Australian Government
Department of Health, Disability and Ageing
Office of the Gene Technology Regulator

29 October 2025

Summary of Licence Application DIR 220

Intervet Australia Pty Ltd (Intervet) has made an application under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of vaccines for the prevention of common infectious diseases in cats. The vaccines include a genetically modified (GM) component for the prevention of feline leukemia virus (FeLV) infection in cats.

Project Title	Commercial supply of multivalent cat vaccines containing a genetically modified component for the prevention of feline leukemia virus infection[1]
Parent organism	Venezuelan equine encephalitis virus (VEEV) strain TC-83
Genetic modifications	
Effects of the modifications	**Deleted genes**: - Viral structural genes are deleted to render the GMO unable to produce new viral particles **Introduced gene**: - Feline leukemia virus glycoprotein gene produced as RNA **Effect of modifications**: - The GMO will produce RNA encoding the glycoprotein, that when transcribed will trigger an immune response against the feline leukemia virus and protect animals against later infection
Principal purpose	Commercial supply of vaccines containing the GMO and non-GM attenuated wild type viruses or bacteria
Previous approvals	The GMO and similar GMOs using the same parent organism have been approved by the US Department of Agriculture (2024)
Proposed limits	
Proposed location	Australia-wide
Proposed period of release	From issue of licence

The application

Intervet is seeking approval for import, transport, storage and disposal of vaccines containing the GMO as part of its commercial supply of multivalent vaccines for cats. Feline leukemia virus is a contagious virus affecting cats. The parent organism for the GMO, VEEV, is transmitted by mosquitoes and primarily infects vertebrates, causing disease in horses.

The activities associated with the commercial supply of vaccines containing the GMO are classified as Dealings Involving the Intentional Release (DIR) of GMOs into the Australian environment.

Other regulatory approvals

The Australian Pesticides and Veterinary Medicines Authority (APVMA) administers the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet code) to regulate agricultural and veterinary chemical products, including veterinary vaccines. Before vaccines containing the GMO can be used, the applicant will

[1] The original title for the application was "*Commercial DIR for Nobivac NXT HCPChFeLV Live Vaccine for cats, plus fall-out vaccine product Nobivac NXT HCPFeLV Live Vaccine for cats".*

need separate authorisation from the APVMA. The APVMA can impose conditions on the use of veterinary products.

Next steps

The Gene Technology legislation sets out what the Regulator must do, as well as what the Regulator can or must consider, before deciding whether or not to issue a licence for this application.

After seeking advice from prescribed experts, agencies and authorities, the Regulator's staff will prepare a consultation version of the Risk Assessment and Risk Management Plan (RARMP) considering aspects of the application in accordance with the legislation.

The Regulator will seek comment on the consultation RARMP from the public, as well as a wide range of experts, agencies and authorities. The public and experts will be invited to provide submissions on the risks to human health and safety, and on risks to the environment from the proposed release.

At this stage, the consultation RARMP is expected to be released for comment in **April 2026**.

After consultation, the Regulator's staff will finalise the RARMP, taking into account advice on relevant matters. The finalised RARMP will form the basis of the Regulator's decision whether or not to issue a licence. The consultation and final versions of the RARMP and associated documents will be available on the OGTR website when they are released.

Other information available from the OGTR website:

- 'Questions and Answers' document for this application
- information on Australia's national scheme for regulation of gene technology and
- information on the DIR application process.

Please use the contact details below if you:

- would like a copy of the application. Please include the identifier DIR 220.
- have any questions about the application or the legislated evaluation process or
- wish to register on the mailing list.

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