Questions & Answers on licence application DIR 220 – Commercial supply of multivalent cat vaccines containing a genetically modified component for the prevention of feline leukemia virus infection

What is this application for?

Intervet Australia Pty Ltd is seeking approval for the commercial supply of multivalent cat vaccines that contain a genetically modified organism (GMO). The GM component protects cats against Feline leukemia virus infection. The vaccines would also include live attenuated, non-GM viruses and bacteria to provide protection against other common contagious diseases affecting cats. The vaccines would be prescription only and would only be administered by qualified veterinarians. The vaccines would be available Australia-wide and the supply 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 the vaccines can be sold and used. Information on the authorisation pathways for veterinary vaccines can be found on the APVMA's website.

What is the GM component in the vaccines?

The vaccines contain GM Venezuelan Equine Encephalitis Virus (VEEV) that produces the glycoprotein from feline leukemia virus as RNA, but cannot produce more viral particles. The GM VEEV does not cause disease in cats but triggers an immune response against the glycoprotein and protects against later infection by feline leukemia virus.

What is the purpose of the commercial supply?

The commercial supply of the vaccines is for the vaccination of cats to protect them from common infectious diseases, including feline leukemia virus infection.

Has the GM component in the vaccines been previously tested or used?

The GM component in the vaccines and a similar GM vaccine against Canine flu has been approved for use by the United States Department of Agriculture since 2024. Laboratory studies have found that the GM VEEV produced no symptoms of either VEEV or feline leukemia virus infection in cats or horses (the natural host of VEEV), and that vaccination with this GM virus protected cats against later infection by feline leukemia virus. The individual non-GM live-attenuated viral and bacterial vaccine strains are already approved by the APVMA for use in Australia.

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 release. 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 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 2026**. 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 full application by contacting the OGTR. Please quote the application number DIR 220. A summary of the application is available on the OGTR website or by contacting the OGTR.