
# Veterinary Medicine Registration in New Zealand

ACVM Information Requirements No 1

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# Veterinary Medicine Registration in New Zealand

## 1 Purpose

This document provides 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.

## 2 Requirement for registration

Under section 21 of the Agricultural Compounds and Veterinary Medicines Act 1997 (the Act), agricultural compounds must be registered before importation, manufacture, sale or use is permitted unless exempted via the Agricultural Compounds and Veterinary Medicines Regulations 2001. A veterinary medicine is any substance, mixture of substances or biological compound used or intended for use in the direct management of an animal. Veterinary medicines are a subset of agricultural compounds.

The Approvals and ACVM Group of the New Zealand Food Safety Authority (NZFSA) is responsible for registration of veterinary medicines in New Zealand.

See Frequently Asked Questions on Regulation under the ACVM Act for more background.

If you have questions, contact us.

## 3 Shared agreement

The Approvals and ACVM Group undertakes to process applications for agricultural compounds, including veterinary medicines, in an effective and efficient way in order to prevent or manage the following risks relevant to the Act (section 4):

- risks to trade in primary produce
- risks to agricultural security

- risks to animal welfare
- risks to public health
- risks to domestic food residue standards.

The applicant undertakes to provide all the information, as detailed in this document, required to enable the application to be processed. Additionally, the applicant undertakes to analyse the hazard profile of their products with the aim of minimising the risks posed by their use. See the website for more information on risk assessment and hazard analysis.

# 4 Types of registration

Applications can be made for two types of registration:

- registration (including variations to a currently registered trade name product)
- provisional registration.

## 4.1 Registration

Registration means obtaining authorisation under section 21 of the Act for importing, manufacturing, selling and using a veterinary trade name product in New Zealand.

## 4.2 Provisional registration

Provisional registration means obtaining authorisation under section 27 of the Act to allow an applicant to carry out product development, research or trial work with a trade name product in order to obtain further information (eg, efficacy, safety, or residues data). Obtaining provisional registration of a trade name product is not a prerequisite for subsequent registration under section 21 of the Act.

Data requirements for provisional registration are not the same as requirements for registration and are not covered in this document. See the website for more information on provisional registration.

**Note**: Where research is to be conducted on animals using an agricultural compound that does not have the characteristics of a trade name product under the Act, a research approval may be required. See the website for more information on research approval.

# 5 Information required for registration

Applications for registration of a veterinary medicine must include, among other information, technical data and/or scientific arguments to support:

- the quality, purity and stability of the product
- the product's effectiveness for all therapeutic claims that relate to the risk areas managed under the ACVM Act. Efficacy of a trade name product is assessed when inefficacy will result in unnecessary pain and distress to the animal.
- the safety of the product on target animals
- any possible impact on trade resulting from the use of the veterinary medicine in food-producing animals
- compliance with domestic food residue standards.

## 5.1 Overall application summary

Registration applications should include a document that summarises the main aspects of the complete application. In particular, the summary should include the following:

- data that are included and how they support the product registration, such as label efficacy claims, safety, shelf life, withholding periods etc
- scientific arguments in lieu of data not included in the data volumes
- references to relevant documents
- clarifications to non-conformances identified in the data assessment reports.

Failure to include the overall application summary may result in the application being rejected at pre-screen.

## 5.2 Data volumes

NZFSA's information requirement documents specify the information that **must** be supplied to support an application. They also provide guidance advice, which is not mandatory. The data should be provided in the form of data volumes, also known as data packages or dossiers. Data volumes required to support an application depend on the application type. This section provides a brief

description of all the data volumes. The table at section 5.4 lists the application types and the data volumes that must be provided to support that application type.

### 5.2.1 Volume 1: Chemistry and Manufacturing

The information provided in this volume defines the identity of the trade name product and must conform to NZFSA's chemistry information requirement document for veterinary medicines and its manufacturing requirements.

