



NZVA
New Zealand Veterinary Association

A Guide to Veterinary Authorising (Prescribing) and Dispensing

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Guidelines for Registered Veterinarians

Authorising (Prescribing) and Dispensing Prescription Medicines, Restricted Veterinary Medicines and Controlled Drugs

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SECTION A: Purpose

The purpose of this guideline is to specify the obligations of registered veterinarians when authorising (prescribing), writing prescriptions and dispensing products licensed under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, the Medicines Act 1981, the Misuse of Drugs Act 1975 and the Misuse of Drugs Regulations 1977.

Conformance with this guideline for prescription writing and dispensing will assist veterinarians in meeting their obligations under the ACVM Act and the Veterinary Council of New Zealand Code of Professional Conduct (COPC) associated with the act of prescribing and dispensing these products. This guideline has been endorsed by the Veterinary Council of New Zealand (VCNZ).

Performance and Technical Standards for Veterinarians

Veterinarians issuing authorisations for the purchase, use or holding of restricted veterinary medicines must comply with the *ACVM Performance and Technical Standards No 1 (December 2009) – Veterinarians Recognised (under s 62, ACVM Act) to issue a valid Authorisation for Purchase and use of Restricted Veterinary Medicines requiring Veterinary Authorisation*.

These standards are required to be met by veterinarians when issuing an authorisation for purchase and use of RVMs that under the conditions of registration require veterinary authorisation. Failure to comply with the ACVM standards may result in a Ministry for Primary Industries (MPI) prosecution and/or loss of recognised person status. This would mean that the veterinarian would be unable to purchase or authorise the use of Restricted Veterinary Medicines (RVMs).

The ACVM standards can be downloaded at <http://www.foodsafety.govt.nz/industry/acvm/vet-medicines/using/>.

All registered veterinarians holding an annual practising certificate issued under the Veterinarians Act 2005 are recognised as persons eligible to issue an authorisation for the purchase and use of RVMs, under section 62 of the ACVM Act.

Veterinarians must also comply with the COPC and any relevant standards issued under the Veterinarians Act 2005. Failure to comply with the COPC may also result in an investigation by the VCNZ.

SECTION B: Definitions

Authorising veterinarian

A veterinarian recognised under section 62 of the ACVM Act to issue veterinary authorisations.

(Veterinary) Authorisation

An instruction from a veterinarian authorising the person named in the authorisation to:

- a. Purchase a RVM.
- b. Hold a RVM in anticipation of its use by that person as per the instructions of the veterinarian (e.g. a farm RVM consultation).
- c. Use a RVM as per the instructions of the veterinarian.

A veterinary authorisation may include:

- a. Clinical case records noting that a RVM was prescribed by the veterinarian and dispensed from the stocks held in that veterinarian's practice.
- b. Letters or other documents to a party providing the authorisation to that party to hold a RVM in anticipation of use (e.g. letter to a feed company to hold RVMs for inclusion in medicated feeds as directed by the authorising veterinarian).
- c. Prescriptions issued by the authorising veterinarian on an ad hoc basis, to be dispensed by another veterinary practice, veterinary pharmacy service or an Approved Seller.

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

For the purposes of this guideline the following distinctions are made - Internal Veterinary Authorisation and External Veterinary Authorisation.

Internal Veterinary Authorisation

Is a 'within practice' documented record of the prescribing decision and record of the dispensing conditions for drugs dispensed from the prescribing veterinarian's own practice either for use at the time of consult or for future use. This can take the form of clinic records or in production animal practices there may be more formal templates to coincide with annual authorisations to allow drugs to be kept in anticipation of future use or the use of Veterinary Operating Instructions.

External Veterinary Authorisation

Is a more formally written documented order to supply an RVM or PM when the product is not supplied immediately by the prescribing veterinarian and is not going to be dispensed from the prescribing veterinarian's own business. See (c) above e.g. to authorise another veterinarian to dispense drugs to your client when they are away or have lost/run out of drugs, to authorise the dispensing of PMs from a pharmacy, and to allow supplying of RVMs and PMs from Approved Sellers.

The original hard copy of the authorisation must be presented to an Approved Seller or pharmacy before products can be supplied.

In exceptional circumstances where the product is required urgently the prescribing veterinarian may communicate the authorisation orally, or provide an electronic copy of the authorisation, to the person who will supply it. In these circumstances the prescribing veterinarian must also forward the original hard copy authorisation to the supplier within 7 days as confirmation of the oral or electronic request.

Controlled Drugs

Controlled drugs are defined under the Misuse of Drugs Act and the Misuse of Drugs Regulations. In general terms medicines are placed under the Misuse of Drugs Act to provide added controls over and above the requirements of the Medicines Act for those products that are subject to abuse, addiction and habituation.

Operating Plans

The ACVM Act allows for an alternative method of selling and using RVMs - operating plans – which are specified as a condition of registration. Operating plans can be issued for products where veterinary involvement is not needed e.g. the use of a specific vaccine. They must be approved by the ACVM Group.

Prescribing

The act of deciding the appropriate veterinary medicine (whether restricted or unrestricted) and specifying the treatment regime for an animal.

