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Australian Pesticides and
Veterinary Medicines Authority

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Submission to the inquiry into the Hendra Virus (HeV) EquiVacc® and its use by veterinary surgeons in Queensland

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FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) welcomes the opportunity to provide a submission to the Agricultural and Environment Committee Inquiry into the Hendra virus (HeV) EquiVacc® and its use by veterinary surgeons in Queensland.

The APVMA is the independent statutory authority responsible for assessing and registering agricultural and veterinary (agvet) chemical products proposed for supply and use in Australia.

As the regulator, the APVMA's role is to ensure that all agricultural and veterinary (agvet) chemicals registered for use in Australia, are effective and can be used safely.

The APVMA submission focusses on the first two items within the inquiry's terms of reference which are relevant to the APVMA:

1. the development, trials and approval processes, and
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.

The remaining terms of reference are outside the jurisdictional scope of the APVMA and therefore the APVMA is unable to comment.

1 ROLES AND RESPONSIBILITIES OF THE APVMA

The APVMA has been the statutory authority responsible for the regulation of agvet chemicals since 1993.

Before agvet chemical products can be legally sold, supplied or used in Australia, they must be evaluated and registered by the APVMA through the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS).

More than 11 000 pesticide and veterinary medicine products are currently registered in Australia, including products for treating crop and garden diseases and pests, and medicines for treating agricultural and companion animals.

The APVMA takes a systematic, scientific, evidence-based approach to decision making. We evaluate the safety and performance of chemicals intended for sale in Australia, to ensure that the health and safety of people, animals, crops and the environment are protected. Registered products must also not unduly jeopardise Australia's trade with other countries.

Our work supports primary industries by allowing the supply of safe, effective animal health and crop protection products. Our work also supports consumers, by ensuring that household and garden pesticides, pool chemicals and pet products are safe to use.

Our role extends beyond registration of pesticides and veterinary medicines to encompass a range of activities aimed at protecting Australians and ensuring that products are safe. We license and audit veterinary manufacturers to ensure adherence to APVMA-prescribed manufacturing standards. We also monitor the market for compliance, and review and take regulatory action on registered pesticides and veterinary medicines when concerns are identified.

The APVMA is a portfolio agency of the Minister for Agriculture and Water Resources.

Legislative framework

The APVMA is established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act). The Administration Act sets out the role of the APVMA to undertake the responsibilities conferred on it by the states and territories under the NRS.

Functions and powers are conferred on the APVMA by the Administration Act, the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code Act) and the *Agricultural and Veterinary Chemicals Code* (Agvet Code). The Agvet Code provides for the evaluation, registration and control of agricultural and veterinary chemical products and related matters.

The APVMA is a corporate Commonwealth entity under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act).

Functions and Powers

The APVMA is responsible for assessing and registering agricultural and veterinary chemical products proposed for supply and use in Australia, and for controlling them up to the point of retail sale. The states and territories are responsible for regulating and managing the use of agricultural and veterinary chemical products once they are sold.

The key functions of the APVMA, which are set out in section 7 of the Administration Act, are to:

- assess the suitability for sale in Australia of active constituents for proposed or existing chemical products, registered chemical products and labels for containers for chemical products
- ensure that approvals and registrations for active constituents for chemical products, chemical products and labels for containers for chemical products comply with the Agvet Code, and the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Agvet Code Regulations)
- provide information to the Australian Government and its agencies, and the states and territories, about approved active constituents for proposed or existing chemical products, registered chemical products and approved labels for such products, and cooperate with the Australian Government and its agencies on matters relating to the management and control of chemical products
- collect and publish relevant information and statistics on approvals and registrations granted and permits and licences issued under the Agvet Code
- with the Australian Government and its agencies, and the states and participating territories, facilitate a consistent approach to the assessment and control of agvet chemicals
- exchange information relating to chemical products and their use with overseas and international bodies that have similar functions to those of the APVMA, and
- report to or advise the Minister on matters relating to the performance of the APVMA's functions.

In fulfilling its role, the APVMA:

- undertakes assessments to evaluate the safety and performance of chemicals intended for sale in Australia to ensure that the health and safety of people, animals, crops and the environment are protected and international trade is not unduly jeopardised by the use of a chemical
- licenses and audits manufacturers to ensure adherence to APVMA-prescribed manufacturing standards
- monitors the market for compliance, and undertakes reviews and regulatory action on registered pesticides and veterinary medicines when concerns are identified, and

- records adverse experience reports to provide early detection of unforeseen problems with registered chemicals.

