Operating Plans Relevant to the Agricultural Compounds and Veterinary Medicines Act 1997: Guidelines

ACVM Information Requirements 19

Prepared for Approvals and ACVM Group

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1 Introduction

You must have a quality system and lodge it with MAF as an operating plan for approval under section 28 of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997:

- when having and complying with an approved operating plan is a condition of registration of a trade name product (section 23); or
- when having and complying with an approved operating plan is a condition of exemption from registration, including an approval in special circumstances under section 8C.

The statutory basis for approving operating plans and an explanation of circumstances when such plans are required is set out in Approval of Operating Plans under Section 28 of the ACVM Act (link below).

1.1 PURPOSE AND SCOPE

This document provides guidance on the minimum information that must be provided in an approved operating plan and covers:

- specifications for operating plans that require approval under section 28;
- suggested ordering of content of an operating plan;
- preparing operating plans for specific activities;
- maintenance requirements and responsibilities;
- consequences of non-compliance.

1.2 DEFINITIONS

Approved operating plan
A documented quality system that is approved as an operating plan under section 28 of the ACVM Act. The plan describes how a person (or an organisation) intends to meet a particular statutory obligation such as the condition of registration for the sale of a restricted veterinary medicine (RVM). The term is used only in reference to an obligation in a condition of registration or condition of exemption from registration that requires the operating plan to be approved by MAF.

Documented quality system
A collection of documents (work instructions, procedures, tasks etc) that describe how tasks are carried out (for example, manufacture, use, sale)

1.3 REFERENCES

Agricultural Compounds and Veterinary Medicines Act 1997 (External website)

Agricultural Compounds and Veterinary Medicines Regulations (External website)

Approval of Operating Plans under Section 28 of the ACVM Act: Operational Interpretation 189 (113 KB PDF)

2 How to apply for approval of an operating plan

With the exception of the templates for sellers of restricted veterinary medicines (RVMs), registrants of hormonal growth promotants (HGPs), and for manufacturers operating under GMP, there is no specific application form for requesting approval of an operating plan. Other requests for approval of an operating plan should be in the form of:

- a covering letter to the Approvals and ACVM Group Director requesting approval under section 28 of the ACVM Act; and
- a copy of the plan to be assessed.

MAF will not specify the form of the operating plan because the plan is likely to be unique to the owner and may cover more than one activity. The plan should take a form that is most useful to the owner and suit the owner's management structure and operating systems.

2.1 COVERING LETTER

The covering letter must provide sufficient detail to allow the request to be considered in the context of the ACVM Act. Any unique characteristics about the plan must be explained to facilitate its assessment. The covering letter should clearly state:

- what activities the plan covers;
- the reason why it needs to be approved (for example, to meet specific conditions of registration or exemption from registration requiring approved operating plans).

2.2 GENERAL REQUIREMENTS OF AN APPROVED OPERATING PLAN

A single plan can cover more than one activity but the activities must be carried out by or be under the control of the plan's owner. Each part of the operating plan that deals with a different activity should contain all the requirements as if that activity were covered by a stand-alone operating plan. However, if general matters such as organisational structure are equally relevant to all the activities, that material can be included once with cross reference to it in other parts of the plan.

If a plan covers matters that are not directly relevant to the ACVM Act, the approval under the ACVM Act applies only to the relevant ACVM content. We will assess the plan and identify the parts we consider relevant to the ACVM Act and for which the approval will be given. All other aspects of the operating plan will be irrelevant to the approval and the owner should not state or imply that MAF has approved those other aspects.

The owner can decide the title of the document. It can be called a standard, guideline, code of practice or code of conduct, but the MAF approval will refer to it as an operating plan.

If the operating plan is written specifically for a particular group/use/crop/species, the approval will specify the purpose for which it has been approved.

2.3 CONTENT OF AN OPERATING PLAN

An operating plan must state the owner of the plan and a point of contact. It must also provide identification and document control information for the plan itself.

The plan must clearly state its purpose and the scope of the processes/activities that are to be governed by the specifications.