Prescription Medicine

A human medicine that is declared by regulations made under the Medicines Act or by notice given under section 106 of the Medicines Act to be one that, except as may be permitted by the regulations, may be sold by retail, or supplied in circumstances corresponding to retail sale, only pursuant to a prescription given by a medical or dental practitioner or a veterinarian.

Note that some human medicines are not prescription medicines and are available ‘over the counter’ without a prescription.

Production Animals

Any animal from which animal products, as defined in section 4 of the Animal Products Act, may be derived. This includes horses.

Restricted Veterinary Medicine (RVM)

A New Zealand registered trade name product with registration conditions that restrict sale, purchase and use. These were previously known as Prescription Animal Remedies (PARs). RVMs are not divided further into separate classes (as previously using the PAR classification) i.e there is just one classification. There are currently very few veterinary medicines with a specific condition of registration that it is only to be administered by a veterinarian.

Veterinarians must decide the risks, appropriateness and the justification for prescribing and dispensing a RVM.

The purchase, use and holding of RVMs must either be authorised by a veterinarian or be used under an approved operating plan.

For more details see:

http://www.foodsafety.govt.nz/elibrary/industry/Classification_Veterinary-Describes_Appropriate.pdf

Veterinary Operating Instruction (VOI)

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.

For more details see:

www.foodsafety.govt.nz/elibrary/industry/Veterinary_Operating-Guidelines_Issuing.pdf

http://www.vetcouncil.org.nz/CPC/VetMed/CPC_VetMedicines.php

SECTION C: Introduction

The Medicines Regulations define the legal obligations of those eligible to prescribe prescription medicines (i.e. certain products licensed under the Medicines Act).

In regard to RVMs, veterinarians issuing authorisations for the purchase, use or holding of RVMs must comply with the *ACVM Performance and Technical Standards No 1 (December 2009) – Veterinarians Recognised (under s 62, ACVM Act) to issue a valid Authorisation for Purchase and use of Restricted Veterinary Medicines requiring Veterinary Authorisation*. In addition veterinarians must comply with the COPC.

This guideline provides further advice for veterinarians to meet their obligations regarding authorising/prescribing and dispensing.

The ACVM Act provides a legislative basis for prevention or management of the risks associated with the use of veterinary medicines.

The risks to be managed are:

- Risks to trade in primary produce.
- Risks to animal welfare.
- Risks to public health.
- Risks to agricultural security.

It is also a requirement that the use of agricultural compounds does not result in breaches of domestic food residue standards.

Section 55 (3) of the ACVM Act states that:

"every veterinarian commits an offence who knowingly fails to provide a client with information to prevent the occurrence, in any primary produce from any animal treated with an agricultural compound, of residues of that compound which contravene any requirements of the Dairy Industry Act 1952, the Meat Act 198, the Animal Products Act 1999 or the Food Act 1981 or any regulations or notices in force under those Acts."

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, or the Animal Welfare Act 1999.

Civil liability may also be a consequence as a result of losses incurred by a client through inadequate advice or service.

SECTION D: Obligations of Veterinarians when Authorising (Prescribing) and Dispensing Prescription Medicines (PMs)

The obligations of veterinarians when prescribing PMs are specified in Part 7 of the Medicines Regulations, which describe:

- the conditions under which veterinarians may prescribe.
- compliance requirements.
- the form of prescriptions.
- the conditions for dispensing prescription medicines.

1. Conditions

- 1.1. Veterinarians shall prescribe PMs only for the treatment of animals under their care.
- 1.2. Veterinarians can **either** prescribe for supply of a PM from a third party in which case the requirements of clause 41 of the Regulations (a written prescription) must be followed **or** where the veterinarian supplies the PM from supplies held in the practice, the PM can be used without a prescription, as permitted by clause 44 (i.e. clinical records will suffice).
- 1.3. A veterinarian shall not prescribe for any animal(s) under his/her care, a quantity of a PM that exceeds 3 months supply.
- 1.4. Prescriptions must not be dispensed on any occasion after 6 months have elapsed from the date on which it was printed or communicated orally.

2. Compliance

- 2.1. Copies of the prescription for PMs must be kept by the veterinary practice for a period of at least 5 years. Audit of records of treatment may be subject to verification. It is recommended that robust systems be set up to ensure adequate records are maintained.
- 2.2. Veterinarians are encouraged to make use of standardised prescription forms. See Appendix I.

3. Form of prescription for supply by a third party (see clause.41)

The prescription shall:

- 3.1. be legible and indelibly printed.
- 3.2. be signed and dated personally by the prescriber with his/her usual signature (not a stamp).
- 3.3. carry the address of the prescriber and veterinary practice.
- 3.4. set out the title, surname, initial of each given name, and the address of the owner of the animal(s).
- 3.5. contain the following statement or words of similar meaning 'not for human use' or 'for animal use only'.
- 3.6. describe the breed, sex and age of the animal(s) to be treated.
- 3.7. indicate the name of the medicine and strength of the medicine required to be dispensed.
- 3.8. indicate the total amount of the medicine that may be sold or dispensed on one occasion, or on each of the several occasions authorised by that prescription.
- 3.9. state if the medicine is to be administered by injection, or by insertion into any cavity of the body, or by swallowing, indicate the dose and frequency of the dose; and

- 3.10. state if the medicine is to be applied externally, indicate the method and frequency of use; and
- 3.11. state if it is the intention of the prescriber that the medicine should be supplied on more than one occasion, bear an indication of:
 - 3.11.1. the number of occasions on which the medicine can be supplied; or
 - 3.11.2. the interval to elapse between each supply; or
 - 3.11.3. the period of treatment during which the medicine is intended to be used.
- 3.12. contain the information that the prescribed period of treatment shall not exceed 3 months.

