the tests double-blind placebo-controlled?

Was the testing done by an independent party?

Unlike challenge testing with the virus, safety testing of the vaccine to look for adverse reactions would be relatively easy, far less costly and not require Bio-security 4 safety measures. It could easily have been continued in greater depth using horses whom owners have voluntarily vaccinated, who could and should have participated in the evaluation of adverse reactions.

## Terms of Reference no. 1 – (cont.)

Finally, the premise that the Hendra vaccine is the single most effective way of breaking the cycle of virus transmission from horses to humans needs to be examined more closely. Judging from the history of human infection, that cycle has already been broken by simple, now routine protocols. There have been 7 human cases (resulting in 4 deaths) from Hendra since its outbreak in 1994 to now (2016), 22 years on. Of those 4 deaths, 2 occurred in the initial outbreak before anyone knew, or had any understanding, of the disease. It was another 5 years before there was another case in horses and 10 years before another, non-fatal, human case, so people in that time would have been wondering if the disease was a rare, one-off occurrence. It would not have been at the forefront of their mind, especially in comparison to the many other ailments and risks that are routinely part of the horse world, and unlikely to have prompted changes in the safety precautions taken during invasive procedures.

In 2008-09, three more people contracted Hendra however, which resulted in 2 deaths. This jolted everyone's awareness level in a huge way and it was fortunate (in a tragic sense) that it did, for in 2011 there was an unusual, unexplained jump in Hendra horse infections to 23 from the usual 3-4 cases normally seen annually. In spite of this, neither at that time, nor since was anyone infected. This strongly suggests that the measures people have followed over the past 7 years have been demonstrably effective, given that there have been 50 cases of Hendra in horses since the last human infection as compared to 43 leading up to the last fatality. Of course another human infection could still happen from a lapse in procedure or unknown cause, but the same is true - perhaps even more so - in dealing with vaccinated horses where the possibility of Hendra is thought to be excluded but, as even suggested by the AVPMA, may not be.

I think that there is also a risk in viewing a vaccine as a panacea in that it creates a false sense of security and overlooks that there are, or in the near future may come to be, other equally serious diseases that careless procedures may expose one to.

## **Terms of Reference no. 2 - The incidence and impact of adverse reactions by horses following vaccination and the reporting of adverse reactions and economic impacts of the HeV EquiVacc® vaccine**

There have been several owner-reported instances of serious adverse vaccine reactions in horses, including death. Indeed horse owner concerns are what have prompted this inquiry and they highlight the deficiencies in the safety review process. Once a vaccine has been approved, its efficacy and safety are taken as virtually iron-clad, established facts - not subject to questioning - and owner observations after this seem to count for little. The latter are uniformly dismissed as anecdotal, unrelated to the vaccine or due to some prior condition.

Actually, I think that the truth is the reverse of this, that a concerned horse owner who is close to their horse is probably the best person to evaluate subtle changes and certainly dramatic ones and that it is the official testing that perhaps needs better scrutiny. Those doing the testing are not without self-interest, nor unintentional biases which is why double-blind, placebo-controlled studies are used whenever possible, and even they are not infallible. One would be reluctant to place much confidence in cigarette safety based on research by tobacco companies, but the same self-interest applies in any field where the research is done by its beneficiary and is even more concerning here, as government health authorities endorse vaccines, as opposed to tobacco, and it is very unlikely for there to ever be independent confirmation of results, especially in the case of a BSL4 pathogen.

The editor of The Lancet recently commented on the state of science research with the following words, *"The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness. As one participant put it, "poor methods get results".*" Richard Horton, Lancet editor-in-chief, <http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736%2815%2960696-1.pdf> The Lancet Vol 385, April 11, 2015

This followed a similar sentiment expressed earlier by the former Editor-in-Chief at the New England Journal of Medicine, Dr. Marcia Angell, (think vaccine for drug) <http://www.nybooks.com/articles/2009/01/15/drug-companies-doctors-a-story-of-corruption/> *"The problems I've discussed are not limited to psychiatry, although they reach their most florid form there. Similar conflicts of interest and biases exist in virtually every field of medicine, particularly those that rely heavily on drugs or devices. It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of The New England Journal of Medicine. One result of the pervasive bias is that physicians learn to practice a very drug-intensive style of medicine. Even when changes in lifestyle would be more effective, doctors and their patients often believe that for every ailment and discontent there is a drug."*

