



Veterinary Operating Instructions

Guidance re: Requirements for Authorising Veterinarians
Notice

28 August 2015

Title

Guidance Document: Veterinary Operating Instructions

About this document

This document provides guidelines for veterinarians to use when issuing veterinary operating instructions (VOIs) for non-veterinarians to use for restricted veterinary medicines (RVMs) or veterinary medicines that are exempt from registration subject to veterinary control. It also includes an appendix with specific guidelines relating to RVMs for deer velvet antler removal.

Related requirements

Requirements for Authorising Veterinarians Notice

Document history

This document replaces:

- Veterinary Operating Instructions (ACVM Guidelines No 65); and
- Xylazine, Yohimbine and Lignocaine for the Purpose of Velvet Antler Removal (ACVM Performance and Technical Standards 1.1)

Contact details

Ministry for Primary Industries (MPI)
Regulation and Assurance Branch
Approvals & ACVM Group
PO Box 2526
Wellington 6140
Email: approvals@mpi.govt.nz

Disclaimer

This guidance does not constitute, and should not be regarded as, legal advice. While every effort has been made to ensure the information in this guidance is accurate, the Ministry for Primary Industries does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

Contents	Page
1 Purpose	3
2 Background	3
3 Definitions	3
4 What is a VOI?	4
5 Guidelines	5
5.1 Identification and life of the VOI	5
5.2 Reason/purpose for the VOI	5
5.3 Personnel	5
5.4 Animals	6
5.5 Veterinary medicines and equipment	6
5.6 Adverse events and unexpected outcomes	7
5.7 Storage of veterinary medicines	7
5.8 Recordkeeping	7
6 Sample forms	9
6.1 VOI template	9
6.2 VOI checklist	10
6.3 Suggested register page format	11
Appendix: Xylazine, Yohimbine and Lignocaine for Velvet Antler Removal	12
Purpose	12
Definitions	12
Requirements	13
NVSB advice on compliance with these requirements	13

1 Purpose

This document provides guidelines for issuing robust veterinary operating instructions (VOIs) for non-veterinarians to use for:

- restricted veterinary medicines (RVMs); or
- veterinary medicines that are exempt from registration subject to veterinary control.

2 Background

The Requirements for Authorising Veterinarians Notice applies to the veterinary authorisation of all RVMs. These requirements allow veterinarians to issue individual VOIs. Note that VOIs are to be used only in cases in which no veterinary discretion, oversight or guidance is needed at the time the RVM is used. The instructions should be sufficient to direct all expected action with the choice of RVM and its use dictated by the standing instructions issued by the authorising veterinarian.

For circumstances in which veterinary judgement is required, any authorisation to hold RVMs should be linked to ongoing disease control/health management programmes regularly monitored and directed by the authorising veterinarian. For example, authorisations to hold antimicrobial products must be directly linked to regular monitoring of the disease status of the herd to ensure that the choice of antimicrobial is always appropriate and necessary. Because of the ongoing direct veterinary management, a VOI is not appropriate.

Following these guidelines should result in a use context for VOIs that gives veterinarians sufficient confidence that their instructions are being and will be followed. Issuing VOIs that are consistent with these guidelines would also provide acceptable evidence to MPI that the authorising veterinarian is meeting the conditions of product registration concerning veterinary authorisation.

These guidelines are not mandatory requirements. The guidelines state that VOIs should contain some statements or should address some matters. However, in some cases, the guidelines state that VOIs must contain some statements. These are still not mandatory requirements. The expectations are stated more strongly because the absence of these statements weakens the document as evidence that the authorising veterinarian is taking due care to comply with the conditions of registration regarding veterinary authorisation.

In addition to the guidance detailed in this document, the Veterinary Council of New Zealand (VCNZ) Code of Professional Conduct and relevant standards issued by VCNZ under the Veterinarians Act 2005 govern acceptable behaviour of veterinarians in relation to their issuing of veterinary operating instructions.

3 Definitions

The following definitions and abbreviations are only for the purposes of this document.

