



SUBMISSION

+64 (0)4 499 4225 | PO Box 5069, Wellington 6140 New Zealand | www.aphanz.co.nz

To: awilda.baoumgren@mpi.govt.nz

Submission on: **New Draft ACVM Application Forms for vet meds**

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Submitter: Jeff Howe
Technical Manager, Animal Health
Animal and Plant Health Association of NZ
111 The Terrace
Wellington

Email: jeff.howe@aphanz.co.nz

1. Introduction

1. The Animal and Plant Health Association of New Zealand (Animal and Plant Health NZ) welcomes the opportunity to provide feedback on the draft new application forms for veterinary medicines.
2. We have provided some specific comments on the forms below.
3. We note that most of the changes appear logical and help to clarify the information requested. However, there are concerns that these forms are not well-suited to biological products. We consider there will be a need to revisit these forms once the guidance document for biological products has been completed.

Key Recommendations/comments

1. Revised VM only 1V form

- Section 8 – Documentation: The information requested in Section 8 on this form appears to be a repetition of same information requested in Section C of the combined C1-C3 application form for listing of information to support C1-C8 and C10 applications.
- If the formulated product is a local/NZ manufacturer, do we still have to provide a current GMP Certificate given that ACVM has this on record as they are the issuer?
- The 1V form for non-hazardous products only has a tick box for self-determination, what about EPA determinations as non-hazardous?

2. New VM only C1-C3 form

A. Supporting information provided

List all data requirements as per the “provide” table in the relevant change in section 7 of the guidance, and the data or information provided in the submission that addresses those submission requirements.

- Listing what is in the guidance document, seems like unnecessary duplication. We propose this section of the form should simply ask for a summary of the data or information provided, without the need for listing what is in the guidance document.

3. Suitability for biologicals

- Concerns have been raised that the current form design is not well-suited for biologicals noting that biotechnology has rapidly evolved in the past thirty years and has outpaced the regulations. Those registrants with biological products are then forced to use the Chemistry and Manufacturing (Pharmaceutical) guidelines, which lack relevance.
- We submit there is an urgent need for a guidance document for biological products which will then provide a basis for subsequent revisions to these forms, or a separate set of forms, to better accommodate this class of applications. We understand that this is a priority for ACVM once the veterinary medicine applications queue has been reduced and we would welcome the opportunity to provide industry input and expertise in developing these guidelines.

About Animal and Plant Health NZ

We are the peak industry association representing more than 85 multinational and New Zealand based companies that manufacture, distribute and sell crop protection and animal health products that keep our animals healthy and crops thriving. Our mission is to protect and enhance the health of crops, animals, and the environment, through innovation and the responsible use of quality products and services.

Our objectives are to:

- Strive for effective and sustainable animal health and crop protection technology through industry leadership and advocacy.
- Achieve a balanced and science-based regulatory environment that gives members freedom to operate and grow in New Zealand.
- Enable farmers and growers to supply high quality food and fibre into domestic and global markets.
- Create an environment that encourages competition through innovation.
- Promote stewardship and responsible use of products.
- Support the health and wellbeing of pets, livestock and people.