Australian Government

Australian Pesticides and Veterinary Medicines Authority

Public consultation on Guideline for out of specifications veterinary vaccine permit applications

Submissions received

October 2023

Animal Medicines Australia
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31 October 2023

Case Management and Administration Unit
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

By email only: enquiries@apvma.gov.au

Dear Case Management and Administration Unit,

RE: Consultation on the revised guideline for out of specifications veterinary vaccine permit applications

Thank you for the opportunity to provide our comments on the revised guidelines for out of specifications veterinary vaccine permit applications.

Animal Medicines Australia is the peak industry body representing the leading animal health companies in Australia. Our members are innovators, manufacturers, registrants and suppliers of a broad range of veterinary medicines, working at the cutting edge of animal health science to prevent, control and treat disease across the livestock, equine and companion animal sectors. Products from our member companies account for more than 90% of all animal health products in Australia.

These technical guidelines provide valuable guidance for registrants on permit applications for out of specification veterinary vaccines to allow legal use of these vaccines in certain situations, whilst ensuring the quality, safety and efficacy of the vaccines.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

A submission for the APVMA on a document open for consultation: Public consultation on Guideline for out of specifications (OOS) veterinary vaccine permit applications Draft for public consultation October 2023
Closing date: 31 Oct 2023, **From:** Syed Ziauddin Hashmi [redacted]

A commentary for consideration

1. Extension of Batch Specific Product Shelf life - The current text in paragraph 1 is as follows: *"The data should include all batch release information – for example pH and moisture content loss on drying."*
   Suggested text: The data should include all batch release information on physical, chemical, biological and microbiological characteristics – for example, physical - moisture content, loss on drying; chemical - pH, biological - potency, titre; microbiological - sterility.
2. Out-of-specification - The current text in paragraph 5 is as follows: *"This guideline covers conventional classes of veterinary vaccines (live/inactivated vaccines, subunit or toxoids vaccines, live recombinants and peptide vaccines)."*
   Suggestion: This list of types of vaccines includes ALL types of "conventional" and "novel" vaccines based on biological moiety. In my view, this document should outline at the outset that it is prepared for the technical assessment of the extension of batch-specific product shelf life for conventional live viral [or vector-based recombinant product] and live bacterial vaccines. In other cases where the active constituent is an inactivated virus or bacteria, a subunit of virus or a subunit peptide of bacteria, or bacterial toxoid, [antitoxins] the case for the extension of shelf life of a particular batch-specific product must be justified with corroborating stability data on the biological potency of the final dosage form. The initial potency data in the animal model or biological titre in the target animal is generated for the stability of the product [final dosage form] during the initial stages of vaccine development. Interestingly, subsequent stability data on the production batches rarely includes target animal data. An applicant should provide a case that has to be presented to the APVMA for consideration. If there is sufficient scientific merit then an extension could be considered by the Technical Assessor at the APVMA.
3. The current text in paragraph 5 is as follows: *"Specific criteria are indicated for products stored in liquid nitrogen or at –70°C where antigens may be stable for more than 5 years"*
   Suggestion: In the above statement there is a tacit acceptance that as "antigens may be stable for more than 5 years" the final dosage form [the product] will be similar in its stability profile. The biological moiety is thermolabile, thereby subtle fluctuations in the temperature could destroy or reduce the number of viable antigens. Unlike a freeze-dried cake where a carrier (e.g. sugar solution of disaccharide and/or monosaccharide with a surfactant) is added to protect the [viral or a bacterial] antigens. Conversely, a liquid product contains transport media, therefore, if there is any change in the constituent excipients then the extension should be considered on the collated shelf life data beyond the original approved shelf life [if available].