## Terms of Reference no. 2 - (cont.)

Because there have been so many reports of horse injury from the vaccine, it should be asked of Zoetis whether they (or Pfizer Animal Health before them, or any other entity that they may have a relationship with) have ever paid out any vaccine-related compensation (regardless of whether they acknowledged culpability) and whether any gag order has been attached – as is typically the case. Such actions, which are not uncommon for corporations to do in order to protect their interests, would further skew reported adverse reactions, especially extreme ones, and the testimony of any individuals involved in this way should be sought.

Of the horses that have reportedly died after receiving the vaccine, what has been done? Were autopsies performed to determine the cause? Why should the onus be on the horse owner to investigate this rather than the pharmaceutical company that insists its newly released product is safe and not responsible? When only individual, concerned horse owners perform an autopsy (and this may become more rare as the cost of heightened bio-security precautions apply) how can meaningful results be correlated between different events to make a finding? Particularly in the case of death, there should be provision for an independent, post-mortem investigation to look for any abnormal pathology. I should think it very difficult from that alone to establish a cause and effect with the vaccine (if there was one), but it would allow for a pattern consistent with adverse reactions to be recognized over time. As it is now, any suggestion of this kind can easily be dismissed as non-proven and being out-weighted by the benefits, etc.

The practicalities of the vaccine as the solution to Hendra have also been overlooked. There are apparently about a million horses in Australia and perhaps around 400,000 or so of them are in the affected areas, however, someone outside of there will still have to vaccinate their horse to compete in those regions or where competitions or other events make it mandatory, so potentially a very large number of horses would be required to be vaccinated. This is not a one time shot either. At present, the interval for immunization boosters is 6 months – for the life of the horse (up to 30 years)! Even if the interval is doubled, it represents a lot of shots and as many opportunities for adverse reactions to develop. I have no idea if vets and the pharmaceutical company would get rich from this, but horse owners would certainly become poorer.

The cost is often trivialized on vet sites by declaring that it is comparable to the cost of shoeing a horse, but this is misleading. One does not shoe a horse its entire life from birth to death and usually only those horses in work are shod. Even then, they are seasonally spelled without shoes to allow their feet to recover. Vaccinating all horses for life would lead to there being far less horses, with many more being killed once their usefulness was over to avoid the additional ongoing cost of immunization.

### **Terms of Reference no. 3 - Who bears the risks of HeV infection and who incurs the costs and receives the benefits from each risk mitigation option**

The risks of HeV infection are obviously borne by anyone who undertakes invasive procedures on a horse without PPE. As for risk mitigation, this requires an understanding of how the disease is spread in the first place and this appears to have some gaping holes.

In virtually all of the literature about Hendra, it is stated that the virus which causes the disease is transmitted by fruit bats to horses. Rather less often, one reads that no one has actually been able to achieve this transmission in the lab, even after several years of attempts. I find this result remarkable. While the virus is certainly to be found in bats, it suggests that our knowledge of how horses contract the disease is critically incomplete or even wrong. Sometimes an "obvious" explanation can be the main hindrance to discovering the real cause.

If the disease is in fact spread by bats, then it suggests that a co-factor may be necessary for inoculation, for it to so rarely occur – and that could be in the horse. For instance, it could be that a mineral deficient horse that has grazed on a heavily herbicide-treated pasture becomes susceptible. This is by no means to suggest that this is the co-factor, but rather to point out that the critical element in the infection process could turn out to be something very simple and its prevention trivial in comparison to what is entailed in – and what is assumed – by insisting on vaccinating all horses.

I also have to question the procedure of immediately killing any horse that tests positive for Hendra, but which is otherwise well. I understand the BSL4 issue, but would think that an animal that recovers or is relatively unaffected would be of extraordinary interest and that one loses a prime research opportunity by failing to study such an animal, even if it is killed later. If this were a human disease, obviously the person who failed to show clinical signs wouldn't be euthanized, rather they would be the subject of intense scrutiny to try and establish why they remained healthy and how that could be used to treat or prevent the disease.

