Australian Government

Australian Pesticides and Veterinary Medicines Authority

Vaccine efficacy claim guidelines

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VACCINE EFFICACY GUIDELINES—EXECUTIVE SUMMARY

The requirement for the development of clear guidance efficacy claims for vaccines emerged from the vaccine industry desire to create a harmonised and standard approach for supporting label claims in veterinary vaccine submissions to the APVMA.

Following consultation through the Veterinary Immunobiological Working Group (VIWG) new guidance has been developed by the APVMA to provide clarity on label efficacy claims for veterinary immunobiologicals.

1 APVMA GUIDELINE ON LABEL CLAIMS OF VETERINARY IMMUNOBIOLOGICALS

The efficacy claims for a veterinary immunobiological should be substantiated through the generation of data from laboratory and/or field studies in the target species.

The following standard efficacy claims should be used where relevant on the label for an immunobiological product.

For active immunisation or passive immunisation of the target species to:

1. **Prevent mortality, clinical signs and/or lesions of the disease**

   Example: Active immunisation of dogs from eight to nine weeks of age: to prevent clinical signs and mortality caused by canine distemper virus (CDV). Onset of immunity: three weeks after completion of the primary course. Duration of immunity: one year following the primary course then three years following the first and subsequent booster doses.

2. **Prevent infection**

   Example: To prevent clinical signs, infection and urinary excretion caused by *L. interrogans serogroup Canicola serovar Canicola*. Onset of immunity: two weeks after completion of the two-dose primary vaccination schedule. Duration of immunity: twelve months.

3. **Reduce mortality, clinical signs and/or lesions of the disease**

   Example: For the active immunisation of pigs from three days of age with maternally-derived antibodies to reduce pulmonary lesions and the decrease in daily weight gain during the finishing period due to infection caused by *Mycoplasma hyopneumoniae*. Onset of immunity: five days post-vaccination. Duration of immunity: 22 weeks post-vaccination.

4. **Reduce infection**

   Example: For the active immunisation of healthy chickens to reduce infection and clinical signs of coccidiosis caused by *Eimeria* spp (*list species)*. Onset of immunity: begins to develop within 10 days post vaccination. Duration of immunity: at least 36 weeks when birds are housed in conditions that permit oocyst recycling.

In addition, the onset and the duration of immunity should be included with the information on the expected protection unless justified. Where data demonstrating the onset and/or duration of immunity has not been generated, a statement should be included on the label reflecting the lack of data.

Data from laboratory and field efficacy studies may also be used to support additional efficacy claims on the nature of the protection, eg:

a. **The nature of immunological response and action**

   Example i): For the active immunisation of sheep from 2.5 months of age to prevent viremia* and to reduce clinical signs caused by Bluetongue virus (BTV) serotype X. Onset of immunity: 20 days after the second dose. Duration of immunity: one year after the second dose. *(Cycling value (Ct) ≥ Y by a validated RT-PCR

method, indicating no presence of viral genome). Immunity has been demonstrated by the development of serum antibodies and cell-mediated immunity by a specific BTV antigen lymphoproliferation assay.

Example ii): For active immunisation of cattle from three months of age to reduce hyperthermia and to minimise the reduction of leukocyte count caused by Bovine Viral Diarrhoea Virus (BVDV-1 and BVDV-2), and to reduce virus shedding and viremia caused by BVDV-2.

b. The extent of prevention/reduction of replication of the pathogen in vaccinated animals

Example: Active immunisation of horses against West Nile virus (WNV) to reduce clinical signs of disease and lesions in the brain and to reduce viremia.

c. The extent of prevention/reduction of dissemination of the pathogen through the body of vaccinated animals

Example: For active immunisation of healthy susceptible, immune competent chickens to reduce mortality, colonisation, invasion and faecal excretion due to *Salmonella enteritidis*, phage type 4.

d. The extent of persistence (percentage or duration) of the pathogen in the body of vaccinated animals (ie carrier status)

Example: For the active immunisation of cattle, sheep and pigs from two weeks against foot-and-mouth disease virus serotype O and A to reduce clinical signs of the disease and reduce the number and duration of carrier cattle harbouring virus in the oropharynx.

e. The transmission of the pathogen from the vaccinated animal to eggs, embryos and/or foetuses.

Example i): For the active immunisation of chickens (layers) from nine weeks of age to reduce air sac lesions and prevent vertical transmission caused by *Mycoplasma gallisepticum*.

Example ii): For active immunisation of cattle against Bovine Viral Diarrhoea Virus (BVD) BVDV-1 and BVDV-2, to prevent the birth of persistently infected calves caused by transplacental infection.

1.2 Study design for efficacy studies

The proposed efficacy claims should be supported by data generated from valid laboratory efficacy studies. The results of the laboratory studies should be further supplemented with data from field trials according the APVMA's efficacy and target animal safety guideline.

Where efficacy claims cannot be substantiated in valid laboratory trial due to the nature of the disease or the intended efficacy claims, field trials can be used to generate the critical efficacy data in the absence of laboratory trials.

For food producing animals production claims are possible, eg reduction in weight loss. Positive statements about improvements in weight gain are generally not accepted, as the base line for comparison should be healthy animals.

Where there is an absence of data to support the efficacy claims this will be reflected on the label eg the absence of efficacy studies to demonstrate the potential interference of maternally derived antibodies (MDA) in young vaccinated animals.

There is also the possibility of adding specific statements regarding cross-protection from data generated through *in vivo* or *in vitro* studies for specific sub-types/serotypes or strains.

Applicants are encouraged to submit a pre-application assistance (PAA) prior to submission for any new efficacy claims for an immunobiological product where clarity on the design of the efficacy studies may be needed to meet APVMA efficacy and label requirements.

1.3 Existing labels

The introduction of the new technical guidance applies only to new applications and will not apply retrospectively, unless the applicant wishes to align their existing labels with the new guidance.

An item 14 application will be required to update a label to the current APVMA Guidance on efficacy claims.