

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

What is this application for?

The University of Queensland is seeking approval for a trial of genetically modified (GM) vaccine for the prevention of respiratory disease in horses, known as Rattles. The disease is caused by *Rhodococcus equi*, a ubiquitous soil bacterium that can lead to severe respiratory disease in foals when inhaled.

The GM vaccine would be manufactured at The University of Queensland. It would be administered to up to 10 young horses at the Queensland Animal Sciences Precinct (UQ Gatton Campus).

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 Australian Pesticides and Veterinary Medicines Authority (APVMA) regulates agricultural and veterinary chemical products, including animal vaccines. The APVMA issues permit 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.

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 protein (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* virulence protein VapA and thus provide protective immunity for foals.

What controls are proposed for this release?

The consultation Risk Assessment and Risk Management Plan (RARMP) prepared for this application trial poses negligible risks to people or the environment. However, as this is a trial under limited and controlled conditions, a number of licence conditions have been drafted to restrict when and where the trial can take place, limit the size of the trial, restrict the spread and persistence of the GM vaccine. For example, there are conditions relating to preparation and administration of the GM vaccine, secure transport and storage of the GM vaccine/treatment and appropriate waste disposal. Full details of the draft licence conditions are available in the consultation RARMP.

How can I comment on this application?

The full consultation RARMP and a summary of the RARMP for application DIR 214 are available on the [OGTR website](#), the [consultation hub](#) (search for DIR 214) or via the contacts listed below. You are invited to submit your written comments (via the [consultation hub](#) or by email) on the consultation version of the RARMP, related to any risks to the health and safety of people or to the environment from the proposed trial. Please note that issues such as **animal safety, quality and efficacy of veterinary products, and marketability and trade implications** do **NOT** fall within the scope of the evaluations conducted under the *Gene Technology Act 2000* as these are the responsibility of other agencies and authorities. Comments must be received by the close of the consultation period on **28 April 2025**.

What are the next steps in the evaluation process?

The RARMP will be finalised, taking into account submissions related to the protection of people or the environment. A de-identified summary of all comments received and consideration of those comments is included in the Appendices to the final RARMP. The finalised RARMP will inform the Regulator's decision on whether or not to issue a licence.

The Office of the Gene Technology Regulator

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