The APVMA uses internationally developed and accepted methodologies for registration and uses the best available evidence to support decision making.

The risk analysis process

An application to the APVMA for active constituent approval or product registration typically contains a number of distinct parts, including data for chemistry and manufacture, toxicology relating to public health and occupational health and safety (OHS), residues, environmental safety, and product efficacy. The APVMA and its external expert assessors perform risk assessments of various parts of the application, assessing both hazard (ie. the intrinsic toxicity of the chemical) and the likely extent of exposure to the chemical.

These assessments determine the hazards of a chemical or product (to humans and to plants and animals in the environment) and the extent to which people, plants or animals are likely to be exposed to the chemical when it is used according to the proposed label.

The APVMA uses these assessments to determine whether the risks associated with the proposed use(s) are acceptable and whether any identified risks can be appropriately managed or mitigated.

The potential risks involved in using a chemical product are communicated to relevant people, such as end users. One of the most important tools for risk communication is the product label that is attached to the product container.

The processes of risk assessment, risk management and risk communication are all part of the risk analysis process. The risk analysis process serves to ensure the APVMA conducts robust, risk-based scientific evaluations to support sound regulatory decisions.

2 HENDRA VIRUS VACCINE PRODUCT REGISTRATION

The Hendra virus vaccine was registered on 4 August 2015 as EQUIVAC HEV HENDRA VIRUS VACCINE FOR HORSES (APVMA product number: 68996) in response to an application made by Zoetis Australia Pty Ltd. Details about the registered product including the approved label and studies submitted in support of the application are publicly available on the APVMA chemicals database and provided at Attachment A and B.

Following the assessment of specific studies, the registration was varied on 20 January 2016 to provide additional information on the use for foals and pregnant mares.

Prior to its registration the vaccine was made available for use in Australia in 2012 through an APVMA minor use permit. The permit was issued as an additional tool to biosecurity measures in response to the increase in Hendra virus cases at the time. This permit has been replaced by the product registration.

About the Hendra virus vaccine product

Equivac® HeV virus vaccine for horses is a 1mL vaccine that is injected intramuscularly. The vaccine is a ‘subunit’ vaccine, meaning it contains only a small part of the protein from the virus surface. It does not contain the virus. The active constituent is the G-Protein (sG) of Hendra virus.

Its indication of use is as an aid in the prevention of clinical disease caused by Hendra virus in horses four months of age or older.

Safety, health and side effects

Safety considerations

Before granting registration of the product the APVMA was satisfied that the vaccine—when used in accordance with the proposed instructions—would:

- not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and
- not be likely to have an effect that is harmful to human beings; and
- not be likely to have an unintended effect that is harmful to animals, plants or the environment.

In granting registration the APVMA has assessed the chemistry and manufacturing aspects of G-Protein (sG) of Hendra virus (the active constituent) and the product and was satisfied that they meet APVMA criteria. The assessment considered data for information about starting materials for the vaccine, master seeds (source, identity, and purity), culture media, vaccine production, quality control, shelf life and batch release analysis. The adjuvants and the excipients were already present in several vaccines registered for use in Australia and were determined to be safe based on previous assessment.

In relation to the assessment of safety in horses the APVMA reviewed 21 separate efficacy and safety studies and 10 chemistry and manufacture studies which supported two separate applications by the registrant. These studies informed the label instructions for the product, its directions for use, advice to people administering the vaccine, as well as precautions and health warnings. We remain satisfied that the data supporting the safety of the product adequately demonstrates that this product is likely to be safe under Australian conditions when used according to label instructions.

A list of the studies considered in this assessment are available on the APVMA website and are included at Attachment B.

Animal safety warnings and side effects

Where assessment of the product identifies that precautions are warranted or there may be possible side effects, these details are included on the product label. The potential side effects are considered as part of the overall assessment of animal safety.

The current approved label includes specific precautions related to use of the product. These safety restraints are supported by evidence the APVMA considered at the time of initial registration and in response to subsequent applications to amend the label use instructions.

Possible post-vaccination side effects include injection site pain, an increase in body temperature, lethargy, inappetance, and muscle stiffness. Transient swelling at the site of vaccination was also identified as a possible side effect in some horses but it should resolve within one week without treatment. Additional side effects include urticaria, sweating, oedema and colic.

The label also warned that clinical signs may vary in severity and, on rare occasions, may require veterinary intervention. A full list of these side effects is included in the label provided online and at Attachment A.

