

ISBN 0-478-07780-7

55 ACVM 11/03

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**ACVM  
OPERATIONAL PROCEDURES STANDARD  
2: THE USE OF VETERINARY  
AND HUMAN MEDICINES BY  
NON-VETERINARIANS GENERALLY**

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**Endorsement:**

**Date:**

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# ACVM OPERATIONAL PROCEDURES STANDARD

## 2: THE USE OF VETERINARY AND HUMAN MEDICINES BY NON-VETERINARIANS GENERALLY

### 1 INTRODUCTION

An Operational Procedure (OP) is a set of veterinarian-endorsed instructions relating to the administration of medicines by authorised non-veterinary personnel to animals under the care of a supervising veterinarian. The OP is necessary to ensure such administration is based on criteria that describe best practice and ensure risks to animal welfare are negligible.

In general, an OP is required for all use of prescription animal remedy (PAR) Class II products where a veterinarian is not present and may be required for PAR I medicines where repeat prescriptions are provided for ongoing management following an initial consultation. OPs are not necessary where prescribing immediately follows a consultation.

In addition, OPs can be useful for providing the risk management required for the veterinary discretionary use of PAR I products, compounded products or human medicines where the label is not adequate. An OP may be approved by the ACVM Group (at the request of the initiator) to confirm compliance with the relevant ACVM standard and/or conditions.

Examples where OPs are likely to be required are:

- All use of PAR II veterinary medicines where a veterinarian is not present, such as use by veterinary nursing staff for premedication or in an emergency.
- Use of PAR I veterinary medicines for ongoing animal management programmes where a consultation has occurred. This includes use for routine surgical procedures, such as laproscopic AI, or where specialist services are being provided from a geographically distant location under an approved code of practice.

OPs should be considered in the following situations:

- Where a consultation is of a generic nature, such as the provision of PAR I medicines for routine use, especially where a number of disease conditions and use patterns are required.
- To manage use and information requirements needed for 'off label' use and the use of formulated medicines.

**The veterinarian providing endorsement of the OP is responsible for supervising the administration of PAR medicines by the personnel authorised to do so in the OP.**

**In the case of PAR II and controlled medicine equivalents, the OP must be robust enough to provide a level of control over the administration of the medicines equivalent to that achieved if the veterinarian were present in the room.**

**The veterinarian is responsible for ensuring the personnel named in the OP are trained to the appropriate standard.**

**The OP must not be used to authorise the use of PAR III medicines by non-veterinary personnel.**

This document incorporates guidelines, which are intended to provide more detailed information and guidance to applicants to assist them in complying with these requirements.

The requirements are shown in this document in **bold font**, while the guidelines are in regular font.

## **1.1 Scope**

**All persons must follow this standard when composing an OP.**

The standard provides an indication of the detail expected in the OP.

## **1.2 Definitions and abbreviations**

### **Adverse event (AE)**

Any observation that is unfavourable and unintentional that occurs in an animal following treatment with a medicine.

### **Expected treatment outcome (ETO)**

The therapeutic response predicted and intended to occur in an animal following treatment with a medicine.

### **Procedure register (PR)**

A detailed record of all medicine used according to the OP in individual procedures that must be updated at the end of each use period throughout the life of the procedure.

### **Review date**

The date nominated at genesis by which the content of the OP must be assessed and veterinarian-endorsed as adequate for renewal.

**Undesirable treatment outcome (UTO)**

A therapeutic response at variance with the predicted and intended therapeutic response in an animal following treatment with a medicine.

**Use period**

A discrete duration of medicine use defined as commencing with the removal of medicine from secure storage and ending upon its return.

**Veterinary discretionary use**

- The use by, or on the authority of, veterinarians of registered or exempt veterinary medicines in a manner not specified in the other conditions that apply to those veterinary medicines under the ACVM Act; or
- The use by, or on the authority of, veterinarians of human medicines scheduled under the Medicines Act 1981 in accordance with the conditions of Schedule 2 of the ACVM Regulations 2001; or
- The use of preparations by, or on the authority of, veterinarians that have been specifically compounded by, or on the authority of, that veterinarian in accordance with the conditions of Schedule 2 of the ACVM Regulations 2001, for use on animals in that veterinarian's immediate care.

## 1.3 References

- Agricultural Compounds and Veterinary Medicines Act 1997
- Agricultural Compounds and Veterinary Medicines Regulations 2001
- ACVM standards (refer [www.nzfsa.govt.nz/acvm](http://www.nzfsa.govt.nz/acvm))

# SECTION A: TECHNICAL CONTENT

## 2 IDENTIFICATION AND LIFE OF THE OPERATIONAL PROCEDURE

- 2.1 Each OP must be uniquely identified and linked to the reason for its existence.**  
Any other information considered appropriate by the institution or veterinarian to ensure an OP remains uniquely linked to the purpose for which it was designed should be included.
- 2.2 The OP must have a commencement and end or review date. All OPs will be valid for a maximum period of twelve months from the date of commencement or last review.**
- Wherever possible, an end date should be included.
  - Where the end date is not known or will fall outside twelve months of the commencement date, a review date should be stated after which time the OP will be considered invalid if not reviewed and re-endorsed by the supervising veterinarian.
  - The review should consider issues such as staff changes and changes to recognised best technique or choice of veterinary medicine.
- 2.3 Operating instructions must be documented.**
- 2.4 To be valid an OP must be endorsed by the responsible veterinarian.**

## 3 REASON FOR THE OPERATIONAL PROCEDURE

**A concise outline of the reason for the OP must be provided. This must include a summary of the aim(s) of the procedure and the reason for the involvement of the medicines.**

- Enough information should be supplied to enable the user of the OP to understand why the medicines are being used.
- Excessive detail is not required or expected.

