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**New Zealand Food Safety Authority**
**Post Office Box 2835**
**Wellington, New Zealand**

# ACVM REGISTRATION INFORMATION REQUIREMENTS FOR VETERINARY MEDICINES IN NEW ZEALAND

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**Endorsement:**
**Date:**

# CONTENTS

## MODULE B: WORKING OUT WHAT INFORMATION TO SUPPLY

# ACVM REGISTRATION

# INFORMATION REQUIREMENTS FOR
# VETERINARY MEDICINES
# IN NEW ZEALAND

## 1 INTRODUCTION

This document has been written by the Agricultural Compounds and Veterinary Medicines (ACVM) Group of the New Zealand Food Safety Authority (NZFSA) in conjunction with industry. It provides guidance to applicants on the data that must be submitted to support an application for registration or for any variation to an existing registration of a veterinary medicine in New Zealand.

Please read this document carefully to ensure that all the necessary documentation required to support your application is supplied to the ACVM Group.

### 1.1 The requirement for registration

Under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 veterinary medicines, unless specifically exempted, must be registered before importation, manufacture, sale or use is permitted. The entity responsible for registration of veterinary medicines in New Zealand is NZFSA's ACVM Group.

### 1.2 The purpose of this document

This document provides an overview of administrative and technical requirements for the registration of a veterinary medicine in New Zealand. It explains how applications should be made to the ACVM Group for:

- registration of a veterinary medicine;
- variation to an existing registration of a veterinary medicine.

This document consists of two modules, a glossary and a set of attachments:

- **Module A** contains general information about registration, importation, sale and use of veterinary medicines.

- **Module B** contains a description of each of the application types, and refers to the standards that must be met. This module also outlines the information that must be supplied to support applications for registration or for variations to existing registrations.

- **Attachments** include:
  - a Registration and Product Datasheet template;
  - definitions to be used with the application form;
  - contact details for queries and information;
  - a list of relevant ACVM publications;
  - a non-hazardous declaration form.

## 1.3 Shared agreement

The ACVM Group undertakes to process applications for agricultural compounds (including plant compounds) and veterinary medicines in an effective and efficient way in order to protect New Zealand's trade in primary products, animal welfare, agricultural security and food safety.

The applicant undertakes to provide the complete information, as detailed in this document, required to enable the application to be processed to mutual satisfaction.

## 1.4 Legislation

Applicants should ensure that they keep themselves informed of any relevant legislation. Updates will be provided on our website and also in our publication *AgVetLink*. (Refer to Attachments 5 and 6 for contact details.)

# MODULE A

# General Information about Registration

# A1 THE REGULATION OF VETERINARY MEDICINES IN NEW ZEALAND

## A1.1 Introduction

The purpose of registration is to ensure that all veterinary medicines meet acceptable standards before they are imported, manufactured for distribution, or sold in New Zealand.

The ACVM Group evaluates applications with respect to risks to:

- trade in primary produce;
- animal welfare;
- agricultural security.

The ACVM Group also evaluates applications to ensure that the use of agricultural compounds (including veterinary medicines) does not result in breaches of domestic food residue standards and to ensure the provision of sufficient consumer information about agricultural compounds.

## A1.2 Legal aspects of registration

### A1.2.1 Definition of an agricultural compound

The legal definition of an agricultural compound as stated in the ACVM Act is:

Any substance, mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land, place, or water on or in which the plants and animals are managed, for the purposes of:

(a) Managing or eradicating pests, including vertebrate pests; or
(b) Maintaining, promoting, or regulating plant or animal productivity and performance or reproduction; or
(c) Fulfilling special nutritional requirements; or
(d) The manipulation, capture, or immobilisation of animals; or
(e) Diagnosing the condition of animals; or
(f) Preventing or treating conditions of animals; or
(g) Enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals; or
(h) Marking animals;

and includes any veterinary medicine, any substance, mixture of substances, or biological compound used for post-harvest pest control or disinfestation of raw primary produce, and any substance, mixture of substances, or biological compound declared to be an agricultural compound for the purposes of this Act by Order in Council made under subsection (2).

**Veterinary medicine** means any substance, mixture of substances, or biological compound used or intended for use in the direct management of an animal.

The definitions refer to substances but registration will be issued for each trade name product. In general terms, veterinary medicines include, but are not limited to:

- anaesthetics, analgesics, and sedatives
- antibiotics and sulphonamides
- anticonvulsant agents
- antidotes, antitoxins and reversal agents
- antifungals
- anti-inflammatories
- antimicrobials
- behaviour modifiers
- bloat remedies
- cardiovascular agents
- coccidiostats and antiprotozoals
- ectoparasiticides
- endocrine agents (hormonal)
- endoparasiticides
- euthanasia agents
- gastrointestinal tract modifiers
- hormonal growth promotants (HGPs)
- musculoskeletal modifiers
- oral nutritional compounds
- parenteral nutrients and electrolytes
- renal and urinary tract modifiers
- respiratory tract modifiers
- skin and coat conditioners
- vaccines
- vertebrate poisons.

Some of New Zealand's trading partners prohibit certain substances (see appendix) from use in food producing animals. In consequence, the ACVM Group shall no longer approve the registration of products containing these substances with label claims for use in cattle, deer, goats, sheep, llamas, ostriches, emus or fish unless agreed tagging and tracking programmes were instituted.

Trade name products that contain the restricted substances and carry claims for use in species other than these animals will still be considered for registration. Where the potential for off-label use of these products in food producing animals that may supply edible product for export is considered likely, specific conditions shall be placed on the product registration to prohibit such use unless agreed tagging and tracking programmes were instituted.

### A1.2.2 Other legislative requirements

The registration of a veterinary medicine by the ACVM Group involves consideration of the requirements of the ACVM Act and its Regulations. Applicants should ensure that they are aware of their legal obligations under this and other Acts.

Other relevant legislation includes:

- Hazardous Substances and New Organisms (HSNO) Act 1996 and its Regulations;
- Biosecurity Act 1993;
- Fair Trading Act 1986 and the Consumer Guarantees Act 1993;
- Health and Safety in Employment Act 1992;
- Animal Products Act 1999;
- Animal Welfare Act 1999;
- Medicines Act 1981 and its Regulations 1984;
- Food Act 1981 and its Regulations 1984;
- Dairy Industry Act 1952.

**It should also be noted that under the HSNO Act, a veterinary medicine trade name product that is a hazardous substance or contains new organisms including genetically modified organisms (GMOs) cannot be registered unless it has prior approval from the Environmental Risk Management Authority (ERMA NZ).**

### A1.2.3 Approval of manufacturers of the formulated trade name product

NZFSA's ACVM Group approves the manufacturer of the final formulated trade name product (TNP). This means that manufacturers of veterinary medicines require approval for the product category for which registration is sought.

Approval of manufacturers will be based on inspection for compliance with the *ACVM Standard for Good Manufacturing Practice*.

To make an application for an approval of a manufacturer, please visit the ACVM Group website (www.nzfsa.govt.nz/acvm/) for an Application for Approval to Manufacture Agricultural Compounds or Veterinary Medicines.

## A2 WHO CAN APPLY?

Any person may apply to register a veterinary medicine. Where an application is made from overseas, the applicant must nominate a New Zealand agent. The application form must be signed by that person or the person authorised to sign for the applicant.

When an applicant appoints a registration consultant to act on their behalf, a letter is required from the applicant giving authority to that representative. The letter must specify the extent of authority that person has in respect of any application for registration and indicate where correspondence should be directed.

## A3 CONFIDENTIALITY

All information submitted to the ACVM Group will be held subject to an obligation of confidentiality to the supplier of that information.

In order to implement the General Agreement on Tariffs and Trade: Trade-Related Aspects of Intellectual Property Rights (GATT:TRIPS) agreement with respect to data provided in an application to register a product with an innovative active ingredient, the ACVM Act provides legislative protection for confidential supporting information (CSI).

To satisfy the provisions of the Official Information Act and the CSI provisions in the ACVM Act, all information submitted to the ACVM Group must be identified as confidential, commercially sensitive or be provided in a form that can be released into the public arena.

# A4 PROCESSING AN APPLICATION

The regulatory process consists of review and evaluation of data that have been assessed to standards set by the ACVM Group. The regulatory review and evaluation can be carried out only by the ACVM Group and is subject to statutory timelines.

