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**Australian Pesticides and  
Veterinary Medicines Authority**



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**Use of New Zealand  
registration of  
companion animal  
veterinary chemicals  
by the APVMA**

Discussion paper

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## CONTENTS

1	INTRODUCTION	4
1.1	About this paper	4
1.2	How to have your say	4
2	BACKGROUND	5
2.1	NZ MPI registration by reference pathway	5
2.2	NZ EPA Group Standards	5
2.3	Scope of non-food producing animals in NZ	6
2.4	Meeting statutory criteria	6
3	THE CONCEPT AND DISCUSSION POINTS	7
3.1	The concept in brief	7
3.2	Submission of data	7
3.3	Access to NZ Assessments	8
3.4	Australian specific requirements	8
3.5	Additional claims	9
3.6	Inclusion of horses	9
3.7	Differences in toxicology assessments	9
3.8	Process for assessment of applications	10
3.9	Ongoing registration of a product	10
3.10	Variation of product registrations	11
3.11	Good manufacturing practice	11
3.12	Miscellaneous matters	12
4	ADDITIONAL CHANGES TO ENHANCE IMPLEMENTATION	13
4.1	Agreement with NZ MPI for exchange of information	13
4.2	Align fee structure with level of assessment required to be undertaken	13
4.3	Consideration of broader scope	13
	ABBREVIATIONS	15

## 1 INTRODUCTION

The APVMA is seeking to leverage relevant New Zealand (NZ) assessment reports and registrations in support of applications to register veterinary medicines for use in non-food producing species in Australia. We have been working with NZ Ministry for Primary Industries (MPI) to understand the current arrangements for registration in NZ and determine what will be required to implement this approach.

Assessments related to agricultural and veterinary chemicals are carried out by two NZ government agencies:

- NZ MPI assesses chemistry, residues, efficacy and trade
- NZ Environmental Protection Authority (EPA) assesses toxicology and environment.

NZ MPI uses a 'registration by reference' to the APVMA assessments pathway for non-food producing species. NZ EPA has set a number of group standards relevant to non-food producing species.

The purpose of the discussion paper is to seek the views of industry on the various elements of the potential use of NZ assessments by the APVMA. This input will help shape a final proposal, which will be provided for further consultation.

### 1.1 About this paper

This discussion paper is broken into three main sections.

- Section 2 describes the current NZ approach to registering non-food producing veterinary chemicals and outlines a number of key concepts that will underpin consideration of this issue.
- Section 3 explores a range of issues related to the use of NZ assessments and poses a number of questions for feedback from industry.
- Section 4 outlines a number of complementary activities to support implementation of the proposed approach.

### 1.2 How to have your say

The APVMA is inviting submissions from any interested person or organisation, on the proposal to implement a registration by reference process, to leverage the NZ assessments. Submissions are to be sent to the APVMA Office of the CEO inbox ([coordination@apvma.gov.au](mailto:coordination@apvma.gov.au)), no later than 5pm on 4 November 2016. If you wish to enquire about your submission or clarify the proposal, you can contact the Office of the CEO on +61 2 6210 4834.

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## 2 BACKGROUND

### 2.1 NZ MPI registration by reference pathway

Under the registration by reference pathway, NZ MPI makes reference to APVMA's regulatory decisions in its own consideration on whether to grant or refuse applications to register veterinary medicines for use in non-food producing animals. Decisions on registration of products in NZ are made under the *Agricultural Compounds and Veterinary Medicines Act 1997* (the ACVM Act). While a common outcome from this approach is utilisation of the APVMA assessment and consequent registration of the products, it is not automatic arising solely from the APVMA registration decision.

Under the NZ model, the applications pass to technical appraisal and risk assessment after the APVMA has provided the relevant assessment reports and decision documentation. Data underpinning the assessments undertaken by the APVMA is still required to be provided by the applicant.

NZ reserves the right to appraise jurisdiction specific risks, label claims and requirements, conditions of registration, antimicrobial resistance concerns, noting differences are likely to arise due to differences in the legal framework, diseases, trade and biosecurity requirements. Where additional data is required in these areas, applicants supply this in addition as part of their application.