Should a veterinarian require a prescription to be filled urgently, he/she may, if necessary, communicate that prescription orally to a pharmacist known personally to that veterinarian, providing that within 7 days, the veterinarian communicates that prescription in writing to that pharmacist as confirmation of the request made orally (see clause 40).

4. Form of prescription when medicines are dispensed from the prescribing veterinarian's own practice (see clause.44)

The prescription takes the form of written clinical records and these records must:

- 4.1. be linked to the correct owner, and owner details must be complete and linked to the specific patient who must be identified by breed, sex and age and these records must be accessible and auditable and kept for at least 5 years.
- 4.2. indicate the name of the medicine and strength of the medicine required to be dispensed.
- 4.3. indicate the total amount of the medicine that may be sold or dispensed on one occasion, or on each of the several occasions authorised by that prescription.
- 4.4. state if the medicine is to be administered by injection, or by insertion into any cavity of the body, or by swallowing, indicate the dose and frequency of the dose; and
- 4.5. state if the medicine is to be applied externally, indicate the method and frequency of use; and
- 4.6. state if it is the intention of the prescriber that the medicine should be supplied on more than one occasion, bear an indication of:
 - 4.6.1. the number of occasions on which the medicine can be supplied; or
 - 4.6.2. the interval to elapse between each supply; or
 - 4.6.3. the period of treatment during which the medicine is intended to be used.

Note: The quantity of a prescription medicine prescribed for any animal shall not exceed 3 months supply. Prescriptions remain valid for a maximum of 6 months from issue.

5. Dispensing of Prescription Medicines (see clause 42)

- 5.1. An agent or employee of a veterinarian may, in any particular case, dispense any PM at the direction of the veterinarian for use in the treatment of any animal under the care of that veterinarian.
- 5.2. Every person dispensing a prescription relating to a PM shall comply with the following requirements:
 - 5.2.1. The prescription may only be dispensed more than once if the prescriber indicates to that effect on the prescription and at the same time indicates the interval to elapse between each prescription.
 - 5.2.2. For prescriptions which have been communicated orally under regulation 40A(1), the prescription must not be dispensed on more than one occasion

before the pharmacist has received the written confirmation of the prescription, as required by regulation 40A(2).

- 5.2.3. The prescription must not be dispensed after 6 months have elapsed from the date on which it was written, or if communicated orally for urgent prescriptions (see clause 40A (1)).
- 5.3. Where a veterinarian refers in a prescription to a medicine by its trade mark or trade name or by reference to the name of its manufacturer, a pharmacist shall supply that medicine accordingly, unless the veterinarian has sanctioned a change:
 - 5.3.1. in relation to that particular prescription; or
 - 5.3.2. in writing generally in relation to that particular prescription; or
 - 5.3.3. in writing generally in relation to medicines in general;

and any such change, together with the date of the sanction, shall be noted on the prescription by the pharmacist who shall sign the prescription, or added to the clinical record.

SECTION E: Obligations of Veterinarians when Prescribing/Authorising and Dispensing Restricted Veterinary Medicines (RVMs)

The purchase, use and holding of RVMs must either be authorised by a veterinarian or be used under an approved operating plan.

COMPANION ANIMALS AND PRODUCTION ANIMALS

1. Conditions

Veterinarians shall authorise RVMs only for animals under their care.

2. Gathering sufficient information

Before authorising the purchase, holding or use of RVMs the ACVM Group's requirement is for the veterinarian to gather sufficient information. The ACVM Group's interpretation on what constitutes sufficient information and how it is gathered is that it should be left to the professional judgement of the veterinarian.

The COPC however, states that the principal method of meeting that requirement is via consultation. An alternative option to consultation, which is only likely to be suitable in certain limited circumstances, is through the use of Veterinary Operating Instructions (VOIs). These two options define the only two processes by which veterinarians can authorise RVMs. The COPC defines a consultation as:

3. Veterinary consultation

A veterinary consultation must include the veterinarian:

- 3.1. interviewing the client (or a legitimate and authorised representative of the client).
- 3.2. 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.
- 3.3. obtaining appropriate consent to the proposed course of action.
- 3.4. being given and accepting responsibility for the on going 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.
- 3.5. 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.

4. Internal veterinary authorisation/external veterinary authorisation

Veterinarians may either authorise (prescribe) a RVM using an internal veterinary authorisation or an external veterinary authorisation.

Internal Veterinary Authorisation

Is a 'within practice' documented record of the prescribing decision and record of the dispensing conditions for drugs dispensed from the prescribing veterinarian's own practice either for use at the time of consultation or to be held in anticipation for future use. This will be

recorded in the medical records or in production animal practice there may be more formal templates to coincide with RVM consultations to allow drugs to be kept in anticipation of future use, and used in a more generalised way.

