Questions & Answers on licence application DIR 224 – Commercial supply of a genetically modified (GM) multivalent vaccine for chickens

What is this application for?
Intervet Australia Pty Ltd is seeking approval for the commercial supply of a genetically modified (GM) multivalent vaccine for chickens. The GM vaccine, known as Innovax-ND-ILT, will be manufactured overseas and imported into Australia. The proposed vaccination would take place at chicken farms throughout Australia and would be ongoing from the date of issue of the licence.

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 vaccine can be sold or used. Import of the vaccine will also require approval from the Department of Agriculture, Fisheries and Forestry.

How has the GM vaccine been made?
The GM vaccine is based on a turkey herpesvirus which has been modified by the insertion of the fusion protein gene from the Newcastle disease virus and glycoproteins gD and gI genes from the infectious laryngotracheitis (ILT) virus. The turkey herpesvirus strain used is non-pathogenic to all known susceptible avian species and does not infect humans and other animals; however, it prevents Marek's disease. Due to the inserted genes, the vaccine is expected to also induce immunity against Newcastle disease and ILT.

What is the purpose of the commercial supply?
The commercial supply of the GM vaccine is for the vaccination of chickens to protect them from common infectious diseases, including Marek's disease, Newcastle disease and ILT infection. These are highly infectious viral diseases that have significant impacts on poultry industry.

Has the GM vaccine been previously tested or used?
The GM vaccine has been approved for use by the United States Department of Agriculture since 2019, and by the European Medicines Agency and the Veterinary Medicines Directorate in the United Kingdom since 2020. Laboratory studies and field trials of the GM vaccine showed that it was able to prevent Marek's disease, Newcastle disease and ILT infection in chickens and it did not harm people or the environment.

What controls are proposed for this release?
The licence application proposes an ongoing commercial release, with no restrictions on how the GM vaccine is used. The Gene Technology Regulator has prepared a consultation Risk Assessment and Risk Management Plan (RARMP), which finds that the proposed commercial release of this GM vaccine poses negligible risk to the health and safety of people or the environment. However, licence conditions drafted in the consultation RARMP 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 224 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 **25 September 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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