

APVMA overview

Implementation and regulatory acceptance of non-animal testing in veterinary vaccines

Dr Mariette van den Berg
Assistant Director, Veterinary Medicines
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Australian Government

Australian Pesticides and
Veterinary Medicines Authority



About the APVMA

- Independent authority responsible for assessing and registering **agricultural and veterinary (agvet)** chemicals proposed for supply and use in Australia.
- Scientifically evaluating the **safety and efficacy of agvet chemicals** to manage the risks of pests and diseases for the Australian community and to protect Australia's trade and the health and safety of people, animals and the environment.
- Monitor and enforce **compliance with the Agvet Code** and other legislation we administer and oversee the import and export of agvet chemicals.

Ethical use of animals in the testing, development and manufacture of veterinary medicines

- Use of animals in research and/or regulatory testing of veterinary medicinal products to support registration by the APVMA is strictly controlled in Australia under the *Animal Research Act 1985*.
- Applicants are to obtain the approval of a properly constituted animal ethics committee prior to the commencement of any trial conducted in Australia.
- There is no specific reference to animal ethics and welfare or the 3Rs in the *Agricultural and Veterinary Chemicals Code Act 1994* and associated Regulations.

Legislative criteria

Safety
5A

Efficacy
5B

Trade
5C

Labelling
5D



Our key assessment areas

Chemistry

Toxicology

Residues
and trade

Worker
safety

Environment

Efficacy and
target safety

Implementation of '3Rs' principle (Reduce, Refine, Replace)

- Applicants to implement Australian ethical values, the 3Rs principle and welfare standards when developing veterinary medicines that are intended for the Australian market to minimise animal usage, suffering and harm.
- Applicants are encouraged to submit data obtained from *in vitro* assay systems, or from alternative methods which use fewer animals according to the 3Rs principle.
- Animal studies, tests or husbandry practices that would not be permitted in Australia should not be undertaken instead in other regions.

Alignment with international standards

APVMA data guidelines are to be considered by applicants in conjunction with:

- Guidelines provided by overseas regulatory authorities and international pharmacopoeia.
- Specific guidance on the conduct of various types of tests or trials (e.g. VICH)

The APVMA generally accepts data generated by tests that have been conducted according to monographs in the most recent editions of the European pharmacopoeia (EP), British pharmacopoeia (BP), US pharmacopoeia (USP) and United States Code of Federal Regulations (9CFR).



Target Animal Batch Safety Testing (TABST)

- Historically up to 2014, the APVMA had the requirement for TABST in data guidelines for new and registered veterinary vaccines.
- Post 2014, TABST for finished product control testing of new and registered veterinary vaccines was removed from the APVMA guideline.
- The requirement for target animal safety testing for the registration of new vaccines has not changed.





2x overdose Target Animal Safety study to GLP for registration of inactivated vaccines

- APVMA guidelines include requirement for a 2 x overdose study for inactivated vaccines (double the volume of a vaccine formulated with the maximum antigen content).
- However, this is waived in alignment with international standards.
- APVMA immunobiological guidelines currently under review – to align with latest international regulatory requirements.

APVMA requirements, acceptance of data and 3Rs

- Acceptance of international data in light of Australian data/study requirements.
- Generally, efficacy data should be generated in Australia for the registration of all veterinary vaccines intended for use in food-producing animal species.
- However based on 3Rs the APVMA accepts omission of certain study/ data requirements to support applications if applicant can provide strong scientific argument that overseas data are applicable to Australia's climatic conditions, genetic stocks and farm management practices.

APVMA requirements

- Additional local studies may still be required when component assessments influenced by use pattern such as residues and exposure assessments cannot be extrapolated to Australian use.
- Australian efficacy data for registration of a veterinary vaccine may also be required where it is necessary to confirm protection afforded to vaccinated animals because of differences in the circulating strains and virulence of disease-causing microorganisms.
- If no specific product guidelines exist for a product, the APVMA recommend overseas data to be confirmed by at least one controlled Australian study.

Acceptance of data and 3Rs

- In alignment with international standards combined GCP field efficacy/safety studies can be performed for live and inactivated vaccines
- Australian confirmative studies – validated *in vitro* based studies will be accepted by the APVMA (e.g. serum neutralisation testing with Australian strains).
- Applicants are encouraged to submit product variations to change *in vivo* to *in vitro* assay testing.
- Acceptance of robust scientific argument to omit (Australian) *in vivo* study requirements.

Pre-application assistance

- Applicants are strongly encouraged to seek pre-application assistance, particularly for immunobiologicals which may be based on international data or different data requirements.
- Allows discussions of how the applicant intends to demonstrate satisfaction with statutory criteria.
- Allows APVMA to provide advice on suitability of arguments/ suggested data (without assessment), as well as timeframes and fees.
- Fee-based process with fees offset against application fees.
- Provides some certainty for applicants.





Summary

The APVMA supports and/or implements the '3Rs' principle

- Generation of data to satisfy the statutory criteria for vaccine registration or variations
- Acceptance of scientific justification to waive data/study requirements
- Waiving of TABST/ x2 overdose in alignment with international guidelines.
- Committed to develop a position statement on website for public awareness

Thank you for listening!

Questions?





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