Prior to an application being accepted into the regulatory process, a data assessment must have been carried out. The ACVM Group offers a discretionary data assessment service or, alternatively, the assessment of any, or all, of the data may be carried out by an independent third party. See the ACVM Group's website for further information on data assessment and data assessment report templates that should be used in this instance. (Note: applicants may choose to do their own data assessment; however, they should be aware that the ACVM Group will have added concerns about possible bias if the reports are not made by independent assessors.)

## A4.1 Screening of the application for the ACVM Group's data assessment service

Before an application can be accepted for data assessment, it should meet a number of criteria via a screening process. These criteria include:

- payment of the appropriate fee,
- completion of a Registration and Product Datasheet, and
- the submission of relevant data.

The screen ensures that the application contains all information as identified on the application form checklist, and that this information is correct for the application type being sought. If deficiencies are identified during screening the applicant will be advised and given the opportunity to resolve those deficiencies.

## A4.2 Accepting the ACVM Group's data assessment service

The ACVM Group will inform the applicant of the estimated number of hours, cost, and likely time to completion for the data assessment. If the applicant wishes to use the ACVM data assessment service, a signed copy of the Data Assessment Service Notice of Conditions and Disclaimer should be returned to the ACVM Group. The data assessment will then commence.

## A4.3 Data assessment of the application

The data assessment process is the most time consuming of the overall application evaluation. During data assessment, data submitted for the application are assessed and may be subjected to a review by experts.

If, during the data assessment process, it is noted that there are data deficiencies, or the ACVM Group requires further clarification on an application, then the applicant will be contacted. Work on this application will cease until the additional information or clarification has been supplied, or the end date stated is reached. In effect, this means that incomplete applications may delay the data assessment process. A data assessment can be carried out with incomplete information or data submitted; however, any deficiencies and resulting implications will be pointed out in the finished reports.

Applications cannot be significantly modified during the data assessment process. If the applicant wishes to modify the application, the application should be withdrawn and a new application submitted.

On completion of the data assessment, completed data assessment reports will be returned to the applicant.

## A4.4 Review and evaluation of the application

A request should be made to the ACVM Group for review and evaluation. The request should be accompanied by the completed data assessment reports, with CVs of expert assessors where applicable, summaries of results for all data assessed, proposed label content and the regulatory pre-screen fee. Raw data used in the data assessment is not required where trials are carried out to ACVM standards, but should be included for chemistry and manufacturing, and any cases where trials were not carried out to ACVM standards. Note: where an MRL is required in order to approve a particular claim, the MRL should be finalised before the application enters the regulatory system.

The ACVM Group will carry out a review and evaluation of the data assessment, addressing the risk areas set out in the ACVM Act. Conditions may be recommended in order to manage any risks identified. Additionally, a Technical Consultative Committee may review the assessor's recommendations to provide further robustness to the evaluation.

Once the application has been reviewed and evaluated, it is submitted to the ACVM Decision Making Committee with a recommendation.

## A4.5 Registration issue and approval of label content

When an application is approved, the ACVM Group issues the appropriate registration to the applicant and approves the label content. The certificate of registration will contain a unique registration number and will also detail specific conditions for that trade name product.

## A4.6 Registration conditions

There are two types of conditions that may apply to registration. These are conditions *of* registration and conditions *on* registration.

- Conditions *of* registration relate to the definition of the trade name product itself. They include conditions relating to formulation and manufacturing.

- Conditions *on* registration relate to the manner in which the trade name product is imported, distributed, stored, sold or used.

If a registrant fails to comply with the relevant conditions, the ACVM Group may revoke the registration of the veterinary medicine and/or apply appropriate sanctions.

## A4.7 Fees

An annual fee for registered veterinary medicines is prescribed in the Regulations under the ACVM Act. The ACVM Group will invoice all registrants in July of each year. Failure to pay this fee means the registrant will be prohibited from importing or manufacturing the registered veterinary medicine until the fee and any penalty payment has been made.

The fees for registration of a new veterinary medicine or a variation to a registered veterinary medicine are prescribed in the Agricultural Compounds and Veterinary Medicines (Fees and Charges) Regulations 2002. Applications will be charged at an hourly rate for time taken, plus disbursements.

# A5 ONGOING OBLIGATIONS

## A5.1 Reporting adverse events

One of the conditions that will be placed on the registration of all veterinary medicines is the requirements for registrants to advise the ACVM Group of any new studies on their product and of any data that contradict previous information supplied to the ACVM Group or that indicate unintended harmful effects from using their product (adverse events).

Registrants must submit a summary of any adverse events reported every twelve months at the time the registration is renewed. If no adverse events were reported, the summary should state 'nil'.

Records should include full details of:

- the notifier's name, address and phone number;
- details of the adverse event;
- investigations carried out by the registrant;
- conclusions on the cause of the adverse event;
- any actions taken.

If the use of a veterinary medicine results in adverse effects that have serious implications for the continued use of the product, the registrant must notify the ACVM Group immediately.

## A5.2 Review of a veterinary medicine registration

The ACVM Group may revoke or suspend a registration under section 57 of the ACVM Act, or reassess the registration of a trade name product under section 29 and section 30 of the Act.

Re-assessments may be prompted by:

- adverse event reports;
- new information; or
- international standards and common best regulatory practices.

Registrants will be advised of any reviews initiated. As a result of any review, the registration may be modified, suspended or revoked.

# MODULE B

# Working Out What Information to Supply

# B1 INTRODUCTION

Applications can be made for two types of registration:

- Registration (including variations to a currently registered product);
- Provisional registration.

This module provides guidance on the information required to support applications for registration or variations to existing registered trade name products (TNP).

## B1.1 Requirements under the ACVM ACT and HSNO ACT

The ACVM Group will initiate the registration process of a trade name product upon receipt of a request to do so provided that the application is accompanied by the appropriate Registration and Product Datasheet.

Under subsections 21(5) and 27(7) of the ACVM Act, however, the ACVM Group is not permitted to register a veterinary medicine trade name product that is a hazardous substance or contains a new organism unless an approval for that hazardous substance or organism has been issued under the Hazardous Substances and New Organisms Act 1996.

Therefore, although the ACVM Group can process an application for a trade name product and approve its registration (where appropriate), the registration for that trade name product cannot actually be issued unless **one** of the following is provided:

- a signed declaration from the applicant stating that the trade name product as formulated is not a hazardous substance, i.e. does not exceed any thresholds prescribed in the Hazardous Substances Minimum Degrees of Hazard Regulations 2001 (a copy of the required non-hazardous declaration is Attachment 7 of this document);

or

- a determination from ERMA NZ that the trade name product is not a hazardous substance;

or

- an appropriate ERMA NZ approval (only where the trade name product is hazardous).

## B1.2 Registration requirements

Applications for registration must include technical data and/or relevant scientific argument to support:

- the quality, purity and stability of the veterinary medicine;
- its effectiveness for all therapeutic claims indicated;
- the choice of target animals;
- any possible impact on trade resulting from use of the veterinary medicine in food-producing animals;
- compliance with domestic food residue standards.

## B1.3 Variations to an existing registered veterinary medicine

Registrants must apply to vary an approved label, registration or any aspect of a registered veterinary medicine. Such variations may relate to changes to formulation, current use patterns or claims. Even minor changes must be approved.

## B1.4 Specified requirements products

Applicants are advised that some veterinary medicines may have separate data requirements to those covered in this document. Applicants should refer to *ACVM Overview of Specified Requirements Products* and *ACVM Specified Requirements Products Standard and Guideline* for both criteria and information requirements (see Attachment 6).

The ACVM Group will verify whether or not a product should be registered as a specified requirements product. Applicants are encouraged to confirm that their product qualifies via a Class Determination before lodging an application for registration so that the information provided is appropriate.

## B1.5 Provisional registration

The purpose of a provisional registration is to allow the applicant to carry out product development research or trial work on a product to support an application for registration under the ACVM Act or a variation to an existing ACVM registration.

These applications have separate data requirements to full registration. Information on the requirements and how to apply for a provisional registration is provided in *ACVM Registration Information Requirements for Provisional Registration* (see Attachment 6).

# B2 STEPS FOR DEVELOPING AN APPLICATION

These are the steps an applicant should follow when preparing an application for registration. If you require assistance in preparing an application, please contact the ACVM Group for a list of consultants.

