Submission to the Agriculture and Environment Committee, Queensland Parliament - Hendra virus (HeV) EquiVac® Vaccine and its use by Veterinary Surgeons in Queensland

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Background

I am currently an equine Veterinarian in private practice in Brisbane involved in the thoroughbred Racing Industry and was the consultant Veterinarian when Hendra virus was first discovered at the racing stables of the late Vic Rail in September 1994. I have practical and scientific knowledge and experience with Hendra virus and the disease.

From 2009 to 2016 I have been a member of the Queensland Government's Hendra virus Interagency Technical Working Group and I am a contributing author to the Queensland Health publication *Hendra virus Infection Prevention Advice* published in October 2014.[1] This document is an informing document for Government agencies and the public for the prevention of Hendra virus infection.

Since 1994 to 2016 I have provided scientific and practically based input into guidelines to deal with Hendra infection with Department of Agriculture and Fisheries [2,3] the Australian Veterinary Association and Equine Veterinarians Australia.[4,5]

In 2013, I provided scientific input into the review and update of the Commonwealth Government's Animal Health Australia Hendra virus Response Policy Brief.[6] This policy brief for the management of an outbreak of Hendra virus infection in Australia is an integral part of the Australian Veterinary Emergency Plan, or AUSVETPLAN.

In 2011, I represented the Australian Veterinary Association and the Queensland Horse Industry at the intergovernmental National Hendra virus Research Program symposium in Brisbane and in 2015 I provided a science based submission to the Australian Competition and Consumer Commission's (ACCC) inquiry into Hendra virus issues.

From 2009 to 2016 I have represented the Australian Veterinary Association on the Queensland Government Horse Biosecurity Market Access Liaison Group (HBMALG).

Hendra virus

1. Hendra virus (HeV) is an RNA virus and member of virus family Paramyxoviridae and the genus Henipavirus. There are 3 known members of this genus – Hendra virus (HeV), Nipah virus (NiV), and Cedar virus (CedPV).

2. HeV and NiV are very closely related viruses and are highly lethal to both humans and several species of animals – horses, cats, pigs, ferrets, guinea pigs, hamsters and monkeys. Dogs are susceptible to HeV, however it does not appear to be highly lethal to them. CedPV is non-pathogenic in a number of laboratory animals.

3. HeV has been identified in all 4 Australian species of flying foxes, whilst NiV has not been identified in Australian flying fox species.

4. From 1994 to 2015 (incl) there have been 55 confirmed outbreaks of HeV in Australia resulting in the death of 97 horses. In this period Queensland recorded 39 outbreaks and NSW 16 outbreaks.

5. From 2011 to 2015 (incl) there have been 41 recorded outbreaks resulting in the death of 48 horses with Queensland recording 26 outbreaks and NSW recording 15 outbreaks. By comparison from 1994 – 2010, NSW only recorded 1 outbreak.

6. NiV outbreaks have occurred in Malaysia, Singapore, India and Bangladesh. In 1998/99 NiV caused the death of 105 people and resulted in the culling of the entire pig population of over 1 million pigs Malaysia.

7. NiV can be transmitted from flying foxes to pigs, from flying foxes to humans and human to human transmission has also occurred.

8. HeV is not present continuously in flying foxes, and the level of excretion in any particular colony fluctuates over time. Flying foxes can be infected and excrete virus at any time of the year and spill-over of virus to horses requires factors other than just the presence of virus.

9. HeV has been shown to be able to transmit from flying foxes to horses, from horses to humans, from horses to horses, and from horses to dogs. Flying fox to dog transmission is uncertain.

10. Whilst HeV is contagious from close contact with body fluids or droplets and is highly lethal, it is not highly contagious e.g. airborne, in the same way that influenza is.

11. There have been no documented cases of HeV transmission directly from flying foxes to humans, or from humans to humans. These routes of transmission have been confirmed for the closely related NiV overseas.

12. Because HeV is an RNA virus, different genetic variants exist in nature.

13. To date, research indicates the HeV genome is highly stable with minimal variability in both flying-foxes and horses. Because HeV is an RNA virus there is some scientific concern that selection pressure on mutations may arise which may cause the virus to act differently.

14. The Equivac® HeV vaccine has been demonstrated to provide complete protection against infection of both HeV and NiV in small animal, non-human primate and horse trials.[7],[8]

15. A post exposure monoclonal antibody treatment for HeV has undergone early human clinical trials at the Queensland Institute of Medical Research (QIMR) and has been offered and used in patients on compassionate grounds.