The consequences of not complying with the plan must be explained and the reader of the plan must be warned where non-compliance would result in breaches of the statutory conditions of the ACVM Act.

There must be enough detail in the plan to show:

- all critical steps in the process/activity, and the circumstances when changes to these steps need to be validated;
- who would be subject to the plan and what their responsibilities are;
- how personnel involved in the process/activity are and will continue to be appropriately qualified and trained;
- premises and space are suitable for the process/activity undertaken;
- authorisation, purchasing, distribution and dispensing systems are specified;
- any equipment and services are suitable for the process/activity undertaken;
- security is adequate to ensure the integrity of the process/activity and prevent diversion, inappropriate disposal and unapproved dispatch of product or produce;
- records made (manually and/or by recording instruments) during the process/activity demonstrate that all the required steps were followed. Any significant deviations must be fully recorded and investigated to determine if there had been an adverse effect on the product/activity;
- complaints regarding the process/activity are investigated and appropriate corrective action taken to prevent recurrence.

3 Suggested ordering and content for an operating plan

1. Title

2. Owner and contact information

3. Purpose for the operating plan

- Reference to the ACVM regulatory requirement the operating plan is to meet:
  - which conditions of registration
  - which conditions on exemption from registration
  - certificate of compliance
- State if the operating plan is **not** intended to meet a specific ACVM regulatory requirement.

4. Scope

- What activities are covered under the operating plan:
  - manufacturing products or types of product (registered veterinary medicine)
  - manufacturing export-only agricultural compounds or veterinary medicines
  - selling restricted products (restricted veterinary medicine [RVM], restricted vertebrate toxic agent [RVTA])
  - RTTO holding and using restricted veterinary medicines
  - RTTO carrying out research, testing or training using substances not specifically authorised;
  - RTTO importing or manufacturing substances not specifically approved
  - using RVMs requiring authorisation for purchase and use via an approved operating plan.
- What agricultural compounds are involved

5. Organisation/administration structure and lines of control (if applicable)

6. Designated personnel and responsibility

- Personnel
- Training

7. Premises and equipment

- Calibration and monitoring

8. Process description

- Process flowchart
- Product or performance measures/quality or performance control
- Non-compliance/remedial action plan

9. Documentation and records

- Process records
- Quality or performance control records
- Non-compliance/ remedial action records
- Reporting and reports

10. Plan review and notification to MAF of change

4 Preparing operating plans for specified functions for approval under section 28

The following are the most common types of operating plans that require approval under the ACVM Act, so specific guidance is given here. This is not a complete list of types. If the type of plan you require is not listed, use the basic requirements listed above to develop your plan. If you have any questions on what to include in your plan, contact the ACVM Group.

4.1 MANUFACTURERS OF VETERINARY MEDICINES

The manufacturing operating plan, comprising of the documented quality system, must be officially approved by MAF under section 28 of the ACVM Act. Refer to:

Application for Approval to Manufacture Veterinary Medicines

4.2 MANUFACTURERS OF EXPORT ONLY VETERINARY MEDICINES

The manufacturing operating plan, comprising of the documented quality system, must be officially approved by MAF under section 28 of the ACVM Act if you expect MAF to issue official assurance for the trade name product(s) manufactured for export. If the export-only products are manufactured at the same plant where veterinary medicines authorised for sale and use in New Zealand are also manufactured we will expect there is a documented quality system that states how the export-only products are segregated and excluded from the authorised products. Refer to:

Application for Approval to Manufacture Veterinary Medicines

4.4 RESEARCH, TESTING AND TRAINING ORGANISATIONS (RTTOS)

A research, testing or training organisation must have an approved operating plan if the organisation is:

- importing, manufacturing, purchasing, supplying and using restricted veterinary medicines for research, testing and training purposes without specific veterinary authorisation;
- carrying out research, testing or training with an agricultural compound under an approval in special circumstances issued under section 8C of the ACVM Act.