**1. To determine your application type, refer to Table 1 below.**

## TABLE 1: DEFINITIONS OF APPLICATION TYPES

| TYPE | DEFINITION |
|---|---|
| **REGISTRATION OF A TRADE NAME PRODUCT** | |
| A1 | These are products containing an active ingredient(s) that has not been previously assessed for registration as a veterinary medicine or plant compound in New Zealand. For a list of registered products by trade name or active ingredient check the ACVM Group website (www.nzfsa.govt.nz/acvm/). |
| A2 | These are products where the formulation type, administration method or target species has not been previously assessed for the active ingredient involved (i.e. the product has a new risk profile). |
| B1 | These are products that are **identical** to an existing registered trade name product**.** The only difference is the trade name. |
| B2 | These are products that are **similar** to an existing registered trade name product**.** To be 'similar', the product referenced must have the:<br>• same active ingredient;<br>• same formulation type;<br>• same dose regime on an active ingredient basis; and<br>• same use patterns. |
| B3 | These are groups of products that only require certain aspects of their chemistry and manufacturing, residues, efficacy or safety to be assessed before registration can be considered. |

| VARIATIONS TO A TRADE NAME PRODUCT | |
|---|---|
| C1 | These are applications for any change in the composition of the final formulation of the registered trade name product. |
| C2 | These are applications for:<br>• any change in the method of manufacture of the final formulation; or<br>• change in site of the manufacturer of the formulated product or the technical active ingredient; or<br>• new or additional manufacturer (approval required for new manufacturer of the formulated product). |
| C3 | These are applications for any change to the shelf life or to the storage/packaging specifications of a final formulated product. |
| C4 | These are applications for extension of use to include an additional target species. |
| C5 | These are applications for the addition of another disease, condition or claim to an existing target species. |
| C6 | These are applications for a change in dose regime. |
| C7 | These are applications for a change to or addition of a method of administration. |
| C8 | These are applications for a change to a withholding period. |
| C9 | These are applications for:<br>• change in name of the manufacturer of the final formulated product or technical active ingredient; or<br>• changes to label text or layout where the revisions do not alter the approved product profile; or<br>• change in trade name only; or<br>• change in name and/or address of the registrant; or<br>• transfer of registration of a trade name product. |

**2. Determine which standards must be complied with for your application type using Table 2, and the explanatory notes following.**

## TABLE 2: STANDARDS REQUIRED FOR THE APPLICATION TYPES

| | | Standards and Guidelines | | | | | |
|---|---|---|---|---|---|---|---|
| **REGISTRATION** | | C | M | $R_1$ | E | S | T |
| TYPE A – New trade name product with a: | | | | | | | |
| A1 | New active ingredient | ◆ | ◆ | ◆ | ◆ | ◆ | * |
| A2 | Known active ingredient with a new risk profile | ◆ | ◆ | ◆ | ◆ | ◆ | |
| TYPE B – New trade name product that is: | | | | | | | |
| B1 | Identical to a registered trade name product | W | W | W | W | W | |
| B2 | Similar to a registered trade name product | ◆ | ◆ | ◆ | ★$_1$ | ◆ | |
| B3 | Specified requirements product | ■ | ■ | ■ | ■ | ■ | |
| **VARIATION**<br>TYPE C – Variations to existing trade name products: | | | | | | | |
| 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 | | | | | | |

**KEY**

**Standards and guidelines**

C Chemistry
M Manufacturing
$R_1$ Residues. Food producing animals only.
E Efficacy
S Target Animal Safety
T Toxicology
◆ Information must be provided to address these areas or an information waiver must be approved
■ Information required will be specified in the relevant standard
W Information waiver
★$_1$ Therapeutic equivalence
* See note on toxicology requirements

## B2.1 Explanatory notes

### 1 STANDARDS AND GUIDELINES

The ACVM Group has developed standards that specify the information that **must** be supplied to support an application. Guidelines have also been developed to use in conjunction with these standards.

The following areas are covered in standards and guidelines for veterinary medicines. They correspond with the data volumes required in an application.

- Chemistry/Manufacturing – Volume 1
- Residues – Volume 2
- Efficacy or therapeutic equivalence – Volume 3
- Target animal safety – Volume 4
- Toxicology – Volume 5

To order copies of the currently available standards, refer to Attachment 6 or visit our website.

**Chemistry/Manufacturing**

The information provided in these volumes defines the identity of the trade name product. For type A and type B applications, all information requested in the chemistry and manufacturing standards must be supplied. The information to be supplied for type C applications is determined by the changes to formulation or manufacturing that are proposed, e.g. a change in shelf life (C3) will require only the stability section of the chemistry standard to be addressed.

**Residues**

Residue data are required to be supplied only for products used on food producing animals. The residue standard sets out the requirements for each application type. If at the same time a maximum residue limit (MRL) is required, this must be made clear in the application. Please note that the relevant standard is the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2002.

**Antibiotic resistance**

All applications for A1 and A2 registrations of antibiotics must provide information addressing the potential for development of antibiotic resistance of relevance to humans. The ACVM Group recognises the VICH guidelines, *Pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance*, as the relevant standard. These guidelines must be followed when submitting an application for a new 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 (VICH Guidelines: http://vich.eudra.org/htm/guidelines.htm).

**Efficacy**
Individual efficacy standards based on product type will be published. Where an efficacy standard is available, the information submitted must comply with that standard.

Where the requirements for efficacy are not yet documented but it is indicated in Table 2 that efficacy data is required, applicants must provide supporting data to show that the trade name product, when used according to directions, is effective for the purposes claimed. 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 can be confirmed. These requirements are specified in the *ACVM Registration Standard for Therapeutic Equivalence of Trade Name Products*. If the argument is based on a combination of efficacy data, literature and therapeutic equivalence, this should be combined into a coherent rationale. It should be noted that some products are more bio-available and are not bioequivalent. In these cases the impact on safety and residues should be addressed.

**Target animal safety**
The target animal safety standard details situations where the full requirements of the standard must be met, and where less information is required.

**Toxicology**
A full toxicology package is required for new active ingredients (type A1 application) in veterinary medicines that do not require ERMA NZ approval under the HSNO Act, but require an MRL to be promulgated under the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2002.

Those ingredients that do have an ERMA NZ approval under the HSNO Act will require a review of the toxicological data and the ADE established by ERMA NZ to be submitted to the ACVM Group in order for an MRL to be considered under the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2002.

## 2 DATA PACKAGE REVIEWS

The Data Package Review is an index supplied with each individual data package (Residues, Efficacy etc.) that points the Technical Assessor to the critical data in those packages as itemised in the prescreening process. They are intended to assist applicants to indicate where data in individual packages might be deficient and to explain why this is so. The ability to easily refer back to specific information in previous applications easily is also intended to improve the processing of queries from applicants and variations to the registration. The summary and argument relating to the volume should also be contained in this review or, if extensive, attached to it. Templates for the individual Data Package Reviews are on the website (http://www.nzfsa.govt.nz/acvm/publications/forms/dpr.htm).

Every data package received by the ACVM Group must contain Data Package Reviews for each volume.

## 3 OVERALL APPLICATION SUMMARY

This should summarise the main aspects of the whole application and should include the main claims, shelf life and withholding periods sought. Sufficient information should be given to provide an understanding of the arguments and data provided as well as any waivers requested. This is to provide a context for each data volume in the event it is assessed separately from the entire application.

A copy must be supplied with the Registration and Product Datasheet and in the first part of any accompanying data package.

## 4 INFORMATION WAIVERS

All information must be provided in the application when it is lodged with the ACVM Group. However, applicants may wish to apply to the Group in advance of making an application to waive the requirement for particular information, if that information is:

- not relevant to the particular application; or
- in the public domain; or
- already held by the ACVM Group.

In the first instance, a case must be presented to explain why the information is not relevant or why some other information would be more appropriate or more relevant. For information that is in the public domain applicants must specify where the information can be readily found or provide the information.

Where applicants wish to cross-reference information that is held on some other trade name product, they must be specific about which trade name product and what information is being referenced, and make the connection to the product that is the subject of the waiver. If the information being referred to is under data protection, applicants must obtain a letter of authority from the owner of the data stating that permission is granted to the ACVM Group to consider the information in regard to the application in question.

Information waivers should be obtained before an application is lodged with the ACVM Group. If issued, the waivers must be provided with the application when it is lodged. For more information on the waiver option contact the ACVM Group. (For information pertaining to information waivers, refer to the ACVM website ‘Fee Schedule’.)

