



ACVM Notice

Requirements for Authorising Veterinarians

For veterinarians (being members of a recognised class of persons) recognised to authorise purchase and use of restricted veterinary medicines

TITLE

ACVM Notice: [Requirements for Authorising Veterinarians]

COMMENCEMENT

[This ACVM Notice comes into force on]

ISSUING AUTHORITY

[This ACVM Notice is issued under section 44ZN of the Agricultural Compounds and Veterinary Medicines Act 1997.]

Dated at Wellington this [..] day of [..... 2015]

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Contents	Page
Introduction	3
Part 1: Requirements	5
1.1 Application of this notice	Error! Bookmark not defined.
1.2 Requirements when deciding to authorise purchase and use of RVMs	5
1.3 Requirements when issuing a veterinary authorisation	6
1.4 Other requirements and restrictions for veterinary authorisations	7
1.5 Issuing a veterinary authorisation to purchase and hold RVMs	8
Schedule 1 – Definitions	9

Draft for
Consultation

Introduction

This introduction is not part of the ACVM Notice, but is intended to indicate its general effect.

Purpose

[This notice specifies the requirements that must be met by the members of a class of persons (being veterinarians) recognised to authorise the purchase and use of restricted veterinary medicines (RVMs) that (under their conditions of registration) require veterinary authorisation.]

Background

[RVMs pose significant risks, particularly in regard to the welfare of the animals treated and residues that could jeopardise trade. Use of RVMs requires oversight to ensure that the ACVM risks are kept at an acceptable level. Conditions of registration are imposed on RVMs so that they can be purchased and used only under appropriate authorisation by a person recognised by MPI.

Part 3A of the ACVM Act provides the powers to recognise persons, classes of persons or agencies, and to underpin a regulatory programme to ensure that the function of authorising is carried out in an appropriate manner. In this case, section 44G is used to recognise veterinarians as a class of persons. Under section 44O each person in a recognised class is a recognised person with the associated duties and conditions. The permissible function-activity is solely the authorisation of the purchase and use of RVMs, including holding product in anticipation of use.

The recognition and function-activity does not extend to the selling of RVMs. All selling activities, including distribution, storage, dispensing and supply of RVMs are subject to the conditions of registration (*ref: ACVM Expectations of Restricted Veterinary Medicine (RVM) Sellers with an Approved Operating Plan*) which specify who can sell RVM products. Recognition is exclusively about authorising the purchase and use of RVMs by non-veterinarians.]

Who should read this ACVM Notice?

[Members of the class of persons (being veterinarians) recognised to authorise the purchase and use of restricted veterinary medicines should read this notice. 'Veterinarians' are those who are registered with the Veterinary Council of New Zealand (VCNZ) and hold a current VCNZ annual practising certificate.]

Why is this important?

[The authorising veterinarian's failure to comply with the minimum requirements of this notice may result in a breach of the trade name product's conditions of registration. The authorising veterinarian, if in breach, may also be prosecuted and/or lose recognition.]

Document history

This notice replaces the 2009 standard: *Veterinarians Recognised (under s 62, ACVM Act) to Issue a Valid Authorisation for Purchase and Use of Restricted Veterinary Medicines Requiring Veterinary Authorisation*.

Other information

In addition to the requirements detailed in this notice, the 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 authorisations.

Relevant guidance material: Veterinary Operating Instructions.]

Draft for Consultation

Part 1: [Requirements

1.1 Application of this notice

- (1) This notice applies to the class of persons, being all veterinarians who are registered with the Veterinary Council of New Zealand (VCNZ) and holding a current VCNZ annual practising certificate, recognised under section 44G of the Act for the following purpose:

To issue veterinary authorisations for the purchase and use of registered trade name products that are RVMs, as required by the relevant conditions of registration imposed under section 23 of the Act.

1.2 Requirements when deciding to authorise purchase and use of RVMs

- (1) An authorising veterinarian may only authorise the purchase and use of RVMs if he or she is satisfied he or she has sufficient information to support the authorisation.

Guidance

- What constitutes sufficient information is generally based on the professional judgement of the authorising veterinarian. However, the veterinarian must be able to defend that judgement successfully in light of common and accepted professional standards and practice of the veterinarian's peers.
- Professional judgement and practice requirements are specified in the VCNZ Code of Professional Conduct.