Terms of reference:

The development, trials and approval processes of Equivac ®HeV vaccine

1. The equine vaccine against HeV (Equivac® HeV) was launched in November 2012 initially on a Minor Use Permit by the Australian Pesticides and Veterinary Medicines Authority (APVMA) regulatory authority and is the first commercially developed and deployed vaccine as a countermeasure against a BSL-4 agent in the world. Other BSL-4 agents include Ebola virus, SARS coronavirus. Full registration occurred in August 2015 and approval for use in breeding females occurred in December 2015.

2. Equivac® HeV is a subunit vaccine meaning it contains protein from the outer shell of the virus and no genetic material. It is the only licensed antiviral approach for Hendra virus infection.

3. Having reviewed the scientific development and publications concerning the trials conducted into Hendra virus vaccine since early 2000, I am of the view that the scientific rigor used to develop and test the vaccine both here and in the USA is soundly based.

4. The development of the vaccine has been the subject of international scientific acclaim. The scientific team at CSIRO's AAHL), in conjunction with internationally renowned scientists from the Uniformed Services University in the USA, the Henry M Jackson Foundation in the USA, and Zoetis (a division of Pfizer) developed the vaccine. The AAHL team were awarded the prestigious CSIRO Chairman's medal for scientific excellence in 2014.

5. Submissions regarding the development, trials and approval process are the subject matter provided by the APVMA and Zoetis to this Parliamentary inquiry.

6. As a member of the Queensland Government Hendra virus Interagency Technical Working Group I reviewed the science behind the development of the vaccine and I continue to concur with, and endorse the advice provided in the *Hendra virus Infection Prevention Advice* document.

7. The specific Aim and Purpose of that document was:

- Aim - To prevent HeV infection in humans

- Purpose - To collate the best available evidence-based advice on risk management regarding the prevention of HeV infection; and to inform the content of relevant publications for human and animal health care providers as well as advice for the public.

8. The specific advice regarding Hendra vaccine and vaccination in that document is:

   Animal-human Infection Control - *"The vaccine is 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. Widespread uptake of the horse vaccine has the potential to significantly reduce the number and risk of human exposures."*

   Animal-human Infection Control Recommendations – General interactions with all horses – Standard Precautions - *"Vaccination is the single best way to prevent HeV infection in horses and is strongly encouraged."*

Terms of reference:

The incidence and impact of adverse reactions by horses following vaccination and the reporting of adverse reactions and economic impacts of the Equivac® HeV vaccine.

1. A database was established for all vaccinated horses by microchip use, as part of the Minor Use Permit issued by the APVMA[9]. The permit allowed use of the vaccine as a high order disease prevention strategy essentially as a result of the significant number of outbreaks which had occurred during 2011 and 2012.

2. As part of the permit, veterinarians were required to report adverse events to Zoetis and the APVMA. This was the first time in Australia that veterinarians were required to report any adverse events for any licensed animal vaccine.

3. To date, ~430,000 doses of Equivac® HeV vaccine have been administered to approximately 120,000 horses. Injection site reaction calculated by the APVMA[10] from 367,759 doses of vaccine administered from launch to 30 June 2015 was 0.18%. Probable reaction incidence was 0.18%. Probable plus possible reaction incidence was 0.22%.

year	Possible	Possible/off-label	Probable	Probable/off-label	Unknown	Unlikely	Total
Total	**136**	**4**	**674**	**3**	83	**77**	**977**

4. Veterinarians in the field report that in the vast majority of horses there is no observable adverse clinical reaction to vaccination. Commentary will be presented by the Australian Veterinary Association confirming this observation.

5. When considering adverse events to any vaccination it is important to realise that adverse events can have other causes besides those due to the vaccine itself. There is little or no published data with which to compare Equivac® HeV, (which required mandatory reporting) to other animal vaccines which require voluntary reporting.

6. The World Health Organisation (WHO) states that it is important to understand the different meanings of an ***adverse event following immunization*** (or AEFI) and an ***adverse vaccine reaction***.[11] This same principle applies for human and animal vaccines.

    i. An ***adverse vaccine reaction*** is a vaccine-related event caused or precipitated by a vaccine when given correctly.

    ii. An ***adverse vaccine reaction*** can be caused by errors in the administration of the vaccine.

    iii. An ***adverse vaccine reaction*** can be the result of unrelated coincidence.