## 5 DATA PROTECTION

Where a registered trade name product contains an active ingredient that already has confidential supporting information (CSI) protection provisions, a letter authorising use of that data will be required from the registrant (or any other party that has the power to grant NZFSA consent to access that data). Where a letter from the relevant registrant cannot be provided, full data must be supplied for the standards required.

## B2.2 Information by application type

It is expected that the indicated data packages will be required with most applications. Where they are not, the appropriate reasoning must be provided and a waiver requested. This should not be assumed.

An expanded version of the requirements outlined in Table 2 follows.

**TYPE A APPLICATIONS**
These are applications for registration of a trade name product that:

### A1 Contains a new active ingredient

These are products containing an active ingredient(s) that has not previously been assessed for registration as a veterinary medicine or plant compound in New Zealand.

**Information required:**
- Chemistry data/Manufacturing data and Data Package Review;
- Residue data and Data Package Review (food producing animal uses only);
- Efficacy data and Data Package Review;
- Safety data and Data Package Review;
- Toxicology (if required refer to B2 Table 2) and Data Package Review;
- Overall application summary in each data volume.

**Note**: Draft labels are required for type A1 applications.

### A2 Contains a known active ingredient with new risk profile

These are products where the active ingredient has previously been assessed, but the characteristics of the proposed product are such that it may change the risk profile, e.g. increase the potential for residues or decrease the efficacy of the product.

**Information required:**
- Chemistry data/Manufacturing data and Data Package Review;
- Residue data and Data Package Review (food producing animal uses only);
- Efficacy data and Data Package Review;
- Safety data and Data Package Review;
- Overall application summary in each data volume.

**Note**: Draft labels are required for type A2 applications.

## TYPE B APPLICATIONS

**Types B1 and B2**
These are applications for registration of a trade name product that is the same as or similar to products that are, or previously have been, registered. If the product is identical to a registered trade name product, the applicant may cross-reference all of the data on the registered product except any of the data that is under data protection. These applications will be type B1 applications. If a product is similar to a registered product, the applicant may cross-reference data from the registered product that is relevant to the proposed product. These will be type B2 applications.

### B1 Identical to a registered product

These are products that are identical to a currently or previously registered trade name product (including manufacturer of the formulated product)**.** The only difference is the trade name.

**Information required:**
- Chemistry data/Manufacturing data and Data Package Review (not normally required);
- Information waiver confirming that the product is identical to another registered product. Applicants are advised to contact the ACVM Group to obtain an information waiver if cross-referencing data is appropriate.

**Note:** Draft labels are required for type B1 applications.

### B2 Similar to a registered product

These are products that are similar to a currently or previously registered trade name product**.** To be 'similar' the product referenced must have the:
- same active ingredient;
- same formulation type;
- same dose regime on an active ingredient basis; and
- same use patterns.

**Information required:**
- Chemistry data/Manufacturing data and Data Package Review;
- Therapeutic equivalence/Efficacy data and Data Package Review;
- Residue data and Data Package Review (food producing animal uses only);
- Safety data and Data Package Review;
- Overall application summary in each data volume.

**Note**: Draft labels are required for type B2 applications.

**Type B3 Specified requirements product**
These are products for which the ACVM Group has developed a registration standard that will state what type of chemistry, manufacturing, residues, efficacy and safety data must be supplied to secure registration.

**Information required:**
See the individual standards for details. They are available on the ACVM website (www.nzfsa.govt.nz/acvm). Data package reviews and data assessment reports are not required.

**Note**: Draft labels are required for type B3 applications.

## TYPE C APPLICATIONS

These are applications for variations to existing registered trade name products.

All applications for variation to a registered product are considered to be type C unless the change results in a change to the risk profile for the product. If the risk profile is changed, the application type will be A2. The rules to establish whether a variation results in a change to the risk profile are under development. Please contact the ACVM Group if it is unclear into which type your application falls.

More than one variation to a registered product can occur in the same application, but the information listed below must be provided for each variation; for example, a change in method of administration that results in a change to the dose regime would mean that the information requirements for a type C6 and a type C7 must be met.

### C1 Change in formulation

These are applications for any change in the composition of the final formulation of the registered trade name product.
These are variations to conditions *of* registration.

**Information required:**
- Chemistry data/Manufacturing data and Data Package Review;
- Residues data and Data Package Review (food producing animal uses only);
- Efficacy data and Data Package Review;
- Safety data and Data Package Review;
- Overall application summary in each data volume.

**Note**: Draft labels are required for type C1 applications where the change is to be included on the label.

## C2 Change in manufacturing process

These are applications for:

- change in the method of manufacture
  (**Note**: where the formulation details change, an application for a type C1 will also be required);
- change in site of the manufacturer of the formulated product or the technical active ingredient; or
- new or additional manufacturer of the formulated product;
- new or additional manufacturer of the active ingredient.

These are variations to conditions *of* registration.

**Information required:**

- Chemistry and Manufacturing data and Data Package Review.

**Note**: Draft labels are required for type C2 applications where the change is to be included on the label.

## C3 Change in shelf life or packaging

These are applications for any change to the shelf life or to the storage/packaging specifications of a final formulated product.
These are variations to conditions *of* registration.

**Information required:**

- Chemistry/Manufacturing data and Data Package Review (packaging specifications and/or stability data).

**Note**: Draft labels are required for type C3 applications.

## C4 Additional target species

These are applications for extension of use to include an additional target species.
These are variations to conditions *on* registration.

**Information required:**

- Residue data and Data Package Review (food producing animal uses only);
- Efficacy data and Data Package Review;
- Safety data and Data Package Review;
- Overall application summary in each data volume.

**Note**: Draft labels are required for type C4 applications.

## C5 Additional disease/condition

These are applications for an extension of use to include control of additional diseases or conditions on the same target species (new or additional therapeutic claim).
These are variations to conditions *on* registration.

**Information required:**

- Efficacy data and Data Package Review.

**Note**: Draft labels are required for type C5 applications.

## C6 Change of dose regime

These are applications for a revision of an existing label claim where there is a change in total dose administered for the target species. This can be a change to the dose rate or a change in frequency of treatments.
These are variations to conditions *on* registration.

**Information required:**

- Residue data and Data Package Review (food producing animal uses only);
- Efficacy data and Data Package Review;
- Safety data and Data Package Review (only required where the dose administered is being increased);
- Overall application summary in each data volume.

**Note**: Draft labels are required for type C6 applications.

## C7 Change to method of administration

These are applications for a change in the method of administration, e.g. from a spray to a pour-on.
These are variations to conditions *on* registration.

**Information required:**

- Residue data and Data Package Review (food producing animal uses only);
- Efficacy data and Data Package Review;
- Safety data and Data Package Review;
- Overall application summary in each volume.

**Note**: Draft labels are required for type C7 applications.

## C8 Change in withholding period

These are applications for a change change in the withholding period for meat, milk, eggs or fibre.
These are variations to conditions *on* registration.

**Information required:**

- Residue data and Data Package Review (food producing animal uses only).

**Note**: Draft labels are required for type C8 applications**.**

## C9 Administrative changes

These are applications for:

- change in name and/or address of the registrant of the trade name product;
- change in name of the manufacturer of the formulated product or the technical active ingredient;
- change in trade name only.

**Information required:**

- The covering letter must outline the new details and include a confirmation/ declaration that other aspects of the registration remain unchanged.

**OR** applications for:

- transfer of registration of trade name product.

**Information required:**

- covering letter from the current registrant notifying of the new registrant;
- a letter from the new registrant confirming the transfer and including a confirmation/ declaration that other aspects of the registration remain unchanged.

**OR** applications for:

- changes to label text or layout, where the revisions do not alter the currently approved product profile.

**Information required:**

- the covering letter must outline the new details and include a confirmation/ declaration that other aspects of the registration remain unchanged;
- label content.

**Note**: a Registration and Product Datasheet is NOT required for type C9 applications.

**Registration/Application Reinstatements**

Applications withdrawn before registration is complete will not be reinstated. Instead, a new application must be made.

Where an applicant wishes to reinstate a cancelled product, if no details have changed, the requirements are as for a type B1 application.

Where there is new information to consider, e.g. for a new registrant/new supporting data, the requirements are as for a type B2 application.