- (2) Before issuing any veterinary authorisation the authorising veterinarian must:
- a) establish that the purchase/holding for use/use of the RVM is appropriate and justified under the circumstances; and
 - b) confirm that any person who will administer the RVM understands and is able to competently carry out the authorising veterinarian's instructions for use; and
 - c) provide direction (or make arrangements) to address anticipated adverse events that are likely to arise from the use of the RVM.
- (3) In regard to adverse events that could arise from the use of the RVM, an authorising veterinarian must:
- a) personally provide any emergency or follow-up care that may be required ; or
 - b) make arrangements for another veterinarian to provide such care ; or
 - c) provide the necessary instructions and training to be confident that a person, acceptable to the authorising veterinarian, will be available to provide the emergency or follow-up care that is likely to be needed.
- (4) If none of the options in sub-clause (3) are practicable, then an authorising veterinarian must not issue a veterinary authorisation for the RVM in the particular case in question.
- (5) An authorising veterinarian must comply with all relevant conditions of registration for the RVM(s) proposed to be authorised.
- (6) An authorising veterinarian must comply with all relevant conditions imposed on their VCNZ registration and/or annual practising certificate.
- (7) An authorising veterinarian must ensure that all necessary information is provided to the person authorised to use the RVM to allow them to comply with the product's conditions of registration.

- (8) For the purposes of sub-clause (7) “necessary information” includes providing guidance, including advising withholding period(s) if applicable, to minimise the risk of animal material from any treated animal intended for human consumption having residues that would not comply with the current New Zealand (Maximum Residues of Agricultural Compounds) Food Standard.
- (9) An authorising veterinarian must provide necessary information to allow the person using the product to meet any animal welfare requirements in the conditions of registration of the RVM by avoiding unnecessary and unreasonable pain or distress to an animal to which the RVM is administered.

1.3 Requirements when issuing a veterinary authorisation

- (1) An authorising veterinarian must document every veterinary authorisation.
- (2) An authorising veterinarian must keep records of each veterinary authorisation issued for five years from the date of issue.

1.3.1 Authorisations in combination with immediate supply of the RVM

- (1) When a veterinarian administers the RVM at the time of the consultation or supplies the RVM to the client to be administered later by the client, the veterinarian is not required to issue a written authorisation.
- (2) If a written authorisation is not given to the client, a veterinarian must still record the decision to prescribe an RVM, and the record (an ‘event record’) must provide sufficient information to link the RVM to the event, the client, the authorisation and the authorising veterinarian.

Guidance

- The form the event record takes is at the discretion of the authorising veterinarian. It could be the case record, diary entry for the consultation, visit log, invoice, a combination of these records or whatever the veterinarian uses to record the event according to accepted standards and as appropriate in the circumstances.

1.3.2 Veterinary authorisations issued to third party must be documented and copies kept

- (1) A veterinary authorisation can be issued to a client to allow the purchase of a RVM from any approved seller of RVMs.
- (2) A veterinary authorisation issued for this purpose must be documented by the authorising veterinarian.
- (3) While the form may vary, every veterinary authorisation must:
 - a) be readily recognisable as a veterinary authorisation;
 - b) contain the essential information (as outlined in section 1.3.3 below); and
 - c) be sufficiently clear and unambiguous to allow the recognised RVM seller to dispense/fill the authorisation according to the authorising veterinarian’s instructions.
- (4) These authorisations must be cross-referenced to the details of the associated event record referred to in 1.3.1(2).

Guidance

- If an authorisation is provided to the client for presentation to the third party, the authorisation must be recognisable as the original document (e.g. not a photocopy).
- If the third party is unable to fill the authorisation as specified by the veterinarian or wishes to suggest an alternative, that person is obliged to contact the authorising veterinarian to discuss alternatives. In such cases, if the authorising veterinarian considers an alternative appropriate, he or she can withdraw the authorisation and provide the supplier with a new one. This can take the form of an electronic version directly supplied to the third party, but it must be documented and linked to the event record.

1.3.3 Veterinary authorisations must contain certain essential information

- (1) A veterinary authorisation must:
- be legible and indelibly printed;
 - be signed and dated personally by the authorising veterinarian or identified in a manner that allows the authorising veterinarian to recognise it as the one he or she issued
 - carry the printed name of the authorising veterinarian, the address and name of the veterinary practice or organisation of the authorising veterinarian;
 - set out the identification and address of the owner (or person in charge) of the animal(s) to be treated;
 - describe the essential identification details of the animal(s) to be treated;
 - identify clearly the registered trade name product and active ingredient(s) being authorised;
 - state the quantity of RVM authorised;
 - specify the dose and frequency of the doses if the RVM is to be administered by injection, or by insertion into any cavity of the body, or by swallowing;
 - specify the method, application rate and frequency of use if the RVM is to be applied externally;
 - specify if it is to be used for repeat supply/filling (if repeats allowed, specify the number of occasions the RVM can be supplied under the same authorisation, or the interval to elapse between each supply, or the period of treatment during which the veterinary medicine is intended to be used); and
 - state the duration of the validity of the veterinary authorisation.

Guidance

- If an authorisation is issued electronically, it must be issued directly from the authorising veterinarian to the third party that will sell the RVM. Electronic authorisations must not be provided directly to the client.

- (2) A veterinary authorisation must also:
- allow dispensing of, or access to, only a quantity of the RVM that is necessary and sufficient to achieve the purpose of the authorisation; and
 - direct the person dispensing the RVM to provide to the person specified in the veterinary authorisation the use instructions and any additional instructions, including withholding periods, to be followed or precautions to be taken as considered necessary by the authorising veterinarian.

1.4 Other requirements and restrictions for veterinary authorisations

- (1) A veterinary authorisation must provide sufficient information to the client to ensure that residues of any substance that may occur in animal material or products intended for human consumption from treated animals do not exceed the relevant residue limit and/or contravene any conditions of registration.

Guidance

- Failure to provide this information is a specific offence under section 55 of the ACVM Act.

- (2) If an authorising veterinarian requires a veterinary authorisation to be filled urgently, that veterinarian may, if necessary, send through an electronic version of the authorisation to the RVM seller filling the authorisation. Any electronic version of an authorisation must be documented by the authorising veterinarian and linked to the event record referred to in 1.3.1(2), and a hard copy provided to the RVM seller within seven (7) days of the authorisation.

1.5 Issuing a veterinary authorisation to purchase and hold RVMs

- (1) If the veterinary authorisation is to provide for a specified person to hold specific RVMs in anticipation of use, the authorising veterinarian must ensure that the content of the veterinary authorisation is adjusted to what is appropriate in the circumstances.

Guidance

The following are examples of permitted types of veterinary authorisation for this purpose:

- **Animal feed manufacturers**

Animal feed manufacturers may need to have RVMs in stock to mix into animal feed in accordance with a veterinary authorisation. This situation requires instructions from the authorising veterinarian to the feed manufacturer, specifying the agreement that the product will be kept secure and only used as per a specific veterinary authorisation or an operating plan agreed between the authorising veterinarian and the feed manufacturer.

- **Specialist team**

There may be circumstances in which a specially trained team will be caring for animals or will carry out treatments of animals in which the individual animals will not be known at the time the RVMs are authorised. The products will be held in anticipation of use and a veterinary authorisation must be issued to allow this to happen. Examples include the care of animals travelling by air or sea, police actions requiring treatment of animals, teams dealing with animal welfare emergencies.

- There are many other cases in which non-veterinarians would be carrying out repeatable treatments for which consultation by the authorising veterinarian is not necessary relative to the RVM being used. In such cases, the authorising veterinarian can issue veterinary operating instructions that anticipate a use for a specified RVM. The veterinary operating instructions (see below) create the context of use that gives the authorising veterinarian the confidence that he or she can issue a veterinary authorisation in anticipation of use.

Guidance

- **Issuing veterinary operating instructions**

The ACVM Veterinary Operating Instructions Guideline contains MPI's expectations of the content of a veterinary operating instruction that would create confidence that the authorising veterinarian was taking due care to comply with the conditions of registration on a RVM when issuing a veterinary authorisation in anticipation of use.

- Compliance to the guideline is not mandatory. However, issuing veterinary operating instructions that are based on the guideline will provide good evidence that the authorising veterinarian is complying with the conditions of registration relating to authorisation and this notice.

Schedule 1 – Definitions

(1) In this notice, unless the context otherwise requires:

Act

means the Agricultural Compounds and Veterinary Medicines Act 1997.

Adverse event (AE)

means any event that brings into question the relevance or reliability of information provided at the time of registration and upon which the decision to register the product was made.

Authorising veterinarian

means a member of a class of persons, being a veterinarian, recognised under section 44G of the Act to issue veterinary authorisations.

Approved seller of RVMs

means a veterinarian or a party who has an operating plan approved by MPI under section 28 of the Act to sell RVMs.

Consultation

means veterinary consultation as defined in the VCNZ Code of Professional Conduct and must include the veterinarian:

1. interviewing the client (or a legitimate and authorised representative of the client)
2. collecting and recording sufficient information relevant to the individual circumstances to ensure the proposed course of action (including treatment) is appropriate and meets the needs and best interests of the animal(s) and the client
3. obtaining appropriate consent to the proposed course of action
4. being given and accepting responsibility for the ongoing health and welfare of the animal(s) concerned in relation to the consultation. This includes arranging emergency care, taking into consideration the circumstances and the potential for adverse effects from, or failure of the agreed course of action
5. determining and providing the appropriate level of advice and training in order to be satisfied that the agreed course of action can occur as planned.

Consultation will usually involve the animal(s) having been seen by the veterinarian at the time of the consultation. If not, they will have been seen recently or often enough for the veterinarian to have sufficient personal knowledge of the condition/health status of the animal(s). This consultation is required in order for the veterinarian to be able to propose the particular course of action/treatment.

Dispensing

means preparing a veterinary medicine to transfer possession to the owner or caretaker of the animal(s) to be treated, and includes transferring one or more doses of a veterinary medicine from its approved commercial packaging into adequate and appropriately labelled alternative packaging.

New Zealand (Maximum Residues of Agricultural Compounds) Food Standard

means the food standard issued under the Food Act 1981, which specifies maximum residue limits in food for human consumption of substances found in veterinary medicines, and any subsequent amendments or replacements to that standard.

Restricted veterinary medicine (RVM)

means a trade name product registered under section 21 of the Act, that is subject to conditions of registration under section 23 that restrict sale, purchase and use, and require authorisation to purchase and use it.

Supply

means handing over a veterinary medicine to the person who is purchasing it, which is within the definition of sale as defined in the Act.

Veterinarian

means a person who is registered with the Veterinary Council of New Zealand (VCNZ) and holds a current annual practising certificate.

Veterinary authorisation

means an instruction from an authorising veterinarian, authorising the person specified in the authorisation to do one or more of the following:

- purchase a RVM by the person or persons specified in the authorisation
- hold a RVM in anticipation of its use by that person under the instructions of the authorising veterinarian detailed in either the authorisation or under a Veterinary Operating Instruction
- dispense an RVM by a veterinarian other than the authorising veterinarian, in accordance with the details of the authorisation, to the person or persons specified in the authorisation
- use a RVM in accordance with the instructions of the authorising veterinarian.

A veterinary authorisation may include:

- clinical case records noting that a RVM was prescribed by the veterinarian and dispensed from the stocks held in that veterinarian's practice
- letters or other documents to a party providing the authorisation to that party to hold a RVM in anticipation of use (such as a letter to a feed company to hold RVMs for inclusion in medicated feeds as directed by the authorising veterinarian)
- prescriptions issued by the authorising veterinarian to address an urgent need for a RVM, to be dispensed by another veterinary practice or veterinary pharmacy service with the appropriate approval.

A veterinary authorisation is considered to be the equivalent to the commonly used expression veterinary 'prescription' or 'authorisation'. If an authorising veterinarian writes a veterinary prescription (script), this is considered to be equivalent to issuing a veterinary authorisation to the person dispensing it.

Veterinary operating instruction (VOI)

means a set of instructions from the authorising veterinarian to a non-veterinarian to hold RVMs in anticipation of use, and to use RVMs only in accordance with the instructions of the authorising veterinarian, in circumstances in which the authorising veterinarian will not be carrying out a case-specific consultation, and all matters requiring consideration by the veterinarian have been addressed in the instructions.

- (2) Unless the context otherwise requires, terms used in this notice that are defined in the Act or the Regulations have those meanings]