For type A and type B applications, all information requested in the chemistry and manufacturing information requirements document must be supplied. The information to be supplied for type C applications is determined by the changes to formulation or manufacturing that are proposed. For example, a change in shelf life (C3) will require only the stability section of the chemistry standard to be addressed. For an understanding of the types of application see Guideline: Product Data Sheet for Registration (or Variation of Registration) of a Veterinary Medicine and Veterinary Medicine Smart Track Application Guidance.

Manufacturers of veterinary medicine trade name products must have an NZFSA-approved Good Manufacturing Practice (GMP) operating plan under section 28 before these products can be registered. This requirement also applies to repackers/relabellers of the formulated product.

Any external quality control laboratories/facilities involved in testing the veterinary medicine trade name product must have either an NZFSA-approved GMP operating plan under section 28 or a quality system that has been independently accredited by a third party, eg ISO 17025 issued by IANZ (International Accreditation New Zealand).

### 5.2.2 Volume 2: Residues

Residue data are required only for products intended to be administered to food-producing animals. It is required to determine the level of certain residues in the edible tissues of treated animals or other specified primary produce obtained from a treated animal. Based on the residue data NZFSA will recommend a withholding period (WHP) for the trade name product. The WHP, which is the time for which a particular agricultural produce must be withheld before entering the food chain, is a regulatory tool used by NZFSA as a condition of registration to manage compliance with the specified residue limits in the current New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards.

The data provided in this volume must conform to the NZFSA's residue information requirement document for veterinary medicines.

If a maximum residue limit (MRL) for the active ingredient is required to be established, this must be made clear in the application. To check the current MRL of an active ingredient, refer to the latest version of New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards.

### 5.2.3 Volume 3: Efficacy and/or therapeutic equivalence

*Efficacy*: Efficacy information is required to justify label claims where lack of efficacy will impact on the risk areas outlined in section 3 above. Efficacy must be demonstrated for use according to the label directions under practical field conditions within New Zealand. Claims must be soundly supported by scientific evidence as per NZFSA requirements.

Risks to animal welfare can arise if the use of a product, or its failure to achieve claims, could result in unnecessary or unreasonable pain or distress in the target animal. In this case efficacy data must verify that the veterinary medicine will prevent or treat diseases characterised by unnecessary pain or distress.

Risks to public health or agricultural security may also arise if a veterinary medicine fails to achieve its claims. In this case efficacy data must verify the product will achieve the label claims.

For production claims, efficacy data is not required.

Efficacy data that is not under New Zealand conditions may be accepted if appropriate argument is supplied that the data is relevant to New Zealand conditions.

NZFSA has developed information requirements documents for a range of veterinary medicine product types, which are available on the website. Overseas guidelines, such as those developed by VICH, WAAVP, or APVMA, can be used where NZFSA does not have one. Where the requirements for efficacy are not yet documented but it is indicated in Table 5.2 that efficacy data are required, applicants must provide supporting data to show that the trade name product, when used according to directions, is efficacious for the purposes claimed in New Zealand under practical conditions. Data generated should follow the requirements outlined in the ACVM Research Standard.

*Therapeutic equivalence*: Less information than is specified in the relevant efficacy standard may be provided where therapeutic equivalence with a registered product can be confirmed. Therapeutic equivalence requirements are specified in the ACVM Registration Standard for Therapeutic Equivalence of Trade Name Products. If the data held by NZFSA regarding the registered product is protected under the provisions of the Act, then appropriate authority to cross-reference the data must be provided. If the registration argument is based on a combination of efficacy data, literature and therapeutic equivalence, these should be combined into a science-based rationale. Note that some products are more bio-available and are not bioequivalent. In these cases the impact on safety and residues should be addressed.

### 5.2.4 Volume 4: Target animal safety

While some pain or distress to the animal is inevitable at times from administration of a product, the intensity and duration must be no more than is necessary to prevent or treat the condition concerned. Target animal safety data, along with the efficacy data, are therefore required to demonstrate that the benefits to the animal from the use of the product outweigh the suffering that may arise from not administering it. The data provided in this volume must conform to NZFSA's target animal safety information requirement document.