**Note**: Cancelled products cannot be reinstated if the cancellation was due to regulatory concerns.

# B3 PRESENTATION OF APPLICATIONS

**Applications must always contain**:

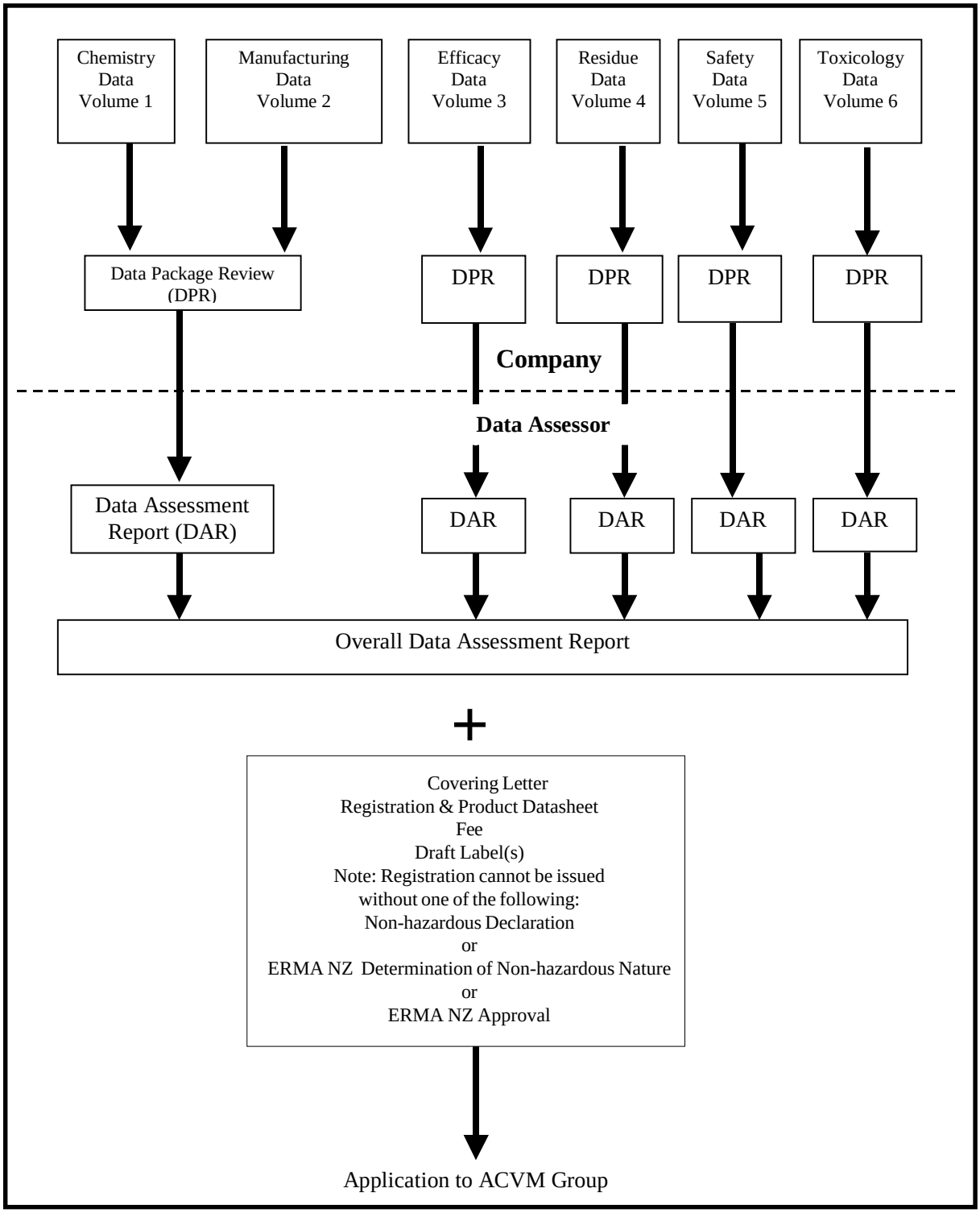
- a covering letter identifying the product and providing a brief outline of the type of application;
- a fully complete Registration and Product Datasheet (for all applications except type C9);
- the appropriate fee.

Note that although the ACVM Group can process an application and approve the registration of a trade name product, registration cannot be issued for that trade name product unless one of the following is supplied:

- a signed declaration that the trade name product is not a hazardous substance; or
- a determination from ERMA NZ that the trade name product is not hazardous; or
- an appropriate approval from ERMA NZ (only if the trade name product is a hazardous substance).

The diagram below shows figuratively the information that must be provided in the most comprehensive application (i.e. type A1 applications). Other application types may not require all of the information shown in the diagram, but should be presented in the same way.

## Contents of an Application



## B3.1 Number of copies required

One copy of the relevant supporting data, one copy of the Data Package Review for each standard that needs to be addressed, and one copy of the overall application summary supplied with the application form and in the first part of any supporting data are required.

## B3.2 Draft labels

Where draft labels are required, three copies of each proposed label (including cartons, vials, leaflets etc.) are required with the application. Where the veterinary medicine is to be marketed in different pack sizes, then draft labels for each pack size are not required unless there are significant differences in layout or text between the pack sizes. Where the application is to vary an existing label, the changes must be highlighted on the draft labels submitted.

Label content should be submitted in a form that can be conveniently placed in an A4 file. Also, an electronic version of the label should be supplied.

Further guidance on labelling can be found in the *New Zealand Labelling Guide for Veterinary Medicines Requiring Registration* (see Attachment 6).

# B4 FORMATTING APPLICATIONS

All submissions must be legible and preferably printed on A4 size paper. If all the technical data accompanying an application is less than twenty pages long, it can be presented in a single volume with the different volumes separated by coloured pages or other appropriate dividers (e.g. separating the Chemistry volume from the Toxicology volume).

Each major data set of an application (e.g. residues, etc.) must begin with the Overall Package Review, a table of contents and a summary of the data in that particular data set.

If a section comprises a series of studies, a concise summary (abstract) should be provided at the start of each study in or attached to the Data Package Review. Within each section, similar studies should be grouped together to facilitate assessment.

## B4.1 International data packages

Information data packages will be accepted from any other country provided:

- the information is submitted in English; and
- the data meets the ACVM standards.

## B4.2 Language

All applications and supporting information submitted must be in English.

If an applicant wishes to submit information not published in English, they must supply a translated copy. The applicant (or supplier of the information) may be asked to provide the original documents if necessary.

## B4.3 Photocopies and photographs

Applicants must ensure that all photocopies are legible. Any unreadable or unclear copies will not be accepted.

Any photographs should be of a quality suitable for reproduction, and preferably lodged as original prints. Photocopies of photographs will be accepted only if they are of good quality and clearly illustrate the subject.

## B4.4 Literature references and testimonials

If specific references are cited in an application, applicants must include a copy of the whole article with the application. Applicants must indicate which part of the reference is applicable to the application.

Testimonials and other forms of anecdotal evidence may be included in an application in addition to scientific literature/data.

## B4.5 Pagination

Applicants must number the pages of their application systematically. It can be difficult for reviewers to locate data or application parts if page numbers are not accurate. 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 of an application may be used as long as it is consistent throughout the application and is accurately reflected in the table(s) of contents. Applicants do not need to erase page numbers on copies of other documents included in an application if those page numbers cannot be confused with the page numbers of the application.

## B4.6 Binding

Data volumes must be securely bound and the front cover of each volume labelled with the following information:

- name of the applicant/supplier of the information;
- common name of the active ingredient and CAS number (or chemical name if no common name available);
- trade name of the veterinary medicine;
- registration number (if known);
- application type;
- volume number and total number of volumes in the application;
- date the application is submitted.

**Note:** Please do not bind the covering letter, application form and draft labels.

# GLOSSARY

**Active ingredient**
The substance or substances in a formulated product that is/are primarily responsible for the biological or other effects that make the product a veterinary medicine.

**ACVM Group**
Agricultural Compounds and Veterinary Medicines Group of the New Zealand Food Safety Authority. The Group is responsible for the registration of agricultural compounds and veterinary medicines, and monitoring their importation, manufacture, sale and use.

**Adjuvant**
A substance added to a formulation to assist the action of the principal ingredient or base
Or- A substance administered with an antigen to augment its immunogenicity.

**Adverse event**
Any unexpected effect on animals, which is thought to be associated with a formulated veterinary medicine when used in accordance with approved registration conditions. This may include side effects, deterioration, lack of efficacy or alleged interactions with other products or compounds.

**Advisor (operations)**
A frontline person who interfaces between customers and the NZFSA organisation.

**Assessor (technical standards)**
ACVM Group person responsible for the technical assessment of application for registration.

