DRAFT

Update to the Veterinary Medicines Section of the Code of Professional Conduct
This document is intended as a draft only. Please review the contents and send us your feedback. All veterinarians must comply with the Code once it is signed off, so it’s important that if you have comments, you send them now.

Please send any comments to Wayne Ricketts wayne.ricketts@vetcouncil.org.nz
### Summary of proposed changes

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<tr>
<th>Glossary</th>
<th>A number of new definitions have been added</th>
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| Section 1 – Product Stewardship |  • This was the 2nd section in the current code.  
• Sections have been rearranged  
• New section on training |
| Section 2 Legislative Requirements |  • This was the 1st section in the current code  
• New requirement for veterinarians to ensure that an inventory of medicines is required |
| Section 3 Authorisation |  • New sections on Review Consultation, Authorisation for future supply, Period of Supply have been added. |
| Section 4 – Veterinary Operating Instructions |  • This explanatory notes have been updated |
| Section 5 - Documentation |  • New section |
| Section 6 – Antibiotic Use |  • New section |
| Section 7 – Controlled drugs |  • New requirement for hard copy Controlled Drug Register  
• Six monthly reconciliations reduced to monthly |
| Section 8 – Off Label Use |  • New title  
• New sections of s.29 medicines and multi-modal use |
| Section 9 – Compounded Veterinary Preparations |  • New title  
• Has been updated in line with MPI’s guidelines |
| Section 10 - Decanting |  • No changes |
| Section 11 – Providing a Dispensing Service |  • No changes |
| Section 12 – Using a Generic Chemical |  • No changes |
| Section 13 – Human Use of Veterinary Medicines |  • No changes |
| Section 14 - Advertising |  • New requirement that veterinarians must not advertise antibiotics |
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Glossary Terms

Advertise: To publicise to the community or to any section of the community using any words, whether written, printed, spoken, or in any electronic form, or of any pictorial representation or design or device used to promote the sale of any agricultural compound, and ‘to advertise’ has a corresponding meaning (ref: section 2 Agricultural Compounds and Veterinary Medicines Act 1997). Advertising does not include general information transfer about animal health, animal welfare, or food safety status or management.

Authorising, dispensing, recommending, selling and using veterinary medicines:

Authorising: 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.

Dispensing: Supplying veterinary medicines strictly in accordance with a written veterinary authorisation. Products must be dispensed in their registered packaging unless otherwise specified in the authorisation.

Recommending: Advising a client to use a particular veterinary medicine.

Selling: Offering for sale a veterinary medicine, including gifting or offering samples.

Using: A veterinarian administering a veterinary medicine to an animal(s) in their care. This includes staff administering in accordance with the veterinarians instructions.

Antibiotic is a medicine that kills bacteria or inhibits their growth in the body. It includes natural substances (e.g. penicillin), semisynthetic substances (e.g. ampicillin) and totally synthetic substances (e.g. enrofloxacin).

Antimicrobial is a drug, chemical, or other substance that either kills or slows the growth of microbes. Substances that are considered antimicrobials include surface disinfectants, antibiotics, parasiticides, and anti-fungal and anti-viral agents.

Clinical Guideline is defined as a document from a recognised source which is based on current evidence and which aims to guide sound clinical practice e.g. the NZVA Guidelines for the clinical use of antimicrobial agents in the treatment of dogs and cats. This definition does not include marketing material and guidelines promulgated by pharmaceutical companies.

Compounding veterinarian is a veterinarian who prepares a CVP; or under whose instruction a CVP is prepared.

Compounded Veterinary Preparation (CVP) is a preparation of one or more ingredients prepared by a veterinarian (or by a person who is not a veterinarian but is under contract to and under the instruction of the veterinarian) for use on animal(s) as a veterinary medicine. This definition highlights (and is limited to) the generic actions of mixing of ingredients and using it on animals as a veterinary medicine.

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.
Critically Important Antibiotics are those antibiotics which are considered to be critically important to both human and animal health as identified by OIE and WHO. These include Quinolones, 3rd and 4th generation Cephalosporins and Macrolides.

Event Record is a record of the decision to authorise an RVM. It provides sufficient information to link the RVM to the client, the authorisation and the authorising veterinarian.

Exempt veterinary medicine is a veterinary medicine that is not registered but still subject to regulatory controls under the ACVM Regulations. An example of an exempt veterinary medicine is a dog shampoo.

First Line or Empirical Therapy represents the first-choice treatment where the decision is based on judgment and experience in the absence of a confirmed diagnosis.

Generic Chemical is a substance that is offered for sale without any veterinary medicine claims being made by the manufacturer, proprietor or seller.

Inventory: A complete list of all RVM products held for sale or use by a veterinary practice.

Off Label Use: Using a registered veterinary medicine (over the counter or restricted) product for a purpose not approved by MPI.

Period of Supply refers to the duration of the validity of the veterinary authorisation for a RVM.

Medicine is defined in Section 3 of the Medicines Act 1981. In summary, it is any substance for administering to a human for therapeutic purposes.

Prescription Medicine is a subset of those products identified as being Medicines which can only be sold under prescription. Veterinarians have an exemption under Section 27 of the Medicines Act that permits them to prescribe a prescription medicine for the treatment of an animal under the care of that veterinarian, or under the care of another veterinarian.

Registered products can either be classified as either be restricted or unrestricted.

Review Consultation describes a subset of Veterinary Clinical Consultation and is most relevant in a production animal context. The veterinarian and client conduct a review of the client’s animal health and production issues covering the previous period, and then forecast the resources needed for the next period. This will include an estimate of the type and amount of the RVMs that will continue to be needed by the client in order to manage ongoing animal health and production needs which the veterinarian has accepted responsibility for. The review does not need to include an examination of the animals or their environment, but will include the gathering of sufficient information in order to be able to make a decision that justifies the authorisation of RVMs for future supply.

In order to authorise RVMs, the veterinarian (or veterinarians from the same practice) will need to have examined the client’s animals for the condition(s) to be treated recently enough to be satisfied there is an ongoing need to continue to treat the condition.

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 it.
**Telemedicine** is the use of electronic communication and information technologies to provide clinical healthcare remotely. It extends to the provision of veterinary services by video-link, text, instant messaging or telephone, or by any other remote means.

**Unrestricted veterinary medicine** is a veterinary medicine that is 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).

**Veterinary Clinical Consultation:** A Veterinary Clinical Consultation must include the veterinarian:

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

**Veterinary medicine** is a compound that is administered directly to or on animals for one or more of the purposes listed in the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. Veterinary medicines include registered veterinary medicines (e.g. restricted veterinary medicines like antibiotics and unregistered veterinary medicines like drenches and wormers), products that are exempted from registration (e.g. dog shampoo), prescription (human) medicines when authorised by a veterinarian, and compounded veterinary preparations.

**Veterinary Operating Instruction (VOI):** 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.
Section 1: Product Stewardship

1. When veterinarians use or recommend an unrestricted veterinary medicine or authorise (prescribe) a restricted veterinary medicine (RVM), they must consider the implications of its use in relation to risks to public health; trade in primary produce; agricultural security; animal welfare; occupational health and safety; and the environment and act accordingly to avoid or mitigate significant risks. Veterinarians must:

   a. Be satisfied that the choice and use of the product is justified and appropriate to achieve the intended effect; ensures the welfare of the animal; and is consistent with the efficacy, safety, and residue expectations of the product.

   b. Determine and provide the appropriate level of advice and training (if any) to:
      i. Administer the veterinary medicine safely and appropriately;
      ii. Monitor the effects of treatment on the animals;
      iii. Make provision for veterinary intervention in the case of adverse effects.

   c. Determine and provide the appropriate level of veterinary involvement (if any) required during and after administration in order to manage the risks.

   d. Provide appropriate advice on the management of residues and withholding periods in food producing animals.

Understanding Section 1

1. This section identifies the relevant expectations when a veterinarian is considering the treatment of an animal with a veterinary medicine with specific reference to product stewardship.

   The stewardship expectations for RVMs apply to the veterinarian whether they personally use or administer the product, or whether they authorise another person to use or administer the product.

   The same expectations also apply to unrestricted veterinary medicines when a veterinarian or a practice employee is using or making recommendations to a client or member of the public about them. Veterinarians should ensure that the practice staff are competent to make recommendations and that they perform to the standard expected in this Code. Where a veterinarian believes that staff are not performing to the expected standards, the veterinarian is responsible for taking steps to address this.

2. Veterinarians must identify and manage the risks associated with using veterinary medicines. The underlying principle is based on the longstanding medical principle ‘First, do no harm’. A veterinarian’s treatment should minimise the risk of unexpected harmful consequences to the patient, the owner, the veterinarian or their staff.
3. Justified use means there is a valid reason to use the veterinary medicine based on accepted medical principles. Veterinarians are expected to make conscientious and judicious use of current best evidence and integrate this with their own clinical expertise and experience when making decisions about the treatment of their patients.