7. Consequently, adverse reactions may be due to any of the events occurring in the 3 categories above, and more correctly called AEFI.

8. WHO also categorises adverse vaccine reactions in humans as follows. It is clear that there can be relatively high percentages of very common or common reactions –

Frequency	Occurrence among persons vaccinated in percent	Severity of reactions
Very common	≥ 10%	**Common and usually minor reactions:** Are part of the immune response to vaccine, Reactions settle on their own, Examples include: Fever, Malaise.
Common (frequent)	≥ 1% and < 10%	
Uncommon (infrequent)	≥ 0.1% and < 1%	**Rare, usually more severe reactions:**

Frequency	Occurrence among persons vaccinated in percent	Severity of reactions
		Usually require clinical management, Examples include: Severe allergic reaction (e.g., anaphylaxis) including an exaggerated response to the vaccine antigen or component,

9. WHO also tabulates the following data in relation to the adverse reaction rates of human vaccines demonstrating that different vaccines have different reaction rates.

Vaccine	Local reactions	Systemic reactions	
	(pain, swelling, redness)	Fever > 38°C	Irritability, malaise and systemic symptoms
BCG	90% – 95%	–	–
Hepatitis B	Adults up to 15% Children up to 5%	1 – 6%	–
Hib	5 – 15%	2% – 10%	
Measles/ MR/MMR	~ 10%	5% – 15%	5% (Rash)
OPV	None	Less than 1%	Less than 1%
Pertussis (DTwP)	up to 50%	up to 50%	up to 55%
Pneumococcal conjugate	~ 20%	~ 20%	~ 20%
Tetanus/ DT/aTd	~ 10%	~ 10%	~ 25%

10. Reaction rates reported by some owners have been published in the HHALTER project[12]. Due to differences in terminology, sampling, and methods of calculation

only limited comparison can be made between data from the HHALTER study on adverse reactions and the APVMA reporting of adverse experiences, published in June 2015. In general, participants in the HHALTER study reported the same more frequently-reported adverse experiences that were reported to APVMA. The APVMA data were reported across a much higher number of doses administered across a higher number of horses and where the causes of the adverse reactions were investigated and categorised. The most frequently reported adverse experience was injection site reaction.

11. Many HHALTER respondents had given their horses multiple doses of vaccine, potentially up to 6 or 7 doses by the time of the final survey in Nov 2014. Moderate or severe swelling around the vaccination site was reported by 39 respondents (10.5% of those who had vaccinated their horses at the time of the final survey). Severe swelling was reported by 10 respondents (2.7%). The number of horses and the number of vaccine doses administered by the respondents are not represented.

12. It is always important to consider any reported adverse rates in the light of the number of the doses administered, the number of horses vaccinated and the common side effects of vaccination (see previous tables) as potentially undifferentiated AEFI rates unless there is convincing clinical or pathological evidence to prove otherwise. Some adverse events are a normal response by the immune system and some may be due to other unrelated causes.

13. Severe reactions need to receive a thorough investigation in order to determine the most probable cause – i.e. true vaccine causation, administration causation (e.g. horse's necks can be difficult to clean and sterilise before intramuscular administration) , co-incidental causation and any relationship with age, breed, or any husbandry management issues of the horse immediately following vaccination.

14. I have administered approximately 1,500 doses of vaccine. I have only seen some mild temporary injection site neck swellings and some lethargy in 2 horses which can be considered as normal responses to stimulation of the immune system by vaccination, and not an adverse event. I have not observed any significant adverse responses to vaccination in the cohort of horses under my care including thoroughbreds and pleasure horses.

15. Several of the racehorses under my care have raced and won races in high metropolitan company only 10 days following vaccination and my clients are keen to vaccinate because of the high degree of confidence they have in the vaccine's ability to prevent infection in their horses, in themselves and in their staff.

16. Queensland's best thoroughbred sprinter 'Buffering' won the Group 1 sprint in the United Arab Emirates, Dubai in March 2016 against a world class field. He was vaccinated against HeV in January, 2 months before he raced and won.

17. No vaccinated horses have ever contracted Hendra virus, whilst 15 laboratory confirmed HeV infections in horses have occurred in Qld and NSW since vaccine release in November 2012.