Specific guidance documents have been developed by the Approvals & ACVM Group of NZ MPI which provide detail on the approach to registration by reference. These include an overview of operational interpretation and information requirements ([www.foodsafety.govt.nz/elibrary/industry/Acvm\\_Registration-States\\_Principles.pdf](http://www.foodsafety.govt.nz/elibrary/industry/Acvm_Registration-States_Principles.pdf)) for the registration by reference pathway ([www.foodsafety.govt.nz/elibrary/industry/registration-by-reference.pdf](http://www.foodsafety.govt.nz/elibrary/industry/registration-by-reference.pdf)). These documents also reference the broader information requirements for veterinary medicine registration in NZ.

The ACVM Act provides the framework for NZ MPI to prevent or manage risks associated with the use of agricultural compounds (which include veterinary medicines) to public health, trade in primary produce, animal welfare and agricultural security. NZ MPI has outlined that for use of veterinary medicines in non-food producing animals the risks are likely to be adequately assessed by reference to APVMA assessment and registration decision reports. It is also a requirement that the product being registered in NZ is identical to the product already registered in Australia, and a similar requirement would be anticipated should the APVMA implement a Registration by Reference system with NZ also.

### 2.2 NZ EPA Group Standards

The NZ EPA group standards are approvals for a group of hazardous substances of a similar nature, type or use. They set out the conditions by which a group of hazardous substances can be managed safely.<sup>1</sup> Group standards are made under the HSNO Act for the purpose of managing the adverse effects of hazardous substances in order to protect the environment and the health and safety of people, including workers.

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<sup>1</sup> [www.epa.govt.nz/hazardous-substances/approvals/group-standards/Pages/default.aspx](http://www.epa.govt.nz/hazardous-substances/approvals/group-standards/Pages/default.aspx)

## 2.3 Scope of non-food producing animals in NZ

In NZ, non-food producing species include cats, dogs, reptiles, ornamental and aviary birds, mustelids (eg ferrets), lagomorphs (eg rabbits and hares), rodents (eg rats and mice) and ornamental fish. Horses are considered food producing animals in NZ.

## 2.4 Meeting statutory criteria

Under Australian law, the APVMA must be satisfied that an application meets the mandatory statutory criteria relating to safety and the trade and efficacy criteria if relevant. Applications for chemical products must also meet labelling criteria. There are many elements underneath each of these criteria that the APVMA must consider and be satisfied that the application meets the criteria.<sup>2</sup>

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<sup>2</sup> Refer to sections 5 (Definition of a veterinary chemical product) and 14 (Approval and Registration) of the *Agricultural and Veterinary Chemicals Code Act 1994* for details.

## 3 THE CONCEPT AND DISCUSSION POINTS

### 3.1 The concept in brief

The APVMA considers that the risks associated with the use of veterinary chemicals on non-food producing species in Australia may be no different to the risks in NZ. Therefore, in principle, registration in Australia of identical products that are registered in NZ for the same use as the intended use in Australia is supported.

The concept is to use the assessment reports compiled by NZ as a 'reference' for the APVMA decision making for veterinary products for non-food producing species without additional assessment being required. The amount of work to consider a registration application will be reduced where assessment reports and decision records from NZ MPI can be leveraged.

Registration will not automatically flow from a registration decision in NZ because the APVMA must assess each application against Australian statutory criteria. It is not proposed to accept the decision of NZ MPI as the sole justification for registration in Australia as there may be components of the decision that may not be appropriate or relevant to Australia, or that automatically apply to uses in Australia.

Nevertheless, the APVMA wants to investigate how far the concept of 'registration by reference' type pathways can be taken for the registration of veterinary chemicals for non-food producing species in Australia.

There are, however, a number of challenges that arise from the different regulatory systems, which are explored further below.

### 3.2 Submission of data

The APVMA would require applicants for registration in Australia to submit all data that has been submitted as part of the registration application in NZ. This will enable the APVMA to apply relevant limits on use of information provisions under the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) and ensure the foundation data and information is available should any subsequent variation or review of the product be required solely in Australia. This approach is similar to that used in NZ.

Applicants would also need to provide a declaration that the information and data provided is identical to that provided for the NZ assessment and that those information and data items must be clearly identified.