4. Appropriate use means the particular product choice and the way it is administered is suitable for the situation.

5. Examples of justified and appropriate use include:
   a. Antibiotics should only be used if there is good evidence of a bacterial infection. Appropriate use will depend on the choice of product for the situation, the dose rate used and the route of administration.
   b. Non-steroidal anti-inflammatory drugs may be a valid choice for pain relief, but an inappropriate analgesic in the hemodynamically unstable patient.
   c. General anaesthesia may be justified in order to carry out a surgical procedure, but may not be appropriate depending on the drugs used and the age and health status of the patient etc.

Training

6. Veterinary medicines are administered to animals to achieve an intended effect. They need to be administered correctly and veterinarians need to know whether the intended effect was achieved, and whether there were adverse effects caused by the treatment. Veterinarians have a responsibility to ensure that people who administer veterinary medicines have the skills to administer the treatments safely and as directed, and to provide training where appropriate. Veterinarians should also be providing advice about the intended effects of the treatment and how to identify and manage adverse effects.

7. In a production animal setting, and especially where RVMs are authorised for future supply, the person administering the veterinary medicine may not be the person who the veterinarian communicated with at the time of the authorisation. The authorising veterinarian must be satisfied that the veterinary medicine will be administered safely and appropriately, and that the veterinary medicine will only be used for the specific purposes authorised. If the veterinarian has doubts, then they should review whether they should be providing an authorisation, or how the appropriate training can be provided. The authorising veterinarian needs to be assured that those making decisions about the treatment of the animals on the farm are competent and capable and this should be reviewed regularly as part of the consultation. The veterinarian needs to make sure that the farm personnel who the veterinarian is communicating with at the time of the authorisation has a good understanding of the requirements. This should be reinforced with written protocols.

Veterinary Involvement

8. The level of veterinary involvement required during and after the administration of a veterinary medicine will depend on the particular circumstances and the degree of risk that needs to be managed. This includes, but is not limited, to:
a. The type of veterinary medicine eg anesthetic, antibiotic etc.
b. The regulatory requirements for that particular product.
c. The accepted standard of care by veterinarians for that particular product or product type.
d. The route of administration e.g. IV, SC, PO.
e. The type of patient and existing condition.
f. The level of training and experience of the person who will be administering the product.
g. Whether the person administering can be appropriately trained to administer the product.
h. The level of monitoring required during and after administration.
i. The training and experience of the administrator to provide adequate monitoring.
j. The potential risks involved with administration.

9. The level of veterinary involvement will vary depending on the circumstances. Contrast the advice given to an owner of a cat or dog in relation to administering a tablet versus the level of supervision of an owner as they are trained to administer insulin injections. Similarly in a production animal setting, contrast the level of training required to show someone how to administer an intramuscular antibiotic injection versus the training requirements to teach someone how to administer nerve blocks in order to disbud calves.

Management of Residues

10. In food producing animals the potential for residues must be addressed and clients must be provided with sufficient information to address any issues.

a. Veterinarians have a professional responsibility, and a legal responsibility under section 55 (3) of the Agricultural Compounds and Veterinary Medicines Act 1997, to provide information to clients to prevent any residues in primary produce occurring from any animal treated with a veterinary medicine which may contravene the requirements of the Food Act 2014 and the Animal Products Act 1999. Veterinarians and their clients may both be charged with offences under this legislation. Whether or not the veterinarian will be accountable depends on the information provided to the client. The advice given should be documented in the client’s records, and a copy provided to the client. Preferably the copy held by the practice should be signed by the client.

b. Veterinarians must use (or give direction for use of) veterinary medicines in a way that is consistent with approved uses for the product and convey the label advice for withholding periods. If a veterinary medicine is being used off-label then it cannot be presumed that the label information on withholding periods is relevant and therefore a default withholding period must be used.
c. If a veterinarian determines that an unrestricted veterinary medicine can be used in an off-label manner and advises an alternative withholding period, then a client may use the product legally in accordance with that advice. If as a result of the professional advice, non-compliances with the Food Act 2014 and the Animal Products Act 1999 thresholds are reported, then the veterinarian may be legally liable for actual losses by the client that are directly attributable to the professional advice.

Impartiality

11. Veterinarians must be impartial and discerning in their sale or recommendation of products so that clients obtain, and, equally importantly, know they can obtain, an unbiased opinion on the safety and efficacy of the products for particular conditions. The expectation is that commercial gain for the veterinarian will not influence the decision to use a veterinary medicine. Veterinarians must be satisfied that the use of a veterinary medicine is necessary to achieve a specific and required clinical effect.
Section 2: Legislative Requirements

1. When using, selling or dispensing veterinary medicines (unrestricted or restricted) veterinarians must:


   b. Comply with the conditions of registration on all registered veterinary medicines. Any registered veterinary medicine which has a specific condition of registration that it is only to be administered by a veterinarian, must not be authorised (prescribed), dispensed or sold by a veterinarian.

   c. Comply with all ACVM regulatory controls when using exempted veterinary medicines.

   d. Maintain an up to date of inventory of veterinary medicines.

   e. Must ensure there are appropriate systems to:

      i. Store veterinary medicines appropriately;

      ii. Report adverse events associated with treatment;

      iii. Maintain the integrity of veterinary medicines;

      iv. Provide security of veterinary medicines;

      v. Ensure safe handling of veterinary medicines;

      vi. Keep records of all activities relating to the requirements for receipt, storage, and for RVMs dispensing;

      vii. Label all RVMs according to requirements.

Understanding Section 2

1. When veterinarians are using or authorising RVMs they must comply with the requirements and expectations of MPI’s ACVM Group in relation to authorisation. These are set out in the current MPI Notice Requirements for Authorising Veterinarians.

2. A veterinarian’s treatment should not cause a detrimental effect to agricultural trade or New Zealand agricultural security. A primary purpose of the Agricultural Compounds and Veterinary Medicines Act 1997 is to prevent or manage risks to public health, trade in primary produce, animal welfare and agricultural security associated with the use of agricultural compounds and veterinary medicines. Veterinarians must comply with the regulatory controls of all veterinary medicines they choose to use, sell or authorise. Inherent in this requirement is the expectation that veterinarians have read the conditions and have systems in place to warn them of any changes which might affect how the
product is permitted to be used. The Health and Safety at Work Act 2015, among other requirements, identifies an employer’s responsibilities to identify hazards and to take steps to remove or manage them.

**Maintain an Inventory**

3. **Veterinarians must ensure an inventory of veterinary medicines is maintained.** Records and verification of all of the activities relating to the requirements for receipt, storage and dispatch (including dispensing or breaking-down, if applicable) must be kept. This includes the following, as applicable:

   a. training records of staff in relation to handling and supply (dispensing);
   b. records verifying stock levels;
   c. receipt and storage conditions;
   d. records of dispensing including dispensing information with dates, batch numbers and other details that make it possible to reconcile stocks on the premises and to contact clients in the event of a product recall;
   e. records of disposal/destruction (if applicable).

4. **Storage means holding supplies of veterinary medicines.** The expectation is that storage will comply with product label requirements, the Hazardous Substances and New Organisms (HSNO) Act 1996, Misuse of Drugs Act 1995 and regulations, and the Health and Safety at Work Act 2015 and regulations.

5. **While there is no legal requirement, there is an expectation that adverse events as a consequence of using a veterinary medicine will be reported to MPI and the manufacturer.** See [Adverse Event Reporting Programme for Veterinary Medicines: Guidelines for Veterinarians and Animal Owners](#).

6. **To maintain the integrity of a product means to store, transport, handle or supply it in a manner that does not compromise the confidence that the product still complies with the manufacturing specification (i.e. it is still as it was supplied by the registrant).** A breach of the integrity of the product includes altering labels, opening sealed internal packaging, decanting, breaking down or supplying information in conflict with the label. All of these things can be done but, in doing so the veterinarian must accept responsibility for the action.

7. **It is also expected that where any RVM is dispensed that its labelling will comply with NZVA’s Guide to Veterinary Authorising (Prescribing) and Dispensing.**

8. **Security refers to:**

   a. the requirements for safe custody of controlled drugs as specified in the Misuse of Drugs Act and regulations.
   b. veterinarians maintaining sufficient security and control of RVMs to ensure they are only used according to a veterinary authorisation or Veterinary Operating Instruction.
   c. ensuring lay staff do not sell RVMs without appropriate authorisation.
9. **Safety of handling refers to the responsibilities that apply under the Health and Safety at Work Act 2015.**
Section 3: Authorisation

1. When using or authorising restricted veterinary medicines, veterinarians must comply with the requirements and expectations of MPI in relation to authorisation. This is set out in their published ACVM Notice *Requirements for Authorising Veterinarians*. Additionally veterinarians must:

   a. Comply with all of the points in sections 1 and 2 above.

   b. Obtain sufficient information to assist risk assessment and to support the choice of that veterinary medicine through either:

      i. Veterinary Clinical Consultation as defined in the glossary; or

      ii. Review Consultation as defined in the glossary; or

      iii. Issuing Veterinary Operating Instructions as detailed in section 4.

   c. Honor requests for written authorisations in lieu of dispensing.

Understanding Section 3

1. Veterinarians are specifically recognised to purchase and prescribe RVMs by the Director General of MPI.

2. The ACVM Notice: *Requirements for Authorising Veterinarians* sets out MPI expectations under the Agricultural Compounds and Veterinary Medicines Act 1997 regarding the standards to be maintained by veterinarians recognised to authorise the purchase and use of RVM that (under their conditions of registration) require veterinary authorisation. Veterinarians are expected to know and comply with the requirements detailed in this document.

