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

April 2026

Summary of Licence Application DIR 224

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 a genetically modified (GM) multivalent vaccine for chickens.

Project Title	Commercial supply of a genetically modified (GM) multivalent vaccine for chickens[1]
Parent organism	Turkey herpesvirus (*Mardivirus meleagridalpha1*) strain FC 126
Genetic modifications[2]	**Introduced genes:** • fusion (F) protein gene from Newcastle disease virus (NDV) – Expression of the F protein • glycoprotein D (gD) and glycoprotein I (gI) genes from infectious laryngotracheitis virus (ILTV) – Expression of the gD and gI glycoproteins
Principal purpose	Commercial supply of a GM multivalent vaccine to prevent Newcastle disease (ND), infectious laryngotracheitis (ILT) and Marek's disease in chickens.
Previous approvals	The GM vaccine has been approved by the United States Department of Agriculture, the European Medicines Agency and the Veterinary Medicines Directorate in the United Kingdom.
Proposed location	Australia-wide
Proposed period of release	Ongoing from issue of licence

The application

Intervet is seeking approval for import, transport, storage, supply and disposal of a live GM multivalent vaccine, known as Innovax-ND-ILT, as part of the commercial supply of the vaccine for chickens.

The GM vaccine is based on an apathogenic strain of turkey herpesvirus, which prevents Marek's disease. It has been modified to express the F protein from NDV and gD and gI glyproteins from ILTV, which together induce immunity against ND and ILT.

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. For commercial products, the normal form of approval is through registration. The APVMA can impose conditions on the use of veterinary products in registrations and permits. The applicant will also require a permit from the Department of Agriculture, Fisheries and Forestry (DAFF) to import the GM vaccine into Australia.

[1] The original title for the licence application submitted by Intervet is "Innovax ND ILT"

[2] Confidential Commercial Information (CCI): Some details of the genetic modification in the GM vaccine have been declared as CCI under section 185 of the Act. This information will be made available to the prescribed experts and agencies that are consulted on this application. CCI is not available to the public.

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 **August 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 224.
- have any questions about the application or the legislated evaluation process or
- wish to register on the mailing list.

The Office of the Gene Technology Regulator, MDP 54, GPO Box 9848, Canberra ACT 2601
Telephone: 1800 181 030
Email: ogtr@health.gov.au