Effectiveness of the vaccine.

Before granting registration of the product the APVMA was satisfied that the product— when used in accordance with the approved instructions —would be effective as an aid in the prevention of clinical symptoms of the disease caused by Hendra virus in horses four months of age or older.

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

Duration of immunity

The approved instructions for the product indicate that a booster dose of the vaccine is required every six months. This is because a duration of immunity has not been demonstrated for more than six months. However, the APVMA is currently considering a variation application to extend the duration of immunity to 12 months, which is due to be finalised by the end of June 2016.

Mandatory vaccination

Mandatory vaccination requirements put in place by the equine industry, event organisers and by some veterinarians are outside the scope and jurisdiction of the APVMA—they are not requirements of the APVMA. The APVMA's role is very specific in terms of assessing whether the vaccine is safe to use and is effective when used in accordance with label instructions.

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3 SUMMARY OF ADVERSE EXPERIENCE REPORTS MADE TO THE APVMA ABOUT HENDRA VIRUS VACCINE

Adverse experience reports about the Hendra virus vaccine are made to the APVMA through the Adverse Experience Reporting Program (AERP). AERP is a post-registration program that assesses reports of adverse experiences associated with the registered use of a veterinary medicine or agricultural chemical product.

Anyone can report an adverse experience to the AERP—ie, farmers, pet owners, gardeners, veterinarians or the general public.

The AERP considers each report of an adverse experience it receives. It then classifies the relationship between the veterinary medicine or agricultural chemical product and the adverse experience.

Trend analyses may be performed periodically or if a cluster of reports is submitted involving a particular product. This may result in us either confirming the registration of a product or allowing it to continue with changes to how the product can be used (therefore requiring a change to label instructions and warnings). We may also cancel the registration of a chemical and remove a product from the market.

The information presented below was collected under a mandatory reporting regime that was required as a condition of the permit authorising the supply and use of the product. Following the registration of the product on 4 August 2015, reports are provided to the AERP on a voluntary basis. However, registrants have an ongoing obligation to report anything that changes to the APVMA as soon as reasonably possible.

Table 1: Number of equine reports classified by the APVMA to 31 December 2015

Note: Reports were mandatory under the permit until 4 August 2015 and then on a voluntary basis from registration to 31 December 2015.

Reaction year	Possible	Possible/off-label	Probable	Probable/off-label	Unknown	Unlikely	Total
2012	4		25		4	8	**41**
2013	52	3	252	1	29	32	**369**
2014	76	1	351	1	41	28	**498**
2015	34		155	1	35	22	**247**
Total	**166**	**4**	**783**	**3**	**109**	**90**	**1155**

Source: AERP

What do the classifications mean?

Probable: A 'probable' classification is given when there is a reasonable association between exposure to a product and the onset of the reported adverse experience, and the description of the presenting signs is consistent (or plausible) with the known pharmacology and toxicology of the product and there are no other alternative explanations.

Possible: A 'possible' classification is given when there is a reasonable association between the exposure to the product and the onset of the reported adverse experience. Therefore, it is reasonable to include the adverse reaction as a differential diagnosis, and it is one of the possible explanations for the adverse experience (for example the use of concurrent medication etc), or the association is reasonable but does not meet the criteria for a probable classification.

Probable or possible off-label: This classification is given as per the classifications of 'probable' or 'possible', but where there is evidence of off-label use. That is use that is not in accordance with the label instructions approved by the APVMA.

Unlikely: An 'unlikely' classification is given when sufficient information exists to establish that the adverse experience was not likely to have been associated with the product.

Unknown: An 'unknown' classification applies when reliable data are unavailable or are insufficient to make an assessment of an adverse experience.

Table 2: Count of presenting signs; equine reports classified by the APVMA as probable and possible to 31 December 2015

Note 1: The data in table 2 below relates to the number of reports in which a presenting sign was identified. A single report may describe a presenting sign in multiple horses.

Note 2: Reports reflect the count rather than the severity of presenting signs.

Note 3: Reports were mandatory under the permit until 4 August 2015 and then on a voluntary basis from registration to 31 December 2015.

