Questions & Answers on licence application DIR 220 – Commercial supply of multivalent cat vaccines containing a genetically modified component for the prevention of feline leukemia virus infection

What is this application for?

Intervet Australia Pty Ltd is seeking approval for the commercial supply of multivalent cat vaccines that contain a genetically modified organism (GMO). The GMO protects cats against Feline leukemia virus infection. The vaccines would also include other attenuated, non-GM viruses and bacteria that provide protection against other common contagious diseases affecting cats. The vaccines would be prescription only and only administered by qualified veterinarians, Australia-wide.

What diseases do the vaccines protect against?

The vaccines protect against feline panleukopenia virus, feline calicivirus, feline herpesvirus, *Chlamydia felis* and feline leukemia virus infection. These infectious pathogens cause gastrointestinal, respiratory, conjunctival, or immunosuppressive disease in cats, and some can be fatal.

What other regulatory processes apply to this commercial release?

The applicant will need to separately apply to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for registration before the vaccines can be sold or used. Import of the vaccines, including the GMO, will also require approval from the Department of Agriculture, Fisheries and Forestry.

How has the GMO been created?

The vaccines contain GM Venezuelan Equine Encephalitis Virus (VEEV) that produces a protein from feline leukemia virus (FeLV) and cannot produce more viral particles. The GMO does not cause disease in cats but triggers an immune response against the protein and protects against later infection by FeLV.

What is the purpose of the commercial supply?

The commercial supply of the vaccines is for the vaccination of cats to protect them from common infectious diseases, including FeLV.

Has the GMO been previously tested or used?

The GMO have been approved for use by the United States Department of Agriculture since 2024. Laboratory studies have found that the GMO does not produce symptoms of either VEEV or feline leukemia virus infection in cats or horses (the most at risk host of VEEV), and that vaccination with the GMO protected cats against later infection by feline leukemia virus. The individual non-GM live-attenuated viral and bacterial vaccine strains are outside the scope of the OGTR risk assessment and will be assessed by the APVMA for use in Australia.

What controls are proposed for this release?

The licence application proposes an ongoing commercial release, with access to the GMO and the vaccines restricted by being prescription only. The Gene Technology Regulator has prepared a consultation Risk Assessment and Risk Management Plan (RARMP), which finds that the proposed commercial release of this GMO poses negligible risk to the health and safety of people or the environment. Licence conditions drafted in the consultation RARMP maintain the risk context and ensure that there is ongoing oversight of the release.

How can I comment on this application?

The full consultation RARMP and a summary of the RARMP for application DIR 220 are available on the OGTR website, the consultation hub 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 release. Please note that issues such as **quality and efficacy of a 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 **2 June 2026**.

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.

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