Australian Government

Australian Pesticides and Veterinary Medicines Authority

Draft Guideline on Data Requirements for Veterinary Immunobiological Products

Submissions received

April 2025

11 April 2025

Director, Veterinary Medicines
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601

Lodgement online: enquiries@apvma.gov.au

Dear APVMA,

Redcap Solutions Pty Ltd is a well-established Sydney-based private consultancy specialising in regulatory affairs within the animal health and associated industries. The directors, Dr. Ruth Davis and Mr. Alan Pyefinch and their highly qualified team of associates have extensive experience in the animal health industry and the team have maintained an excellent and long-standing working relationship with APVMA over many years. Redcap Solutions represents many different clients from Australia and overseas, including large multi-national companies to small start-ups and individual entrepreneurs.

We are pleased to provide this submission in response to the APVMA request for feedback regarding proposed updates to the Draft Guideline on Data Requirements for Veterinary Immunobiological Products. APVMA's commitment to meaningful engagement and collaboration in the development of updated guidelines for immunobiological products is welcomed.

Redcap Solutions is generally supportive of the proposed new guideline which provides detailed advice regarding APVMA expectations for data quality and quantity. Clear guidelines improve efficiency for both applicants and the APVMA by improving mutual understanding and expectations around dossier content.

Further improvements to the proposed draft guideline are suggested as follows:

- Include the definition of immunobiological product from the Agvet Code Regulations in the introduction.

- Ensure consistent terminology is used throughout the guideline. For example, page 8 indicates '*Veterinary vaccines* are generally exempt from residues, human health and safety evaluations …'. It is not clear whether the statement is intended to apply to all veterinary immunobiological products.

- Part 1 (Application Overview) describes a substantial amount of information that is already provided in the application form (eg applicant names & addresses, reference to GMP, formulation, label wording) with some also repeated again in the relevant dossier section. Repetition should be avoided where possible, particularly where it provides unnecessary opportunities for discrepancies to arise when APVMA requests permission to amend the application during assessment. A separate application overview was previously required for all applications prior to the introduction of the APVMA online application system. The overview is now embedded in the electronic application form for all product types and no longer requires a summary of each section where a separate dossier is provided for assessment. There is no apparent value in still providing the

Overview as a separate document for immunobiologicals. Any non-standard information described in the Overview guidance for immunobiologicals could still be required in an appendix.

- References to genetically modified organisms (GMOs) suggest an OGTR licence is required for all products containing genetically modified starting materials. Further clarification should be provided as OGTR does not issue licences for various situations including GM-dealings which occur outside Australia or for materials derived from GMOs, but which are no longer an 'organism'.

- It is strongly recommended that APVMA adopts the globally recognised numbering and structure of the PART 2 dossier in Section IIIb (Requirements for Immunological Veterinary Medicinal Products) in Annex II to Regulation (EU) 2019/6 (https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=PI_COM:Ares(2020)6563775). The proposed APVMA guideline already includes a very similar outline and could still allow for different interpretations where relevant. However, utilising the same numbering structure would facilitate establishment/use of a common international dossier for many products and would reduce the cost of tailoring a regulatory submission specifically for Australia. It would also align better with advice in the EMA guideline on vaccine platform technology master files (vPTMF), which APVMA advises applicants to refer to.

- Despite numerous references to 'active constituents' throughout the guideline and understanding the APVMA legislative obligation to separately create a Record for every approved active constituent, the guideline does not explain how the term 'active constituent' applies to immunobiologicals. The Glossary indicates the active constituent is the 'chemical or biological component in a formulation that is principally responsible for the effect being claimed', however no further interpretation is provided. The guideline should clearly indicate what APVMA intends to enter in the Record of the active constituent, whether that is the master seed (biological component) or the bulk antigen (for example). The requirement to define the 'purity and composition' as a particular of the active constituent should also be explained. Point 1.2.3 requires clarification of whether the product contains a 'new active constituent' for the Australian market but doesn't establish what APVMA classifies as a 'new active constituent'. Particularly for novel immunobiological products such as those utilising recombinant technology and platform manufacturing processes, it is important to understand what APVMA deems to be the 'active constituent'.

- APVMA legislation requires that veterinary chemical products (including immunobiologicals) are manufactured in accordance with the manufacturing principles and the Australian GMP Code (or a comparable standard for overseas manufacturers). However, the same criteria is not prescribed for active constituents. Further to the point above, requesting further clarification of the distinction between the immunobiological product and the approvable active constituent, APVMA is requested to clearly indicate in the data guideline how the legislation applies to the requirement for demonstration of GMP compliance at various stages throughout the manufacturing process.

Thank you for the opportunity to comment on the draft guideline. Please do not hesitate to contact us if we can be of further help.