#### Industry Discussion Point 1

What, if any, issues do you see with applicants submitting all the data and providing a declaration as proposed?

### 3.3 Access to NZ Assessments

There are two options for the APVMA to gain access to the assessments conducted for NZ registration:

1. the applicant obtains the assessment reports to submit to the APVMA
2. the APVMA obtains the assessment report directly from NZ MPI by request, using the current Memorandum of Understanding that exists between the two agencies.

For option 2, applicants would need to provide a letter of consent from the NZ registrant as part of their application for the APVMA to request assessment reports from NZ MPI. Applicants will need to ensure appropriate consent is provided if using confidential information of a third party as part of the application.

It must be noted that if the APVMA is to obtain assessments from the NZ MPI, it might not be possible to guarantee legislative timeframes will be met, as the APVMA would be reliant on the resources and priorities of the NZ MPI in providing the requested information.

#### Industry Discussion Point 2

Which option would applicants prefer in terms of obtaining access to NZ assessments and why?

### 3.4 Australian specific requirements

There are a range of Australian specific requirements for non-food producing animals, including:

- different vaccine strains specific to Australian diseases
- assessment of recombination of DNA in live vaccines
- registered vaccines in Australia do not ordinarily include antigens for exotic diseases
- limits on uses of antibiotic products in Australia in consideration of antibiotic resistance concerns
- parasite species and strains must be relevant to those in Australia (eg paralysis tick (*Ixodes holocyclus*) only occurs in Australia and brown dog tick (*Rhipicephalus sanguineus*) strains vary between countries)
- parasite pressure must be relevant to the geographical / climatic conditions in Australia (eg flea (*Ctenocephalides* spp.), noting pressure seen in subtropical and tropical parts of Australia is significantly greater than in other parts of the world)
- the parasite efficacy threshold for Australia needs to be met (eg Australia considers the efficacy threshold against most parasite species to be 95 per cent).

Applicants will be required to submit information to support the assessment of Australian specific requirements. The intention will be to provide detailed guidance material for such requirements.

The APVMA would also consider scientific submissions from industry or applicants for the removal of Australian specific requirements for non-food producing animals.

#### Industry Discussion Point 3

What, if any, issues are there with providing additional information to support Australian specific requirements?  
Are there any Australian specific requirements for non-food producing animals that should be reviewed and, if so, on what scientific basis should that review occur?



### 3.5 Additional claims

Applicants will be required to provide information to support the assessment of claims that are in addition to those assessed as part of the NZ registration.

#### Industry Discussion Point 4

What, if any, issues do you see with applicants submitting information to support additional claims?

### 3.6 Inclusion of horses

In NZ, horses are declared 'food animals'. This is not the case in Australia. NZ does not include horses in their registration by reference scheme, but the APVMA wants to explore the inclusion of horses in the approach proposed in this paper as there are no additional risks posed in relation to horses as other companion animals.

#### Industry Discussion Point 5

What do you think about the inclusion of horses into the scope of the proposed approach?

### 3.7 Differences in toxicology assessments

The major difference between NZ and Australia relates to toxicology assessments. NZ relies on the use of group standards which involve self-assessment and self-classification by applicants. A record must be kept of that self-determination and must be available for inspection, by the EPA or an enforcement agency. The record must contain sufficient information to allow for independent verification that the substance complies with the scope of the Group Standard. A preliminary analysis of the group standards suggest they may not fully satisfy the Agvet Code safety criteria in terms of health. The labelling elements may not match our safety directions and warning statements. It may still be possible for APVMA to ask for that record and to use it for their assessment of an application, noting additional information may also be needed.

Applicants may need to provide a toxicology package (if a toxicology assessment is required) noting the record of self-assessment against the group standard could also be provided for consideration by the APVMA.

The question then arises as to whether the use of other assessments (like chemistry and efficacy) will provide sufficient savings to applicants to warrant pursuing the proposed approach to registration using NZ assessments.

#### Industry Discussion Point 6

What, if any, input do you have that may assist the APVMA in resolving the different approaches to satisfying toxicology related criteria between NZ and Australia?