External Veterinary Authority

Is a more formally written documented order to supply an RVM or PM when the product is not supplied immediately by the prescribing veterinarian and is not going to be dispensed from the prescribing veterinarian's own business e.g. to authorise another veterinarian to dispense drugs to your client when they are away or have lost/run out of drugs, to allow the supply of RVMs and PMs from Approved Sellers and to authorise the supply of PMs from a pharmacist. New Zealand veterinarians can only authorise the purchase of RVMs from another veterinary clinic or an approved RVM seller from within New Zealand, there is no allowance for the importation of RVMs from overseas. If a veterinarian wishes to authorise an RVM not available in New Zealand, the veterinarian must apply for an Approval in Special Circumstances from the Ministry for Primary Industries (MPI) and manage the importation of the product themselves.

5. Compliance

- 5.1. Records of the prescription must be kept by the veterinary practice. These may take the form of formal written records or take the form of patient clinical records. Audit of both types of records may be subject to verification. It is recommended that robust systems be set up to ensure adequate records are maintained. Prescription/authorisation records should be kept for 5 years after the date of the last consultation.
- 5.2. Veterinarians are strongly encouraged to make use of standardised prescription forms when prescribing for supply outside the veterinarian's own clinic.

6. Form of external authorisation/prescription

The authorisation/prescription shall:

- 6.1. be readily recognisable as a veterinary authorisation.
- 6.2. be legible and indelibly printed.
- 6.3. be signed and dated personally by the authorising veterinarian with his/her usual signature (not a stamp).
- 6.4. carry the printed name of the authorising veterinarian, address and contact details of the veterinary practice or organisation of the authorising veterinarian.
- 6.5. set out the title, surname, initial of each given name, and the address of the owner (or person in charge) of the animal(s) to be treated.
- 6.6. describe the breed, sex and age of the animal(s) to be treated.
- 6.7. indicate the trade name, and strength of the RVM required to be dispensed.
- 6.8. state the quantity of the RVM authorised and the duration of the validity of the veterinary authorisation and if it is to be used for repeat supply/filling.
- 6.9. state the route of administration, dose/application rate and frequency of doses.
- 6.10. state the number of occasions on which the RVM can be supplied; or
- 6.11. state the interval to elapse between each supply; or
- 6.12. the period of treatment during which the RVM is intended to be used.
- 6.13. direct the dispenser to provide the use instructions and any additional instructions or precautions to be followed to the person named in the veterinary authorisation.
- 6.14. contain the following statement or words of similar meaning 'not for human use' or 'for animal use only'.

When being dispensed by a third party, the prescriber cannot prescribe any amount smaller than the smallest commercial pack size.

For production animals the following requirements are in addition to the above:

- a. The withholding period for the RVM, if applicable, in order to prevent residues; (**note** that it is an offence under section 55 of the ACVM Act, not to provide this information)
- b. When prescribing for medicated feed:
 - i. the specific feed if being added to feed.
 - ii. the specific quantity of medicated feed, containing the RVM, to be supplied.
 - iii. the final concentration of the medication in the feed or water (e.g. kg/tonne).

Copies of the prescription shall be:

- a. kept by the veterinarian; and
- b. supplied to client(s) and/or supply company(s) with the recommendation that such documents are kept for audit purposes.

7. Form of internal authorisation/prescription

In the case of an internal authorisation (dispensed from veterinarian's clinic) records can be via clinical notes or in the case of RVM for production animals for future use it is recommended that a more formal written record is kept (see Appendix IV). In either case records must:

- 7.1. be linked to the correct owner, and owner details must be complete and linked to the specific patient who must be identified by breed, sex and age and these records must be accessible and auditable and kept for at least 5 years.
- 7.2. indicate the name of the medicine and strength of the medicine required to be dispensed.
- 7.3. indicate the total amount of the medicine that may be sold or dispensed on one occasion, or on each of the several occasions authorised by that prescription.
- 7.4. state if the medicine is to be administered by injection, or by insertion into any cavity of the body, or by swallowing, indicate the dose and frequency of the dose; and
- 7.5. state if the medicine is to be applied externally, indicate the method and frequency of use; and
- 7.6. if it is the intention of the prescriber that the medicine should be supplied on more than one occasion, bear an indication of:
 - 7.6.1. the number of occasions on which the medicine can be supplied; or
 - 7.6.2. the interval to elapse between each supply; or
 - 7.6.3. the period of treatment during which the medicine is intended to be used.

8. Labelling

- 8.1. **Labels requirements: The container in which veterinary medicines are dispensed must be legibly and indelibly labelled with the following information:**
 - 8.1.1. Name and address and 24 hour contact phone numbers of the veterinary practice.
 - 8.1.2. Date dispensed.
 - 8.1.3. Trade name of the drug, and the active ingredient and the concentration of the drug if compounded.

- 8.1.4. Directions for use, including dose rate, frequency of treatment, route and method of treatment and duration of treatment.
- 8.1.5. Number of tablets, capsules or volume of liquid.
- 8.1.6. Name of owner/owner's agent.
- 8.1.7. Name or identification of animal/group to be treated.
- 8.1.8. Name of prescribing veterinarian (initials are adequate as long as they identify a particular veterinarian).
- 8.1.9. The statement "Keep Out of Reach of Children".
- 8.1.10. The statement in bold print "**FOR ANIMAL TREATMENT ONLY**".
- 8.1.11. Essential warnings if necessary (e.g. for external use only, special storage conditions and any special conditions in regard to operator safety).
- 8.1.12. The registered withholding period (or estimated withholding period for compounding) when used in food producing animals.

