

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

What does this licence allow?

This licence allows Intervet Australia Pty Ltd to commercially supply a vaccine containing canine distemper virus (CDV) and genetically modified (GM) canine parvovirus (CPV). The vaccine received approval under the *Gene Technology Act 2000* and protects dogs against canine distemper and canine parvovirus disease. The vaccine is only available in Australia by prescription, and can only be administered by qualified veterinarians within veterinary clinics.

What diseases does the vaccine protect against?

CDV and CPV are highly contagious viruses that can both cause severe respiratory and gastrointestinal diseases. The viruses primarily affect 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.

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 protein has been further modified to reduce its ability to cause disease. As a result, the 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 vaccine been previously tested or used?

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

What is the role of the OGTR in approving the vaccine?

The Gene Technology Regulator (Regulator) has a specific responsibility to protect the health and safety of people and the environment. The Regulator identifies any risks posed by or as a result of gene technology, and manages those risks through regulating dealings with genetically modified organisms. The Regulator must issue an approval before the vaccine can be distributed.

What controls have been imposed for this vaccine?

The licence is for an ongoing commercial release. The vaccine is also subject to approval from the Australian Pesticides Veterinary Medicines Authority (APVMA). As the vaccine is yet to be registered with the APVMA, the Regulator has imposed specific measures to support the risk assessment's conclusion that this release poses negligible risks to the health and safety of people or the

environment. General conditions have also been imposed to ensure that there is ongoing oversight of the vaccine's release.

Want more information?

A number of documents relating to this decision are available on the [DIR-202](#) page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan (RARMP), a summary of the RARMP and the licence.

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