Questions & Answers on licence application DIR 202 – commercial supply of a vaccine containing canine distemper virus and a genetically modified canine parvovirus (Nobivac Puppy DP Plus) for dogs

What is this application for?

Intervet Australia Pty Ltd is seeking approval for the commercial supply of a live attenuated vaccine containing canine distemper virus and a genetically modified (GM) vaccine, Nobivac Puppy DP Plus, to protect dogs against canine distemper virus (CDV) and canine parvovirus (CPV). The proposed vaccine would be available by prescription only and would only be administered by qualified veterinarians within veterinary clinics, Australia-wide.

What diseases does the vaccine protect against?

CDV and CPV are highly contagious viruses can cause severe respiratory and gastrointestinal diseases respectively, primarily affecting dogs between 6 weeks and 6 months of age. Although CPV infects other mammals including foxes and cats, it does not infect people or other animals.

Who else needs to approve this commercial vaccine?

The applicant will need to separately apply to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for registration before this vaccine can be sold and used. Information on the authorisation pathways for veterinary vaccines can be found on the APVMA's website.

How has the vaccine been made?

The GM CPV contained in the vaccine is derived from a vaccine strain that is already used in Australia. The vaccine strain was modified to include a protein from a currently circulating CPV-2 strain. The included protein has been further modified to reduce its ability to cause disease. The resulting vaccine is a weakened strain unable to cause disease in dogs but triggers an immune response to protect against later infection. The canine distemper virus is an attenuated wild type strain and contains no genetic modifications.

Has the GM vaccine been previously tested or used?

The GM vaccine has been previously approved for use in 36 countries by the European Medicines Agency and the Philippine Food and Drug Agency to vaccinate dogs from the age of 4 weeks. Laboratory studies have found that the GM vaccine causes no disease itself and protects animals against later infection with either disease.

What controls are proposed for this release?

The licence application proposes an ongoing commercial supply, with access to the GM vaccine 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 GM vaccine 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 202 are available on the OGTR website or via the contacts listed below. You are invited to submit your written comments (including 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 therapeutic 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 **19 June 2024**.

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.

The Office of the Gene Technology Regulator

OGTR Website

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