### 5.2.5 Volume 5: Toxicology

Submitting human toxicological data is not a standard requirement for most applications. However, very occasionally NZFSA may request these data on a case by case basis where it is deemed relevant to ACVM risk thresholds.

## 5.3 Antimicrobial resistance information requirements

In addition to the above data volumes, applications for A1, A2, C4 and C5 registrations of antimicrobials must provide information addressing the potential for development of antimicrobial resistance of relevance to humans. NZFSA recognises the VICH guidelines, *Guidance on pre-approval information for registration of new veterinary medicinal products for food-producing animals with respect to antimicrobial resistance*, as the relevant information requirement document.

Applicants must follow these guidelines when submitting an application for a new antimicrobial active or an existing active with a new use pattern or formulation type. In addition, they provide guidance for applicants whenever additional information is required as part of a review or a request for further information or for any application that may change the existing potential for antibiotic resistance, i.e. a new species or mass medication claim. The VICH guidelines set out the basic requirements as well as guidance for optional data. Gaps in the information provided will lead to conservative conclusions from a resulting risk analysis and the likelihood of restrictive use conditions.

## 5.4 Information required for each application type

The table below lists the application types and the data volumes that must be provided to support that application type. For an understanding of the types of application see Guideline: Product Data Sheet for Registration (or Variation of Registration) of a Veterinary Medicine and Veterinary Medicine Smart Track Application Guidance (links in 5.2.1 above).

| Application Type | | Data Volume | | | | |
|---|---|---|---|---|---|---|
| | | Chemistry & Manufacturing | Residue | Efficacy | Safety | Toxicology |
| A1: | New active ingredient | ◆ | ◆ | ◆ | ◆ | ⛝ |
| A2: | Known active ingredient with a new risk profile | ◆ | ◆ | ◆ | ◆ | |
| B1: | Identical to a registered trade name product | Dev | Dev | Dev | Dev | |
| B2: | Similar to a registered trade name product | ◆ | ◆ | ⌘ | ◆ | |
| B3: | Specified requirements product | ⭘ | ⭘ | ⭘ | ⭘ | |
| C1: | Change in formulation | ◆ | ◆ | ◆ | ◆ | |
| C2: | Change in manufacturing process | ◆ | | | | |
| C3: | Change in shelf life or packaging | ◆ | | | | |
| C4: | Additional target species | | ◆ | ◆ | ◆ | |
| C5: | Additional disease/condition | | | ◆ | | |
| C6: | Change of dose regime | | ◆ | ◆ | ◆ | |
| C7: | Change to method of administration | | ◆ | ◆ | ◆ | |
| C8: | Change in withholding period | | ◆ | | | |
| C9: | Administrative changes | Explain the changes in a letter | | | | |

**Key**

◆ Information must be provided or a deviation from the information requirements be submitted
⛝ See toxicology data requirements (section 5)
Dev Deviation from the Information Requirements (section 6)
⌘ Therapeutic equivalence data (section 5)
⭘ See the website for the level of information required for registration of these products

## 5.5 Data package review

The data package review provides an index and a summary of the data or information that is provided in a data volume/package. The reviews point the NZFSA to the critical data in these packages. Data package reviews also point the applicants where data in individual packages might be deficient, which

helps identify where a deviation from the information requirements may be required. Applicants must complete and include the relevant data package review with each data volume/package when lodging an application for registration for a trade name product. NZFSA has developed specific templates relevant to each data volume, which are available online.

## 5.6 Data assessment

Before an application is accepted for registration the supporting data must be summarised and evaluated to confirm that they meet the general and specific information requirements as outlined under section 5.2 above. This process is called data assessment. See the website for more information on data assessment.

## 5.7 Format

The data volumes, including all the raw data, must be provided in full, preferably printed on A4 paper, securely bound, and the front cover of each volume labelled with the following minimum information:

- trade name of the product and registration number (if known)
- volume number (eg, Volume IV: Efficacy)
- date
- name of the applicant/supplier of the information.