18. In 2014 there were 6 humans who were extensively exposed to Hendra virus from infected horses in NSW and Qld[13]. These people were hospitalised in a public hospital in Qld, and offered a monoclonal antibody therapy developed by Queensland Health in conjunction with the Australian Institute of Bioengineering and Nanotechnology at the University of Queensland. The economic impact of the costs of these investigations, admissions, and treatments in the context of therapeutic development costs should be calculated.

19. Economic, staffing and resource impacts incurred by QDAF, QH and QWHS responses to outbreaks and laboratory testing of suspect cases needs to be considered in light of the benefits of vaccination. Widespread uptake of the vaccine has the potential to significantly mitigate against these State Government costs. In 2011 there were resulted in 18 outbreaks across Qld (10) and NSW (8). We should not assume that this high degree of spillover risk could not re-occur particularly if vaccination rates reduce.

20. There is a high level of confidence in the vaccine held by both Qld and NSW State Governments and the Australian Government through the Animal Health Committee. This has been evidenced in outbreak situations since the vaccine became available. From 2013-2015 there were 7 horse deaths in NSW. On the 7 NSW properties affected there were 19 horses in contact with the HeV positive cases who had not been vaccinated. These 19 in contact horses were then vaccinated and subsequently did no become infected. In an outbreak in Queensland on the Atherton Tablelands in July 2015 where one horse died from HeV, there were also 6 vaccinated horses and 3 unvaccinated horses on a property. These 6 vaccinated horses were regarded by QDAF's Biosecurity Queensland as "low interest" horses and subsequently released early from quarantine in line with national Animal Health Committee policy.

21. Compared to the annual costs of keeping a horse the annual costs of Hendra vaccination are small. e.g. 60 cents (approx.) per day based on boosters every 6 months, or 30 cents (approx.) per day if annual boosters are required.

Terms of reference:

Who bears the risks of HeV infection and who incurs the costs and receives the benefits from each risk mitigation option.

1. Horse owners and their family members, handlers, Veterinarians, farriers, lay horse dentists, horse trainers and their staff, horse agistment businesses and breeding establishments, horse sale companies, horse transport operators, race day jockeys, standard bred racing reins persons, race day horse swabbing staff, race day horse

barrier attendants, race day stewards, and the general public who interact with horses on race day all bear the risk of a HeV infection.

2. For vaccination, which is a recognised by QWHS as a higher order of disease risk mitigation and the single best method of disease prevention, the costs are incurred by the owner or manager of the horse and the benefits are received by all of the above.

3. The Government receives cost benefit savings in disease incident investigations and responses including laboratory exclusion testing from the effective protection afforded by widespread horse vaccination.

4. For PPE, which is a lower order of disease risk mitigation, the costs are essentially born by the Veterinarian, their staff, and horse owners. Benefits are essentially limited to those in contact with the horse. The Queensland Government sponsored rebate scheme for PPE used to investigate suspect cases where exclusion test samples are submitted to the laboratory ceases in 2016.

5. Horse owners with insured horses bear the risk of non-payment of mortality insurance claims if their horses are not currently vaccinated against HeV if the animal becomes infected with HeV, or dies as a result of waiting for veterinary treatment pending the result of an exclusion test for HeV. Mortality insurance policies issued through Australian brokers have a Hendra virus Endorsement stating that :-

   This Insurance does not cover any loss directly or indirectly caused by, happening through, in consequence of, or contributed to by:

   - *Hendra virus unless the insured provides to the Underwriters verification from a veterinarian that the vaccination status of the horse is current and up to date against such virus in accordance with the vaccine manufacturers' recommendations;*
     Or
   - *Any cause, where an attending veterinarian declined to treat the horse because of the failure of the insured to provide to the veterinarian verification that the vaccination status of the horse is current and up to date against such virus in accordance with the recommendations of the vaccine manufacturer.*

6. A significant issue for Veterinarians is the inability to be insured for business interruption losses caused by a quarantine of a minimum of between 20-30 days being imposed on their premises after a confirmed HeV infection on the premises.

7. In summary, the benefits to be obtained from vaccination are shared by all those mentioned under paragraph 1 above. In addition there are benefits to Racing Queensland and ultimately to Government by insuring, through the protection afforded by vaccination, for continuity of business and the uninterrupted maintenance of the significant taxation revenue stream derived from betting turnover.