Expected treatment outcome (ETO)

means the therapeutic or pharmacological response predicted and intended to occur in an animal following treatment with a veterinary medicine.

Issuing veterinarian

means an authorising veterinarian who issues a VOI to support the veterinary authorisation he or she has issued.

Review date

means the date, nominated when the VOI is issued, by which the content of the VOI must be assessed and endorsed by the issuing veterinarian as adequate for renewal.

Unexpected treatment outcome (UTO)

means a therapeutic or pharmacological response at variance with the predicted and intended response in an animal following treatment with a veterinary medicine.

Use period

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

VOI

means a veterinary operating instruction.

4 What is a VOI?

A VOI is a set of instructions from an authorising veterinarian (AV) to a non-veterinarian to hold RVMs in anticipation of their use, and to use RVMs only in accordance with the AV's instructions in circumstances in which the AV will not be carrying out a case-specific consultation. All matters requiring consideration by the AV have been addressed in the instructions.

VOIs are issued by AVs at their discretion to support their role as persons recognised under section 44G of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 to issue a valid authorisation for the purchase and use of RVMs.

VOIs are not necessary if all of the instructions for use are specified in the veterinary authorisation itself.

VOIs are not appropriate when veterinary discretion, oversight or guidance should be applied in the particular circumstances.

VOIs do not have to be approved by MPI. The issuing veterinarian is expected to monitor compliance with his/her instructions and to withdraw his/her authorisation if not satisfied with the level of compliance.

The issuing veterinarian is responsible for:

- monitoring storage and use of the RVM in question by the personnel authorised to do so in the VOI; and
- ensuring the personnel named in the VOI are trained sufficiently to carry out the instructions.

Because the treatment plans resulting from annual consultations commonly undertaken in production animal practices are to be managed by direct veterinary oversight through both ongoing consultation with the farmer and on-farm visits to monitor conformance to the treatment plan, the drafting of a VOI following an annual consultation is not required.

The minimum expectations for robust VOIs are shown in this document in **bold font**. If you have any questions, contact us (approvals@mpi.govt.nz).

5 Guidelines

5.1 Identification and life of the VOI

Each VOI should be uniquely identified and linked to the reason for its existence.

Any other information considered appropriate by the issuing veterinarian to ensure that a VOI remains uniquely linked to the purpose for which it was issued may be included.

The VOI should have a commencement and end or review date. All VOIs should be expressed as 'valid for no longer than twelve (12) months' from the date of commencement or last review.

- An end date should be included for the VOI.
- If the end date is not known or will fall outside twelve months of the commencement date, a review date, of no longer than 12 months, should be stated. After this time the VOI should be considered invalid if not reviewed and re-endorsed by the issuing veterinarian.
- The review should consider issues such as staff changes and changes to recognised best technique or choice of veterinary medicine.

The VOI template in part 6.1 sets out the recommended information to be addressed by an issuing veterinarian in a VOI he/she issues. A VOI may be prepared according to that template, in light of the guidelines set out below, and using the checklist in part 6.2

VOIs must be documented and signed by the issuing veterinarian.

5.2 Reason/purpose for the VOI

A concise outline of the reason for the VOI should be provided. This should include a summary of the aim(s) of the procedure dealt with in the VOI and the reason for the need for the veterinary medicines.

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

The uses for the RVM should be specified and it must be made clear that using the RVM for any other purpose(s) is not authorised by the VOI.

The VOI must provide adequate criteria to ensure that the persons specified in it can identify when and how the products should be used, or be based on a training that provides the use criteria.

At times the treatment or manipulation of the animals is specified in a protocol for the procedure. Access to essential RVMs to carry out that procedure is always done as per that protocol. In such cases, rather than reiterating the instructions, it would be sufficient to specify that the protocol instructions constitute the authorising veterinarian's instructions.

5.3 Personnel

Every person authorised to use veterinary medicines under the VOI must be named, their responsibilities must be defined, and the skill or qualification levels required by them must be specified.