Each data volume must have a table of contents, followed by a summary of the data in that particular volume. Different sections within the volume must be separated by tabbed dividers and the tabs marked with identifiers/headings. If a section within the data volume comprises a series of studies, a concise summary (abstract) should be provided at the start of each study. Within each section, studies should be assembled in terms of their logical groupings.

Photocopies must be legible. Photographs should be of a quality suitable for reproduction, and preferably lodged as original prints. Colour copies should be used, for diagrams, graphs, photographs etc where use of black and white copies makes it difficult to interpret the information.

All supporting literature (eg, the scientific papers) must be submitted in full.

The pages of the data volumes must be numbered systematically. Pages can be sequentially numbered from start to finish or, if an application is in several volumes, sequentially numbered within each volume. Any system for numbering the pages may be used as long as it is consistent throughout the application and is accurately reflected in the table(s) of contents.

If all the technical data is less than twenty pages long, it can be presented as a single dossier with the different volumes separated by tabbed dividers (eg, separating the Chemistry and Manufacturing volume from the Efficacy volume). Otherwise, each data volume must be contained in its own dossier.

## 5.8 International data volumes

Data volumes will be accepted from any other country provided:

- the information submitted is in English. NZFSA may request documents in the original language if those submitted are translated copies
- the data meet the relevant NZFSA information requirements
- data package reviews are included (see section 5.5).

## 5.9 Electronic submission

If you wish to submit data electronically, please contact NZFSA.

# 6 Deviations from the information requirements

An application that is not in the specified form or does not contain the required information is rejected as an invalid or incomplete application. However, section 16 of the Act allows an applicant to request the Director-General to waive the information requirements (or some part of the requirements) or to give a direction about the terms on which the information must be supplied. See the website for details on submitting a deviation from the information requirements.

# 7 Data protection

Confidential supporting information (CSI) submitted with an application (type A1) for the registration of a trade name product that contains an “innovative agricultural compound”, as defined in section 72 of the Act, will be eligible for CSI protection (aka data protection). The period of protection is 5 (five) years from the date of acceptance of the application for registration and if the trade name product is registered (or declined registration) within this period, for a further 5 years from the date of registration (or decline of registration).

Other applicants wishing to apply for registration of a trade name product containing the same active ingredient within this protected period have to either supply full data according to the information requirements or obtain a letter of support from the organisation holding the data protection during the protected period. See the website for more information on data protection.

# 8 Other requirements

## 8.1 ERMANZ approval

Under section 21(5) of the ACVM Act, NZFSA is not permitted to register a trade name product that is a hazardous substance or contains a new organism unless an approval for that hazardous substance or the organism has been issued under the Hazardous Substances and New Organisms (HSNO) Act 1996. The HSNO Act is administered by Environmental Risk Management Authority of New Zealand.

Most veterinary medicines will be deemed to be hazardous under the HSNO Act. Applicants are advised to contact the Hazardous Substance Group of ERMANZ for a 'Status of Substance' determination of their products. If the product contains a live organism, applicants are advised to contact the New Organisms Group of ERMANZ for a determination under section 26 of the HSNO Act.

Applicants must include the HSNO approval(s) with their application for ACVM registration of their products.

## 8.2 Ministry of Health consent

Under section 21(4) of the Act, NZFSA is not permitted to register a trade name product without the consent of the Director-General of Health if that product is a prescription medicine within the meaning of section 3 of the Medicines Act 1981.

## 8.3 MAF Biosecurity New Zealand clearance

A biosecurity clearance issued under the Biosecurity Act 1993 must be included with the registration application if the product contains an ingredient originating from an organism (plant, animal, fungus, etc) and is intended to be imported. If not included, the application will not be processed. This requirement is in place to mitigate the risks associated with bringing risk items into New Zealand from a biosecurity perspective. Applicants are advised to contact the Imports Group in the Border Standards Directorate of MAF Biosecurity New Zealand for more information on biosecurity clearances.