Terms of reference:

- **Whether the guidelines/procedures required for veterinarians attending horses that are not vaccinated against HeV are proportionate to the consequences.**
- **Impacts on the equine industry and the economy arising from veterinarians applying a policy not to treat unvaccinated horses.**
- **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.**

1. Whilst HeV causes a sporadic disease, it is highly lethal and the consequences of not taking the risk seriously can have fatal consequences. Veterinarians and their staff are most at risk because they attend, examine and treat sick horses.

2. There is a level of complacency in the horse community about these risks. This is evidenced by the results of the HHALTER investigation and by the fact that horses continue to become infected notwithstanding Government and veterinary advice on ways to mitigate the risk. Complacency in the horse community will become more of a concern if the number of outbreaks declines because of the protection provided by vaccination. Consequently veterinarians and horse owners/handlers will continue to be at risk from unvaccinated horses.

3. Early clinical signs of HeV infection can be similar to other equine diseases and infected horses can shed virus from the nose and mouth before the onset of clinical signs. Infection risk increases with disease progression in the horse and many horse owners fail to take proper personal biosafety precautions in attending to sick horses.

4. Hendra virus can only be diagnosed with an approved Government or CSIRO (AAHL) laboratory test, so therefore veterinarians have to manage risk according to approved guidelines and workplace health and safety standards, before receiving these results. In some cases laboratory results may require confirmation causing further delays.

5. From 1994 to date, 55 disease outbreaks have occurred in coastal Queensland as far west as Chinchilla and as far south as Kempsey in the mid central coast of New South Wales resulting in 97 horse deaths. There have been 41 recorded outbreaks from 2011 – 2015 resulting in 48 horse deaths, with 15 in NSW and 26 in Queensland. Private practice Veterinarians have investigated these outbreaks.

6. The outbreaks have occurred within the range of the black flying fox and the spectacled flying fox.[14] The range of the black flying fox is continuing to move southwards below Sydney[15]. Because virus transmission dynamics in flying foxes, their colonies and between flying fox species are incompletely understood, the transmission spillover risk from flying foxes to horses in other parts of Australia is uncertain.

7. Disease transmission from flying foxes to horses is more likely to occur via infected flying fox urine, but transmission dynamics are complex and many horse owners fail to recognise the presence of flying foxes on their properties or premises.

8. The guidelines for veterinarians, horse owners, event organisers, and the public which are prepared by Government departments are evidence based according to best available scientific advice and are proportionate to the consequences. The QDAF document *Guidelines for veterinarians handling potential Hendra virus infection in horses* outlines the appropriate actions a veterinarian should take. After conducting a risk assessment appropriate to the individual case, veterinarians are required to follow these guidelines and the guidelines *Hendra virus – information for veterinarians* prepared and published by WHSQ[16]

9. Options to reduce the risk of Hendra virus infection in horses and people include horse vaccination, preventing horse contact with flying fox excretions, wearing personal protective equipment and good personal hygiene.

10. In the context of workplace health and safety, vaccination of horses is acknowledged as the single best method of disease prevention and is strongly encouraged by all government departments and Veterinarians in general. Although HeV human disease risk is rare, the consequences of infection are death and therefore risk is categorised as extreme. Vaccination is regarded as reasonably practicable in a workplace health and safety context and cost is not regarded as a significant argument against vaccination for prevention of extreme risk.

11. Horse owners who do not vaccinate at risk horses and require veterinary attention for their horses should understand the significance and therefore the manner in which veterinarians are obliged to respond to comply with guidelines under the Work Health and Safety Act 2011[17] (WHS Act). Under the Act, horse and property owners also have a responsibility to provide a safe workplace for veterinarians and their staff.

12. There may unfortunately be animal welfare impacts if horses remain untreated due to a lack of access to equine veterinary services or before exclusion test results are received. Some of this is caused as a result of the reluctance of veterinarians to attend horses because of the onerous legal responsibilities in having to manage the biosecurity of others in contact with suspect or positive cases. The consequences of these actions can result in potential prosecutions under the WHS Act.

13. Risk mitigation processes other than vaccination include the wearing of personal protective equipment (PPE), and preventing contact with flying fox excretions. Full PPE including impermeable boots and overalls, double nitrile gloves, goggles or face shield and a P2-respirator is required to be worn by veterinarians and attendants until HeV has been excluded for suspect horses.