As for the benefit, or more precisely the benefactor, of the vaccine mitigation option, it certainly represents a wonderful opportunity for the company making it - a rare animal disease (less testing/costs to develop than for human vaccines and the bonus of a lower regulatory bar), that can be extremely deadly to the animal as well as to humans (hence something people and governments will want, may help pay for and could mandate), that needs to be injected every 6 months for the life of the animal (maybe later 12 mos). Best of all, its efficacy is unlikely to be challenged. Symptoms of Hendra are similar to many other very common horse conditions, so a vaccinated horse that exhibits these signs will be assumed to be immune and not Hendra tested (why would one test unnecessarily anyway and risk regulatory intrusion?). Thus any lack of effectiveness has little chance of even being recognized, or in the very rare instance that it is, can easily be discounted as "no vaccine is 100% effective" which for such a rare disease, as long as adverse effects can be managed or marginalized, means that it could have a very long and profitable market life.

**Terms of Reference no. 4 - Whether the guidelines/procedures required for veterinarians attending horses that are not vaccinated against HeV are proportionate to the consequences**

It's not so much the Hendra-related recommendations themselves that are the issue as it is the charges and potential fines that have been levied against vets who have been accused of being in breach of these in some way. Vets who treat an unvaccinated horse that afterwards is found to have Hendra, risk being charged with an offence and incurring exorbitant, punitive fines if they are deemed to have not followed appropriate bio-security measures prior to first testing for Hendra, yet the APVMA's own guidelines advise treating vaccinated horses the same as unvaccinated ones.

*"The potential for a vaccinated horse to pass on the Hendra virus cannot be ruled out. As a precaution, **it is recommended people take the same steps to protect vaccinated horses from exposure to infection—and to prevent humans being infected by horses—as are recommended for unvaccinated horses.** Personal protective equipment should be worn whenever infection is suspected even in vaccinated horses."* (emphasis added) <http://apvma.gov.au/node/12881>

It is frequently declared that one should vaccinate their horse so that a vet may attend a horse without first needing to test for Hendra, but this seems to be more a matter of avoiding selective prosecution than following the guidelines used to justify them.

Since the symptoms that would cause a vet to suspect Hendra are common to a host of ailments, including colic (which is very common), this in effect makes every case of colic a possible Hendra case.

Contrast the justification for imposing these punitive fines to doctors treating human patients. They do not turn patients away unless they first have HIV, TB, serious pneumonia, Hep C, etc tests before examining them. Emergency workers who may easily be exposed to infectious disease when treating casualties wear protective equipment, such as gloves, but they are not in positive pressure suits either. Someone performing a high-risk surgery might be, but it would not be expected in a GP who first saw the patient when they were still alive and the most infectious. It is all about balancing risks and in the case of what has been imposed on vets, the balance has been skewed completely out of reason.

I do think it reasonable to require vets to wait for a Hendra test clearance before performing an autopsy on a *dead* horse that displayed symptoms consistent with the disease and to secure the corpse and surrounding area appropriately until then, but to impose the same requirement on virtually every unwell horse is not.

I think it also important to reflect on the effect that these regulatory actions have on dampening cooperation and gleaning helpful information from vets in the field. Consider, for example, the following advice found on a legal firm's website regarding this matter,

**Terms of Reference no. 4 – (cont.)**

*“Hendra is a bat-borne virus deadly to horses and humans. Its management is heavily regulated to limit the risk vets and horse handlers face while attending animals that may have the virus.*

*From speaking with local vets these cases have had the devastating impact of many vets refusing to attend horses in need of treatment that have not been vaccinated against Hendra for fear of prosecution.*

*Workplace Health and Safety are active in pursuing prosecutions where they consider they have sufficient evidence to do so. You should be aware that when communicating with any regulatory authority their primary purpose, however friendly they appear, is to obtain evidence against you. We recommend that you carefully consider all information that you provide and if you have any doubt about this information you should obtain independent legal advice particularly if you are requested to provide documentation or attend an interview.”*

<https://www.emerylegal.com.au/equine---horse.html>

## **Terms of Reference no. 5 - Impacts on the equine industry and the economy arising from veterinarians applying a policy not to treat unvaccinated horses**

I think veterinarians have the right to refuse to do anything that they feel to be unsafe and are under no obligation to treat unvaccinated horses, if they feel that is an unacceptable risk to themselves. On the other hand, vets who are willing to treat unvaccinated horses, should not in effect be prevented from doing so by having heavy-handed fines imposed on them – as has been done. The result of the current situation is that a horse with colic, for instance, will die an agonizing death by the time a Hendra test result is obtained. The retort that owners should simply vaccinate their horses to protect both the horse and the vet ignores the adverse consequences, including horse deaths, which have occurred to some owners who have followed this advice.