Note

If the pack is too small for the label with all the instructions, use a "flag" method to fix to the pack **or**, if this is not possible attach the label to a re-sealable plastic envelope containing the product. Ensure the practice label does not obscure essential information on the manufacturer's pack. If this occurs, label the product to identify the practice, client, date, veterinarian and product contained and then provide a product information sheet that provides all the information required.

For **compounded preparations** the labelling requirements encompass all of 8.1 and also the name/details of compounder (if a third party), active ingredient(s) and their concentrations, use by date or expiry date if applicable, and a batch number or equivalent.

8.2. Labelling ointments, creams or lotions

For topical use and liquids for external use, these are normally dispensed in the manufacturer's pack. If the pack is too small for the label with all the instructions, use a "flag" method to fix to the pack or (if this is not possible) attach the label to a resealable plastic envelope containing the product.

Ensure the practice label does not obscure essential information on the manufacturer's pack. If this occurs, label the product to identify the practice, client, date, veterinarian and product contained and then provide a product information sheet that provides all the information required.

8.3. Labelling injectable products

These are normally dispensed in the manufacturer's pack. If dispensed in smaller amounts/volume than the manufacturer's pack, a practice label must be placed on the container ensuring the practice label contains all essential information on the manufacturer's pack or if this is not physically possible the product must at least have a practice label identifying the practice, client, date, veterinarian, product contained, animal group to be treated and then provide a product information sheet that provides all the information required.

8.4. Labelling pre-loaded syringes

If dispensing in pre-loaded syringes, ensure the needle is protected by a cap but preferably use a syringe cap without a needle. A label must be attached to the pre-loaded syringe to at least identify the practice, date and product contained. It is preferable for this label to also identify the prescribing veterinarian, client and animal and accompany the syringe with an information sheet that provides all the other necessary information.

8.5. Labelling safety instructions

For any treatment administered, dispensed or prescribed including discretionary use (excluding use of medicines in clinic), the animal's owner/owner's agent must be advised of any special considerations in regard to operator safety. Where possible this information must be printed on the drug label.

8.6. Labelling multi packs

For food producing animals where the product is dispensed in the manufacturer's pack, a practice label detailing the information above must be attached to the pack, **or** in the case of multiple packs to the outer package, **or** products can be dispensed with an information sheet which details the above information but the outer pack must be labelled to at least identify the clinic of origin, e.g. dry cow syringes.

8.7. Point of entry labelling of RVMs and PMs

Practice labels that identify the veterinary practice of origin and its phone number should be attached at point of entry into the clinic for all large animal RVMs and PMs likely to be dispensed in their manufacture's packs (the outer of multiple packs such as mastitis syringes is acceptable).

9. Period of supply of a Restricted Veterinary Medicine

There is no maximum period of supply of a RVM – it will depend on the product (type of product, storage etc.), the animal's condition (is it likely to change with time and therefore should be seen again by a specific date) and the client (ability to administer, compliance with administration requirements, ability to detect changes in animal's condition) and the risks associated with use such as antibiotic resistance or residues.

A maximum of **6 months** supply is suggested for individual animal treatments and **6-12 months** for RVMs authorised for future supply for production animals.

When determining the time period and volumes to be prescribed via external authorisations, veterinarians should consider the likely frequency of farm visits and contact with the client for the supply period. It is recognised there is a higher risk associated with less farm visits and farmer contact and therefore veterinarians should select conservative time periods (**e.g. 6 months**) and volumes.

Note: For RVMs issued under VOIs, a maximum period of **12 months** only is permitted.

10. Dispensing of Restricted Veterinary Medicines

RVMs will be either dispensed by the authorising veterinarian, employees of veterinarians or by an Approved Seller that has an approved ACVM Operating Plan. An employee of a veterinarian may dispense RVMs at the direction of the veterinarian, for use in the treatment of any animal under the care of that veterinarian. Employees who dispense RVMs must be trained and competent to do so. Approved Sellers must be approved by the ACVM Group and comply with the standards set by the Group.

Every person dispensing a prescription relating to a RVM shall comply with the following requirements:

- 10.1. The prescription may only be dispensed more than once if the prescriber indicates to that effect on the prescription and at the same time indicates the interval to elapse between each prescription;
- 10.2. Where a veterinarian refers in a prescription to a RVM by its trade name that RVM shall be supplied accordingly, unless the veterinarians has sanctioned a change:
 - 10.2.1. in relation to that particular prescription; or
 - 10.2.2. in writing generally in relation to that particular prescription; or
 - 10.2.3. in writing generally in relation to RVMs in general.

and any such change, together with the date of the sanction shall be noted on the prescription by the dispensing person who shall sign the prescription, or added to the clinical record.

10.3. Label appropriately.

SECTION F: Veterinary Operating Instructions

1. A VOI is 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, where the authorising veterinarian will not be carrying out a case-specific consultation. Examples may be vaccination of animals in a shelter or the use of analgesics for the disbudding of calves by a technician.
2. VOIs should only be issued in circumstances where there is no reasonable expectation that either veterinary judgement or a veterinary diagnosis would be needed to ensure that the use of the product in the specific case is appropriate and justified.
3. When issuing VOIs, veterinarians must comply with the requirements and expectations of the ACVM Group.

These can be found at:

www.foodsafety.govt.nz/elibrary/industry/Veterinary_Operating-Guidelines_Issuing.pdf.

4. The document states that compliance with the guidelines for VOIs is not mandatory. However, the COPC requires that veterinarians must follow these guidelines and meet the minimum suggested requirements.
5. In addition, the COPC also sets out further requirements for the issuing of VOIs. Veterinarians must:
 - 5.1. Tightly define the specific treatment circumstances in which each restricted veterinary medicine is authorised to be used under a VOI.
 - 5.2. Authorise use of RVMs under a VOI only in circumstances where there is no reasonable expectation that either veterinary judgement or a veterinary diagnosis would be needed to ensure that the use of the product in the specific case is appropriate and justified.
 - 5.3. Be able to provide evidence that the process for developing and issuing a VOI has been followed appropriately prior to implementation of the instructions.
 - 5.4. Be able to provide evidence that they have identified:
 - 5.4.1. the specific competencies required of personnel authorised in the VOI.
 - 5.4.2. appropriate detail on the training and assessment of the personnel in relation to those competencies.
 - 5.5. Make it a requirement of the VOI that specific records are kept in relation to every instance of use of the RVMs by the VOI specified personnel. Records must document sufficient information to permit easy assessment of compliance with the terms of the VOI.
 - 5.6. Be able to provide evidence of sufficient monitoring that allows the veterinarian to be confident that the terms of the VOI are being complied with.
 - 5.7. Review the competency of the personnel at least annually by personally assessing the use of the restricted veterinary medicines by the user.
 - 5.8. Withdraw the VOI immediately in situations of non compliance.
 - 5.9. A sample VOI template is provided in the ACVM Group document.
 - 5.10. VOIs are not limited to only using RVMs on animals belonging to the veterinarian's clients. Neither are they limited to using the products following a consultation between the veterinarian and the owner of the animals. Consequently there is not necessarily a veterinarian-client relationship between the veterinarian issuing the VOI and the owner or the person in charge of the animals being treated under the authority of the VOI. While it is technically feasible for a VOI to be written to be used on animals that are geographically remote from the authorising veterinarian, authorising veterinarians should

bear in mind that it may be difficult to meet all of their VOI responsibilities (e.g. supervision of the VOI, managing adverse events etc.) in relation to the VOI when the authorised person is acting remotely from them. Veterinarians are strongly advised to consider carefully and act with caution when considering issuing VOI for situations where the animals to be treated do not belong to their clients.

6. There are very few exceptions where veterinary diagnosis and judgement would not be considered a requirement in order to justify the appropriate use of antibiotics. Therefore, VOIs are unlikely to be considered an appropriate way to authorise the use of these products.
7. VOIs must not be issued for Controlled Drugs.
8. VOIs must be reviewed every 12 months.

SECTION G: Controlled Drugs

1. Controlled drugs are administered under the Misuse of Drugs Act and the Misuse of Drugs Regulations.
2. Class A drugs are those for which Ministerial approval is required for use. This class is subject to very tight controls and includes etorphine.
3. Class B drugs include morphine, amphetamines, Ritalin, pseudoephedrine and ephedrine. Some class B drugs can only be prescribed with ministerial approval, (particularly ephedrine and pseudoephedrine). Class B drugs such as Morphine, Pethidine, Methadone and Fentanyl which are more commonly used by veterinarians do not require ministerial approval.
4. All classes of controlled drugs (with a few minor exceptions) are subject to specific secure storage requirements.
5. Controlled drugs commonly found in veterinary practices include but are not limited to: morphine, fentanyl, pethidine, buprenorphine, codeine, ephedrine, pseudoephedrine, diazepam, midazolam, pentobarbital and ketamine.
6. Every instance of sale or use of a controlled drug must be linked to a veterinary consultation. There must also be an accurate record which can be readily reported and reviewed. The COPC requires veterinary businesses that do not use a computerised medical record system that is able to quickly and easily report on the sale or use of each controlled drug, to record each individual sale or use in a Controlled Drug Register. This register must take the form of a bound volume with consecutively numbered pages set out and used as described in Form 1 Schedule 1 of the Controlled Drugs Regulations. Each page of this register must only be used for one kind and one strength of controlled drug.
7. Where computerised medical records are used to carry out the reconciliations the reports must include the following fields: authorisation date; name and address of client; name of patient; name and strength of controlled drug; volume or amount used; and authorising veterinarian.
8. Controlled drugs will either be prescribed for supply by a pharmacist or supplied from the veterinarian's practice.
9. Veterinarians do not have to write on the triplicate controlled drug prescription form, (as required for human medical doctors) as the legislation requires these are used only for prescribers of medicines intended for human use.
10. Veterinarians must still abide by the legislation in terms of what must be written on the prescription as per regulation 29 of the Misuse of Drugs Regulations. This includes:
 - 10.1. be legibly and indelibly written.
 - 10.2. include the date on which it is signed.
 - 10.3. the address of the person by whom it is signed: provided that the address may be stamped on the prescription.
 - 10.4. the name of the controlled drug to be supplied.
 - 10.5. the name of the person having custody of the animal to which the controlled drug is intended to be administered.
 - 10.6. not be written in cipher, or abbreviated, otherwise than by abbreviations recognised in the British Pharmacopoeia, the British Pharmaceutical Codex, or other standard reference books on materia medica or pharmacy.
 - 10.7. indicate the total amount of the controlled drug that may be sold or dispensed on the one occasion, or on each of the several occasions, authorised by that prescription.
 - 10.8. the dose and frequency of the dose, or, in the case of a controlled drug for external use, directions for use.

10.9. include the wording 'for animal treatment only'.

Note:The quantity of a prescription medicine prescribed for any animal shall not exceed 3 months supply. Prescriptions remain valid for a maximum of 6 months from issue.

11. If the prescription takes the form of written clinical notes they must:

11.1. be linked to the correct owner, and owner details must be complete and linked to the specific patient who must be identified by breed, sex and age and these records must be accessible and auditable and kept for at least 5 years.

11.2. indicate the name of the medicine and strength of the medicine required to be dispensed.

11.3. indicate the total amount of the medicine that may be sold or dispensed on one occasion, or on each of the several occasions authorised by that prescription.

11.4. state if the medicine is to be administered by injection, or by insertion into any cavity of the body, or by swallowing, indicate the dose and frequency of the dose; and

11.5. state if the medicine is to be applied externally, indicate the method and frequency of use; and

11.6. state if it is the intention of the prescriber that the medicine should be supplied on more than one occasion, bear an indication of:

11.6.1. the number of occasions on which the medicine can be supplied; or

11.6.2. the interval to elapse between each supply; or

11.6.3. the period of treatment during which the medicine is intended to be used.

Note: The quantity of a prescription medicine prescribed for any animal shall not exceed 3 months supply.

Prescriptions remain valid for a maximum of 6 months from issue.

12. Regulation 41 of the Misuse of Drugs Regulations provides an exemption for veterinarians from the requirement to maintain controlled drug registers and prescription books. However, because of the potential for abuse, the VCNZ considers that there is an overriding professional obligation for veterinarians to oversee and manage the use of controlled drugs to a higher standard than the obligations imposed by law.

13. The COPC requires that veterinarians regularly reconcile the physical stock of these products against sales and purchases. An important component of this process is the need to account for variances.

14. The NZVA expectation is that there must be a responsible veterinarian specified in each clinic who ensures that reconciliations take place and that the monitoring is adequate to manage the risks associated with each drug.

15. Where this reconciliation identifies stock of controlled drugs which cannot be accounted for the responsible veterinarian must provide a reasonable and justifiable explanation to the VCNZ.

16. Any extraordinary variances in the reconciliation that cannot be explained or are thought to be due to unauthorised use must be reported to the VCNZ by the responsible veterinarian.

17. The minimum frequency for regular stocktaking and reconciling controlled drugs required by the COPC is 6 monthly. NZVA recommends that the level of reconciliation is expected to reflect the risk profile of that specific drug and be more frequent as required.

18. Documented records of the stocktaking and reconciliation process must be made and maintained for 5 years to allow review if needed.

19. Dispensing of Controlled Drugs

19.1. Controlled drugs will either be dispensed from a veterinary clinic's own supplies or by a prescription to a pharmacist. Pharmacists need to ensure they meet the requirements for

the labelling of a controlled drug prescribed by a veterinarian as detailed in regulation 25(5) of the Misuse of Drugs Regulations.

- 19.2. An agent or employee of a veterinarian may, in any particular case, dispense any controlled drug at the direction of the veterinarian for use in the treatment of any animal under the care of that veterinarian.
- 19.3. Every person dispensing a prescription relating to a controlled drug shall comply with the following requirements:
 - 19.3.1. The prescription may only be dispensed more than once if the prescriber indicates to that effect on the prescription and at the same time indicates the interval to elapse between each prescription.
 - 19.3.2. The prescription must not be dispensed after 6 months have elapsed from the date on which it was written, or if, communicated orally for urgent prescriptions (see Regulation 40A (1)).
- 19.4. Where a veterinarian refers in a prescription to a medicine by its trade mark or trade name or by reference to the name of its manufacturer, a pharmacist shall supply that medicine accordingly, unless the veterinarian has sanctioned a change:
 - 19.4.1. in relation to that particular prescription; or
 - 19.4.2. in writing generally in relation to that particular prescription; or
 - 19.4.3. in writing generally in relation to medicines in general;and any such change, together with the date of the sanction, shall be noted on the prescription by the pharmacist who shall sign the prescription, or added to the clinical record.
- 19.5. In cases of emergency, a pharmacist may, at the direction of the veterinarian supply to any person a controlled drug that is dispensed pursuant to a prescription communicated orally or by telephone.
- 19.6. The veterinarian shall forthwith put the prescription to writing so as to comply with regulation 29, and shall, within 2 business days, deliver it to the pharmacist whom he or she authorised to dispense it, with an indication written thereon to the effect that it is intended only in confirmation of a prescription already communicated orally or by telephone on a date stated in that indication; and thereupon the prescription, and the pharmacist in respect thereof, shall be subject to all the provisions of these regulations relating to prescriptions for the supply of controlled drugs and to the duties of persons in respect of such prescriptions.
 - 19.6.1. The quantity of a prescription medicine prescribed for any animal shall not exceed 3 months supply.
 - 19.6.2. Prescriptions remain valid for a maximum of 6 months from issue.

Appendices: Templates for Prescription Documents

The following templates are included in these appendices:

- a. Appendix I - Sample companion animal prescription form for external authorisation.
- b. Appendix II - Sample production animal prescription form for external authorisation (for individual animals).
- c. Appendix III - Sample prescription label.
- d. Appendix IV - Sample Production Animal Authorisation for Future Supply of RVMs.
 - Suggested topics to be covered in the consultation.

Appendix I: Sample Companion Animal Prescription Pad

Note: It is recommended that the size of this form be A5

COMPANION ANIMAL PRESCRIPTION PAD

This prescription is for **ANIMAL USE ONLY**

1. Prescribing veterinarian

Name

Practice name

Address

Contact details

Signature Date.....

2. Restricted Veterinary Medicine/Prescription Medicine

Name

Strength

Quantity to be dispensed on each occasion

Instruction:

 Dose

 Frequency of dose

 Administration site

 Period of treatment

 Number of repeat supplies

 Precautions

3. Owner (owner's agent) of animal(s)

Name

Address

Contact details

4. Animal(s)

Species.....

Name.....

NOTE: For Prescription Medicines, this prescription must be first dispensed within 6 months of the date of writing or if issued verbally (in the case of urgent prescriptions). A maximum of 3 months supply may only be prescribed for Prescription Medicines. A copy of this prescription must be kept by the prescribing veterinarian. New Zealand veterinarians can only authorise the purchase of RVMs from another veterinary clinic or an Approved RVM Seller from within New Zealand, there is no allowance for the importation of RVMs from overseas.

Appendix II: Sample Production Animal Prescription Pad

Note: It is recommended that the size of this form be A5. Please ensure writing is clearly printed and legible.

PRODUCTION ANIMAL PRESCRIPTION PAD

Date of authorisation consultation

This prescription is for **ANIMAL USE ONLY**

1. Prescribing veterinarian

Name

Practice name

Address

Contact details

Signature Date

2. Restricted Veterinary Medicine/ Prescription Medicine

Name

Active ingredient

Strength

Quantity to be dispensed on each occasion

Instruction:

Dose

Frequency of dose

Administration site

Where applicable:

Feed to which RVM is added

Quantity of feed to be supplied

Final concentration in feed or water

Number of repeat supplies

Supply start and end date

Withholding period

Other precautions

NOTE: Animals must not be slaughtered until AFTER the withholding period has expired.

3. Owner (owner's agent) of animal(s):

Name

Farm name where applicable

Address

Contact details

4. Animal(s) description:

.....

NOTE: For Prescription Medicines, this prescription must be first dispensed within 6 months of the date of writing or if issued verbally (in the case of urgent prescriptions). A maximum of 3 months supply may only be prescribed for Prescription Medicines. A copy of this prescription must be kept by the prescribing veterinarian. New Zealand veterinarians can only authorise the purchase of RVMs from another veterinary clinic or an Approved RVM Seller from within New Zealand, there is no allowance for the importation of RVMs from overseas.

Appendix III: Sample Prescription Label

Practice Name

Practice Address & Phone Number

Date: Vet:

Client: Animal:

RVM: Strength:

Directions:

.....

.....

.....

Warnings:

Withholding times : Meat

Milk.....

For Animal Treatment Only

KEEP OUT OF REACH OF CHILDREN

Appendix IV: Production Animal Authorisation for Future Supply of RVMs

Practice name..... Veterinarians name.....

Practice address and phone number.....

Production Animal Authorisation For Future Supply of RVMs

Name Farmer/manager:		Address:					Date of consultation:	
		Farmer supply number:						
Product:	Amount authorised:	For treatment of the following animals (classes of stock) under my care, for the conditions mentioned:	Active Ingredient and Concentration:	Route of administration, dose and treatment length:	Dispensed/ initials /Date:	Milk and Meat WHT Special Instructions:	Expiry date of Product:	Date of expiry of authorisation: (date)

Following this consultation the listed RVM(s) may be dispensed. By signing this form, the farmer/manager agrees that they will use the drugs according to instructions, contraindications and withholding times and accepts responsibility for ensuring that staff complies with the expectations of this authorisation. Use of these drugs will be

documented as to the animal on which they were used, the time, date and dosage, as well as withholding period.

'Practice name' reserves the right to refuse sale of such drugs if the documentation of on-farm drug use does not satisfy requirements.

On farm training for correct administration and storage of these medicines has been offered ()

Prescribing Veterinarian's Name:

Date:

Signature:

Farmer/manager:

Date:

Signature:

Suggested topics to be covered in the consultation

- Updated client details including new staff
- Required RVMs identified, dosage, treatment regime, administration and restrictions discussed
- Vaccine products identified, dosage, treatment regime, administration discussed
- Requirements of identification of treated animals and withhold requirements discussed
- Record keeping to identify treated animals, products, dates, treatment regime, dose/duration and withholding information
- Adverse reactions
- Disposal of needles, syringes, surplus expired products

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