14. There are risks from wearing this PPE around unpredictable, fractious horses especially if they are sick and wobbly. Protective eyewear can limit vision, PPE can

become torn and dislodged, and the risks of personal injury, needle stick injuries, or heat stress are increased.

15. HHALTER results indicate that advice about removing horses from paddocks where there are flying foxes, or preventing horses from contacting flying fox excretions has failed to significantly change behaviour of horse owners and that implementation of this risk mitigation strategy is not widespread. A large majority of horse owners (85%) reported that their horses always had access to uncovered water, and around half reported that their horses always had access to uncovered food. These figures changed little over time.

16. With vaccinated sick horses, the infection risk is significantly lower and so the Veterinarian's risk assessment may conclude that lower levels of PPE are warranted. Consequently, the financial cost to the owner is also lower. The Queensland government sponsored rebate scheme for PPE used to investigate suspect cases where exclusion test samples are submitted to the laboratory ceases in 2016

17. Other proposed methods of risk mitigation include ***Stall-side testing***, ***Titre testing*** **and** ***Health Testing***

18. ***Stall-side testing*** refers to the test of a biological sample from an animal in a device at, or close to, the "point-of-care" in the field. In the case of Hendra virus it refers to the test for evidence of the presence of this BSL4 pathogen.

    i. Hendra virus is a notifiable disease in all States of Australia. All testing is conducted in the approved State Government laboratories and the CSIRO Australian Animal Health laboratory (AAHL) in accordance with NATA certification and under the highest of biocontainment laboratory facilities to prevent human infection. Management and control is conducted in Queensland by QDAF, QH and WHSQ.

    ii. The tests employed in these laboratories which are used to detect the presence of the virus, or the antibody response to infection in an animal or human, have been developed and refined over several years. They are standardised and highly sensitive in detecting or excluding HeV. All State governments rely on the validity of these tests to inform their decisions around management of HeV incidents in horses and in those incidents involving transmission of infection to people.

    iii. It was thought that development of a stall-side device which was safe to use and accurate might be a useful tool to be able to detect the presence of HeV in the field more quickly than it takes for sample testing results to be obtained from approved Government laboratories, which usually occurs within a day, but where delays can occur of up to 4 days in some instances.

iv. Several devices have been developed over recent years after initially showing some earlier promise, albeit with some significant reservations. Of those developed and tested it has been found that these devices are not as accurate as the approved laboratory tests when used under field conditions. No devices are in current use by Veterinarians or human health care professionals or approved for this purpose. In addition, there have been no peer reviewed scientific articles published which demonstrate that the accuracy – the sensitivity and specificity - of any of these devices is the equal of the approved Government laboratory testing protocols.

v. Currently, local researchers are in the early stages of research into a device which, prematurely, is already being strongly advocated, especially in social media, to be used as a potential "stall-side test" for Hendra virus for use by Veterinarians to inform their decision making around the management and treatment of potentially infected horses. It is also being proposed to be used by event organisers to inform risk management decisions as substitute for the higher order risk management strategy of vaccination. There are several very important and highly significant occupational workplace health and safety and test accuracy "hurdles" yet to be addressed with this device. The Australian Government's Department of Health Therapeutic Goods Administration (TGA) approval would also be required to use this test and, as part of NATA, competence of the operator in the performance of the assay has to be assessed and signed off on.

19. ***Titre testing*** refers to a laboratory test to determine the concentration of antibody to a particular infectious pathogen in the serum of an animal or human, and the test is referred to scientifically as either the virus neutralisation test (VNT) or the serum neutralisation test (SNT).

i. In the case of a horse vaccinated against Hendra virus, or naturally infected with the virus, the antibody titre can be measured by its ability to neutralise infectious Hendra virus in the laboratory. Because experiments or tests using infectious Hendra virus can only be performed safely under the highest of biosecurity conditions in the laboratory, known as PC4, all titre testing must be conducted at the CSIRO Australian Animal Health Laboratory (AAHL) in Geelong which is the only laboratory in Australia that routinely provides this service.

ii. Experiments conducted at AAHL in which horses were directly challenged with extremely high doses of infectious virus 6 months after having received 2 doses of Hendra vaccine were completely protected from infection and shedding of infectious virus. Animals with antibody titres lower than those experimental horses may well be protected from field exposure to Hendra virus (which is not as high as the doses used to challenge the experimental animals), either from circulating antibody or by generating a "memory" immune response, however these experiments have not been performed at AAHL.