**Buffer**
A weak acid and its conjugate base that is used to maintain the pH at a desired level.

**Companion animal**
All domesticated animals not used for legal human food production.

**Confidential supporting information (CSI)**
Confidential information (trade secrets, information of commercial value) given in relation to an innovative application.

**Decision Making Committee (DMC)**
The body responsible for making formal decisions on all applications for registration.

**Diluent**
A chemically inert substance added to a solution to increase the volume and reduce the concentration.

**Emulsifier**
A surface active agent used to enable the dispersion of one liquid in another when one is not dissolvable in the other.

**Filler**
An inert bulking agent used to assist in measurement or distribution of an end use product.

**Food producing animal**
All animals where meat, milk, eggs or other products are legally produced for consumption by humans. This includes horses.

**Innovative veterinary medicine application**
An application that refers to an active ingredient that has not been referenced in any other application to the ACVM Group. Refer to the guideline for determining and protecting confidential supporting information.

**Label**
Any written, pictorial or other descriptive material (including cartons, vials, leaflets), affixed to or contained in the packaging, which gives information about the remedy that is to be marketed or sold. Refer to the *New Zealand Labelling Guide for Veterinary Medicines Requiring Registration*.

**Label content**
This refers to the text or graphics on a label that relates to the requirements of the ACVM Act.

**Manufacture**
In relation to any veterinary medicine, 'manufacture' includes all the following aspects: acquiring materials, making up, preparing, producing or processing, and assessing the veterinary medicine for release; it also includes the packing of a veterinary medicine in a container for the purposes of sale.

**Manufacturer**
Any person who manufactures a veterinary medicine. Where the process of manufacturing is carried out on different sites or by independent contractors on behalf of the applicant, all such contributors shall be recorded as manufacturers of the product and the applicant shall be deemed to be the manufacturer in the register.

**New Zealand agent**
A New Zealand person or organisation specified by the registrant to act on their behalf.

**Preservative**
Any chemical additive that prevents or retards spoilage (e.g. sodium benzoate).

**Registrant**
Any person who applies to register a trade name product or the person to whom a registration is transferred.

**Registration**
The regulatory process by which a registration is obtained.

**Registration certificate**
A registration certificate issued by the ACVM Group under the ACVM Act to any person to manufacture or import the veterinary medicine named on it.

**Registration consultant**
A person acting on behalf of the registrant to assist in preparing an application and/or managing the application through the application process.

**Scientific argument**
Argument based on accepted scientific principles, data published in peer-reviewed journals, relevant texts, case studies and or clinical studies.

**Shelf life**
The time interval from date of manufacture that a product is expected to remain within the approved specification, provided that it is stored under the conditions defined on the label in the proposed containers and closure.

**Specified requirements products**
Product groups that include, but are not limited to, those that would be exempt from registration were it not for their failure to comply with a particular condition of exemption. In the opinion of the ACVM Group, they do not need a full assessment and only require assessment of certain aspects of their chemistry and manufacturing, efficacy, safety or residue profiles for the registration to be considered.

**Surfactant**
A substance that aids or enhances the surface modifying properties of a formulation (also known as wetting agent).

**Suspending agent**
A substance that evenly disperses solid or liquid material in a liquid or gas phase.

**Trade name product**
A veterinary medicine containing one or more active ingredients, normally mixed with non-active ingredients (such as surfactants, solvents, diluents, suspending agents), intended for application, with or without additional dilution prior to use, and which is labelled with directions for use.

**Variation**
An alteration to the conditions of registration as defined in Table 1 in Module B.

**Veterinary medicine**
The legal definition is stated in section 2(1) of the ACVM Act. Refer to Module A.

**Vertebrate poison**
A trade name product used to control an unwanted mammal, bird, reptile, amphibian, or fish.

**Withholding period (WHP)**
The minimum permissible time between the final application of the medicine to an animal and the collection of eggs or milk from that animal, or its slaughter for human consumption.

# APPENDIX
# LIST OF PROHIBITED SUBSTANCES

Substances prohibited from use in food producing animals by some New Zealand trading partners.

- Chloramphenicol
- Colchichine
- Chloroform
- Nitrofurans (including, but not limited to, nitrofurazone, nihydrazone, furazolidone, furaltodone)
- Nitroimidazoles (including, but not limited to, dimetridazole, ronidazole, metronidazole, carnidazole)
- Chlorpromazine
- Dapsone
- Substances with the pyrazolidone moiety within the chemical makeup (for example, but not restricted to, phenylbutazone, ramifenazone, dipyrone)
- Arsenilic acid
- Nandrolone

In consequence, the ACVM Group shall no longer approve the registration of products containing these substances with label claims for use in cattle, deer, goats, sheep, llamas, ostriches, emus or fish unless agreed tagging and tracking programmes were instituted.

Trade name products that contain the restricted substances and carry claims for use in species other than these animals will still be considered for registration. Where the potential for off-label use of these products in food producing animals that may supply edible product for export is considered likely, specific conditions shall be placed on the product registration to prohibit such use unless agreed tagging and tracking programmes were instituted.

# REGISTRATION AND PRODUCT DATASHEET

# Veterinary Medicines

**Information sheet and application form for registration or variation of registration of a veterinary medicine.**

Send signed completed application to:
Agricultural Compounds and Veterinary Medicines Group
New Zealand Food Safety Authority
Post Office Box 2835
Wellington, New Zealand

## Part A: General Information

### 1 Trade name of the veterinary medicine

### 2 Registration number (if assigned)

### 3 Registrant details

| | | |
|---|---|---|
| Name: | | |
| Postal address: | | |
| Street address (if different from above): | | |
| Tel: | Fax: | E-mail: |
| Contact name: | | |

### 4 NZ agent (complete if different from above)

| | | |
|---|---|---|
| Name: | | |
| Postal address: | | |
| Street address (if different from above): | | |
| Tel: | Fax: | E-mail: |

### 5 General use claim (brief summary of approved and proposed claims)

### 6 Warnings and contraindications

(in ballpoint pen)
Product name:
Initials & date:

**7 Manufacturer(s) of the formulated product** (complete for each manufacturer)

Company name:

Postal Address:

Street Address of manufacturing plant (if different from above):

**8 Has the manufacturer of the formulated veterinary medicine been notified to the ACVM Group? Y/N**

If not, please advise your manufacturer to obtain an Application for Approval to Manufacture Agricultural Compounds and Veterinary Medicines from the ACVM Group's website (www.nzfsa.govt.nz/acvm/).

**9 Has the product been imported unfinished for repacking or relabelling? Y/N**

These products are defined to include any formulations, bulk products, unlabelled products and products that are labelled with foreign labels that need to be relabelled to complete them for sale as a registered product in New Zealand.

**10 Active ingredient(s) and concentration (in g/L or g/kg)**

**11 Date of first licence/registration issue**

Expiry date (if applicable)

**12 Product type**

Select a product type from Attachment 2,
*ACVM Registration Information Requirements for Veterinary Medicines in New Zealand*.

**13 Administration method**

Select an administration method from Attachment 3,
*ACVM Registration Information Requirements for Veterinary Medicines in New Zealand*.

**14 Formulation type**

Select a formulation type from Attachment 4,
*ACVM Registration Information Requirements for Veterinary Medicines in New Zealand*.

**15 Use of veterinary medicine**

Delete those that do not apply. State species. See Glossary, *ACVM Registration Information Requirements for Veterinary Medicines in New Zealand* for definitions.

- Companion animal
- Food producing animal
- Vertebrate pest control
- Other

**16 Details of use**

Include host(s), target organism(s), dose rate(s) and dose timing. This information may be inserted here or the label may be referenced (see #23).

(in ballpoint pen)
Product name:
Initials & date:

## 17 Packaging

Give details of the packaging in which the final formulated product is marketed. Include pack sizes and construction of the container.

## 18 Withholding period

## 19 Approved shelf life of formulated product

## 20 Does your product contain an ingredient originating from an organism (e.g. plant, animal, fungus etc.)? Y/N

If product is being imported, include a biosecurity clearance (contact details in Attachment 5, *ACVM Registration Information Requirements for Veterinary Medicines in New Zealand*). If one has been provided with a previous application and is still valid, this may be referenced.