Skills or qualifications required should be at least the minimum necessary to enable competent use of the specified veterinary medicines.

If there is a chain of command, this must be clearly stated.

The veterinarian must be confident that the specified persons are capable of complying with the VOI.

Means of training and training material are at the discretion of the veterinarian issuing the VOI as are the parameters to be used to measure competency. Confirming competency will be a professional judgement made by the issuing veterinarian.

5.4 Animals

The animals to be treated under the VOI must be clearly identified.

The information, in addition to the identification, that the issuing veterinarian wants recorded should be specified. If the actual animals are not known, then the VOI should give directions as to how to judge that an animal could be considered appropriate for treatment. For example, only horses with the proper clearance and examination for export acceptable to the authorising veterinarian could be considered relevant to VOIs governing the care of horses travelling by air or sea.

5.5 Veterinary medicines and equipment

All veterinary medicines to which the VOI applies should be specified by trade name and described. Only specified veterinary medicines should be used under the VOI.

The trade name, strength if appropriate (e.g. Acepromazine 10%), formula type (e.g. tablet), product type (e.g. anaesthetic) and classification (e.g. RVM) of each veterinary medicine covered by the VOI should be stated.

Precise details of veterinary medicine administration should be stated and must include the preparation required (if applicable), dose, administration technique and site(s) of administration (if applicable).

Preparation includes anything necessary to prepare the veterinary medicine for administration.

Obvious instructions, such as removal from packaging, do not need to be stated.

Dose should be stated as mg/kg and, if appropriate, ml, gm or tablets/kg.

Information regarding administration technique and sites of administration must be detailed enough to ensure correct administration will occur.

All equipment and/or techniques necessary to achieve veterinary medicine administration and the method for their disposal should be stated if such equipment or techniques are not specified elsewhere as in a referenced protocol.

Such equipment may include restraint devices considered appropriate (e.g. head bails, twitches, crushes, nets) and equipment used to administer the veterinary medicines.

If, in the opinion of the issuing veterinarian, any equipment or technique may be specifically contraindicated or is considered to pose a significant risk, this should also be stated.

A precise description of the expected treatment outcome (ETO) of veterinary medicine administration should be provided.

The depth of information required will depend on the veterinary medicine and its use, the relevance of the information to the user, and the skill level of the user (where skilled technicians are employed such information can, justifiably, be brief).

This information is of most importance for veterinary medicines with a rapidly achieved end-point and should be sufficient to enable the target response of veterinary medicine administration to be recognised in the treated animal.

5.6 Adverse events and unexpected outcomes

Anticipated negative reactions or side effects should be stated and categorised into those requiring veterinary intervention and those not requiring veterinary intervention.

Expected reactions include incidents such as non-painful small swellings at the site of injection that do not require veterinary intervention. These types of expected reactions should be dealt with in training of persons specified in the VOI so they will not be alarmed.

Unexpected reactions that may require intervention would include incidents such as large, painful swellings and skin sloughing at the site of injections, anaphylactic shock, unusual overdosing etc.

Unexpected treatment outcomes (UTOs) associated with the use of the veterinary medicine should be anticipated (wherever 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.

5.7 Storage of veterinary medicines

The VOI should state how veterinary medicines are to be stored and used in a manner that ensures that they can and will be used only in accordance with the VOI and not be diverted to any other use.

The issuing veterinarian should consider the level of risk posed by the veterinary medicines specified in the VOI and should give storage and use instructions that will minimise those risks and the risk of diversion of the veterinary medicine to unauthorised uses.

Any product supplied by the authorising veterinarian should be identified with his or her contact information.

If veterinary medicines are being supplied by some other party, the VOI should explain how the record of the use of the product and reconciliation of the stocks are to be incorporated into the VOI record/register and linked to the veterinary authorisations supporting the VOI.

5.8 Recordkeeping

The VOI must state that records must be kept for all veterinary medicines used under the VOI for as long as the authorising veterinarian requires.