Presenting signs	Probable	Possible
Injection site reaction	502	17
Oedema	251	19
Lethargy	233	51
Pain	215	21
Anorexia	139	24
Pyrexia	124	28
Swelling (local)	104	4
Stiffness	85	14
Lump (local)	58	5
Muscle stiffness	51	3
Urticaria	40	12
Ataxia	29	6
Sweating	25	10
Colic	22	20
Depression	13	4
Lame	13	2
Site reaction	13	0
Malaise	9	11
Abdominal pain	9	6
Behavioural change	9	6
Coat colour change	9	2
Listless	7	1
Recumbency	5	8
Nasal discharge	5	5
Walking (difficult)	5	1
Alopecia (localised)	4	7
Tachypnoea	4	2
Disorientation	4	1
Distress	4	1
Shaking	4	1
Adipsia	4	0
Panting	4	0
Pruritus	4	0
Restless	4	0

Presenting signs	Probable	Possible
Lymphadenopathy	3	2
Tachycardia	3	2
Aggression	3	1
Hives	3	1
Coughing	2	4
Laminitis	2	4
Alopecia	2	2
Tremor	2	2
Hyper salivation	2	0
Hypersensitivity reaction	2	0
Site reaction (swelling)	2	0
Weight loss	1	5
Polydipsia	1	2
Abnormal breathing	1	1
Agitation	1	1
Anaphylaxis	1	1
Dermatitis	1	1
Epistaxis	1	1
Facial oedema	1	1
Pale mucous membranes	1	1
Paresis	1	1
Stranguria	1	1
Bradycardia	1	0
Conjunctivitis	1	0
Haematoma	1	0
Hyperaesthesia	1	0
Incoordination	1	0
Inflammation	1	0
Laryngitis	1	0
Lesions	1	0
Polymyositis	1	0
Vomiting	1	0
Weakness	1	0
Welts	1	0

Presenting signs	Probable	Possible
Death	0	7
Diarrhoea	0	5
Dyspnoea	0	3
Preputial swelling	0	2
Respiratory problems	0	2
Allergy	0	1
Anuria	0	1
Atrophy	0	1
Azoturia	0	1
Coat discoloration	0	1
Colitis	0	1
Confusion	0	1

Presenting signs	Probable	Possible
Eczema	0	1
Fasciculation	0	1
Hepatopathy	0	1
Hyperactivity	0	1
Hypersensitive to stimuli	0	1
Lymphadenitis	0	1
Periorbital swelling	0	1
Scrotitis	0	1
Urine (abnormal)	0	1

Source: AERP

Table 3: Reaction incidence %; equine reports classified by the APVMA as probable and possible to 31 December 2015

Note 1: Reaction Incidence calculated on the understanding that 416,267 doses of vaccine have been administered from launch to 31 December 2015.

Reaction Incidence % = Total number of animals where a presenting sign has been classified as probably or possibly linked to the administration of the Hendra vaccine / Number of doses sold*100

Note 2: The data in this table relates to the number of horses for which a reaction has been reported that has been assigned a classification of possible or probable.

Note 3: Reports were mandatory under the permit until 4 August 2015 and then on a voluntary basis from registration to 31 December 2015.

Presenting signs	Reaction %
Injection site reaction	0.18
Lethargy	0.10
Oedema	0.10
Pain	0.08
Pyrexia	0.06
Anorexia	0.05
Swelling (local)	0.04
Stiffness	0.03
Lump (local)	0.02
Muscle stiffness	0.02

Presenting signs	Reaction %
Urticaria	0.02
Colic	0.01
Sweating	0.01
Ataxia	0.01
Behavioural change	0.01
Malaise	0.006
Listless	0.005
Abdominal pain	0.005
Alopecia (localised)	0.005
Depression	0.004

Presenting signs	Reaction %
Lame	0.004
Coat colour change	0.003
Recumbency	0.003
Site reaction	0.003
Nasal discharge	0.003
Coughing	0.002
Disorientation	0.002
Laminitis	0.002
Alopecia	0.002
Death	0.002
Lymphadenopathy	0.002
Tachypnoea	0.002
Weight loss	0.002

Presenting signs	Reaction %
Agitation	0.001
Pruritus	0.001
Restless	0.001
Tachycardia	0.001
Walking (difficult)	0.001
Diarrhoea	0.001
Distress	0.001
Polydipsia	0.001
Shaking	0.001
Stranguria	0.001
Tremor	0.001

Source: AERP

The following presenting signs each had a reaction incidence of <0.001%:

Adipsia, Aggression, Lymphadenitis, Panting, Paresis, Dyspnoea, Site reaction (swelling), Abnormal breathing, Anaphylaxis, Coat discoloration, Confusion, Dermatitis, Epistaxis, Facial oedema, Hyper salivation, Hypersensitivity reaction, Pale mucous membranes, Preputial swelling, Respiratory problems, Allergy, Anuria, Atrophy, Azoturia, Bradycardia, Colitis, Conjunctivitis, Eczema, Fasciculation, Haematoma, Hepatopathy, Hyperactivity, Hyperaesthesia, Hypersensitive to stimuli, Incoordination, Inflammation, Laryngitis, Lesions, Periorbital swelling, Polymyositis, Scrotitis, Urine (abnormal), Vomiting, Weakness, Welts.