## 21 Does the product contain a viable new organism, including GMOs? Y/N

## 22 Physico-chemical properties of the formulated product

- Flashpoint:
- Oxidising properties:
- Corrosive properties:
- Acidity/alkalinity (pH):
- Density (specific gravity):

## 23 Attach copies of current label or draft label content

Three copies are required for applications for registration or variation of registration.

(in ballpoint pen)
Product name:
Initials & date:

# PART B: Commercially Sensitive Information

**This information is required as part of the Product Datasheet for use by the ACVM Group. Information in Part B will not be placed on the Public Register.**

## 1 Manufacturer(s) of the active ingredient(s)

Complete for each active ingredient and for each manufacturer if more than one manufacturer

| |
|---|
| Active Ingredient and Technical Grade Purity: |
| Company name: |
| Postal address: |
| Street address (if different from above): |

## 2 Active ingredient impurities

List all impurities present in the active ingredient(s) at levels greater than or equal to 0.1%, and less than 0.1% for toxic/ecotoxic impurities. List impurities present at any level where the toxicity/ecotoxicity is unknown.

## 3 Components that are organisms

This information may be provided as an attachment if required.

List the following if applicable:

- systematic name and strain of the bacteria, protozoa, fungi, Rickettsia, nematode or virus and the taxonomic description of the agent, serotype, strain or mutant;
- common name or alternative and superceded names;
- composition of the unformulated material, microbiological purity, nature and identity of any culture media, impurities and content of extraneous organisms.

## 4 Formulation details

Provide details of the full composition of the final formulated trade name product in the table below:

**Ingredient name:** Enter the accepted ISO common name or IUPAC name for the active ingredient or where this has not been established, provide the chemical name. **If trade name products are used as an ingredient, please provide full formulations** of all trade name products used, or arrange to have complete formulations sent directly to the ACVM Group by the supplier.

**CAS number:** Enter the CAS registry or colour index number, where assigned.

**Quantity:** The concentration of all ingredients must be provided.

- Chemical-based formulations are to be expressed in **g/litre for liquids** and **g/kg for solids.**
- Biological-based formulations are to be expressed in appropriate international units ensuring consistency.

(in ballpoint pen)
Product name:
Initials & date:

**Function:** Describe the purpose for each of the ingredients, e.g. active ingredient, emulsifier, surfactant, filler etc. Definitions can be found in the Glossary, *ACVM Registration Information Requirements for Veterinary Medicines in New Zealand*. Do not use 'inert'.

| **Ingredient name (common or chemical)** | **CAS number** | **Quantity** (g/kg or g/L) | **Function** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
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| | | | |

NB: If the application includes a formulation change, include currently registered and proposed formulations

(in ballpoint pen)
Product name:
Initials & date:

# Part C: Registration and Product Datasheet Declaration

The information being collected is required by the Agricultural Compounds and Veterinary Medicines Group to support the:

- new registration; or
- variation of existing registration.

The agency collecting and holding this information is:

Agricultural Compounds and Veterinary Medicines Group
New Zealand Food Safety Authority
Post Office Box 2835, WELLINGTON

A copy of this information may be provided to the Environmental Risk Management Authority (ERMA NZ).

You have the right of access to, and correction of, personal information supplied in this form as provided by the information privacy principles in section 6 of the Privacy Act 1993.

All information provided is subject to the Official Information Act 1982. Specific protection is provided to Confidential Supporting Information under sections 73, 74, 109 and 121 of the ACVM Act.

## Declaration

I declare that all information in this Registration and Product Datasheet that I have provided in support of this application for registration or variation of registration is true and correct.

**(For Consultants/New Zealand Agent use only)**
I declare that I, (*insert name*) have been given authorisation from (*insert name of company*) to act on their behalf and declare that all information in this Registration and Product Datasheet provided by me in support of this application for registration or variation of registration is true and correct.

Signature: _____

Name: _____

Date: _____

(in ballpoint pen)
Product name:
Initials & date:

# Part D: Application Information for Registration of a Veterinary Medicine

## 1 Fees (For details, see the ACVM Group website: www.nzfsa.govt.nz/acvm/)

Payment of prescreen fee

☐ cheque enclosed $_____

☐ approved creditor (invoice)

Payment of registration application fee for application type _____

☐ cheque enclosed $_____

☐ invoice

☐ approved creditor (invoice)

**Make cheques payable to NZFSA.**

## 2 Application type

New registration: (select one if the application is for a new trade name product [TNP])

A1 – New active ingredient (a.i.)
A2 – Registered a.i., new risk profile

B1 – Identical to existing TNP
B2 – Similar to existing TNP

Variation to an existing registration: (select one or more if the TNP is already registered)

C1 – Formulation change
C2 – Manufacturing change
C3 – Shelf-life, storage/packaging change
C4 – Additional target species
C5 – Additional disease/condition
C6 – Change in dose regime
C7 – Change in method of administration
C8 – Withholding period change
C9 – Administrative change

## 3 Overseas regulatory status

List countries where the product is already registered.

(in ballpoint pen)
Product name:
Initials & date:

## 4 Is this product a hazardous substance or new organism? Y/N

If yes, please note that, although we can process your application, we can issue registration for a TNP only after a copy of the relevant ERMA NZ approval has been provided. If no, supply:

(a) a signed declaration stating that the substance is not hazardous (see Attachment 7, *ACVM Registration Information Requirements for Veterinary Medicines in New Zealand*.); or

(b) advice from ERMA NZ that the trade name product is not a hazardous substance or new organism by providing:
   1. status of substance (SOS) advice; or
   2. s26 determination; or

(c) advice from ERMA NZ that the substance is covered by an existing approval (legally existing).

## 5 Registration consultant (if used to help prepare this application)

| | | |
|---|---|---|
| Name: | | |
| Postal address: | | |
| Street address (if different from above): | | |
| Tel: | Fax: | E-mail: |

## 6 Data package reviews provided? Y/N

A Data Package Review is provided for all data volumes submitted. The application may be returned during the prescreen process if not submitted.

## 7 Overall application summary provided? Y/N

An overall application summary must be provided with each volume.

## 8 Confidential information

Where information is confidential, ensure that you have contacted the manufacturer/ supplier to arrange for information to be supplied to us directly.

## 9 Checklist

Applications **must** always contain:

- ☐ Covering letter
- ☐ Registration and Product Datasheet form (including signed Part C)
- ☐ Fee
- ☐ Clear identification of confidential supporting and/or commercially sensitive information.

Include **if applicable**:

- ☐ Draft labels (3 copies)
- ☐ Letter of authorisation for registration consultant
- ☐ Letter of consent (CSI if applicable)

(in ballpoint pen)
Product name:
Initials & date:

☐ Data volumes for:

Chemistry and Manufacturing (Volume 1)
Residues (Volume 2)
Efficacy (Volume 3)
Safety (Volume 4)
Toxicology (Volume 5)

☐ HSNO requirements:

The following must be provided prior to issuing a registration for the trade name product.

- ☐ a declaration signed by the applicant stating that the trade name product is not a hazardous substance; or
- ☐ a determination from ERMA NZ that the trade name product is not a hazardous substance or new organism; or
- ☐ an appropriate ERMA NZ approval for the trade name product.

(in ballpoint pen)
Product name:
Initials & date:

# ATTACHMENT 2

## Definitions of Product Types

Use the definitions provided below to help determine your product type.

**Anaesthetic:** Any drug or agent administered to bring about partial or complete loss of sensation, and to achieve adequate muscle relaxation during surgery.

**Analgesic:** Any drug or agent administered to relieve the sensation of pain.

**Antibiotic:** Any drug or agent based on a chemical substance produced by a micro-organism that has the capacity to kill, or inhibit growth of other micro-organisms (includes sulphonamides).

**Anticonvulsant:** Any drug or agent that inhibits convulsions by depressing the central nervous system. (This can include specific motor depressants, or narcotics and sedatives.)

**Antidote:** Any agent that counteracts the effect of a poisonous substance or drug. These can be chemical, physiological, mechanical or universal agents. (This class will include anti-toxins, anti-sera and reversal agents.)

**Antifungal:** Any agent administered to destroy or suppress the growth of fungi.

**Anti-inflammatory:** Any agent administered to reduce the inflammatory response to infection, trauma, surgery or musculoskeletal disease.

**Antimicrobial:** Any agent (usually chemical) administered to destroy micro-organisms, or suppress their multiplication and growth.