The minimum requirements for an approved operating plan for RTTOs to carry out any of these activities are:

- The operating plan must specify how protocols for use of agricultural compounds for research, testing or training activities are to be issued by a manager/officer of the organisation. It must set out organisational responsibilities and the specifications for the process/activity, the critical control points and the parameters to be inspected, tested, measured, and/or recorded to confirm compliance with the specifications in the relevant protocols.
- There must be a system of administration orders that authorise parties to carry out specified steps in each protocol.
- There must be security arrangements that ensure that only persons authorised in RTTO protocols have access to and use the agricultural compounds as specified.

- There must be specifications in each protocol on how animals and plants exposed to the agricultural compounds, and the produce harvested from those animals or plants, are to be dealt with to give effect to conditions on the quality system/plan authorisations.
- The plan must specify what agricultural compounds are to be used, giving effect to any prohibitions or restrictions imposed on them or the process/activity.
- There must be record keeping specifications and arrangements to ensure that there is appropriate and adequate evidence that specifications for the process/activity have been met.

If registered trade name products are used in the research, testing or training, the conditions of registration will specify if MAF approval of the operating plan is required.

For more information, see:

FAQ - operating plans for RTTOS

4.5 SELLERS OF RESTRICTED PRODUCTS

The operating plan is prepared by the entity that is selling or intends to sell the restricted veterinary medicines (RVMs). The plan contains specific information about how it operates on a day to day basis in compliance with the conditions of registration on such products.

Veterinarians selling RVMs only in the course of their professional practice for animals under their care are not required to have an approved operating plan. Refer to:

RVM sellers operating plan template

4.6 REGISTRANTS OF HORMONAL GROWTH PROMOTANTS (HGPS)

An operating plan is required by registrants of hormonal growth promotants. Refer to:

Operating Plan Guidelines for Hormonal Growth Promotants (link to be added)

4.7 OPERATING PLANS REQUIRED TO MEET A CONDITION OF REGISTRATION OF SOME RESTRICTED TRADE NAME PRODUCTS

The conditions of registration for some products will specify that an operating plan is required. This may be to control distribution or use (as in the case of exotic disease vaccines). The conditions will specify what the operating plan should relate to. The ACVM Group will discuss specific requirements on a case by case basis.

5 Maintenance of approved operating plans

Once approved, the title of an approved operating plan will be maintained on a list for MAF administrative purposes only. Where required, lists may also be published on MAF's website, such as the lists of approved GMP manufacturers and of sellers of RVMs with an approved operating plan.

The plan's owner will be responsible for maintaining, reviewing and amending the plan. However, if MAF receives information that indicates the plan needs amendment (or revocation), then we will consult with the owner first, before taking any action.

The owner or their delegate will be responsible for the use of the plan and implementing whatever training may be necessary to give effect to the plan.

The owner will be responsible for making arrangements for any monitoring/auditing of practices specified in the plan.

MAF will investigate all suspicions or allegations of non-compliance with an approved operating plan where compliance to the plan is compulsory in the ACVM Act.

Amendments proposed by the owner to any approved part of the plan must be notified to MAF. MAF will determine whether or not the plan amended as proposed should retain MAF approval. If the proposed amendment is determined by MAF to mean the approval is no longer appropriate, the owner will be advised if any changes are appropriate to retain the approval, or if approval is no longer required.

If the plan is no longer appropriate the owner will be advised of what changes would be required to make it acceptable. If the changes suggested are unacceptable to the owner, approval will be revoked and the plan will be removed from the MAF administrative list of approved operating plans. If this happens, further performance of the specified activity may be an offence.

We will review the status of all approved operating plans every three years (or sooner if there are significant changes to the ACVM standards or conditions) to ensure that they continue to be appropriate.

MAF must be notified of any event that does not meet the plan's specifications if this results in a breach of the conditions of authorisation of an agricultural compound or prescribed conditions.

6 Consequences of not complying with approved operating plan requirements

If conditions of registration or exemption from registration impose an obligation to comply with an approved operating plan, then failure to do so is an offence that, upon conviction, may result in fines and/or imprisonment, and possibly the loss of the relevant authorisation for the agricultural compounds involved.

For fees and charges, see website.

For more information, contact us.