ACVM Registration by Reference to APVMA Registration

ACVM Information Requirements 18

Prepared for Approvals and ACVM Group

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Ministry of Agriculture and Forestry
Te Manatū Ahuwhenua, Ngāherehere

BIOSECURITY NEW ZEALAND

NEW ZEALAND FOOD SAFETY AUTHORITY

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This publication is also available on the MAF website at
www.foodsafety.govt.nz/industry/elibrary

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1 Introduction

The Ministry of Agriculture and Foresty (MAF) has established a pathway whereby, under certain circumstances, it will consider the decisions of the Australian regulatory body, the Australian Pesticides and Veterinary Medicines Authority (APVMA), in lieu of data assessments to support an application for registration of veterinary medicines under section 21 of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. MAF has named this pathway ACVM Registration by Reference to APVMA Registration, shortened to **registration by reference**.

Registration by reference is part of an ongoing work programme with APVMA to align, where appropriate, the regulatory standards and requirements between Australia and New Zealand for agricultural compound authorisation.

This is not a mutual recognition initiative. While APVMA assessments will be used by MAF as the baseline for its consideration of applications for registration, the reverse arrangement has not been made. Differences in environment and production systems, as well as differing use patterns for agricultural compounds, make the mutual recognition of every regulatory decision in the two countries difficult.

MAF recognises that in certain circumstances and for certain product types sufficient similarities exist for components of the regulatory considerations of APVMA to be relevant to the New Zealand situation. New Zealand is a relatively small market for many agricultural compounds, particularly those for minor use/minor species. It is expected that registration by reference will reduce the lead time for submission of an application and costs associated with registration in New Zealand. This could potentially encourage a greater range of products to be registered in the New Zealand market, particularly for products with a limited demand, where costs of registration may previously have acted as a deterrent. Other benefits occurring from this will be more choices for treatment of animals by consumers and professionals and better management of animal welfare.

Products submitted for registration by reference will still be appraised to consider the risks and benefits as described in the ACVM Act. Conditions of registration and labelling requirements will be imposed by MAF as appropriate for New Zealand circumstances.

2 Scope

This document is intended for those applying for authorisation under section 21 of the ACVM Act of APVMA-approved veterinary medicines. It provides guidance on:

- products suitable for registration by reference;
- information requirements for registration by reference;
- screening process for products submitted via the registration by reference pathway;
- technical appraisal and risk assessment of registration by reference applications;
- circumstances when cross-referencing of APVMA-registered products is acceptable;
- subsequent status of trade name products authorised by the registration by registration pathway.

3 Relevant documents

For guidance on the information that must be provided to support applications for registration of a new veterinary medicine trade name product or for variations to existing registrations of veterinary medicine trade name products read:

Veterinary medicine registration in New Zealand – ACVM information requirements 1
(97 KB PDF)

For background read:

ACVM registration by reference to APVMA registration – ACVM operational interpretation 192
(77 KB PDF)

4 Products suitable for registration by reference

Registration by reference will apply only to veterinary medicines for use on non-food producing animals. This includes products for cats, dogs, reptiles (for example, lizards and geckos), pigeons, aviary birds, game birds (such as mallards, partridges, pheasants, and quails), aquaria animals, mustelids (such as ferrets), lagomorphs (such as rabbits and hares) and rodents (such as rats and mice).

For products intended for species such as rabbits and game birds, which may occasionally be food-producing, residue risks will be managed by default withholding period statements.

Veterinary medicines submitted for registration by reference must be identical to the APVMA registered product, including the trade name. This means the product must be manufactured as approved by the APVMA.

5 Information requirements

The information requirements for registration by reference are the same as for any other veterinary medicine application (see Veterinary Medicine Registration in New Zealand – ACVM Information Requirements 1). However, in lieu of data assessment and presentation of data assessment reports, the applicant must provide MAF with two copies of the letter of consent, signed by the Australian registrant, authorising APVMA to share the details of the relevant regulatory decisions relating to the product (including decision documentation) with MAF. The format of the consent letter is included as an appendix.

All relevant data volumes (including the data on which the APVMA assessment is based) must be included.

Data assessment is required for any claims not assessed by APVMA if requested in New Zealand.

The cover letter should clearly indicate that the application is to be processed by the registration by reference pathway.

6 Screening process

After receipt of an application for registration by reference, MAF will forward a copy of the consent letter to APVMA for release of the decision documentation. Applications will be passed for technical pre-screen after receipt of APVMA's decision documentation. The regulatory time frame for completing technical appraisal and risk assessment will start from the date the application is accepted at technical pre-screen.

7 Technical appraisal and risk assessment

MAF will treat the details of APVMA's regulatory decision as equivalent to a data assessment report package. The application will be technically appraised and risk assessed to manage risks specified in the ACVM Act. This means appraising New Zealand specific risk management issues, New Zealand specific label claims and requirements, conditions of registration, antimicrobial resistance and restrictions on use from a New Zealand perspective. The appraisal will take into consideration differences in law (for example, the Ministry of Health's requirements for prescription drugs), diseases and conditions, trade and biosecurity issues.

MAF reserves the right to request any further information required to adequately address the risks under the ACVM Act.

8 Cross-referenced products

MAF will only consider applications that cross-reference another APVMA-registered product if that product is also currently registered under the ACVM Act. MAF must hold the relevant data for the referenced product, which must not be under data protection.

9 Variation applications

Subsequent variations to products registered by the registration by reference pathway will be subject to the requirements outlined in Veterinary Medicine Registration in New Zealand – ACVM Information Requirements 1 (link above).

Changes to the APVMA registration or withdrawal of the APVMA registration will not affect the ACVM registration unless the change or withdrawal is prompted by an adverse issue relating to the product. Under such circumstances, MAF may require the product to be reassessed under section 29 of the ACVM Act. The product's registration conditions obligate the registrants to advise MAF as soon as practicable after becoming aware of any new information that relates to the relevance, reliability or correctness of information provided at the time of registration and upon which the decision to register the product was made.

Appendix: Format for letter of consent for release of confidential APVMA evaluation reports to the ACVM Group of MAF

[Letterhead with identical name to Australian authorising party]
Street address
Contact details

[Insert date]

The Manager
Application Management and Enquiries
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
AUSTRALIA

Dear Sir/Madam

Authorisation for APVMA to share regulatory decision details with MAF for the purpose of a registration by reference proposal in New Zealand

I hereby authorise APVMA to share the details of its regulatory decision (including decision documentation) in relation to application [**insert application number**] for [**insert product name**] (product number: [**insert product number**]) with the Agricultural Compounds and Veterinary Medicines (ACVM) Group of the Ministry of Agriculture and Foresty (MAF) for use in the evaluation of a related application.

I declare that I am authorised to give this consent being the interested person[1] notified with APVMA for this product. I understand that once given, this consent cannot be withdrawn.

Yours faithfully

[Name of letter author]
[Title]

[1] As defined by Section 3 of the Schedule to the Agricultural and Veterinary Chemicals Code Act 1994.