Is there merit in the record of self-assessment being provided to the APVMA to support the toxicology assessment by the APVMA?

Even if the APVMA cannot find a solution relating to the use of NZ group standards, is it still worth pursuing the proposed approach for other assessments?

### 3.8 Process for assessment of applications

Applications to the APVMA will undergo preliminary assessment to determine that the applicant has indicated where they are seeking the APVMA to be satisfied on the basis of an assessment undertaken by NZ MPI, that all data submitted to NZ MPI has been provided with the application and that data and/or scientific argument has been provided where assessment specific to Australia is required.

The application will either include the relevant NZ MPI assessments and underlying data or provide the APVMA with a consent letter from the NZ registrant to request the relevant assessment and decision reports from NZ MPI during the preliminary assessment period. It is envisaged that the application will pass into evaluation after one month, noting that if the APVMA is requesting the assessment and decision reports, the information from NZ MPI may not be received until after the evaluation period has commenced. The APVMA will monitor the impact on expected completion dates in situations where there is a delay in receiving the relevant information from NZ MPI.

The APVMA will then assess the application in relation to the safety, efficacy and trade criteria under the Agvet Code and, where relevant, include any Australian specific requirements for labelling and conditions of registration.

Any additional claims or Australian specific requirements that have not been assessed by NZ MPI will continue to be assessed in line with the current APVMA assessment processes and timelines.

#### Industry Discussion Point 7

What, if any, issues do you see with the proposed process for assessing applications?

### 3.9 Ongoing registration of a product

Under Australian legislation, the APVMA must make its own decision to register a product, taking into consideration whether statutory criteria are met. As such, the fact a product is registered in NZ does not automatically guarantee registration in Australia. Nevertheless, using NZ assessments could considerably shorten the time taken to assess applications for identical products with identical uses in Australia.

Registration in Australia will continue as per Australian law, even if the product is no longer registered in NZ. In circumstances where registration in NZ ends as a result of an adverse issue relating to the product, the APVMA would decide whether to review the chemical using the reconsideration powers under the Agvet Code.

In NZ, conditions of registration place an obligation on registrants to advise NZ MPI if there are any risk management reasons why a registration may be affected. In Australia, this is managed through the Agvet Code, which places an obligation on product registrants to advise the APVMA in the event they become aware of any information that may suggest the product no longer meets the safety, trade or efficacy criteria.

#### Industry Discussion Point 8

What, if any, issues do you see in relation to registration of a product that has been assessed under the proposed approach if the product is then no longer registered in NZ?

### 3.10 Variation of product registrations

A product will need to be registered in Australia before an application is made to vary it.

There are two ways to vary a product registration:

1. use the Australian registration and submit an application to vary through the normal processes
2. use the Australian registration and leverage NZ assessments through the same approach as was used to initially register the product.

In relation to option 1, by providing data along with the assessment reports, registration by the APVMA will provide the basis for variations in the future, without the need to refer back to the original NZ registration. The process for applying for variations will remain the same as presently.

In relation to option 2, subsequent variation applications in NZ could then also be leveraged through the proposed approach where the same variation is made in Australia, noting that variations to product registration in NZ would not automatically be adopted in Australia.

The APVMA is proposing that the pathway to leverage assessments undertaken by NZ MPI would also be applicable to variation applications where the same change is being made to the product registration. If the variation is not the same, then those applications will be managed through the standard pathway in line with generally established data requirements.

Applicants would also need to demonstrate that registered products in both NZ and Australia remain the same to ensure the variations are based on the same product. Any 'drift' in the products registered in both countries (particularly in its chemistry) could render any assessments no longer comparable or relevant.

#### Industry Discussion Point 9

What, if any, issues do you see in relation to varying a product registration involving products registered in both NZ and Australia?

### 3.11 Good manufacturing practice

The APVMA registration process will continue to require evidence of good manufacturing practice (GMP) where required for registration of a veterinary chemical product in line with the requirements of the:

- Agvet Code
- *APVMA Agricultural and Veterinary Chemicals Code (Manufacturing Principles) Determination 2014* (Manufacturing Principles)
- *Australian Code of Good Manufacturing Practice for Veterinary Chemicals, 2007* (GMP Code).

