Questions & Answers on licence DIR 214 – Trial of a genetically modified (GM) vaccine for the prevention of respiratory disease in horses

What does this licence allow?

The University of Queensland is conducting a trial under limited and controlled conditions, of a genetically modified (GM) vaccine for the prevention of *Rhodococcus equi* induced respiratory disease in horses, commonly known as rattles.

The vaccine will be produced at The University of Queensland's (UQ) St Lucia campus and administered to up to 10 horses at UQ's Gatton campus over a period of 5 years.

How has the GM vaccine been created?

The GM vaccine is based on Adenovirus, which is commonly used as the backbone of vaccines and treatments. It has been modified by deletion of multiple genomic regions which render it unable to replicate or evade immune detection. A single gene to produce the virulence-associated protein A (VapA) from the soil bacterium *R. equi* has been inserted into the GM vaccine.

What is the purpose of the trial?

The trial is to test the ability of the GM vaccine to elicit an immune response against *R. equi* in foals. Following administration, the vaccine is expected to induce antibodies against the *R. equi* VapA and thus provide protective immunity for foals.

What other regulatory processes apply to this trial?

Before commencing, the trial would require approval from the Australian Pesticides and Veterinary Medicines Authority (APVMA). The APVMA regulates agricultural and veterinary chemical products, including animal vaccines. The APVMA issues permits to allow testing of a new product during its development. The APVMA can impose conditions on the use of veterinary products in their registrations and permits. In addition, the University of Queensland may also require approval from other agencies, such as Department of Agriculture, Fisheries and Forestry, to conduct the trial.

The proposed trial has been approved by The University of Queensland Animal Ethics Committee.

What controls are imposed for this release?

The Risk Assessment and Risk Management Plan (RARMP) for this application concludes that the trial poses negligible risks to people or the environment. However, as this is a trial, UQ must comply with a range of licence conditions that restrict when and where the trial can take place, limit the size of the trial, and to minimise the potential for the GM vaccine to spread in the environment. For example, there are conditions relating to administration of the GM vaccine, secure transport and storage of the GM vaccine and appropriate waste disposal. Full details of these control measures are in the licence.

Want more information?

A number of documents relating to this decision are available on the DIR 214 page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan (RARMP), a summary of the RARMP and the licence.

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