



The Queensland Parliamentary Inquiry by the Agriculture and Environment Committee (AEC) into the Equivac HeV (Hendra) vaccine and its use by veterinarians has delivered its report and made 11 recommendations.

Most importantly, the inquiry recommended that the Hendra vaccine for horses is not to be made mandatory¹. These decisions are to be left to the discretion of equestrian event organisers to require as a condition of entry and for horse owners to decide based on risk.

In a big win for the horse industry, the committee recommended the inclusion of equine industry representatives in future meetings of the Hendra Virus Inter Agency Technical Working Group that provides technical advice on Hendra virus to the government².

The committee recommended that the Department of Agriculture and Fisheries (DAF) promote Hendra vaccination³. The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Commonwealth Government regulatory body which registered the vaccine and determined its safety and efficacy. The efficacy or effectiveness of the vaccine is stated below from the AEC report:

*“In its submission, the APVMA explained the efficacy of the vaccine as follows: Efficacy studies in horses demonstrate that the vaccine is effective as **an aid to alleviate the clinical symptoms** of disease caused by the Hendra virus, conclusive data is not yet available to demonstrate that **vaccinated horses which become infected with Hendra cannot continue to shed live virus and may present a source of infection to unvaccinated horses or people**. The approved label and the APVMA website **recommend people take the same steps to protect vaccinated horses from exposure to infection as are***

¹ Recommendation 9

² Recommendation 8

³ Recommendation 10

recommended for unvaccinated horses. Personal protective equipment should be worn whenever infection is suspected even in vaccinated horses.

The Department of Agriculture and Fisheries accepts the safety and efficacy of the HeV vaccine as determined by the APVMA.⁴
(emphasis added)

The APVMA is only claiming that this vaccine is an aid in alleviating the symptoms of the Hendra virus disease in a vaccinated horse. It is not claiming that the vaccine will prevent Hendra virus infection or viral shedding in horses.

For clarity, the definition of a symptom is “any subjective evidence of disease”⁵. This implies that a vaccinated horse which has Hendra virus disease may appear less sick than an unvaccinated horse that has Hendra virus disease.

The APVMA further explained (as above) that viral shedding and transmission of Hendra virus infection cannot be ruled out from the HeV vaccinated horse that becomes infected with the Hendra virus. Therefore, biosecurity measures to help prevent the Hendra virus disease need to be to the same standards in both vaccinated and unvaccinated horses.

Importantly, the claim in the approved label, of the vaccine’s effectiveness was downgraded from an “*aid in the prevention of clinical disease caused by the Hendra virus*” to an “*aid in the prevention of clinical symptoms of the disease caused by Hendra virus*”, on 31 March 2015.

This could lead to confusion among the public who have been under the impression that owners, vets and horses would be reliably “protected” from Hendra virus infection by the vaccine. Claims that overstate the effectiveness of the vaccine are not in line with the

⁴ Australian Pesticide and Veterinary Medicines Authority, 2016, Submission No.197, p.8 as reported in AEC report.

⁵ MedicineNet (<http://www.medicinenet.com/script/main/art.asp?articlekey=5610>) accessed 7 November 2016

modest determination of efficacy by the APVMA, as in the AEC inquiry report, the APVMA's submission (quoted above) and in the efficacy claim on the Equivac HeV label.

Other risk mitigation strategies

The AEC inquiry report acknowledged the use of PPE as one of a number of risk mitigation actions to protect both people and horses from the rare but serious Hendra virus infection - for both vaccinated and unvaccinated horses alike. The report explained guidelines for the use of more extensive PPE for high risk procedures in clinically normal horses as well as contact with potential or confirmed HeV and then stated that these "*guidelines are proportionate to the consequences and should be observed by veterinarians regardless of whether a horse is vaccinated for HeV*".

Safety of the HeV vaccine

The Parliamentary inquiry came about in part because of concerns people had about the safety of the Equivac HeV vaccine.

The AEC report, while explaining that the APVMA, Australian Veterinary Association (AVA) and the product manufacturer Zoetis all indicated a low and acceptable adverse reaction rate to the vaccine, acknowledged that "*horse owners describe adverse events linked to the HeV vaccine as commonplace*". The APVMA collects and assesses adverse experience reports to veterinary medicines and this helped them determine the safety profile of the vaccine. However, the AEC report identified problems that may have affected this safety evaluation both at the APVMA itself and in the integrity of the adverse event reporting.

The report identified issues at the APVMA of slow processing and investigation of adverse reaction reports and found that "*The authority hasn't released annual reports for the adverse event system since 2013.*" It suggested that these delays "*may have weakened the APVMA's system.*"

The report also mentioned horse owner disagreements with vets and in some cases decisions by veterinarians to not report horses' conditions as adverse reactions to the vaccine.

It indicated *“that many horse owners are adamant that adverse reactions to the vaccine are more prevalent and under-reported ... and that vets and Zoetis have clear vested interests in not reporting adverse reactions”*.

The committee sought to *“improve the integrity of the reporting of adverse reactions to the vaccine”*, and recommended *“Raising awareness of processes for self-reporting adverse reactions to the Hendra vaccine”*⁶ for owners and others to the APVMA directly.

Another recommendation was to remind veterinarians of their obligation to explain risks to owners before administering the vaccine *“off label”*⁷, such as administering the vaccine with other medicines or vaccines, or to sick horses. The report noted *“Where the off label use of the vaccine results in adverse reactions, those reactions are not classified as adverse reactions to the vaccine by Zoetis or the APVMA.”*

Other recommendations

Recommendations for improving timeframes for HeV exclusion testing⁸ and supporting the development and evaluation of a stall side test⁹ would help in reducing delays in diagnosing horses suspected of HeV infection.

Another recommendation by the committee was to consider the use of temperature indicators for vaccine packs¹⁰ to help verify the uninterrupted cold chain of the HeV vaccine, including while in the field.

A recommendation that has been welcomed by veterinarians includes changes to their workplace health and safety responsibilities¹¹ to limit their liability in dealing with a suspected or confirmed HeV infected

⁶ Recommendation 5

⁷ Recommendation 4

⁸ Recommendation 1

⁹ Recommendation 2

¹⁰ Recommendation 3

¹¹ Recommendation 11

horse to just themselves and their staff, rather than owners and others, as is presently the case.

Two other recommendations include revision of both Biosecurity Queensland¹², and Workplace Health and Safety guidelines¹³.

In conclusion

The report and recommendations comprises sensible elements that if accepted will help resolve the Hendra vaccine issue for the horse industry in Queensland. The Queensland government minister is required to provide an interim response to the recommendations within three months, and final responses are required within six months of the tabling of the report.

Many horse owners, event organisers and veterinarians, depending on their circumstances, have developed best practice policies in regard to the Hendra virus. Best practice should continue to evolve based on solid evidence and the continued accurate assessment of the actual risks and risk mitigation strategies.

The Hendra vaccine is not the silver bullet to all biosecurity risks that may challenge the equine industry.

Equestrian Queensland will continue to engage with relevant agencies on this important matter which has a significant impact on its membership and the equine community.

MATT HELMERS



EQUESTRIAN QUEENSLAND- CEO

DAVID FINCH



EQUESTRIAN QUEENSLAND- CHAIR

¹² Recommendation 6

¹³ Recommendation 7