iii. Titre testing at AAHL is advertised currently at $318 per test with results being available by Monday if the samples are received at the laboratory by the previous Thursday. This cost does not include the sampling of the horse, packaging and courier costs. AAHL prefers the serum samples from horses to be submitted by Veterinarians.

iv. Titre testing can be used to provide a degree of certainty about whether a horse has responded to vaccination, or has ever been exposed to and recovered from a natural infection, and risk management decisions can therefore be informed.

v. In the case of a horse which is presented, or is intended to be presented, to an event with a history of having received a vaccine but whose vaccination status is not current, a titre test can be used to make a decision on the risk presented by this animal. It is a normal phenomenon for antibody levels to decrease over time in all animals and humans, and the timing of the last vaccination and the interval between titre testing and the event needs to be considered. Bearing in mind that these parameters are based on several degrees of uncertainty, decisions about the risks posed by these animals are likely to be less certain than decisions based around the risks posed by animals which have a current vaccination status.

20. ***Health testing*** refers to taking a range of samples from horses to test for the presence of antibodies, the virus or virus RNA being shed from that horse. A range of samples have to be taken from the horse (e.g. blood, nasal cavity, oral cavity, urine, faeces) to increase the likelihood of detection and submitted by Veterinarians to Government approved laboratories. There are some significant limitations on the interpretation of results e.g. a horse could be incubating the disease and therefore not showing symptoms or shedding virus when the samples are taken, the interpretation of the mere presence of antibodies, or a horse could become infected subsequent to the samples being taken and analysed.

21. Human infections with HeV occurred in 1994 (3), 2004 (1), 2008 (2) and 2009 (1). In workplace health and safety investigations which have been conducted, investigations generally revealed the need to increase the awareness of the disease, the potential for transmission risks based on available scientific evidence and ways to mitigate those risks. This raised the need for an increased level of biosecurity to be applied by veterinarians and members of the public.

22. WHS investigations, particularly in Queensland, have also occurred whenever positive horse cases are confirmed to determine the level of compliance with guidelines and whether any risk to humans has occurred. Prosecutions of three veterinarians have had the result of dissuading some veterinarians from attending horses, or leaving equine

practice altogether and even relocating to other States or areas which have not recorded Hendra virus outbreaks.

23. Veterinarians must take all reasonable steps to prevent or minimise the risk of infection and are reluctant to treat or admit suspect cases to hospitals because of the health risks posed and the significant consequences should a quarantine of 20-30 days be imposed. Some Queensland businesses have not survived, while others have been very severely compromised after a mandated HeV quarantine event.

24. Veterinarians are advised not to perform invasive procedures in suspect horses an exclusion test result is known. This equates to treatment delay, and increased pain, suffering and potentially death for the affected horse. These types of scenarios also have a significant emotional and in some cases financial impact on the horse owner. Faster and more available exclusion testing to reduce the impacts to horses and their owners will come at a financial cost to government which currently funds exclusion testing.

Summary

Hendra virus is endemic in flying foxes in this State and continues to pose serious health risks. Horse owners, horse organisations and veterinarians all have obligations placed on them to control these risks in a reasonably practical way. Everyone has this responsibility, not just veterinarians.

The legislative framework for this risk mitigation is defined under the WHS Act 2011, and the new Biosecurity Act (2014)[18] which comes into effect on 1 July 2016.

The Biosecurity Act supports a "shared approach" to managing biosecurity obligations of people and organisations within the State in order to protect

1. the economy
2. the environment
3. the community

Under the Biosecurity Act, if individuals and organisations are aware that their activities pose a risk then they must take all reasonable steps to prevent or minimise that risk.

All individuals and stakeholders in the horse industry should be informed, aware and most importantly respond to these obligations and legislative requirements in relation to the emerging disease threat of Hendra virus, and be prepared to work together to achieve resolution of any conflicts.

Continuous propagation of misinformation about the important role that a safe, effective vaccine plays in practical risk minimisation will have the unfortunate effect of significantly undermining these objectives.

In my view, the Agriculture and Environment Committee has critical role to play in the evaluation and support of evidence based, scientifically evaluated information about the benefits of Hendra vaccination.

The Queensland Government also has a critical role to support effective dissemination of this information to all stakeholders to achieve the ultimate aim of preventing human fatalities, and to protect the horse industries in this State as a result of any uncertainty which might be generated from the terms and the call for this inquiry.

References

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