ATTACHMENTS

Attachment A APVMA Approved Label – Equivac Hev Hendra Virus Vaccine for Horses

Attachment B Protected data details – Equivac Hev Hendra Virus Vaccine for Horses

RLP APPROVED

Company Name: ZOETIS AUSTRALIA PTY LTD
Product Name: EQUIVAC HEV HENDRA VIRUS VACCINE FOR HORSES
APVMA Approval No: 68996/103910

DISPLAYED BY INFOPEST

Label Name:	EQUIVAC HEV HENDRA VIRUS VACCINE FOR HORSES
Signal Headings:	FOR ANIMAL TREATMENT ONLY
Constituent Statements:	100 µg/mL G-POTEIN (sG) OF HENDRA VIRUS 0.1 mg/mL THIOMERSAL
Claims:	An aid in the prevention of clinical symptoms of the disease caused by Hendra virus in horses 4 months of age and older.
Net Contents:	10 mL glass vial, 1 mL glass syringe
Directions for Use:	Read the enclosed leaflet for full instructions DIRECTIONS FOR USE
Restraints:	Not Applicable
Contraindications:	The Product should not be used in sick or immunocompromised horses.
Precautions:	The effectiveness of Equivac HeV vaccine in the face of Hendra virus disease outbreak has not been studied. While all horses receiving the recommended vaccine course and booster vaccination at 6 months were antibody positive, the potential for vaccinated horses to shed virus if exposed to and infected with the Hendra virus cannot be ruled out. It is recommended that good hygiene practices are observed when horses are being handled. This product has been found to be safe for administration to pregnant mares. However, in pregnant mares it is important to avoid the use of vaccines during critical stages of pregnancy. For this reason avoid vaccinating during the first 45 days after mating and the last 14 days before the expected date of foaling.

	Duration of immunity has not been demonstrated for more than 6 months following the primary vaccination course. The compatibility of Equivac HeV Hendra virus vaccine with other vaccines and veterinary chemical products has not been studied.

Side Effects:	Transient swelling may develop at the site of vaccination in some horses but should resolve within one week without treatment. In some horses transient post-vaccination reactions including injection site reaction, pain, increase in body temperature, lethargy, inappetence, and muscle stiffness have also been observed. Additional reported clinical signs have included urticaria, sweating, oedema and colic. Clinical signs may vary in severity and occasionally may require veterinary intervention. Systemic allergic reactions such as anaphylaxis may require parenteral treatment with adrenaline, corticosteroid and antihistamine as appropriate and should be followed by appropriate supportive therapy.

Dosage and Administration:	Contents must be left in outer package until immediately before use. The dose on all occasions is 1 mL injected intramuscularly in horses 4 months of age and older. The most convenient site for injection is the centre of the side of the neck. Before the vaccine is injected, the proposed site of inoculation on the horse's skin may be cleaned by swabbing with cotton-wool soaked in a suitable antiseptic solution, such as methylated spirits. For primary immunisation two doses of vaccine should be administered 3 to 6 weeks apart. A third dose 6 months after the second primary dose is also required. Booster doses are required every 6 months thereafter. When vaccinating foals born to mares vaccinated with Equivac HeV, it is recommended that the foal's primary vaccination course be delayed until 6 months of age to ensure an effective immune response to vaccine antigen. Summary of Dosing Schedule Vaccination Type ---- Timing Interval First Dose ---- Day 1 Second Dose ---- Day 21 - 42 Third Dose ---- 6 months after the second dose Followed by 6 monthly boosters It is recommended that good hygiene practices are observed when horses are being handled.

General Directions:	Equivac HeV Hendra virus vaccine for horses contains soluble forms of G-Protein [sG] of Hendra Virus adjuvanted with immunostimulating complex. Each mL of vaccine contains ≥ 100 µg G-Protein [sG] of Hendra Virus. Thiomersal at 0.1 mg/mL has been added as a preservative. This vaccine may contain residual hygromycin.