## 4 PERSONNEL

- 4.1 The veterinarian who has endorsed the OP and is responsible for overseeing the procedure must be named and must sign the document.**

- 4.2 All staff members authorised to use the OP must be named, their responsibilities defined, and the skill or qualification levels required by them must be specified.**
- **Skills or qualifications required must be at least the minimum necessary to enable competent use of medicines on animals, as directed by the veterinarian.**
  - Where institution specific qualifications are nominated as appropriate levels of training, these should be veterinarian-endorsed as appropriate and available for audit.
- 4.3 Where there is a chain of command, this must be clearly stated.**

## **5 ANIMALS**

**The animals to which the OP applies must be clearly identified.**

Minimum information required, if known:

- Species/Breed
- Gender
- Age
- Weight (actual or estimated)
- Method of identification
- Location
- Number.

Any other information considered pertinent to the OP should also be stated. This would include any reasons for non-inclusion.

## **6 MEDICINES AND EQUIPMENT**

**6.1 All medicines to which the OP applies must be named and described. Only medicines named may be used.**

The name (trade name or generic), strength (if appropriate, e.g. Acepromazine 10%), formula type (e.g. tablet), product type (e.g. anaesthetic) and classification (e.g. PAR or human) of each medicine should be stated.

**6.2 Precise details of medicine administration must be stated and must include preparation required (where applicable), dose, administration technique and site(s) of administration (where applicable).**

- Preparation includes anything necessary to prepare the medicine for administration.
- Obvious instructions, such as removal from packaging, do not need to be stated.
- Dose should be stated as mg/kg and, where appropriate, ml, gm or tablets/kg.
- Information regarding administration technique and sites of administration should be detailed enough to ensure correct administration will occur. Techniques that are referenced to institutional standard operating procedures should be veterinarian-approved as appropriate and available for audit by a third party.

**6.3 All equipment and/or techniques necessary to achieve medicine administration and the method of their disposal must be stated if such equipment or techniques are not specified elsewhere.**

- Such equipment may include restraint devices considered appropriate, e.g. head bails, twitches, crushes, nets etc. and equipment used to administer the medicines.
- Where any such equipment or technique may be specifically contraindicated, this should also be stated (e.g. the type of anaesthetic machine to be used).

**6.4 A precise description of the expected treatment outcome (ETO) of medicine administration must be provided.**

- The depth of information required will depend on the medicine and its use, the relevance of the information to the user and the skill level of the user.
- This information is of most importance for drugs with a rapidly achieved end-point, such as anaesthetics, and should be sufficient to enable the target response of medicine administration to be recognised in the treated animal.
- Where skilled technicians are employed, such information can be justifiably brief.

## **7 ADVERSE EVENTS AND UNDESIRABLE OUTCOMES**

**7.1 Anticipated adverse events (AEs) must be stated and categorised into those requiring veterinary intervention and those not requiring veterinary intervention.**

- Expected AEs include incidents such as non-painful small swellings at the site of injection.
- Unexpected AEs would include incidents such as large, painful swellings and skin sloughing at the site of injection.

**7.2 Undesirable treatment outcomes (UTOs) associated with the use of the medicine must be anticipated (where considered possible) and appropriate intervention methods stated.**

- A commonly encountered example of a UTO is a greater depth of anaesthetic plane than would be expected with the dose given.
- Responses to commonly recognised UTOs that are referenced to institutional standard operating procedures should be veterinarian-approved as appropriate and available for audit.

# SECTION B: ADMINISTRATIVE CONTENT

The following section is not considered compulsory for individual veterinary clinic settings; however, it is advisable as best practice. This section is highly advisable in institutional settings.

## 8 STORAGE OF MEDICINES

All medicines used under an OP must be kept in a securely locked room, safe, box or cupboard with one nominated person responsible for access and security.

## 9 RECORD KEEPING

9.1 A detailed protocol or procedure register (PR) must be kept for all medicines used according to the OP. All records must be kept for a minimum of four years. A suggested register page format is appended.

9.1.1 A separate page should be kept for each medicine used and each page should be identified with the name of the medicine and the identification number of the OP.

9.1.2 The PR must be completed after each use period. The use period will depend on the frequency of drug usage. For trial protocols that require ongoing use of drugs on a daily basis, an entry summarising the day's medicine usage should be made in the PR on completion of the day's work before returning the medicines to storage. Where medicines are used infrequently or on a periodic basis, an entry should be made after each use.

9.1.3 Minimum data to be included in the PR are:

- Date of medicine usage;
- Initials or identification code of authorised administrator;
- Reason for use;
- Reconciliation of drug on-hand and drug used.

9.2 Records of all drug purchases and disposals must be kept by the organisation and periodically reconciled with the PR. This should be conducted at least every six months.

9.3 All OPs are subject to an audit by the ACVM Group at any time. An independent party should conduct internal audits annually.

Any amendments made to the OP must be documented and endorsed by an authorised veterinarian and kept with the original OP.

