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). These highly contagious viruses can cause severe respiratory and gastrointestinal diseases, primarily affecting dogs between 6 weeks and 6 months of age. Although CPV infects other mammals including foxes, wolves and cats, it does not infect people or other animals. The proposed vaccination would be prescription only and would only be administered by qualified veterinarians within veterinary clinics. The vaccine would be made available Australia wide and would be ongoing from the date of issue of the licence.

What other regulatory processes apply to 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 GM component of the vaccine been made?

The GM CPV contained in the vaccine was produced through recombination of two CPV strains, an attenuated vaccine strain and a circulating strain. The resulting vaccine strain is a weakened strain unable to cause disease in dogs but triggers an immune response against the currently circulating CPV strain and protects against later infection by this strain. 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 old. Laboratory studies have found that the GM vaccine produced milder symptoms than both diseases and vaccination with this GM virus protected animals against later infection with either disease.

What is the process for considering this application?

The licence application will be subject to comprehensive, science-based risk analysis. The process includes two rounds of stakeholder consultation. In the first round, the Regulator will seek advice from prescribed experts, agencies and authorities prior to preparing a draft Risk Assessment and Risk Management Plan (RARMP). The RARMP focuses on identifying risks to people and to the environment that may be posed by the commercial supply . Following public release of the draft RARMP, submissions will again be sought from stakeholders, this time including the public. The RARMP will then be finalised taking into account submissions received, and will inform the Regulator's decision whether or not to issue a licence.

How can I comment on this application?

The comprehensive RARMP for this application is expected to be released for public comment in **April 2024**. Its release will be advertised in newspapers, and it will be available on the OGTR website along with a range of supporting information. While comment is not being sought from the public at this stage, you can obtain a copy of the application by contacting the OGTR. Please quote the

application number DIR 202. A summary of the application is available on the OGTR website or by contacting the OGTR.