3. In addition to MPI’s requirements this Code identifies further professional expectations that apply to veterinarians when authorising RVMs. There is a strong expectation that veterinarians will exercise sound professional judgement and adhere to both the legal and professional requirements that apply.

4. In order to authorise the use of a RVM the veterinarian must have gathered sufficient information to support that decision. The principal method of meeting that expectation is via consultation (see (6) below), or Review Consultation (see (16) below). An alternative option to consultation, which is only likely to be suitable in certain limited circumstances, is through the use of Veterinary Operating Instructions (see Understanding Section 4). These options define the only processes by which veterinarians can authorise RVMs.

5. There are statutory requirements under the Agricultural Compounds and Veterinary Medicines Act 1997 and potentially the Misuse of Drugs Act 1975 for record keeping in relation to use of veterinary medicines and prescription medicines. There are particular expectations about records and the quality of records identified in the *VCNZ Competence Standards and Performance Indicators*. This Code also requires that records be kept and maintained in relation to treatment with veterinary medicines.
6. A veterinary consultation is a specific interaction between the veterinarian and client usually involving animal(s) that the client is in charge of. There are several components to a consultation (see Glossary for definition). For a more detailed breakdown of what is expected in terms of these components, refer to the VCNZ Competency Standards and Performance Measures for Veterinarians in relation to obtaining, recording and analysing information. The purpose of the consultation is to collect sufficient information about an issue of concern to the client (usually an animal health or production problem) in order to be able to decide on a course of action. Consultation will always involve collecting sufficient information through an interview with the client, and will usually involve an examination of the animal(s) and/or their environment. The resulting course of action could involve (but is not limited to) any or all of the following:

i. collection of further information through diagnostic testing

ii. treatment with a veterinary medicine

iii. treatment using a veterinary procedure

iv. advice or recommendations

v. referral to another veterinarian

vi. ongoing monitoring and follow-up.

7. What VCNZ will consider as 'sufficient information', and whether the consultation process is adequate will depend on the particular circumstances. Ultimately in the event of a complaint investigation the test of reasonableness will be applied. That is taking into account the generally accepted standard of care that exists for this set of circumstances in practice, and consideration of what actions or decisions another veterinarian with the same training and experience would reasonably make or take in the same circumstances.

8. VCNZ may from time to time publish statements setting out what is considered reasonable for specific circumstances. An example is the VCNZ Statement on the Information Requirements for Authorisation of Dry Cow Therapy. This sets out the minimum requirements for prescribing dry cow therapy.

9. When RVMs are being used to treat or control clinical or production problems that are being managed as a herd or flock problem, the expectation is that the requirements of consultation will be applied to the herd or flock rather than the individual animals within the herd or flock.

10. Veterinarians are required to obtain appropriate consent before proceeding with treatment. This is discussed in detail in the Client Relationships section of this Code, and related explanatory notes.

11. A specific requirement of any veterinary consultation is that the veterinarian must accept responsibility for the ongoing health and welfare of the animal in relation to the matters that have been consulted on. Following a consultation that leads to a particular course of action the veterinarian must make provision for the appropriate ongoing management of the case in order to be able to reasonably achieve the agreed and identified outcome. 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.

In ‘making provision’ the veterinarian may delegate the ongoing management to another veterinarian or person with the appropriate skills.

Accepting responsibility for the ongoing health and welfare does not mean the veterinarian is expected to accept the financial responsibility to achieve the agreed and identified clinical outcome. All anticipated costs associated with every stage of an agreed course of action should be communicated to the client and agreed upon as part of the consent process. In these circumstances, the responsibility for ongoing health and welfare is specific and limited to the animals and the clinical matters that have been consulted on. This responsibility does not extend to other animals owned by the client, or other unrelated clinical matters.

12. There are certain circumstances where it is considered acceptable for the veterinarian providing the authorisation not to have recently examined or seen the animals as part of a consultation. For example, if a client’s usual veterinarian has recently seen, and therefore has personal knowledge of the health condition/status of the animal(s), and would have otherwise authorised a veterinary medicine; the authorisation could be given by a colleague at the same practice who works in the same area of practice.

Other than this there are few situations where not seeing or examining the animals would be acceptable.

**Authorisation for future supply**

13. Following a veterinary clinical consultation or a review consultation, RVMs may be authorised for future supply. This means the RVMs are authorised to be used according to specific instructions on specified animal(s) in specific circumstances over and above immediate use requirements. When authorising RVMs for future supply in production animals, veterinarians must continue to monitor the health status of the animal(s) to ensure that the ongoing use and choice of RVMs remains appropriate and necessary. Veterinarians should obtain sufficient information throughout the period of the authorisation to ensure that circumstances haven’t changed. This can occur in a number of ways including discussion with the client, reports from technicians who have worked on the farm and review of farm records.

14. Farmers are responsible for managing the inventory of authorised RVMs on farm and for ensuring that they only have product on hand that hasn’t expired. However to assist farmers, veterinarians must provide sufficient accurate information about the products they authorise and provide, and they must also take account of products that are already on the farm before authorising more. Before authorising RVMs for future supply, veterinarians must request and review information from the farmer about what stocks of products are already on farm, and the expiry dates of that stock. Further detail about the documentation to be provided for newly authorised RVMs is found in section 5.

**Period of supply**
15. There is no maximum period of supply for an authorisation. In a general sense, the maximum period of supply depends on the particular RVM and the condition being treated. While there is no hard and fast rule that limits the period of supply for any particular RVM or class of RVM (except for antibiotics see section 6), it is generally accepted that for production animals a period of 12 months is acceptable, and for companion animals a 6 month period applies.

Review Consultation

16. A Review Consultation is a subset of a Veterinary Clinical Consultation and is most relevant in a production animal context, but may also apply when treating other groups of animals including competition or race horses and working dogs. This form of authorisation is not suitable for treating individual animals.

   a. In order to authorise RVMs as part of a Review Consultation, the veterinarian (or veterinarian(s) from the same practice) will need to have examined the client’s animals, for the condition(s) that needs to be treated, recently enough to be satisfied there is an ongoing need to continue to treat the condition.

   b. The frequency and timing that Review Consultations should take place will depend on the group of animals, on the seasonality of animal health needs and how predictable treatment requirements are. In a general sense the maximum period for a review consultation should be 12 months, but more frequent may be applicable.

   c. While the period of time between Review Consultations may be 12 months, the period of supply for some product classes may be shorter – e.g. 3 months for Critically Important Antibiotics. Veterinarians will need to keep this in mind when setting out their authorisations (see Section 6 on Antibiotics).

   d. The authorising veterinarian must be satisfied that anyone who will be administering the product has been trained and is able to provide the treatment correctly. The record of the Review Consultation should document the training that will be given to staff who will be using the products.

   e. The veterinarian will provide the client a printed summary of all of the RVMs authorised for future supply to the client. This summary will identify:

      i. details of each specific product;
      ii. the class of animals to be treated;
      iii. what the product is to be used for;
      iv. the period of supply;
      v. the amount of product authorised for the period;
      vi. the amount which can be dispensed per time and period between dispensing;
      vii. the instructions for use;
storage instructions and information about withholding periods.

f. Veterinary practices need systems in place to create alerts when authorised amounts have been exceeded. In situations where an authorisation for supply exists but the quantity has been exceeded, it is reasonable for the staff to dispense product but the authorising veterinarian must be advised and follow up with the client to discuss any further supply.

g. The Review Consultation for sheep and beef farmers will potentially take place on farm because of the relatively infrequent times veterinarians are on farm.

h. The documented summary provided to the client is not an authorisation which could be taken to an approved seller to allow the purchase of RVMs.

i. A Review Consultation may be described by other e.g. RVM Consult or ACVM Consult.

Electronic authorisation

Veterinarians should carefully consider the circumstances in which they use electronic means for authorising restricted veterinary medicines. Veterinarians using telemedicine to authorise the use of veterinary medicines are expected to provide their animal patients with the same standard of care and comply with the same expectations around consultation regardless of the communication method or service delivery mechanism used. Both of the following requirements apply when the authorisation of a restricted veterinary medicine follows a telemedicine consultation:

a. The veterinarian must have seen the animal(s) recently enough to have sufficient personal knowledge of the condition/health status of the animal(s) in order to be able to propose the particular course of treatment.

b. The veterinarian must be satisfied that a direct physical examination would not add critical information about the management of the case.

Written authorisations

Where there has been a consultation and a veterinarian has proposed treatment with a veterinary medicine, the client is entitled to ask the veterinarian for a written authorisation to have the product dispensed by a MPI approved seller of RVMs, rather than have the consulting veterinarian dispense it. The consulting veterinarian must comply with that request. The expectation is that this applies in every situation where the veterinarian would have otherwise dispensed a product themselves.

There is no requirement for a veterinarian to provide a written authorisation to take away in a situation where the product would not normally be dispensed. For example where the product would normally be personally administered by the veterinarian for reasons of managing the risks associated with use, or where an adequate consultation has not occurred.