This has also had a severe impact on horse events that require vets to be present causing events to be canceled or limiting who may attend by requiring that only vaccinated horses be allowed to compete.

I think it is important to again re-emphasize that the entire crisis which has led to this parliamentary inquiry stems from the malicious prosecution of vets who have chosen to treat unvaccinated horses. Prior to this, it was largely an individual decision on what to do – as it should be. Some vets chose not to treat non-vaccinated horses, while other vets would, but once prosecutions began, the latter in many cases felt as though they had no option but to stop, leaving many horse owners and event organizers in the lurch. If one wishes to quickly resolve this matter, all that would be required is to end this campaign against the vets.

It is easy to see why vets in general would support vaccination. For them there is no downside. They get a consult twice a year to inject a horse, they (hopefully) won't be harassed by government regulatory agencies, they may be less at risk for contracting Hendra themselves, there are less problems with insurance and so on. Contrast this with vets willing to treat a non-vaccinated horse. For them, there may not be insurance, their livelihood, reputation, and license to practice are all put in jeopardy. They represent a soft target for prosecution and even if they win, the lost time, cost and effort of mounting a defense and the additional stress from it all is something few in their right mind would want to risk.

Why this is being done and what the real agenda behind all this is, is what should really be investigated.

**Terms of Reference no. 6 - The impact of Workplace Health and Safety actions on the decision by veterinarians not to attend unvaccinated horses and results of previous Workplace Health and Safety HeV investigations where there have been human infections**

Three vets are being prosecuted under Section 28 of the Workplace Health and Safety Act, facing individual fines of up to \$100,000 from Workplace Health & Safety Queensland in connection with treating unwell, non-vaccinated horses without first obtaining results of a Hendra test <http://www.abc.net.au/news/2015-09-25/vets-prosecuted-over-hendra-cases/6801422> . Their veterinary practices could also face fines of \$600,000 and the principal sentenced to 5 years jail, if found guilty. <http://www.queenslandcountrylife.com.au/story/3684554/hendra-impasse-must-be-resolved-frecklington/>

These prosecutions are an outrageous abuse of the regulatory power. Veterinarians are not some mega-corporation with flowery mission statements, who can thumb their nose at environmental/safety issues and treat such fines as just part of the cost of doing business. Vets **are** the ones on the frontlines. **They** are the ones who risk an injury - unlike some corporate office-dwelling management team. They have a difficult job at the best of times, subject to being called out at any time of day or night to try and help an animal in distress, often in difficult and unpleasant circumstances, risking bites, kicks and other injuries while under pressure to diagnose/treat an animal in time to save its life. It is a profession that has one of the highest suicide rates from the stress that is part of the job.

*"Workplace mental health: the dark side of veterinary practice"* Feb 2015,

<http://www.abc.net.au/local/photos/2015/02/26/4187918.htm>

"Study: 1 in 6 veterinarians have considered suicide" Mar 2015,

<https://www.avma.org/News/JAVMANews/Pages/150401d.aspx> (USA)

I can understand that WHSQ is probably used to dealing with large corporations that require a cudgel to garner their attention, but that is not the situation here and I think they owe the horse vets who are just trying to fulfill their duty of care as best they can, an apology.

It may also be that the motive for this is to indirectly mandate Hendra vaccination. Instead of officially making this mandatory - which would involve consultation and debate - they have effectively achieved the same result by imposing onerous regulatory penalties upon veterinarians, in effect compelling compliance throughout the entire horse industry. There have been no human deaths in 7 years and the spike in horse cases was 5 years ago, so this recent decision seems to have been made on the grounds of coercing an agenda by intimidation, instead of constructively working together with vets and the horse industry on how to best deal with this issue. It would be interesting to know how the present situation has come to be. It seems improbable that someone at WHSQ just woke up one morning and decided that they wanted to add some vet scalps to their collection – so who made this call and what is actually driving it?