No legislative changes are anticipated to be required for GMP as a result of the proposal.

The APVMA and NZ MPI recognise GMP certification where audits are conducted by each agency. Therefore, in practice, it is anticipated GMP requirements will be relatively easily managed.

Where products registered in NZ have been manufactured in countries other than Australia or NZ, the APVMA will continue to work with applicants to validate that the GMP requirements for Australian registration are satisfied by those overseas manufacturers.

#### Industry Discussion Point 10

What, if any, issues do you see in relation to GMP registration requirements?

### 3.12 Miscellaneous matters

There are a range of matters that will be considered as part of the final proposal. These include:

- Provisions for appeal under the agvet legislation stand, should an applicant wish to appeal a decision where the APVMA may not have accepted the outcomes of a NZ assessment.
- Reconsideration provisions in the Agvet Code for chemical review stands, regardless of the status of the product registration in NZ.
- Additional legislative requirements related to management of biosecurity, GM technology and environmental risks in Australia may also impact on supply of the product in Australia, noting these requirements are managed through other agencies such as the Department of Agriculture and Water Resources, OGTR and the Department of the Environment. Applicants in Australia will still need to ensure these additional requirements are met.

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## 4 ADDITIONAL CHANGES TO ENHANCE IMPLEMENTATION

### 4.1 Agreement with NZ MPI for exchange of information

The Agvet Code provides a regime to support sharing of information between regulators where the consent of the owner of the information has been provided. The APVMA and NZ MPI have a Memorandum of Understanding that supports the sharing of assessment reports, decisions and information between the agencies. This includes information about both product registration and evidence of GMP.

Historically, the primary focus has been on assessments and information from Australia being provided to NZ, particularly for product registration. In line with this proposal, the APVMA will work with NZ MPI to reflect the increased focus on a two-way exchange of assessment reports, decisions and information and to ensure the arrangements for accepting GMP certification support the proposal in revising the Memorandum of Understanding.

A key element of revising the arrangements will be to ensure the process for the exchange of information is streamlined to ensure there are no delays in evaluation of the application that will affect the overall timeframe for expected completion.

### 4.2 Align fee structure with level of assessment required to be undertaken

The APVMA will work with the Department of Agriculture and Water Resources as part of ongoing reform for agvet chemical regulation on the fee structures for the type of assessment proposed in this paper. Future cost recovery impact statements will be undertaken to more directly align the fees and timeframes for assessment of registration applications where NZ MPI assessments are leveraged with the level of assessment actually required to be undertaken by the APVMA.

Improved alignment of fees and timeframes to the level of assessment actually required to be undertaken is also a factor that will be considered by the APVMA with the increased focus on use of international assessments more broadly and the implementation of lower regulatory approaches to registration.

In the interim, the APVMA will use its existing ability to provide for partial waiver or refund of fees to reflect any reduced assessment requirements as outlined above. Details of how waivers or refunds are to be determined will be developed once this policy is finalised.

### 4.3 Consideration of broader scope

Subject to any concerns raised with this proposal, following implementation, the APVMA and NZ MPI will be looking to work with industry to consider broadening the scope of products that could be considered under the registration by reference pathway. We will also consider whether there is any avenue to progress to a registration decision from either regulator being automatically adopted for particular product types.



APPENDICES

## ABBREVIATIONS

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ACVM Act	<i>Agricultural Compounds and Veterinary Medicines Act 1997</i>
agvet	agricultural and veterinary
Agvet Code	<i>Agricultural and Veterinary Chemicals Code Act 1994</i>
APVMA	Australian Pesticides and Veterinary Medicines Authority
DNA	deoxyribonucleic acid
EPA	Environmental Protection Authority
GM	genetically modified
GMP	good manufacturing practice
GMP Code	<i>Australian Code of Good Manufacturing Practice for Veterinary Chemicals (2007)</i>
Manufacturing Principles	<i>APVMA Agricultural and Veterinary Chemicals Code (Manufacturing Principles) Determination 2014</i>
MPI	Ministry for Primary Industries
NZ	New Zealand
OGTR	Office of the Gene Technology Regulator

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