The expectation is that the written authorisation should be provided to the client within a reasonable timeframe. Except in exceptional circumstances, VCNZ considers that a reasonable timeframe would be within 24 hours.
21. The veterinarian writing the authorisation (not the trader ultimately dispensing the product) is in every case responsible for meeting all of the requirements in sections 2 and 3 of this part of the Code.

22. Veterinarians are able to dispense RVMs to their clients, but must be approved by MPI to dispense RVMs authorised by another veterinarian not in their practice.

23. Veterinarians are entitled to charge a reasonable fee for writing the authorisation. However, it would be unethical for a veterinarian to require that the client meet a different standard of consultation for a written authorisation, compared to the standard of consultation that would normally be required if the veterinarian was dispensing the product. For example making the client undertake further diagnostic work because a written authorisation has been requested, when such work wasn't considered necessary for the veterinarian to originally dispense the product themselves.

Operating plans

24. The requirement for veterinary authorisation is removed where the use of a RVM is allowed according to an operating plan approved under section 28 of the Agricultural Compounds and Veterinary Medicines Act 1997.

An approved operating plan describes how a person (or an organisation) intends to meet a particular statutory obligation such as the conditions of registration of a restricted veterinary medicine. In the context of using RVMs, an approved plan describes the circumstances by which a specified veterinary medicine will be used by specified people who are not veterinarians, in order to achieve identified treatment objectives. The operating plan provides the statutory basis for the authorisation of the RVMs, and removes the requirement for veterinary authorisation.

Operating plans approved under section 28 of the Agricultural Compounds and Veterinary Medicines Act 1997 are not the same as veterinary operating instructions.
Section 4: Veterinary Operating Instructions

1. When issuing Veterinary Operating Instructions (VOIs), veterinarians must comply with the requirements and expectations of MPI in relation to VOIs. These are set out in MPI’s Guidance Document Veterinary Operating Instructions Guidelines.

2. The MPI guidance document states that the guidelines are not mandatory. However VCNZ’s expectation is that veterinarians must follow them. Additionally, veterinarians must:
   a. Undertake sufficient monitoring (which is recorded) that allows the veterinarian to be confident that the terms of the VOI are being complied with.
   b. Withdraw the VOI immediately in situations of non-compliance.
   c. Not use VOIs to authorise the use of RVMs in circumstances where veterinary diagnosis and judgement are required.
   d. Not use VOIs to authorise the use of any controlled drug as defined in the Misuse of Drugs Act 1975.
   e. Veterinarians are not obliged to issue VOIs; it is up to the discretion of each veterinarian.

Understanding Section 4

1. VOIs are specific (documented) instructions for a specified person(s) to use a specified RVM to carry out a specified task, on a specified animal(s) or class of animals. RVMs specified in the VOI can only be used for the specified purpose documented in the VOI.

2. VOIs do not have to be linked to a case-specific veterinary consultation in relation to the animals being treated.

   VOIs can only be used in cases in which no veterinary involvement is required at the time the RVM is used. This means that a veterinary diagnosis is not required and veterinary judgment is not required at the time a decision is made to use the RVM.

   In order to treat a bacterial infection a diagnosis is required and judgment about the choice of antibiotic, dose, route of administration, period of treatment are all required, so a VOI would not be appropriate. In effect, this means that VOIs will only be used in limited situations.

3. VOIs are generally used to authorise the use of RVMs on animals that do not belong to that veterinarian’s clients. VOIs don’t require a veterinary-client relationship between the veterinarian and the owner of the animals. This means that VOIs can be issued for RVMs to carry out procedures on other veterinarian’s clients’ animals eg disbudding by a third party operator.

   An authorisation should be used in cases where veterinarians are dispensing RVMs to their own clients to use on their own animals. There is no need to use a VOI in these situations.
4. VOIs must define an end date or review date which must be no longer than 12 months from the date of commencement.

5. There is no list of RVMs which can and cannot be issued under a VOI. However, VOIs should not generally be used for antibiotics, as veterinary involvement is required as part of good antimicrobial stewardship. There are some exceptions e.g. prophylactic use where no veterinary diagnosis is required eg AI programmes; grooms travelling with horses by air or sea.

6. VOIs must not be used for controlled drugs. Under the Misuse of Drugs Act and Regulations, controlled drugs can only be prescribed by veterinarians for animals under their care. This rules out using VOI as a mechanism for authorising their use. The penalties for non-compliance with the Misuse of Drugs Act and Regulations can be severe. This does not limit their authorisation following a veterinary consultation.

7. If a veterinarian is concerned that the procedures to be undertaken by a layperson may result in negative animal welfare outcomes, he or she should decline to issue the VOI eg a lay equine dentist carrying out tooth removal.

8. Possible adverse events and how they will be managed must be identified. The person(s) authorised under the VOI must be appropriately trained to manage those events which can be reasonably dealt with, without veterinary involvement. Veterinary intervention will be necessary in order to appropriately manage certain adverse events. In those situations, the VOI must define how that veterinary involvement will be provided. Unless provision for veterinary care in such events is readily available, it may not be appropriate to issue a VOI. The authorising veterinarian will either need to provide that care themselves, or alternatively make prior arrangements with other veterinarians so that the service will be readily accessible if the need arises.

9. VOIs may be written to be used on animals that are geographically remote from the authorising veterinarian. However, authorising veterinarians should bear in mind that it may be difficult to meet all of their VOI responsibilities (eg supervision of the VOI, managing adverse events etc) and therefore it unlikely to be appropriate to issue a VOI in these circumstances. Veterinarians are advised to seek advice from VCNZ.

10. For the purposes of illustrating how VOI might be used, it is likely that most animals treated under VOIs will fit into one of three groups:

   a. Prophylactic treatment of healthy animals for the purpose of preventing disease eg vaccination of animals admitted to a shelter organisation for the purposes of adoption.

   b. Chemical restraint of healthy animals to allow for a procedure or manipulation. Examples might include:

      i. Use of local anesthetic/xyazine for disbudding calves;

      ii. Develveting of deer (Veterinarians should comply with the ACVM Guidance Document: Veterinary Operating Instructions Guidelines Appendix: Xylazine, Yohimbine and Lignocaine for Velvet Antler Removal).
c. Treatment of an animal(s) identified to have a particular condition or state of health, which has been clearly described in the VOI such that the use of a RVM listed in the VOI is justified eg sedation of an agitated horse by a groom on an export flight or shipment.

11. The veterinarian must be satisfied that the person(s) identified in the VOI is adequately trained and experienced in the use of the specified RVM, and is able to carry out the instructions as documented. The veterinarian may have to provide training and/or assessment of the competency of the person(s) specified in the VOI. The training might be provided by a third party. Where VOIs are renewed annually the veterinarian must be satisfied that the persons remain competent. This may require an annual assessment.

12. Veterinarians and the persons identified in the VOI are required to keep accurate records of the use of the RVMs specified in the VOI. These should include:

   a. how, when, where and on whose animals RVMs were used and in what circumstances.
   b. date of use; name and address of person in charge of the animals; identity of the animals (or herd or flock); identity of the person using or providing the RVM; volume or amount of product used; method of administration; reason for use; adverse reactions or events; and sufficient details to allow immediate stock reconciliation.

13. Veterinarians must use their professional judgement to determine the level of monitoring/auditing that is needed in order to be confident that the terms of the VOI are being complied with.

14. Reconciliation of all RVM purchases and disposals against the record of use must be conducted frequently enough for the veterinarian to be confident that product use remains in compliance with the VOI. It is expected that veterinarians will reconcile RVM use at least every 6 months, or at the conclusion of the term of the VOI if that is a shorter period.

15. If the user specified in the VOI does not purchase the RVM from the issuing veterinarian, an authorisation is required for the user to purchase it from an approved seller of RVMs. While the VOI might be issued for up to 12 months, the veterinarian may choose to provide authorisations for purchase for shorter periods. This will allow for monitoring and ongoing auditing of compliance with the VOI.

16. VOIs do not need to be approved by MPI, nor are they routinely audited. A veterinarian may be required to produce them in the event of an adverse outcome or for other reasons (e.g. on-farm audits).

Section 5: Documentation

1. When veterinarians authorise a Prescription Medicine (PM) or Restricted Veterinary Medicine (RVM) the following expectations for documentation apply:

   a. Veterinarians must record every instance of the authorisation of a PM or RVM in a way that links their decision to use the PM or RVM to:
i. the animal(s);
ii. the client;
iii. the authorisation;
iv. the authorising veterinarian.

b. Where an external written authorisation is provided to the client to be filled by a MPI approved seller of RVMs, its form must comply with the requirements as set out in the NZVA Guide to Veterinary Authorising (Prescribing) and Dispensing Section D(3) for PMs, and Section E(6) for RVMs.

c. In every situation where a PM or RVM is authorised by a veterinarian and then dispensed by that veterinarian’s practice to the client, the products must be labelled according to the NZVA Guide to Veterinary Authorising (Prescribing) and Dispensing Section E(8).

d. Veterinarians must facilitate the traceability of RVMs. The treatment of an individual animal must be able to be linked back to a specific authorisation, through veterinary records; records of written authorisations provided to clients; and labelling of products that have been dispensed.

i. To facilitate this, veterinarians must provide the farmer with a documented summary of each product they have authorised at the time of authorisation, including those authorised for future supply.

ii. The information in their event records must comply with Section E(7) of NZVA Guide to Veterinary Authorising (Prescribing) and Dispensing Section.

Understanding Section 5

1. The MPI Requirements for Authorising Veterinarians sets out the ACVM requirements for veterinarians including:
   a. records of veterinary authorisations must be kept for 5 years;
   b. the decision to authorise must be recorded, and the record must provide sufficient information to link the RVM to the event, the client, the authorisation and the authorising veterinarian;
   c. The event record must be readily accessible and traceable to the event;
   d. The form the event record takes is at the discretion of the authorising veterinarian. It could be the case record, diary entry for the consultation, visit log, invoice, a combination of these records or whatever the veterinarian uses to record the event according to accepted standards and as appropriate in the circumstances.

2. The requirements for documentation apply to all veterinarians regardless of whether they work in production animal practice or companion animal practice.
3. While section 4 is most applicable to production animal practice, authorisations for future supply may also be relevant for competition animals, breeding and kennel facilities, and for working dogs.

4. Some clients (primarily farmers) will be subject to audits of RVM use. In order to facilitate a client’s ability to keep their own records and be able to provide the necessary information when faced with an audit, veterinarians must provide them with a written summary of all RVMs they have authorised at the time of the authorisation. Appendix 4 of the NZVA Guide to Veterinary Authorising (Prescribing) and Dispensing can be used as a template. As a minimum, the summary should include:

   a. veterinarian’s name, practice name and address.
   b. farmer name, address and supply number.
   c. details of each specific product, active and concentration.
   d. the class of animals to be treated.
   e. what the product is to be used for.
   f. the amount of product authorised for the period.
   g. date of expiry of the authorisation.
   h. the amount which can be dispensed per time and period between dispensing.
   i. instructions for use.
   j. storage instructions and information pertaining to milk and meat withholding periods.

   The above information, as well as batch numbers and expiry dates of products dispensed must be provided to clients on request.

5. The copy of the summary of RVMs authorised for future supply provided to the farmer is not and cannot be used by the client as an external authorisation/prescription to be filled by a RVM trader.
Section 6: Antibiotic Use

1. In order to encourage prudent use and minimise the risk of antibiotic resistance veterinarians must:
   a. Comply with sections 1 - 5 above.
   b. Only use or authorise antibiotics in situations where there is good reason to believe there is a bacterial infection that needs to be treated to protect the health and welfare of the animal.
   c. Where practical, when deciding to use or authorise an antibiotic veterinarians must:
      i. take steps (microscopy and or culture) to identify the type of bacteria causing the infection; and
      ii. Select the most appropriate antibiotic, considering:
         i. the likely bacteria to be treated;
         ii. the ability to achieve therapeutic concentrations at the site of infection;
         iii. immune status of the patient;
         iv. concurrent diseases;
         v. age and physiological status of the patient.
      iii. Choose an antibiotic with a spectrum of activity that is appropriate for the suspected infection and as narrow as practical considering the options available.
   d. Consider whether there is any other evidence based treatment or management option which might be used as an alternative or adjunctive to antibiotic therapy, or which can be used to increase the chances of a successful outcome, eg antisepsis, drainage.
   e. Not use antibiotics routinely for prophylactic or metaphylactic purposes in place of good clinical or animal husbandry practices.
   f. Use doses, duration of therapy and routes of administration in accordance with accepted Clinical Guidelines.
   g. Clearly document in the clinical record the basis for the decision to use a particular antibiotic.
   h. Limit the period of supply for Critically Important Antibiotics in an authorisation to 3 months and for all other antibiotics to 6 months.
   i. When using or authorising Critically Important Antibiotics veterinarians must:
      i. Comply with points (a)-(h) above; and
ii. Restrict use to situations where first line antibiotics have been shown to be ineffective and when supported by bacteriological tests or the use is indicated and supported in accepted Clinical Guidelines; and

iii. Not use Critically Important Antibiotics as preventive treatment in feed or water in the absence of clinical signs in the animal(s) to be treated; and

iv. Limit off label use for instances where no alternatives are available.

2. Veterinarians must not advertise antibiotic products to clients.

Understanding Section 6

1. Prudent use refers to the optimal selection of drug, dose and duration of antibiotic treatment, and the reduction of inappropriate and excessive use as a means of slowing the emergence of antimicrobial resistance.

Principles include:

a. stricter veterinary oversight when antibiotics are authorised and used.
b. restricting prophylactic and metaphylactic use of antibiotics.
c. restricting antibiotic use to situations where there is good evidence of bacterial infection that needs to be treated.
d. reserving the use of Critically Important Antibiotics.
e. use of other strategies to prevent disease eg vaccination.
f. following recommended dose rates and duration.
g. public education about responsible antibiotic use.

2. To justify use there must be sufficient evidence of bacterial infection that can reasonably be expected to respond to the chosen antibiotic and where antibiotic treatment is needed to protect the health and welfare of the animal. The veterinarian must make a clinical diagnosis and then use their professional judgment to choose an appropriate antibiotic. Sufficient evidence will include appropriate clinical symptoms which should be supported where possible by cytology and or culture.

3. The basis for deciding to use the antibiotic must be documented in the records. This must include the diagnosis; results of any diagnostic tests which led to the decision for treatment; the name of the product and details about administration. Ideally clinical symptoms and relevant history should also be recorded in order to provide a broader context.

4. Veterinarians must only use antibiotics in those situations where antibiotics are needed in order to protect the animal’s health and welfare. For example, some bacterial infections may not need antibiotic treatment:

   a. Uncomplicated infectious canine respiratory disease complex (kennel cough).
b. Uncomplicated balanoposthitis.

As well, antibiotics should not be used for those clinical presentations which do not have bacterial infection as the basis for the symptoms, for example:

a. Idiopathic cystitis in cats.

b. Primary viral upper respiratory infections in cats.

4. Veterinarians must consider whether other evidence-based clinical or management strategies can be used to reduce or remove the need to use antibiotics:

a. Strict application of aseptic principles for surgery and good surgical technique so that the need for peri-operative antibiotic use is minimised.

b. Use of antiseptic treatments (e.g. shampoos) or topical applications as an alternative to systemic antibiotics for skin conditions.

5. Antibiotic prophylaxis describes the use of antibiotics to prevent bacterial infections, rather than to treat existing infections. Usually, prophylactic use will be at the time of performing a procedure, such as surgery, although not always, as is the case with whole herd dry cow therapy. Veterinarians must restrict prophylactic antibiotic use to those situations where it is justified e.g. immunocompromised patients, or where accepted clinical guidelines exist to support such use. When deciding whether to treat prophylactically, veterinarians should consider factors such as patient health, the presence of implants, the type and duration of surgery, the amount of tissue damage and the level of contamination. Where antibiotics are used prophylactically the choice of antibiotic, route and timing of administration are all critical and must be consistent with recommended protocols.

6. Antibiotic metaphylaxis refers to the treatment of herds and flocks with antibiotics if they are considered at risk of suffering an outbreak of infectious disease due to exposure to disease agents or unfavorable host or environmental conditions. There will be a certain level of disease already present, and treatment is to prevent further animals becoming infected. Antibiotic metaphylaxis should be considered only when there is a real need for treatment. In such cases, the veterinarian should justify and document the treatment on the basis of clinical findings and the development of a disease in a herd or flock. Antimicrobial metaphylaxis should never be used in place of good animal husbandry and management practices.

7. First line or empirical antibiotic therapy involves the use of an antibiotic without knowing the type of bacteria involved or its sensitivity. Veterinarians must select the most appropriate antibiotic considering:

a. the likely bacteria to be treated.

b. the ability to achieve therapeutic concentrations at the site of infection.

c. the age and immune status of the patient.

d. concurrent diseases.

e. the physiological status of the patient.
f. relevant controlled clinical trial data (where available), or recommendations from Clinical Guidelines.

The spectrum of activity of the antibiotic should be appropriate for the suspected infection and as narrow as possible. Common first line antibiotics include penicillin; amoxicillin; 1st- and 2nd-generation cephalosporins, tetracyclines and trimethoprim sulphonamides.

8. Second line antibiotic therapy may be considered when culture and susceptibility testing, plus patient and infection factors, indicate that no first-line drugs are reasonable options. Second line antibiotics may include Critically Important Antibiotics. The use of these antibiotics is restricted because they are considered more important in the treatment of serious bacterial infections in humans, or because of concern about the development of antibiotic resistance. The Critically Important Antibiotics should not be used empirically without good justification, e.g. use is supported in clinical guidelines or peer reviewed references. There must be a legitimate and sound clinical rationale. It is not sufficient to authorise their use because a client requests the product or for reasons of convenience, ease of use and withholding periods. Veterinarians must be able to demonstrate they are acting appropriately as risk managers when authorising these products. Examples include:

a. Swabs have been sent to the lab for culture and sensitivity from 5 horses from the same stable with the same clinical symptoms. Results indicate the need to treat with a Critically Important Antibiotic. A sixth horse from the same stable develops the same symptoms. This would provide a sufficient epidemiological background to support treating the sixth horse with the same antibiotic. However, this wouldn’t be sufficient to justify the same treatment in a horse with the same symptoms from a different stable.

b. It is not acceptable for a veterinarian to treat a cow with a 3rd or 4th generation cephalosporin after a difficult calving just because they are not confident in the client’s ability to administer daily injections. The same principle applies to the treatment of a cat with a bite wound abscess with a long acting 3rd or 4th generation cephalosporin. Bacteriological testing and evidence that appropriate first line therapy is insufficient are needed.

c. An experienced farmer has a sick cow with severe mastitis in multiple quarters where the cow is likely to die before the results of bacteriological testing are available. In an emergency like this, the decision to treat empirically with tylosin might be justifiable if samples are collected for bacteriological testing so that the infection can be identified to assist with decision making in future instances.

9. Dose rate, duration of treatment, frequency and route of administration should be evidence based and consistent with label instructions to maximise the chances of clearing the infection as quickly as possible. This not only benefits the patient but also minimises antimicrobial usage and selection pressure for resistance.

10. Clients should be informed about the importance of using antibiotics responsibly. Compliance with instructions for use should be emphasised. Veterinarians should give
consideration to choosing acceptable dosing regimens which are achievable for the owner.

11. Veterinarians must not advertise the sale of antibiotics to their clients as this has the potential to impact on prescribing decisions. The decision to authorise the use of any particular antibiotic product should be based on the clinical need following a veterinary diagnosis, rather than a client request.
Section 7: Controlled Drugs

1. Veterinarians must ensure that protocols exist in their practice to securely receive, store and reconcile the use of any controlled drugs used. Veterinarians must ensure protocols are followed by all staff. Protocols must address the following minimum requirements.
   
a. Controlled drugs must be stored in accordance with section 28 of the Misuse of Drugs Regulations 1977.

b. Every instance of sale or use of a controlled drug must be linked to a veterinary consultation.

c. A Controlled Drug Register must be used to record controlled drugs and allow reconciliation of stock. 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 Misuse of Drugs Regulations 1977.

d. Controlled drugs must be reconciled at least monthly.

e. For every strength of each controlled drug, there must be a reconciliation of the opening stock, closing stock, purchases and sales. This must be documented. Any volume or amount which is not accounted for in the reconciliation must be investigated.

f. Reconciliation records must be kept for 4 years.

g. There must be documented procedures in place for dealing with discrepancies.

h. Extraordinary variances in the reconciliation that cannot be explained or are thought to be due to unauthorised use must be discussed with VCNZ.

i. Any unauthorised use at any time must be reported to VCNZ.

2. The requirements of this section are the minimum professional requirements for veterinarians regardless of any exemptions given to veterinarians in the Misuse of Drugs legislation.

Understanding section 7

1. All controlled drugs are either registered as prescription medicines (under the Medicines Act 1981) or as restricted veterinary medicines (under the Agricultural Compounds and Veterinary Medicines Act 1997). The Misuse of Drugs Act 1975 and the Misuse of Drugs Regulations 1977 also apply.

2. To authorise the use of controlled drugs for the treatment of animals, veterinarians must comply with sections 1, 2, 3 and 5 of the Veterinary Medicines section of this Code. Veterinarians must have met the requirements for consultation, and have created and maintained appropriate records detailing the treatment decision.

3. Schedules 1 to 3 of the Misuse of Drugs Act 1975 identify those drugs which pose a risk of harm to individuals or to society through misuse and refers to these drugs as
controlled drugs. Veterinarians are expected to know which controlled drugs (and which trade name products containing controlled drugs) are used in their practice and what is required to comply with the legislation and this Code.

4. Controlled drugs commonly found in veterinary practices include but are not limited to: morphine, fentanyl, pethidine, buprenorphine, codeine, ephedrine, pseudoephedrine, alprazolam, diazepam, midazolam, oxazepam, pentobarbital, phenobarbitone and ketamine.

Storage

5. Section 28 of the Misuse of Drugs Regulations 1977 sets out the legal requirements for the custody of controlled drugs. The regulations apply to any person in possession of a controlled drug for the purposes of sale or for use in the course of their profession.

6. Veterinarians must ensure that protocols exist in their practice covering the receipt, use, storage, security and reconciliation of controlled drugs. All staff must be aware of and comply with those protocols. While veterinarians have overall responsibility for the controlled drugs, many of the tasks associated with storage, monitoring etc. can be delegated to non-veterinary personnel. It is recommended that protocols managing the receipt of controlled drugs into the practice are established and strictly adhered to, as this can be a major area where reconciliation is an issue.

7. All controlled drugs not required for immediate use must be kept in a locked cupboard or compartment (‘safe’) which meets the specifications set out in section 28 of the Misuse of Drugs Regulations 1977, and which is of an ‘approved type’. ‘Immediate use’ means the amount of controlled drug which can be reasonably expected to be used in the course of a working day. These drugs still should still be closely monitored throughout the day. At the end of the working day, those controlled drugs which have been available for immediate use must be locked up securely in the controlled drugs safe.

8. The safe must be constructed of either metal or concrete or both. Where the safe is installed after 1977, it must be of an approved type. The safe must be fixed to the building or to vehicle. When the key to the cupboard or compartment is not being used, it must be kept in a safe place. When the building/vehicle is unoccupied, the key must not be kept in it. The safe can be fitted with a combination lock of an approved type. Specifications for safes to store controlled drugs are noted in Appendix I.

Vehicles

9. Veterinarians who carry controlled drugs in their vehicles for use in the course of their work must comply with the statutory requirements. Those controlled drugs not required for immediate use must be stored in a locked metal compartment securely fixed to the vehicle. If the vehicle is left unattended the veterinarian must take all reasonable steps to secure the vehicle against unlawful entry. A locked vehicle boot or locked glove box is deemed to meet the requirements.

10. The following applies to controlled drugs which are kept in vehicles:

   a. Only the smallest quantities of the drugs should be carried.
b. The key to the compartment in the vehicle must not be left in the vehicle when unattended.

c. If the drugs remain in the vehicle overnight then the cabinet must be locked and the vehicle preferably parked in locked garage or secure area. It may be safer to remove the drugs if there is no secure area overnight.

**Controlled Drugs register**

11. VCNZ requires veterinarians to use a Controlled Drug Register to record the receipt, sales and stock levels and document reconciliations; this is despite Section 41 of the Misuse of Drugs Regulations 1977 providing an exemption for veterinarians.

12. Veterinarians may use computer reports to assist with reconciliations and to ensure that controlled drug usage is recorded.

13. Veterinarians must be able to quickly and easily produce the Controlled Drugs Register detailing the use of controlled drugs within their practice for examination and review.

14. Reports must include the following fields: authorisation date; name and address of client; name of patient; name and strength of controlled drug product; volume or amount used; and authorising veterinarian.

**Reconciliation**

15. Veterinarians must reconcile the physical stock of these products against sales and purchases. An important component of this process is the need to account for variances. Where this reconciliation identifies stock of controlled drugs which cannot be accounted for, the veterinarian must provide a reasonable and justifiable explanation. Discrepancies need to take into account multi-injection vials, leakage, loss by evaporation, product remaining in needle hubs and syringes, breakages and unused product remaining in a vial or bottle. Strategies need to be put in place to address how to deal with discrepancies including recording issues and human error.

16. The minimum frequency for regular stocktaking and reconciling controlled drugs is weekly since it is can be difficult to explain reconciliations easily and accurately at less frequent reconciliations. At least 2 people should be responsible for the reconciling process.

17. After stocktaking, the purchases and sales for each strength of every controlled drug used must be reconciled with the physical stock for each product. This reconciliation only needs to take account of the total volume of sales and purchases in the first instance. If the reconciliation for any particular controlled drug does not balance there a need to investigate the circumstances and determine whether there is a reasonable explanation for the variance. This may involve the examination of individual sales and purchase transactions, and/or the administrative process for recording sales and purchases.

18. In situations where the reconciliation does not balance veterinarians are expected to address the variance, identify a reason where ever possible and take corrective actions to ensure that the reconciliation balances next time.
19. In situations where the variance is considered ‘extraordinary’ and unable to be explained, or possibly associated with unauthorised use, veterinarians must notify VCNZ. Where corrective action is taken to improve the accuracy of future reconciliations but there continues to be extraordinary variances, this must be reported to VCNZ. It is difficult to quantify what an extraordinary variance is since it also depends on the volume of usage and time period, frequency as well as poor recording practices and human error. Veterinarians should seek advice from VCNZ if they are unable to explain large or recurring errors in the reconciliation.

20. The following strategies may help with compliance with the above requirements:
   a. Ensure the receipt of the controlled drugs is accurately recorded.
   b. Develop good systems to ensure that all purchases and use are accurately tracked.
   c. Maintain a logbook that tracks purchases and use full packs of controlled drugs to make reconciliation easier.
   d. Increase the frequency of reconciliations.
   e. Products that are used more frequently and/or products in multi injection vials should be reconciled most frequently.
   f. Consider reducing the number of controlled drugs used in the practice.

Disposal of Controlled Drugs

21. Expired, damaged, returned or unused controlled drugs must be in a way that destroys them so that they are non-recoverable and their consumption is impossible or improbable; and they therefore not capable of being abused (i.e. diversion). The Ministry of Health’s principal concern is to prevent diversion. If there is no access to a commercially available disposal system, the Ministry considers the most appropriate disposal method (to prevent diversion) of controlled drugs is flushing into the sewerage system but recognises the potential harmful environmental consequences. The following principles apply:
   a. All steps to prevent diversion must be taken.
   b. Controlled drugs must be rendered inactive in the disposal process.
   c. Any controlled drugs being disposed of away from the practice must remain under the control of a veterinarian or the veterinarian must be satisfied that there are suitable controls in place to prevent diversion.
   d. The following methods are suggested:
      i. Small amounts remaining in syringes, bottles or ampules are placed in a sealed, tamper proof sharps container and destroyed by a company specialising in destruction of bio-medical products.
      ii. Tablets should be crushed and ampules opened and then disposed of into a sharps container (and destroyed by a company specialising in destruction of bio-medical products.)
iii. Full or incomplete bottles (depending on volume) can either be disposed of into a sharps container and (destroyed by a company specialising in destruction of bio-medical products) or be emptied into the sewerage system.

iv. Delivery to a pharmacist who has agreed to accept them for disposal.

v. Disposal of controlled drugs (if being carried out within the clinic) must be witnessed by another person – veterinarian, nurse or veterinary technician. The clinic recording system for controlled drugs must be appropriately amended to reflect this disposal, the amount, and the date. The disposal must be signed (or recorded if a computerised system) by both parties.
## SUMMARY OF REQUIREMENTS FOR THE CUSTODY OF CONTROLLED DRUGS: STEEL SAFES

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<thead>
<tr>
<th>Construction</th>
<th>Up to and including 600mm in any dimension (height, width, depth)</th>
<th>Over 600mm in any dimension (height, width, depth)</th>
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**Note:** Steel safes must withstand reasonable physical attack with handheld tools and weapons, and must be built and finished in a professional manner with negligible gaps between all fixed parts.

### MECHANISM

<table>
<thead>
<tr>
<th>Number of locking mechanisms of robust strength and security performance than a five lever mortice dead lock complying with BS3621:1998 fitted to the safe door</th>
<th>One</th>
<th>Two*</th>
</tr>
</thead>
</table>

**Note:** Door handles must be designed to break off under leverage.

*The second mechanism can be an indirect locking mechanism (e.g., locking bolts activated by a handle).*

### FIXING

<table>
<thead>
<tr>
<th>Bolted to the following minimum number of surfaces of solid construction</th>
<th>One</th>
<th>Two</th>
</tr>
</thead>
</table>

**Note:** Bolt shafts, used to attach the safe to the premise, must be a minimum of 10mm in diameter and when bolted into concrete, use expanding or chemical setting bolts. Where the safe is bolted to a wooden floor, it should be bolted through to a steel plate which exceeds the floor area of the safe and is retained on at least two floor joists. All nuts must be on the inside of the safe, and bolts welded or burned to resist removal.
Section 8: Off Label Use

1. When using or authorising any registered veterinary medicine (restricted or unrestricted) off label, a human medicine or a compounded veterinarian preparation, veterinarians must:
   
   a. Comply with all of the points in sections 1-7 above.
   
   b. Consider if there is a registered veterinary medicine that will adequately achieve the intended effect and ensure the welfare of the animal; and if appropriate, choose the registered veterinary medicine in preference.
   
   c. Not supply any consented or unconsented human medicine for use as a veterinary medicine, or any registered veterinary medicine off label, unless the additional risks can be justified.
   
   d. Only import unconsented human medicines or veterinary medicines from overseas after obtaining Special Circumstances Approval from MPI.
   
   e. When considering combining different products (multi-modal use) ensure that the two products are clinically compatible for concurrent use and that appropriate withholding period advice is provided to the end user.

Understanding section 8

General Requirements

1. The VCNZ statement The Discretionary Use of Human and Veterinary Medicines by Registered Veterinarians sets out VCNZ expectations in relation to using or authorising these types of products.

2. Off label use of a registered veterinary medicine occurs when the use does not comply with the approved claims i.e. the route of administration, dose rate, duration of treatment, target species or the condition being treated. Not all restricted veterinary medicines are permitted to be used off label. If off-label use is not allowed, the medicine will have a condition of registration identifying. Where an OTC product is allowed to be used off label, it will carry a condition of registration stating that before off-label use, the user ‘seek advice from an appropriately qualified source and confirm that the intended use is not likely to cause unnecessary or unreasonable pain or distress in the animal treated.’

The product label includes all of the information MPI has approved as being able to be supplied to the person the product is sold to, irrespective of the form of that information. Label information therefore includes:

   a. The physical label attached to the product.
   
   b. Label information on product packaging.
   
   c. Additional loose material packed with the product.
3. Medsafe (New Zealand Medicines and Medical Devices Safety Authority) is a business unit of the Ministry of Health and is the regulator responsible for administering the Medicines Act 1981. This Act establishes a pre-market evaluation and approval system for human medicines that is designed to ensure that new medicines meet the required standards. Medsafe does not assess human medicines in relation to their use in animals. To find out whether a human medicine is licensed in New Zealand go to Medsafe database search.

4. Where human medicines are used in animals, and when registered veterinary medicines are used off label, there has been no regulatory assessment to determine the safety and efficacy of the product in these circumstances. Such use will likely involve additional risks over and above the use of a registered veterinary medicine which has been assessed for use for the particular purpose.

5. Where the use of either a human medicine or a registered veterinary medicine is outside the mainstream standards of care, the veterinarian must obtain the informed consent of the client for this purpose.

6. If there is a registered veterinary medicine that can be used to achieve the same intended effect within the label and registration conditions, it should be chosen before the use of a human medicine or the off-label use of a restricted veterinary medicine. It is accepted that there may be circumstances where a human medicine or the off-label use of a restricted veterinary medicine may be chosen in preference. This is acceptable if the decision can be justified and it is the exception rather than the rule. The routine use of a prescription medicine in place of a restricted veterinary medicine should not be based solely on the cost where the cost of a prescription medicine is less, although this may be one of the factors considered in an individual case.

**Unconsented or S29 medicines**

7. Unconsented human medicines (section 29 medicines) can be used legally by veterinarians to treat animals. However, the Medicines Act 1981 does not allow veterinarians to purchase these products from a New Zealand based wholesaler. Veterinarians must import them after obtaining Special Circumstances Approval from MPI. Except in certain circumstances, they can only be imported in quantities to treat a specific case, and not held in anticipation of future use. In certain circumstances MPI will allow veterinarians to import and hold unconsented human medicines in anticipation of use-these medicines are referred to as ‘animal welfare medications’.

8. The criteria that have been applied in determining an animal welfare medication are:
   a. It is needed to avoid unnecessary or unreasonable pain or distress (i.e. animal is likely to die, require euthanasia, or will suffer significant pain or distress without medication).
   b. It must be available for immediate use when cases arise.
   c. There is not likely to be any party who is prepared to register it as a trade name product in New Zealand.
   d. No practical alternative registered veterinary medicine or consented human medicine is available in New Zealand.
9. The current list of animal welfare medicines which have been approved by MPI for companion animals can be found in the Special Circumstances Approval ACVM Information Requirements.

Multimodal Use

10. When authorising more than one product to be used concurrently in the treatment of a food producing animal, veterinarians must ensure that all products are clinically compatible for concurrent use and that appropriate withholding period advice is provided to the end user.

   a. The veterinarian must consider the pharmacology and elimination of each product and their active ingredients, as well as the individual withholding periods applied to the registered veterinary medicines. The veterinarian must assign a withholding period that allows for any interactions between concurrently administered products, changes in the elimination of the drugs, and any other impacts the concurrent use may have on the efficacy, safety, and residue elimination of the active ingredients.

   b. The pharmacology and elimination of a product can change significantly depending on the species it is administered to, the dose, the administration route, and concurrent use of other products. In food producing animals, the veterinarian authorising use in any way other than as stated on the product label, including the concurrent use of more than one product, is responsible for ensuring that the authorised use does not cause residues that exceed the maximum residue levels (MRLs) or maximum permissible levels (MPLs) for all medicines used by providing appropriate withholding period advice to end users. This requirement applies to all products for which MRLs apply under the Food Act and for which the MPLs apply under the Animal Products Act.

   c. The withholding periods approved for a veterinary medicine are based on residue trial work on the use of that one product, in the approved species, and according to the approved dose rate and interval. Use in any other way has not been evaluated by MPI and the withholding period approved for the product does not apply.

   d. If no suitable withholding period can be determined, or if one or more of the concurrently used products is not a registered veterinary medicine, the MPI default withholding periods for the patient’s species must be applied.
Section 9: Compounded Veterinary Preparations

1. When using or authorising a Compounded Veterinary Preparation (CVP) for animals under their care, veterinarians must:
   a. Comply with all the points in sections 1-7 above;
   b. In situations where there is no veterinary medicine approved for the treatment of the condition (i.e. there is no on-label indication and dose rate), consider whether there is:
      i. an approved veterinary medicine which would be appropriate to use off-label to achieve the same therapeutic effect; or
      ii. if there is an appropriate consented human medicine that will achieve the same therapeutic effect.
         If any such trade name product is available and will adequately achieve the intended effect and ensure the welfare of the animal, it must be chosen in preference to a CVP.
   c. Consider whether there is an unconsented human medicine, or overseas registered veterinary medicine which could be imported using MPI Special Circumstances Approval within an acceptable timeframe, which might be able to be used in preference to a CVP.
   d. Ensure that CVPs do not contain prohibited or restricted substances as defined by MPI and it is compounded, sold and used for the treatment of an animal under the compounding veterinarian’s direct care in accordance with ACVM regulations.
   e. In situations where the CVP is compounded personally, be competent in all aspects of formulation and compounding and take full responsibility for the product including its preparation, packaging, shelf life and labelling.
   f. Be satisfied that any third party contracted to do the compounding is competent, and issue the third party with a compounding order specifying the ingredients, quantity, packaging, shelf life and labelling. The veterinarian requesting the compounding is responsible for all aspects of compounding even when it is carried out by a third party.
   g. Ensure that there is a documented system for compounding in place.
   h. Compound only enough CVP to manage short-term requirements and must not store the preparation in anticipation of future needs.
   i. Not advertise or promote CVPs as veterinary medicine trade name products or display them for sale to the general public.
   j. Not import CVPs without approval from MPI.
Understanding Section 9

1. MPI and VCNZ recognise that veterinarians need to be able to compound preparations for the treatment of animals when the need arises. However, in accepting that the need exists, veterinarians should recognise that CVPs have not undergone the usual regulatory assessment, and so expose the veterinarian, the animal(s) treated, the people involved with treatment and the public interest to potential risks (see section 1(a)). Being able to compound veterinary medicines is a privilege granted to the veterinary profession that carries particular responsibilities. For further information refer to the Statement on Compounding Veterinary Medicines and MPI Guidelines on Developing a Documented System for Compounded Veterinary Preparations.

2. Veterinarians may compound a CVP under entry 9 in schedule 2 of the Agricultural Compounds and Veterinary Medicines (Exemption) Regulations 2011. A veterinarian who chooses to compound a CVP is subject to ACVM requirements in Regulations 7, 10, 12 and 14 and the CVP Notice. It is important that the veterinarian clearly understands those expectations and complies with them. For further information refer to the VCNZ Statement Veterinarians and Manufacturing of Veterinary Medicines.

3. Animals must be under the care of the compounding veterinarian (or under the authorisation which would only be issued after a veterinary consultation specifically regarding the animals) and can only be used on animals specified by the compounding veterinarian.

4. Compounding a CVP should be seen as a last resort and only undertaken because a trade name product in the desired form or presentation is otherwise unavailable for animal treatment. The guiding principle should be that the CVP improves the animal(s) welfare over and above anything else that is currently available and is therefore a more appropriate veterinary medicine to use.

5. The process of reaching a decision about treatment choice can be compared to a linear cascade. If there is a registered veterinary medicine that can be used in compliance with the label and registration conditions to achieve the intended clinical effect, it should be considered first. If there is no such suitable product, a registered veterinary medicine that can be used off label should be considered next. Following that a human medicine, and following that a CVP.

6. Veterinarians should only compound sufficient material to satisfy their short-term requirements, and not in anticipation of future needs. Although the preparation should really only be compounded for a particular case, it is recognised that there are situations where more than what is needed for one case has to be compounded at the same time. However, it is not acceptable for veterinarians to purposely set out to compound so much of a CVP that it must be stored in anticipation of future use. Sale of a CVP to other veterinarians or traders contravenes the ACVM Act and its Regulations.

7. The expectation is that compounding should only happen in order to provide a preparation for a particular case and for the treatment of animals under the direct care, or with the authorisation, of a veterinarian. As such compounded veterinary medicines must not be advertised, promoted, or displayed for sale.
Section 10: Decanting

1. When decanting or breaking down a trade name product, veterinarians must ensure that:
   a. The product is not altered in any material way, other than to change the original packaging and labelling.
   b. No additional hazards are introduced through careless or inappropriate procedures during decanting or breaking down.
   c. The choice of alternative packaging does not jeopardise the quality of the product.
   d. All the crucial information about the product is provided to the client including the veterinarian’s contact information and additional instructions.

Understanding Section 10

1. At times, a client may not be able to use all the product in the smallest pack size available. A veterinarian may, under the exemption from registration for compounding, decant off a portion of a liquid trade name product or break down a non-liquid/gas trade name product into smaller quantities. In addition to the above requirements the veterinarian must ensure that:
   a. All the crucial information about the product is provided to the client, including such details as:
      i. the veterinarian’s contact information;
      ii. storage temperature where appropriate;
      iii. the withholding period;
      iv. “shake before use” if appropriate;
      v. “do not crush tablets” if appropriate.

This information is necessary to ensure that the product will work in the way that was intended based on its registration assessment.

2. Having breached the integrity of the trade name product, the veterinarian must take full responsibility for any adverse consequences.
Section 11: Providing a Dispensing Service

1. When providing a dispensing service for RVMs authorised by any veterinarian outside the practice, veterinarians must:
   a. have the appropriate MPI recognition to sell restricted veterinary medicines (an MPI approved RVM seller) if applicable.
   b. be satisfied that the authorisation is authentic and the person requesting the veterinary medicine is the one authorised to purchase it.
   c. give effect to the instructions of the authorising veterinarian as written.
   d. if changes need to be made to the authorisation as written, the authorising veterinarian must be contacted to discuss the changes and a new authorisation issued if those changes are accepted.
   e. keep a record of the transaction with a copy of the authorisation.

Understanding Section 11

1. Some veterinarians may wish to operate a restricted veterinary medicine dispensing service (i.e. a veterinary pharmacy) to fill authorisations from either other veterinarians not in the same practice; or other people recognised by MPI to authorise the purchase and use of RVMs via approved operation plans. In order to do this the veterinarian must have an operating plan approved by MPI governing the sale of restricted veterinary medicines. MPI should be contacted for guidance on the development of operating plans.

2. The accepted standard of practice for providing this dispensing service is detailed in the MPI ACVM Notice: Requirements for Authorising Veterinarians.
Section 12: Using a Generic Chemical

1. For a generic chemical to be used as a veterinary medicine veterinarians must:
   
a. Recognise that there has been:
      
i. no regulatory assessment of the chemical for that purpose;
      
ii. no regulatory control of the quality and fitness for purpose for treatment of animals.
   
b. Address the risk management in an adequate manner.
   
c. Make the client aware of the situation and provide adequate risk management advice.
   
d. Ensure the client is provided with appropriate withholding period advice about residues resulting from the use of the generic chemical (where applicable).

Understanding Section 12

1. See the glossary definition for generic chemical. Examples include methylene blue, zinc oxide, potassium permanganate and magnesium sulphate, but does not include chemicals that are active ingredients that would prompt the requirement for registration eg zinc bacitracin, chloramphenicol etc.
Section 13: Human Use of Veterinary Medicines or PMs

1. Veterinarians must not use, recommend or authorise the use of veterinary medicines, prescription medicines, pharmacy-only medicines or restricted medicines (as defined in the Medicines Act 1981) for use on humans.

Understanding Section 13

1. Recommending or authorising the use of veterinary medicines for use on humans is illegal and unethical and needs no further explanation. It must not be done.

2. The Medicines Act 1981 contains a specific exemption allowing veterinarians to authorise the sale, supply or administration of prescription medicines (as defined in the Medicines Act 1981) for the treatment of animals under the care of that veterinarian. The same legal restraint applies to pharmacy-only medicines and restricted medicines. It is illegal and unethical for veterinarians to authorise the use of these medicines for the treatment of humans.
**Section 14: Advertising**

1. When considering advertising RVMs veterinarians must take the following principles into account:
   
a. The reasons for advertising are for the promotion of products to improve animal health, animal welfare, animal production or animal husbandry.

b. Advertising must state that the product is only available under veterinary authorisation.

c. RVMs should not be advertised if it is likely to jeopardise the risk management role of the authorising veterinarian.

d. Advertising must not be used to influence decision-making about authorising a certain product.

2. Veterinarians must not advertise antibiotics.

3. Veterinarians must not advertise products that have a specific condition of registration prohibiting this. For such products there is no discretionary judgement to be made. The products must not be advertised or promoted, and no purchase incentives may be offered.

4. Veterinarians must not display registered veterinary medicines in view of the public.

**Understanding Section 14**

1. Veterinarians may advertise or promote RVMs to end users (including offering purchasing incentives) provided there is no specific condition of registration prohibiting this, and the product is not an antimicrobial.

2. The MPI document *Advertising guidelines for products registered under the ACVM Act* sets out MPI expectations under the Animal Compounds and Veterinary Medicines Act 1997 regarding the standards to be maintained by veterinarians when advertising and promoting veterinary medicines. Veterinarians are expected to know and comply with the requirements detailed in this document.

3. In all cases, the advertising veterinarian should emphasise that end users should discuss treatment options with their veterinarian.

4. Particular veterinary medicines may have a specific condition of registration that prohibits advertising to end users.

5. For further information refer to the Professional Integrity Code Section 9 and explanatory notes.