**Antiprotozoal:** Any agent administered to destroy protozoa, or suppress their multiplication and growth.

**Behaviour modifier**: Any agent administered to regulate behaviour patterns (includes psychotropic/tricyclics).

**Bloat remedy:** Any agent administered to alleviate tympany of the rumen, abomasum, stomach or caecum.

**Cardiovascular agent:** Any agent administered to alter or enhance the activity of the cardiovascular system (includes ionotropes, vasodilators, etc.).

**Coccidiostat:** Any agent administered to destroy coccidia or suppress their multiplication and growth (usually in the form of a feed additive).

**Ectoparasiticide:** Any agent administered to destroy external parasites or suppress their multiplication and growth.

**Endocrine agent (hormone):** Any agent administered to regulate or enhance the activity of the endocrine system.

**Endoparasiticide:** Any agent administered to destroy internal parasites or suppress their multiplication and growth.

**Euthanasia agent:** Any agent administered to cause humane death by cessation of cardiac and central nervous system activity.

**Gastrointestinal tract modifier:** Any agent administered to alter or enhance the activity, motility or secretions of the gastrointestinal tract (includes probiotics).

**Hormonal growth promotant :** Any hormone administered to influence protein, carbohydrate and lipid metabolism to control or alter the rate of skeletal and visceral growth.

**Musculoskeletal modifier:** Any agent administered to influence the activity of the musculoskeletal system (includes polysulphated aminoglycans).

**Oral nutritional compound:** Any substance ingested by an animal as feed, or a nutritional preparation intended for oral administration to an animal to achieve a nutritional benefit.

**Parenteral nutrient/electrolyte:** Any substance containing ions which are essential to the normal function of cells, or that provides nourishment from minerals, vitamins, fats, protein, carbohydrates and water administered in an injectable formulation.

**Renal and urinary tract modifier:** Any agent administered to alter or enhance the function of the kidneys or urinary tract (includes pH modifiers).

**Respiratory tract modifier:** Any agent administered to alter or enhance the function of the respiratory tract (includes bronchodilators, antitussives etc.).

**Sedative:** Any agent administered to depress the activity of the central nervous system to calm nervousness, irritability and excitement (includes pre-anaesthetic agents).

**Skin/coat conditioner:** Any agent administered solely to improve or enhance condition of the skin and coat.

**Vaccine:** Any suspension of attenuated live or killed micro-organisms (bacteria, viruses or rickettsiae administered for prevention, amelioration or treatment of infectious diseases.

**Vertebrate poison**
A trade name product used to control an unwanted mammal, bird, reptile, amphibian, or fish.

# ATTACHMENT 3

## Administration Methods

Bolus
Collar
Dip
Implant
Inhalation
Intra-aural
Intrauterine
Intramammary
Intranasal
Injectable (also select one of the following)
Intramuscular (IM), Intravenous (IV), Subcutaneous (SC)
Epidural
Intra-articular
Intradermal
Interosseous
Intraruminal
Intratumoural
Oral
Ocular
Scarification
Spray
Topical
Other (please specify)

# ATTACHMENT 4

## Definitions of Formulation Types

| | |
|---|---|
| **Aqueous solution or suspension:** | A formulation of particles dissolved or suspended in water. |
| **Block (salt lick)**: | A prepared mixture of salt and minerals formed into blocks for oral consumption by groups of animals as a feed supplement. |
| **Bolus:** | A rounded concentrated mass of pharmaceutical or nutritional preparation ready to be swallowed. |
| **Capsule**: | A soluble structure containing a dose of a pharmaceutical preparation. |
| **Cerate:** | A pharmaceutical preparation of wax-like consistency, usually for topical intramammary use. |
| **Cream**: | An oil in water emulsion generally used topically in the treatment of skin disease. |
| **Gel:** | A colloid of firm consistency, although containing much liquid. |
| **Granule:** | Solid formulation comprising small particles usually for administration without further dilution. |
| **Impregnated material**: | Any solid pharmaceutical preparation inserted into intact tissues or body cavity (includes HGPs and CIDRs). Also includes collars. |
| **Oily solutions or suspension:** | A colloid mixture of two immiscible liquids, one dispersed throughout the other in small droplets. |
| **Ointment:** | A semi-solid pharmaceutical preparation usually for topical application. |
| **Paste:** | A highly viscous pharmaceutical preparation containing a large amount of powder. |
| **Powder:** | An aggregation of fine particles usually obtained by grinding. |
| **Syrup:** | A viscous concentrated solution of a sugar used as a vehicle for medications. |
| **Tablet/pellet:** | A small solid pharmaceutical preparation usually for oral administration. |
| **Vapour releasing product:** | A formulated product containing one or more volatile ingredients, the vapours of which are released into the air. Evaporation rate normally is controlled by using suitable formulations and/or dispensers. |

# ATTACHMENT 5

## Contacts

**1 Agricultural Compounds and Veterinary Medicines Group (ACVM Group)**

For any information concerning registration of a veterinary medicine please contact the ACVM Group on:

Phone: +64 4 463 2550 or DDI
Fax: +64 4 463 2566
E-mail: [user id]@nzfsa.govt.nz or acvm@nzfsa.govt.nz
Website: (http://www.nzfsa.govt.nz/acvm/)

**Sending an application**

Mail to: Agricultural Compounds and Veterinary Medicines Group
New Zealand Food Safety Authority
Post Office Box 2835
Wellington
New Zealand

or deliver to: Agricultural Compounds and Veterinary Medicines Group
86 Jervois Quay (South Tower)
Wellington
New Zealand

**Correspondence**

All correspondence between the ACVM Group and an applicant must be correctly dated and include:

- the approved veterinary medicine trade name or its proposed trade name;
- the registration number (if known); and
- the contact person, position, telephone and fax numbers.

Correspondence may be sent by facsimile, letter or e-mail.

## 2 Biosecurity Clearances

Ingredients of plant or animal origin that are contained in imported veterinary medicines must meet relevant import health standards under the Biosecurity Act 1993. Confirmation that the ingredients meet the standard may be obtained from the:

National Manager Import Management, Animal Biosecurity
Plants Import Section, Plant Biosecurity Group **OR**
Import Management Section, Animal Biosecurity Group
Biosecurity Authority
Ministry of Agriculture and Forestry
Post Office Box 2526
WELLINGTON
Ph: +64 4 498 9624

## 3 Environmental Risk Management Authority

For applications for products containing a new organism or hazardous substance contact:
The Operations Manager
Environmental Risk Management Authority
Post Office Box 131
WELLINGTON
Phone: +64 4 973 8426
Fax: +64 4 973 8433

# ATTACHMENT 6

## Publications

A list of the titles of documents referred to in this guide as well as useful reference material are listed below. Documents are available on our website (www.nzfsa.govt.nz/acvm/). Others can be obtained from the sources noted below.

There are documents still to be published. As these are finalised, they will be published on the website. Notification of upcoming documents will be given in *AgVetLink*.

**Information Requirements, Standards and Guidelines**
*ACVM Registration Information Requirements for Veterinary Medicines in New Zealand*
*ACVM Registration Information Requirements for Provisional Registration*
*ACVM Information Requirements for Research Approval*
*ACVM Overview of Specified Requirements Products*
*ACVM Specified Requirements Products Standard and Guideline*
*ACVM Registration Standard and Guideline for the Chemistry of Veterinary Medicines*
*ACVM Standard for Good Manufacturing Practice*
*ACVM Guideline for Good Manufacturing Practice*
*ACVM Research Standard*
*ACVM Standard for Oral Nutritional Compounds*
*ACVM Standard and Guideline for the Determination of a Residue Withholding Period for Veterinary Medicines*
*ACVM Registration Standard and Guideline for Target Animal Safety*
*ACVM Registration Standard and Guideline for Therapeutic Equivalence of TNPs*
*ACVM Registration Standard and Guideline for Efficacy of Anticoccidials in Poultry*

**Labelling**
*New Zealand Labelling Guide for Veterinary Medicines Requiring Registration*
Definition of terms for use on parasiticide labels in New Zealand
(available from the ACVM Group)

**Forms**
Forms are available at www.nzfsa.govt.nz/acvm/

***AgVetLink***
To be added to the mailing list please contact the ACVM Group.
This publication is also available on the ACVM Group website.

# ATTACHMENT 7

## Non-Hazardous Declaration

## [Company Letterhead]

(trade name), as formulated in accordance with the attached product datasheet, is not a hazardous substance and does not exceed any thresholds prescribed in the Hazardous Substances Minimum Degrees of Hazard Regulations 2001.

Signature:
Date: