NZVA | Recommended Best Practice | December 2020

Veterinary Authorisation and Dispensing

Contents

Introduction

All registered veterinarians holding an annual practising certificate issued under the Veterinarians Act 2005 are part of a class of persons recognised to authorise the purchase and use of restricted veterinary medicines (RVMs), under section 44G of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

This recognition is exclusively about authorising the purchase and use of RVMs on animals under that veterinarian's care. The recognition does not extend to the selling of RVMs, outside of this care relationship. A veterinarian who is not recognised cannot authorise the purchase and use of RVMs.

All selling activities (excluding those captured by the above relationship), including distribution, storage, sale, dispensing and supply of RVMs are subject to the conditions of registration which specify who can sell RVM products. RVM sellers must operate under a Ministry for Primary Industries (MPI) approved operating plan, and should refer to the Guidance Document: Operating Plans for Restricted Veterinary Medicine Sellers.

Veterinarians issuing authorisations to purchase, use or hold restricted veterinary medicines must comply with the ACVM Notice: Requirements for Authorising Veterinarians. Failure to comply with the ACVM requirements may result in a prosecution and/or loss of recognised person status.

In addition to the requirements under the ACVM and Medicines Acts, veterinarians must also comply with the Veterinary Council of New Zealand (VCNZ) Code of Professional Conduct (CoPC) and any relevant standards issued under the Veterinarians Act 2005. Failure to comply with the CoPC may result in an investigation by the VCNZ.

The CoPC notes: *"Veterinarians have an exemption under Section 27 of the Medicines Act 1981, that permits them to prescribe a {prescription medicine (PM)} to treat an animal under the care of that veterinarian, or under the care of another veterinarian."*

The purpose of this standard is to specify the duties and conditions veterinarians must observe when issuing authorisations and dispensing medicines for use in animals, as required by the following (not exhaustive list) legislative instruments:

- Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, and Notices
- Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011
- Medicines Act 1981
- Medicines Regulations 1984
- Misuse of Drugs Act 1975
- Misuse of Drugs Regulations 1977
- Veterinarians Act 1996
- VCNZ Code of Professional Conduct
- Animal Welfare Act 1999
- Animal Welfare (Care and Procedures) Amendment Regulations 2020

Compliance with this standard will assist veterinarians in meeting their obligations under the above legislation.

Veterinarians should note that failure to comply with their obligations may result in a complaint being laid before the VCNZ and/or prosecution under the ACVM Act 1997, Animal Welfare Act 1999, and/or any other relevant statute.

Civil liability (i.e. a small claims court or other proceeding) may also be a consequence because of losses incurred by a client through inadequate advice or service.

Authorising non-veterinarians to use veterinary medicines

For the purpose of this document 'veterinary medicines' refers to restricted veterinary medicines, prescription medicines used to treat animals, and controlled drugs used to treat animals.

The VCNZ CoPC notes, *"Unrestricted veterinary medicine is a veterinary medicine registered for use as a veterinary medicine under the ACVM Act where it has been determined that its risk profile is such that direct veterinary authorisation and oversight of its use is not required. Colloquially known as an 'over the counter' (OTC) product."* These products are not considered in this Standard, but veterinarians are reminded of their obligations to product stewardship and other legislated and/or codified requirements regarding these products (e.g. flea treatments, deworming pills)

Broadly speaking, there are four (4) mechanisms by which veterinarians can authorise non-veterinarians to use medicines for the treatment of animals under the authorising veterinarian's care:

1. Veterinary authorisation of restricted veterinary medicines (RVMs)
   - Which are dispensed by the authorising veterinarian (or their practice)
   - Which are dispensed by an approved seller (i.e. not dispensed by the authorising veterinarian or their practice)

2. Veterinary authorisation of prescription (human) medicines
   - Which are dispensed by the authorising veterinarian (or their practice)

- Which are dispensed from a pharmacy (i.e. not dispensed by the authorising veterinarian or their practice)

3. Veterinary Operating Instructions (VOI)
   - Authorised veterinary medicines are dispensed by the authorising veterinarian (or their practice)
   - Note – using this mechanism, animals may not be under the care of a veterinarian issuing the VOI

4. Veterinary authorisation of compounded veterinary preparations
   - For instructions of compounding VMs refer to Vert Med Section of Code

The requirements for each of these methods are summarised below.

Requirements prior to authorising veterinary medicines

The authorising veterinarian must have sufficient information to support the authorisation/use of any RVM

In the ACVM Notice, interpretation on what constitutes 'sufficient information' and how it is gathered is left to the professional judgement of the veterinarian. 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.

VCNZ's CoPC states that a consultation is required in order for the veterinarian to be able to propose the particular course of action/treatment. This will usually involve the animal(s) having been seen by the veterinarian at the time of the consultation.

Veterinarians can also, in limited circumstances, authorise the use of RVMs using a Veterinary Operating Instruction (VOI).

For some specific circumstances, VCNZ may publish statements setting out what is considered as reasonable to support the authorisation. For example, the VCNZ Statement on Disbudding and Dehorning.

The authorising veterinarian must confirm all persons authorised to use the RVM(s) are competent

The ACVM Notice requires the authorising veterinarian to confirm the competence of persons as it relates to the instructions for use (i.e. all persons authorised by the veterinarian to use the RVM can do so appropriately).

The VCNZ CoPC also states the veterinarian is responsible for '*determining and providing the appropriate level of advice and training so as to be satisfied that the agreed course of action can proceed as planned*'[1]. This includes responsibility for competence as it relates to any procedure undertaken as part of the RVM use (e.g. if local anaesthetic is authorised to use for disbudding

calves, the veterinarian is expected to ensure users are competent to disbud calves, as well as administer the local anaesthetic, recognise adverse events, and emergencies, and provide appropriate support to the affected animals).

The authorising veterinarian must also ensure all necessary information is provided to allow the user(s) to comply with the conditions of registration for the products authorised. **This includes providing withholding period (WHP) advice (where applicable).**
Where RVMs are used in combination (i.e. concurrent use), WHP advice should be provided for the combination.

The authorising veterinarian must arrange for ongoing care

The ACVM Notice states the authorising veterinarian must make arrangements to address adverse events that may arise from use of the RVM(s). Where these adverse events threaten the welfare of the animal(s) treated, the authorising veterinarian must:

a) Personally provide any emergency/follow-up care; or
b) Make arrangements for another veterinarian to provide emergency-follow-up care; or
c) Provide necessary instructions/training to be confident that another person can provide emergency-follow-up care.

The VCNZ CoPC additionally requires veterinarians to accept responsibility for the ongoing health and welfare of the animal in relation to the matters that have been consulted on.
This includes *'…appropriate follow up treatment and monitoring, appropriate communication with the client, and making provision for emergency care in case of technical failure, adverse events or unexpected complications.'*

If none of the above three conditions can be met, a veterinarian must <u>not</u> issue an authorisation.

If none of the above three conditions can persist (subsequent to authorisation being issued), then the authorisation must be revoked.

Requirements when issuing a veterinary authorisation for restricted veterinary medicines (RVMs)

Authorising veterinarians must meet all relevant requirements

Requirements for veterinary authorisation are specified within the VCNZ CoPC, the ACVM Notice, and other relevant legislation. Authorising veterinarians should be familiar with these requirements and must ensure they are met.

Veterinary authorisations must contain certain essential information

The ACVM Notice details all information which is required within a veterinary authorisation. Veterinarians should ensure all essential information is captured, regardless of the form the authorisation takes (see below).

[1] VCNZ CoPC - Definition of a Veterinary Consultation; point 5.
Two authorisation templates are provided within this standard:

- Appendix 1 – template for authorisation of a single veterinary medicine
- Appendix 2 – template for authorisation of multiple RVMs (e.g. for a herd health programme)

A veterinary authorisation should be hand-dated and hand-signed personally by the authorising veterinarian.

Veterinarian authorisations allow use of RVM for a limited period of time

The VCNZ CoPC specifies that the quantity of any RVM authorised must not exceed the following:

- 4 months – critically important antibiotics in any species (as defined in the Code)
- 6 months – non-critically important antibiotics and all other RVMs for use in companion animals (excluding equids)
- 12 months – non-critically important antibiotics and all other RVMs for use in production animals and equids

The authorising veterinarian must document every authorisation. ACVM advises that records must be kept for a minimum of 5 years (ideally 7 years).

Veterinarians should note that VCNZ CoPC indicates that in general terms veterinarians are advised to keep patient medical records (which will include records of authorisations) as long as the information has use or relevance, and in order to comply with statutory expectations. On that basis and more specifically, veterinarians should keep patient medical records while the client's animal is still alive and still a patient of the practice, from the date of the first consultation onwards, and for a period of seven years after the date of the last consultation.

RVMs dispensed by the authorising veterinarian

The ACVM Notice indicates that a written authorisation is not required where the RVM is administered at the time of the consultation or dispensed to the client to be administered later.

However, the consultation/event record must contain sufficient information to link the RVM to the consultation/event, the client, and the authorising veterinarian. The form this record takes is at the discretion of the authorising veterinarian. Whatever recording method is used must be appropriate and record the event to an accepted standard. Examples include clinical/case records, diary entries, and/or invoices.

If authorising RVMs for future supply, the VCNZ CoPC requires the authorising veterinarian to make a printed summary available to the client. This summary is NOT an authorisation to allow dispensing from another seller and this should be made clear on the summary document (e.g. the shed sheet).

RVMs dispensed by approved RVM sellers

The ACVM Notice indicates a (written) veterinary authorisation may be issued to a client to allow purchase of RVMs from an approved seller. The authorisation must be documented by the authorising veterinarian (as above) and linked to the consultation/event record.

The authorising veterinarian (not the seller dispensing the product) is responsible for meeting all authorisation requirements. The seller dispensing the product is responsible for meeting dispensing requirements (e.g. labelling (can be delegated to third party per MPI Operating Plan)).

The form of the (written) authorisation is at the discretion of the veterinarian, but must:

a) be readily recognisable as a veterinary authorisation;
b) be clear/unambiguous to allow the RVM seller to dispense according to the instructions; and

c) contain all essential information – including a hand-written date/signature.

Where a (written) authorisation is provided to a client for presentation to an MPI-approved RVM seller, it must be recognisable as the original document – not a copy.

Veterinarians must honour requests for written authorisations

The VCNZ CoPC expects veterinarians to comply with requests for written authorisation to be provided to allow purchase of RVMs from an approved seller. Written authorisations are expected to be provided within 48 hours (except in exceptional circumstances).

The VCNZ CoPC makes it clear the requirement to issue a written authorisation does not extend to RVMs which would ordinarily be personally administered by the veterinarian (i.e. not normally dispensed).

Summary documents are not written authorisations

Authorising veterinarians must make available to the client, a printed summary of all RVMs authorised for future supply. Such documents are typically requested for audit compliance (e.g. 'shed sheet' for an NZCP1 Audit).

These documents are **not** written authorisations and should clearly indicate that RVMs cannot be dispensed upon presentation of such documents. The authorising veterinarian should advise the client of this.

Authorisations sent electronically must be followed-up with an original copy within 7 days

Where the veterinary authorisation needs to be filled urgently (and an original copy cannot be immediately provided) the ACVM Notice indicates the authorising veterinarian may send an electronic version of the authorisation **directly** to a legitimate seller to dispense.

The electronic authorisation must be documented by the authorising veterinarian and linked to the consultation/event record (as above).

Both the ACVM Notice and the Medicine Regulations 1984 require a written copy to be sent to seller/dispenser within seven (7) days.

A veterinary authorisation must only allow access to a necessary quantity of the RVM(s)

This generally means only the amount required to treat the current condition (which has been consulted on) should be authorised. However, an authorisation may be provided to allow a specific person to purchase RVMs to hold in anticipation of use.

The VCNZ CoPC requires the authorising veterinarian to obtain or hold enough information throughout the period of authorisation to ensure the circumstances have not changed, that would require an alteration of the authorised products or their use.

The ACVM Notice states that the quantity of RVM and duration the RVM can be held must be limited and appropriate, taking into consideration the potential for the circumstances to change. There are four (4) examples of activities listed for which this may be appropriate:

1. **Animal feed manufacturers** – to hold RVMs in stock for addition to feed as required by veterinary authorisation or operating plan.

2. **Specialist teams** – to hold RVMs where individual animals needing treatment may be unknown (e.g. air transport; animal welfare emergency responders).

3. **Herd health or disease control programmes** – to hold RVMs for those circumstances where a particular RVM must be administered as soon as specified signs are noticed. The authorising veterinarian is expected to make regular, and appropriately frequent, checks such that the authorising veterinarian is satisfied, and documents this, that the standards are being met in relation to the appropriate use of the RVMs. The documentation should include, but not be limited to, the accuracy of the diagnosis, treatment selection and administration, successful treatment rate, treatment failures, and any concerns relating to antimicrobial resistance etc.

4. **Veterinary operating instructions** – to hold RVMs to undertake repeat treatments in accordance with specific instructions from the authorising veterinarian. Veterinary operating instructions are discussed later in this standard.

A veterinary authorisation must provide sufficient information to manage (food) residue risks

The ACVM Notice requires authorising veterinarians (where applicable) to advise an appropriate withholding period (WHP) to manage the risk of residues in food products (e.g. meat, milk or eggs) derived from any animal treated with RVM(s).

Any WHP set by the authorising veterinarian should ensure food products derived from any animal treated with RVM(s) comply with the current Maximum Residue Level (MRL) for the product(s). Food products must also comply with all relevant food safety requirements under the Animal Products Act.

Where a product is being used extra-label and/or concurrently with other products that may cause residues and there is insufficient data to determine an appropriate WHP, default WHPs should be applied.

Requirements when issuing a veterinary authorisation for Prescription Medicines (PMs)

Authorising veterinarians must meet all relevant requirements

Requirements for veterinary authorisation of prescription medicines are specified within the VCNZ CoPC, the Medicines Act 1981 and Medicine Regulations 1984, the Misuse of Drugs Act 1975 and other relevant legislation.

Authorising veterinarians should be familiar with these requirements and ensure these are met.

Veterinarians must only authorise PMs for animals under their care

Under the Medicines Regulations 1984, a veterinarian may only authorise (prescribe) a PM for treatment of an animal under that veterinarian's care.

The PM may be dispensed by the authorising veterinarian, or a third party (e.g. human pharmacy) on presentation of a written authorisation (prescription).

The period of supply for PMs is limited to 3 months

The Medicines Regulations 1984 specifies that the quantity of any PM authorised cannot exceed three (3) months' supply.

PMs cannot be dispensed after six (6) months have elapsed from the date of authorisation.

An authorisation (prescription) for PMs must contain essential information

The Medicines Regulations 1984 specify the form a veterinary authorisation (prescription) for PMs must take. Veterinarians should ensure all essential information is captured in the specified form.

See Appendix 2 for a template for written authorisation of a Prescription Medicine.

The authorising veterinarian must document every authorisation. Records should be kept for a minimum of 7 years

Neither the ACVM Act nor Notice set a specified time for retention of PMs authorisation (prescription) documentation, but veterinarians are encouraged to do so for 7 years in line with VCNZ CoPC expectations.

The VCNZ CoPC indicates that in general terms veterinarians are advised to keep patient medical records (which will include records of authorisations) as long as the information has use or relevance, and in order to comply with statutory expectations. On that basis and more specifically, veterinarians should keep patient medical records while the client's animal is still alive and still a patient of the practice, from the date of the first consultation onwards, and for a period of seven years after the date of the last consultation.

Authorisations (prescriptions) sent electronically must be followed-up with an original copy

Where the veterinary authorisation needs to be filled urgently (and an original copy cannot be immediately provided) the Medicine Regulations 1984 permit a veterinarian to orally communicate with a pharmacist (to whom the veterinarian is personally known) either in person or via telephone.

The authorising veterinarian is required to provide a written copy to the pharmacist within seven (7) days.

Controlled drugs

Authorising veterinarians must meet all relevant requirements

Requirements for veterinary authorisation of controlled drugs are specified within the VCNZ CoPC, the ACVM Notice, the Misuse of Drugs Act 1975, the Misuse of Drugs Regulations 1977 and other relevant legislation.

Authorising veterinarians should be familiar with these requirements and ensure these are met.

Veterinarians may only authorise controlled drugs for animals under their care

Under the Misuse of Drugs Regulations 1977, a veterinarian may only authorise (prescribe) controlled drugs for administration to an animal under that veterinarian's care.

Controlled drugs are listed in Schedule 1, Schedule 2, and Schedule 3 of the Misuse of Drugs Act 1985

Veterinarians must store controlled drugs appropriately

The VCNZ CoPC requires veterinarians to store all controlled drugs as required by Section 28 of the Misuse of Drugs Regulations 1977. When a controlled drug is not required for immediate use, this means:

- It must be stored in a locked cupboard or compartment constructed of metal and/or concrete.
- If constructed after 1977, the cupboard/compartment must be an 'approved type'.
- The cupboard/compartment must be part of (or securely fixed to) the building or vehicle.
- If the lock requires a key, the key must be kept in a safe place, and cannot be kept within the same building/vehicle as the stored drugs if it is unattended.
- Combination locks of an approved type may be used.

VCNZ currently consider a locked vehicle boot, locked ute service box, locked cabinet within the service box or locked glove box meet these requirements.

Veterinarians must keep a Controlled Drugs Register

Irrespective of any exceptions within legislation, the VCNZ CoPC requires veterinarians to keep a Controlled Drugs Register for all drugs in Schedule 1 (Class A), Schedule 2 (Class B), and Schedule 3 (Class C) of Part 4 of the Misuse of Drugs Act 1975. The register may be in electronic format, or manual format.

Controlled Drugs Registers must be kept for a minimum of four (4) years after the last entry made therein.

Veterinarians must reconcile physical stock of controlled drugs monthly

The VCNZ CoPC requires reconciliation of controlled drugs to be undertaken at least every month. At least two (2) people should carry out the reconciliation process. The process differs depending on whether the register is electronic or manual.

Veterinarians must investigate any variances identified during reconciliation and should identify a reason where possible and take corrective actions to ensure that the reconciliation balances next time.

In situations where corrective action is taken to improve the accuracy of future reconciliations, yet unexplained variances continue, or could possibly be associated with unauthorised use, veterinarians should seek advice from VCNZ.

Records of reconciliation and stocktake of controlled drugs must be kept for four (4) years.

Controlled drugs must be disposed of in a manner which destroys them

The primary concern is diversion (abuse) of drugs after disposal. The VCNZ CoPC provides suggested methods for disposal of controlled drugs.

Disposal of controlled drugs should be witnessed by another veterinarian or allied veterinary professional, and accurately recorded in the Controlled Drugs Register.

Requirements when issuing a Veterinary Operating Instruction (VOI)

A VOI must meet all veterinary authorisation requirements

A VOI is a veterinary authorisation for named persons to purchase and hold an RVM in anticipation of use in accordance with specific instructions from the authorising veterinarian.

It is therefore part of a veterinary authorisation and must comply with all requirements for veterinary authorisation under the VCNZ CoPC, the ACVM Notice, and all relevant legislation.

This includes meeting all requirements for provision of emergency/follow-up care, including adverse events.

Authorising veterinarians must comply with the MPI Guidance Document: Veterinary Operating Instructions

MPI indicates compliance with the Guidance Document: Veterinary Operating Instructions is not mandatory.

However, the VCNZ CoPC expects that veterinarians must follow the guidelines from MPI and meet the minimum suggested requirements in order to demonstrate compliance with the CoPC.

Controlled drugs must not be authorised via VOI

Under the Misuse of Drugs Regulations 1977, a veterinarian may only authorise (prescribe) controlled drugs for administration to an animal under that veterinarian's care.

As a VOI permits administration of a veterinary medicine to animals not known to the authorising veterinarian (i.e. not under that veterinarian's care), controlled drugs must not be authorised via VOI.

A VOI is only appropriate where veterinary assessment is not required prior to use

The ACVM Notice indicates a VOI is appropriate for non-veterinarians carrying out repeatable treatments where veterinarian consultation isn't necessary for each individual use.

The VCNZ CoPC specifies a veterinarians can only authorise RVMs via VOI where there is no reasonable expectation that a veterinary judgement or diagnosis is needed.

An example is the issuing of a VOI to a lay technician for use of local anaesthetic to undertake calf disbudding.

Antibiotics are not considered appropriate to authorise via a VOI

The life of a VOI is limited to 12 months

The VCNZ CoPC requires every VOI to have an end (or review) date. This must be no longer than 12 months from the date of commencement for the VOI.

A VOI must contain essential information

The Guidance Document: Veterinary Operating Instructions specifies the minimum expectations for a robust VOI. Authorising veterinarians should ensure all essential information is captured in the VOI.

Appendix 3 contains a template for creating a VOI.

The authorising veterinarian is expected to ensure all persons named in the VOI are trained and competent

As a VOI is a specific set of instructions, the authorising veterinarian must ensure **every** person named in the VOI is able to follow the instructions correctly and perform any associated procedures and medicine administration techniques competently in order for the agreed course of action to proceed as planned. Training may be provided by the authorising veterinarian, or another suitable person.

Under the VCNZ CoPC the authorising veterinarian must be able to provide evidence of competencies required by persons named in the VOI, including evidence of training and assessment of these persons.

The authorising veterinarian is required to review the competency of all users at least annually.

The authorising veterinarian is expected to monitor VOI compliance

Monitoring must be able to be evidenced and includes:

- Storage and use of the RVM authorised in the VOI
- Treatment records
- Product reconciliation
- Record keeping

The veterinarian may use professional judgement when determining the appropriate level of monitoring to ensure compliance. However the VCNZ CoPC expects auditing to be undertaken **at least every six (6) months.**

The issuing (authorising) veterinarian is expected to monitor compliance with their instructions and to withdraw their authorisation if not satisfied with the level of compliance.

Where the authorising veterinarian suspects or identifies non-compliance, they must revoke the VOI.

Geographical distance from the authorising veterinarian

As a VOI may be issued in the absence of an established veterinary-client relationship, it is possible that the animals being treated under the VOI could be geographically distant from the authorising veterinarian.

In such cases, the authorising veterinarian **must** still meet all their VOI requirements (irrespective of the distance) – including provision of emergency/follow-up care, including adverse events, and monitoring VOI compliance (as above).

The VCNZ CoPC indicates it is unlikely to be appropriate to issue a VOI if the authorising veterinarian is in a different region from the animals being treated.

Veterinarians are advised to seek advice from VCNZ.

Dispensing own authorisations and others (via an MPI-approved Operating Plan (OP))

Operating plans are not required where RVMs are dispensed by the authorising veterinarian (or their practice) for use on animals under their care.

A veterinarian (or practice) must not **routinely** dispense RVMs authorised by a veterinarian outside the practice unless they have an operating plan approved by MPI.

Further information, including a current list of registered sellers (those with an operating plan) can be found on the MPI website.

The authorising veterinarian must be contacted if doubt exists

The VCNZ CoPC requires veterinarians providing a dispensing service to contact the authorising veterinarian if there is any doubt about the validity or authenticity of the written authorisation provided. The dispensing veterinarian must also contact the authorising veterinarian if any changes need to be made to the authorisation. A new authorisation must be obtained if changes have been made.

A copy of the transaction must be kept along with a copy of the authorisation.

Veterinarians may fill one-off urgent authorisations without an OP

The VCNZ CoPC indicates a veterinarian who does not have an MPI-approved OP may dispense a one-off urgent authorisation.

Examples given include:

- Where a person has gone away, and forgotten to take a pet's medication
- Where a veterinary practice has run out of stock (e.g. over the weekend or a holiday) and a product is needed urgently

Veterinary medicines must be labelled with specific information

The ACVM Guidance: Operating Plans for Restricted Veterinary Medicine Sellers specifies the information registered sellers must include with any RVMs they supply.

Veterinarians dispensing veterinary medicines (which they have authorised) must ensure any labelling requirements are met:

- For prescription (human) medicines, labelling must comply with Section 13 of the Medicines Regulations 1984.
- For controlled drugs, labelling must comply with Section 25 of the Misuse of Drugs Regulations 1977.

When dispensing RVMs, there are currently no specific labelling requirements under the ACVM Act 1997, nor the VCNZ CoPC. In the absence of specific regulation, regulators refer veterinarians to international regulation for guidance (see below for the recommended label inclusions).
Where alternatives to this recommendation are used, veterinarians should be able to defend their decisions and judgement successfully, in light of common and accepted professional standards and practices of the veterinarian's peers.

If the RVM is dispensed in its original packaging and with that labelling still being accessible and legible, this information is sufficient to meet some of the labelling requirements specified below. Additionally, off-label use or deviation from label dose rates would need to be stated.

Where products are not dispensed in original packaging/labelling, veterinarians should consider providing the following information:

- Name of the authorising veterinarian
- Name, address, and 24-hour contact phone number(s) of the authorising veterinarian's practice
- Date of the relevant veterinary consultation, and duration of validity of the authorisation
- Name of the owner/person in charge of animal(s) to be treated
- Identification of the animal(s) to be treated
- Registered trade name of the product, the active ingredient(s) [include the concentration of active ingredient if the product is compounded]
- Quantity of product authorised (volume/number)
- Directions for use, including dose size, dose frequency, and route of administration
- Withhold period advice if used to treat food producing animals
- The statements, 'Keep out of reach of children' and 'FOR ANIMAL TREATMENT ONLY'
- Essential warnings or contraindications (e.g. 'for external use only' or 'discontinue use if vomiting or diarrhoea occurs')

Ensure additional labelling does not obscure essential information on the original packaging, if it is not included in the affixed label. If the pack is too small for the label, use a "flag" method to fix to the packaging. If this is not possible, attach the label to a larger re-sealable container containing the product.

Glossary

Authorising means a veterinarian creating a documented approval allowing a client to purchase a particular restricted veterinary medicine to administer to a particular animal(s) in accordance with the instructions of the veterinarian.

Controlled drug means any substance, preparation, mixture, or article specified or described in Schedule 1, Schedule 2, or Schedule 3 of the Misuse of Drugs Act 1975.

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

Duration of validity means the period during which the authorised veterinary medicine may be held and used by the person authorised. After this period has elapsed (i.e. the authorisation has 'expired') any remaining product should be destroyed, or a new authorisation issued to allow continued holding and use of the product.

Prescription is a written instruction that contains the required information set out in section 41 of the Medicines Regulations 1984, is signed and dated by a veterinarian, and gives details for a pharmacy to dispense a prescription medicine.

Prescription Medicine (PM) is a subset of those products identified as medicines that can only be sold under prescription. They are often referred to as 'human medicines'. Veterinarians have an exemption under Section 27 of the Medicines Act that permits them to prescribe a PM to treat an animal under the care of that veterinarian, or under the care of another veterinarian.

Restricted veterinary medicine (RVM) means a trade name product registered under section 21 of the Agricultural Compounds and Veterinary Medicines Act 1997 that is subject to conditions of registration under section 23 that restrict sale, purchase and use, and require authorisation to purchase and use.

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 an RVM by the person or persons specified in the authorisation
- hold an 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 an RVM in accordance with the instructions of the authorising veterinarian.

A veterinary authorisation may include:

- clinical case records noting that the veterinarian authorised an RVM and dispensed the RVM from stocks held in their veterinary practice
- letters or other documents to another person or entity providing the authorisation to them to hold an 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)
- authorisations issued by the authorising veterinarian to address an urgent need for an RVM, to be dispensed by another veterinary practice or veterinary pharmacy service with the appropriate approval.

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

Veterinary medicine means a compound administered directly to or on animals for one or more of the purposes listed in the Agricultural Compounds and Veterinary Medicines Act 1997. Veterinary medicines include registered veterinary medicines, products that are exempted from registration, prescription (human) medicines when authorised by a veterinarian and compounded veterinary preparations.

Veterinary Operating Instruction (VOI) means a set of instructions from an authorising veterinarian to a non-veterinarian to hold restricted veterinary medicines (RVM) in anticipation of their use, and to use RVMs only in accordance with the authorising veterinarian's instructions in circumstances in which the authorising veterinarian will not be carrying out a case-specific consultation.

Templates for use/modification

Appendix 1 – veterinary authorisation (single veterinary medicine)

THIS AUTHORISATION IS FOR ANIMAL USE ONLY	
Authorising veterinarian Name Signature	
Veterinary practice Name Address 24-hr contact number	
Date of consultation	**Authorisation end/review date**
Repeat supply permitted within the duration of validity of the authorisation? Y/N Details:	
Owner/person in charge of animal(s) Name Address	
Name(s) of any other person(s) authorised to use this veterinary medicine	
Animal(s) to be treated Name/number Other identification	
Product Trade name Active ingredient [Concentration]	
Quantity authorised	
Treatment instruction Dose size Dose frequency Method of administration	
Other instructions Storage Record-keeping Disposal of excess product	
Withholding period (if applicable) Meat Milk	
Warnings Contraindications Adverse event procedure	
Notes:	

Appendix 2 – veterinary authorisation (multiple veterinary medicines)

THIS AUTHORISATION IS FOR ANIMAL USE ONLY			
Authorising veterinarian Name Signature		**Veterinary practice** Name Address 24-hr contact number	**Owner/person in charge of animal(s)** Name Address
Date of consultation	**Authorisation end/review date**	**Repeat supply permitted within the duration of validity of the authorisation?** Y/N Details:	Name(s) of any other person(s) authorised to use these veterinary medicines

Product trade name	**Active ingredient** [Concentration]	**Quantity authorised**	**Animal/s to be treated**	**Condition to be treated** **(refer to external documentation for more details re decision making – e.g. 1st line treatment - heifer mastitis in spring vs 1st line treatment - cow mastitis, mid-season)**	**Treatment instruction** Dose size Dose frequency Method of administration	**Warnings** Contraindications Adverse event procedure	**Withholding period** Meat Milk

Notes:

Appendix 3 – Veterinary Operating Instruction

THIS AUTHORISATION IS FOR ANIMAL USE ONLY		
Authorising veterinarian Name Signature		
Veterinary practice Name Address 24-hr contact number		
VOI unique identifier	**VOI Commencement date**	**VOI end/review date**
Purpose of VOI Note: using the RVM for any other purpose is not authorised		
Process for monitoring VOI compliance		
Person(s) authorised to operate under this VOI		
Name Address Responsibility	Name Address Responsibility	Name Address Responsibility
Name Address Responsibility	Name Address Responsibility	Name Address Responsibility
Process for skill training and assessment		
General description of animal(s) to be treated under this VOI Note: individual animals are to be identified in treatment records		
Geographic area in which this VOI may be used Note: authorising veterinarian is responsible for emergency care, and must be able to respond		
Procedure to be performed under this VOI **Procedure instructions**		

Equipment required for above procedure:
Expected treatment outcomes
Possible negative and/or unexpected treatment outcomes (adverse events), and required responses
Process for managing adverse events **Emergency veterinary contact details**

RVM product details Trade name Active ingredient [Concentration]	**Quantity authorised**
Repeat supply permitted within the duration of validity of the authorisation? Y/N Details:	
Treatment instruction Dose size Dose frequency Method of administration	
Information to record with each use Date of use Initials/code of authorised user Reason for use Reconciliation of RVM on-hand and RVM used	
Process for RVM product reconciliation Note: all records of RVM purchases and disposals must be kept and periodically reconciled (at least every 6 months)	
Other instructions Product storage Record-keeping (location of records, and length of time records kept) Disposal of excess product	
Withholding period (if applicable) Meat Milk	
Warnings Contraindications Adverse event procedure	
Notes:	