Robyn Hammond, BScAgr (Hons), ADRBA
Regulatory Consultant

Padula Serums PTY LTD

24 March 2025

Re: Comments on *Draft Guideline on Data Requirements for Veterinary Immunobiological Products, March 2025*

Dear APVMA,

As a manufacturer of immunosera I wish to provide some feedback on the Draft Immunobiological document, specifically on Annex 2 (immunosera).

Comment 1: Page 64, Section 2.7 Control tests on the finished product. D) Extraneous agents.

The testing of freedom from extraneous agents using cell cultures would seem to be inappropriate for snake antivenom, tick antiserum and tetanus antitoxin products. There are no details in here of which agents would be required to be tested for. Control over these comes from testing donors, maintaining good biosecurity practices and data on effect of downstream processing on viral load.

Comment 2: Page 64, Section 2.7 Control tests on the finished product.

There is no mention of endotoxin in the control tests which suggests that it is not required.

Regards,

Dr ANDREW PADULA | Managing Director
BVSc(Hons) PhD MACVSc DipECAR

Bruce Jackson, Vet Consultant

Inquiries: Bruce Jackson
[redacted]

7 April 2025

Director, Veterinary Medicines
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Draft Guideline on Data Requirements for Veterinary Immunobiological Products

Thank you for the opportunity to comment on this guideline.

Rather than make comments under specific paragraph numbers, I would like to make some general comments.

In a situation where an inactivated vaccine has been used extensively for a number of years in the field in Australia under research and/or emergency permits without significant numbers of complaints about safety or efficacy, some concessions should be made in the requirements under the relevant safety and efficacy sections of the guideline.

In situations where there is little cross-protection between serogroups, variable combinations of serogroups in a multivalent vaccine may have to be customised for particular farms. In this situation data from a representative selection of serogroup combinations should be accepted as sufficient evidence that all possible combinations of serogroups will be efficacious and safe.

Thank you for the opportunity to comment.

Yours sincerely

Bruce Jackson
Veterinary Consultant

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14 April 2025

Director, Veterinary Medicines
Australian Pesticides and Veterinary Medicines Authority
Canberra

By email only: enquiries@apvma.gov.au

Dear Director,

Re: Draft Guideline on Data Requirements for Veterinary Immunobiological Products

Thank you for the opportunity to provide comment on the *Draft Guideline on Data Requirements for Veterinary Immunobiological Products* ('the Guideline'). We are pleased to provide the following comments for consideration by the APVMA.

Animal Medicines Australia (AMA) is the peak industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. Our member companies are the local divisions of global innovators, manufacturers, formulators and registrants that supply essential veterinary medicines and animal health products that are critical to supporting Australia's $34 billion livestock industry and the $33 billion pet industry. Our members represent more than 90% of registered veterinary medicine sales in Australia.

The majority of AMA's comments have been added as tracked changes and comments in the attached copy of the Guidance. Please let me know if further clarity on any point would assist.

In addition to those specific comments, AMA members wish to make the following suggestions to improve the revised Guidance:

- Multinational companies utilise registration dossiers based on overseas submissions (for example, applications to the European Medicines Agency (EMA) or Centre for Veterinary Medicines (EVM) (US)). The general information requirements for the EMA, CVM and APVMA are similar, however the layout and presentation of this information is not aligned. Reorganising the information from one format to another is a significant task. The regulatory burden could be considerably reduced if there was greater flexibility in the layout of information required by the APVMA in Part 2, with greater alignment with, or acceptance of, the layouts used by the EMA or CVM.

- Reference is made to monograph Ph.Eur.5.2.5 regarding testing for extraneous agents in starting materials and finished products. However, this monograph now permits the use of extraneous agent risk assessment, rather than strict testing requirements. The new APVMA guidance should be aligned with Ph.Eur.5.2.5.

- Part 10.1 references an EMEA guideline on live recombinant vector vaccines for veterinary use. However there are circumstances in which the EMEA classification of GMOs (or non-GMOs) may differ from the OGTR definitions. In Australia, it may be more appropriate to refer to the OGTR's requirements for a Dealing Involving Release application. In such cases, care must also be taken to minimise regulatory overlap and duplication between OGTR and APVMA.

- AMA would suggest that the new Guidance more explicitly reflects the 3R's principles to reduce the number of studies needed and minimise the use of animals where possible. For example:
    - overdose studies to be used in lieu of a single dose study,
    - combined field efficacy and safety studies, and
    - waivers for field trial requirements where field challenge is sporadic or cannot be predicted, where laboratory or pen studies provide sufficient data.

I hope that these comments are of assistance. If you have any questions, please feel free to contact me.

Yours sincerely,

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