Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

10 January 2024

Summary of Licence Application DIR 202

Intervet Australia Pty Ltd (Intervet) has made an application under the *Gene Technology Act 2000* (the Act) for the commercial supply of a live attenuated vaccine containing canine distemper virus (CDV) and a genetically modified canine parvovirus (GM CPV) for dogs, Nobivac Puppy DP Plus.

Project Title	Commercial supply of a live attenuated vaccine containing canine distemper virus and a genetically modified canine parvovirus (Nobivac Puppy DP Plus) for dogs[1]
Parent organism	Canine Parvovirus (CPV)
Genetic modifications	
Introduced genes	Introduction of the capsid (viral envelope) of a circulating CPV into the existing attenuated vaccine strain CPV 154
Effect of genetic modification	The resulting GM component of the vaccine is a weakened strain unable to cause disease in dogs but able to trigger an immune response against the currently circulating disease and protect animals against later infection.
Principal purpose	Commercial supply of a vaccine containing an attenuated wild type strain of CDV and a GM strain of CPV.
Previous releases	The vaccine including the GM CPV is approved for use by the European Medicine Agency and the Philippine Food and Drug Administration.
Proposed limits	
Proposed location/s	Australia-wide
Proposed period of release	Ongoing from date of issue of licence

The application

Intervet is seeking approval for import, transport, storage, supply and disposal of a vaccine containing a wild type attenuated strain of canine distemper virus and a GM canine parvovirus (Nobivac Puppy DP Plus) as part of its commercial supply of a vaccine for dogs. Canine parvovirus is a highly contagious virus affecting dogs. Symptoms include lethargy, vomiting and diarrhea and animals often require lengthy hospitalisation due to the severity of these symptoms.

The activities associated with the commercial supply of the Nobivac Puppy DP Plus vaccine are classified as Dealings Involving the Intentional Release (DIR) of genetically modified organisms (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 Nobivac Puppy DP Plus vaccine can be used, the applicant will

[1] The title for the licence application submitted by Intervet is "Nobivac Puppy DP Plus Live Vaccine".

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 Gene Technology Regulator (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 consultation with the prescribed experts, agencies and authorities, the Regulator's staff will prepare a consultation version of a 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. These stakeholders 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 2024**.

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 202.
- have any questions about the application or the legislated evaluation process.

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