It is recommended that the issuing veterinarian specifies that records must be kept for a minimum of 5 years. It is also recommended that the authorising veterinarian keep records of his or her veterinary authorisation for the same period, i.e. a minimum of 5 years.

A separate page should be kept for each veterinary medicine used and each page should be identified with the name of the veterinary medicine and the identification reference of the VOI.

The record/register should be completed after each use period.

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

Minimum data to be included in the record/register should be:

- **date of veterinary medicine usage; and**
- **initials or identification code of authorised administrator; and**
- **reason for use; and**
- **reconciliation of veterinary medicine on-hand and veterinary medicine used.**

A suggested register page format is provided in part 6.3.

The VOI must state that records of all veterinary medicine purchases and disposals must be kept and periodically reconciled with the record/register.

Reconciliation (of all RVM purchases and disposals, against the record/register) should be conducted at least every 6 months.

The issuing veterinarian should explain how compliance to the VOI will be monitored.

To confirm that the conditions of registration of RVMs are being met, MPI may, in addition to examining the records of the authorising veterinarian, request to examine any relevant VOI and how it is being followed at any time.

After discussion with and acceptance by the party involved, any amendments made to the VOI should be documented and endorsed by the issuing veterinarian and kept with the original VOI.

At the time of issuing a VOI, the issuing veterinarian should explain to the holder of the VOI the consequences of not complying with the VOI. These consequences are that the purchaser, holder or user of the RVM, to whom the VOI has been issued, will be in breach of the corresponding condition of registration for that product. In other words, non-compliance with the instructions of the authorising veterinarian is an offence under s55 of the ACVM Act, if the breach was committed 'knowingly'.

6 Sample forms

6.1 VOI template

Veterinary Operating Instructions	
Veterinarian's name and contact information	
Purpose	
Commencement date	
End/Review date	
Personnel	
Animals	
Veterinary medicines and equipment	
Expected treatment outcomes	
Instructions	
Adverse events and unexpected outcomes	
Storage of veterinary medicines	
Record keeping	

6.2 VOI checklist

Veterinary Operating Instructions Checklist	
Operating instructions	Comment
Have you left written veterinary operating instructions?	
Have you uniquely identified the veterinary operating instructions and linked them to the reason for their existence?	
Have you specified a commencement and end or review date?	
Have you included your name, contact information and signed the instructions?	
Have you outlined the reason for the operating instruction, including a summary of the aim(s) of the procedure and the reason for the need of the specified veterinary medicines?	
Have you adequately limited the uses for which each veterinary medicine can be used?	
Have you provided adequate criteria to apply when deciding if a case is relevant and the use of one of the veterinary medicines is justified under your operating instructions?	
Have you named the person you expect to follow the operating instructions, and defined their responsibilities?	
Have you confirmed that the specified persons have the skill, experience or qualification to carry out the instructions?	
Have you written the instructions in a manner that is compatible with the management structure and procedures of your client?	
Have you specified the name, strength, formula type (e.g. tablet), product type (e.g. anaesthetic) and classification (e.g. RVM, human medicine, compounded preparation) of each medicine?	
Have you provided precise details for administration, including preparation required (if applicable), dose, administration technique and site(s) of administration (if applicable)?	
Have you specified the equipment and/or techniques necessary to achieve the administration and the method of disposal of any excess?	
Have you provided a description of the expected treatment outcome?	
Have you explained possible adverse events and explained which ones require your attention and which ones could be handled without contacting you?	
Have you provided details on how to manage an adverse event that does not require your attention?	
Veterinary medicine management and record keeping	
Have you labelled all product supplied by you or your practice with your ID and contact information?	
Have you explained how each veterinary medicine must be kept by the person specified as responsible for access and security?	
Have you explained how you want the information on use recorded?	
Have you made it clear what information you want kept on the animals treated?	

Have you made it clear what information you want kept on the veterinary medicines and the reconciliation with stock supplied, stock use and stock on hand?	
Have you made it clear how you want information kept on product supplied by a third party to be reconciled in the records?	
Have you explained how you intend to monitor the operating instructions and the stocks of veterinary medicines?	
Have you explained what the consequences will be if the operating instructions are not followed?	