Withholding Periods:	MEAT WITHHOLDING PERIOD: Not Applicable

Trade Advice:	EXPORT SLAUGHTER INTERVAL (ESI): ESI Not Applicable

Safety Directions:	Not Applicable

First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.

First Aid Warnings:	

Additional User Safety:	User Safety Information Take care to avoid accidental self-injection. Accidental self-administration may result in local bruising, pain and swelling. In the event of self-administration, seek medical attention and show the package leaflet or the label, to the Medical Practitioner. This material may cause a mild allergic reaction in sensitive individuals on skin contact. Avoid skin contact. If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. If splashed in eyes, wash out immediately with water. Personal Protective Equipment (PPE) should be worn whenever Hendra virus disease is suspected even in vaccinated horses as not all vaccines can provide a guaranteed protection.

Environmental Statements:	Not Applicable

Disposal:	Dispose of empty syringe and needle by immediately placing into a designated and appropriately labelled 'sharps' container. Dispose of container by wrapping with paper and putting in garbage.

Storage:	Store between 2°C and 8°C (Refrigerate. Do not freeze). Protect from light.

Product: EQUIVAC HEV HENDRA VIRUS VACCINE FOR HORSES
Product No.: 68996
Protected data details

Data type	Title
Chemistry and Manufacture	In-process control tests during production of the active substance
Chemistry and Manufacture	Formulation (Qualitative and quantitative particulars of the constituents) /composition of product
Chemistry and Manufacture	Controls applied during the formulation of the adjuvant
Chemistry and Manufacture	Control tests on the final product
Chemistry and Manufacture	Manufacturing process of the final product
Chemistry and Manufacture	Container specification
Chemistry and Manufacture	Inactivation / detoxification
Chemistry and Manufacture	Specifications and supporting documents
Chemistry and Manufacture	Container specifications
Chemistry and Manufacture	Stability of the finished product
Efficacy and Safety	Experimental Infection of a Horse with Hendra Virus/Australia/Horse/2008/Redlands
Efficacy and Safety	Protection of horses from Hendra Virus disease by vaccination - 2
Efficacy and Safety	Evaluation of two alternative vaccination regimens using the Hendra virus vaccine for horses
Efficacy and Safety	Protection of horses from Hendra virus disease by vaccination
Efficacy and Safety	Efficacy and Safety of a novel Hendra Virus vaccine in horses under field conditions
Efficacy and Safety	Safety of a novel Hendra Virus Vaccine in minimum age horses
Efficacy and Safety	Safety of the Hendra Virus Vaccine for Horses (Equivac HeV) in 3 month old foals.
Efficacy and Safety	Safety evaluation of the Hendra virus vaccine for horses (Equivac HeV) in pregnant mares.
Efficacy and Safety	Protection of horses from Hendra virus disease by vaccination - 2
Efficacy and Safety	Efficacy and Safety of a novel Hendra Virus vaccine in horses under field conditions.
Efficacy and Safety	Equivac HeV Hendra Virus Vaccine for Horses
Efficacy and Safety	Equivac HeV Hendra Virus Vaccine for Horses
Efficacy and Safety	Equivac HeV Hendra Virus Vaccine for Horses

Data type	Title
Efficacy and Safety	Protocol for serological monitoring of horses vaccinated with Equivac HeV in Northern Australia, Janes Cook University Equine Hendra Surveillance
Efficacy and Safety	Protocol for Comparative efficacy of Equivac HeV when formulated with and without irradiation of the subunit HeV G protein antigen.
Efficacy and Safety	To assess the efficacy of the Equivac HeV (Hendra) vaccine in generating and maintaining effective serum neutralizing antibody titres in adult horse over 12 months.
Efficacy and Safety	Safety evaluation of the Hendra virus vaccine for horses in pregnant mares under Australian field conditions.
Efficacy and Safety	Safety evaluation of the Hendra virus vaccine for horses (Equivac HeV) in pregnant mares
Efficacy and Safety	Evaluation of the Equivacï?? HeV vaccine when Pregnant Mares are inoculated in Early, Mid and Late Gestation
Efficacy and Safety	Safety of the Hendra Virus Vaccine for Horses (Equivac HeV) in 3 month old Foals
Efficacy and Safety	Evaluation of Equivac HeV in 3 month old foals born to vaccinated dams-effect of maternal antibodies on the immune response to vaccination.

Source: APVMA website