6.3 Suggested register page format

VOI #: _____

VETERINARY MEDICINE: _____

Date	Initials	Reason for Use (Number of animals, amount)	Reconciliation		
			In	Out	Balance

Appendix: Xylazine, Yohimbine and Lignocaine for Velvet Antler Removal

Purpose

The following relates to veterinarians authorising the purchase, use (and storage in anticipation of use) of Xylazine, Yohimbine or Lignocaine, which are restricted veterinary medicines (develvetting RVMs) used to facilitate the removal of deer velvet antler intended for human consumption.

This appendix constitutes a specific refinement of the requirements of the MPI Director-General specified under section 44G of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, as stated in the Requirements for Authorising Veterinarians Notice. The requirements are referred to in the conditions of registration for the relevant RVMs, which are available on MPI's public website.

The Requirements for Authorising Veterinarians Notice applies to the veterinary authorisation of all RVMs. These requirements allow veterinarians to issue individual veterinary operating instructions (VOIs). However, when authorising the purchase and use (and storage in anticipation of use) of RVMs to remove deer velvet that will be exported or used for human consumption, veterinarians are advised to refer to the guidance in this appendix rather than issuing individual VOIs. This is to avoid risks to trade in deer velvet antler and New Zealand products containing deer velvet antler.

Definitions

Definitions in the Requirements for Authorising Veterinarians Notice apply.

For the purposes of this appendix, these additional terms have the following meanings:

Authorised person

means a person authorised by a supervising veterinarian to purchase and use develvetting RVMs.

Develvetting RVMs

means RVMs containing Xylazine, Yohimbine or Lignocaine.

Manual

means the Farmer Velvet Antler Removal Manual issued by the NVSB.

NVSB

means the National Velveting Standards Body, consisting of two representatives from the New Zealand Deer Farmers Association and two from the New Zealand Veterinary Association.

Supervisory contract

means a contract between a supervising veterinarian and an authorised person in a form approved by the NVSB.

Supervising veterinarian

means an authorising veterinarian who meets the requirements of a supervising veterinarian specified in the Manual.

Requirements

Requirements for authorising veterinarians

An authorising veterinarian should meet all requirements in the Manual to become, and carry out the functions of, a supervising veterinarian in relation to develvetting RVMs including, without limitation:

- meeting the educational requirements of the NVSB
- signing a Supervisory Contract with each person authorised by the veterinarian to purchase and use develvetting RVMs (authorised person)
- carrying out supervisory visits and monitoring the performance of the authorised person
- providing reports to the NVSB in accordance with the Manual.

Requirements for authorised persons

Training, assessment and certification of authorised persons

A supervising veterinarian may authorise a person to purchase and use develvetting RVMs only if the person has met and continues to meet all requirements of the Manual that apply to training, assessment and certification of the authorised person in relation to develvetting RVMs including, without limitation:

- signing a supervisory contract with the supervising veterinarian
- meeting the educational and training requirements of the NVSB
- meeting all requirements relating to visits by the supervising veterinarian, and visits by any other veterinarians required by the Manual
- being certified for the purchase and use of develvetting RVMs by the NVSB.

Use of develvetting RVMs by authorised persons

A supervising veterinarian may authorise a person to purchase and use develvetting RVMs only if the person meets all requirements of the Manual in relation to the use of develvetting RVMs including, without limitation:

- care and storage of develvetting RVMs
- administration of develvetting RVMs
- care and management of welfare of stags in preparation for, during and following administration of develvetting RVMs
- response to adverse events arising from administration of develvetting RVMs
- keeping full and accurate records of usage of develvetting RVMs.

NVSB advice on compliance with these requirements

The Director-General will have regard to any decisions of the NVSB about compliance with the Manual by the supervising veterinarian or any authorised person when:

- assessing whether a supervising veterinarian has complied with these requirements; and
- making any decisions under section 44G of the Act in relation to the supervising veterinarian.