

Explanatory Notes Veterinary Medicines Section

The various actions a veterinarian may undertake in relation to veterinary medicines (using, selling etc) are defined in the COPC glossary.

1. Understanding Section 1

- a. Section 1 recognises that in practice (as defined in the COPC glossary) veterinarians are not obliged to maintain an inventory of veterinary medicines. This section only applies to those veterinarians who purchase or stock veterinary medicines in order to use, sell or dispense them in the course of their practice.
- b. 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) legislation, Misuse of Drugs Act and Regulations, and the Health and Safety in Employment (HSE) Act.
- c. While there is no legal requirement, there is an ethical expectation that adverse events as a consequence of using a veterinary medicine will be reported to the ACVM group of NZFSA and the manufacturer.
- d. There is an ethical expectation that where any restricted veterinary medicine is dispensed that its labeling will comply with the NZVA guideline *A Guide to Veterinary Pharmacy and Dispensing*.
- e. Security refers specifically to the requirements for controlled drugs as specified in the Misuse of Drugs Act and Regulations. The COPC does not define specific security requirements for particular products. However, there is an ethical expectation that veterinarians must maintain sufficient security and control on all restricted veterinary medicines to ensure they are only used according to veterinary authorisation. From an NZFSA perspective, security also means ensuring lay staff do not sell restricted medicines without appropriate authorisation.
- f. Safety of handling refers to the responsibilities that apply under the HSE legislation.
- g. 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.
- h. The labeling requirements for human medicines, off label use and compounded products are set out in the Code of Practice on the Discretionary Use of Human and Veterinary Medicines.
- i. Guides to ACVM, HSNO, HSE and Misuse of Drugs legislation can be found on the NZVA website. The legislation itself can be found at www.legislation.govt.nz.

2. Understanding Section 2

- a. Section 2 identifies the relevant expectations when a veterinarian is considering the treatment of an animal with a veterinary medicine. These expectations summarise the ethical responsibilities of veterinarians with respect to their product stewardship of the products.

When the product is a restricted veterinary medicine these expectations apply to the veterinarian whether they personally use or administer the product, or whether they authorise another person to use or administer the product.

When the product is an unrestricted veterinary medicine these expectations apply equally whether a veterinarian or one of the practice employees is using the product, or making recommendations about the product. In every practice, irrespective of the nature of the ownership of the practice one or more “responsible veterinarians” must be clearly nominated to take reasonable care to ensure that the staff of the practice are competent and that they perform to the standard expected in this Code. The nominated veterinarian(s) will be considered responsible for the actions of the non veterinary employees in this context.

- b. A primary purpose of the ACVM Act 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 including veterinary medicines. Veterinarians must comply with the conditions of registration on 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 HSE Act, among other requirements, identifies an employer’s responsibilities to identify hazards and to take steps to remove or manage them. As an extension of these legislative requirements, section 2(a) of this part of the COPC sets out the ethical expectation that veterinarians will identify and manage the risks (as identified) associated with using veterinary medicines. The underlying premise in this case 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. Similarly a veterinarian’s treatment should not cause a detrimental effect to agricultural trade or New Zealand biosecurity.
- c. 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, efficacy and worth of the products for particular conditions. The ethical 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.
- d. 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.
- e. Appropriate use means the particular product choice and the way it is administered is suitable for the situation.

- f. Examples demonstrating justified and appropriate use include:
- i. The use of an antibiotic may be justified in order to treat a bacterial infection. Whether the use is appropriate will depend on the choice of product for the situation, the dose rate used and the route of administration;
 - ii. Non steroidal anti-inflammatory drugs may be a valid choice for pain relief, but an inappropriate analgesic in the haemodynamically unstable patient;
 - iii. General anaesthesia may be able to be justified in order to carry out a surgical procedure, but may not be appropriate depending on the drugs used, the age and health status of the patient etc.

- g. In all situations involving food producing animals the potential for residues must be addressed and clients provided with sufficient information to address any issues.

There is an ethical responsibility, and under section 55 (3) of the ACVM Act, a legal responsibility for veterinarians to provide information to prevent any residues in primary produce occurring from any animal treated with a veterinary medicine which contravene the requirements of the Food Act and the Animal Products Act.

Veterinarians or their clients may be charged with an offence (under provisions of the Animal Products Act, Food Act or both) for supplying primary produce that contravenes this legislation. The offence under section 55(3) of the ACVM Act is specific to veterinarians and relates to whether or not they provided the client with information about not supplying the non compliant primary produce. Whether or not the veterinarian will be accountable depends on the information provided to the client.

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 the label use is not approved then it cannot be presumed that the label information on withholding periods is relevant.

For an OTC product such as an anthelmintic, if a veterinarian provides professional judgement for its use in an off-label manner and advises an alternative withholding period, then a farmer may use the product legally in accordance with that advice. If as a result of the professional advice, non-compliances with the Animal Products Act 1999 thresholds are reported, then the veterinarian is legally liable for actual losses by the farmer that are directly attributable to the professional advice.

Failure to provide appropriate advice to clients on residues in food producing animals or keep a record of the advice given places the veterinarian at risk of prosecution.

- h. 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 requires managing including but not limited to:
- i. The type of veterinary medicine e.g. anaesthetic, antibiotic etc;
 - ii. The regulatory requirements for that particular product;
 - iii. The accepted standard of care upheld in the profession for that particular product or product type (ultimately if necessary this will be judged by a veterinarian's peers);
 - iv. The route of administration e.g. IV, SC, PO;
 - v. The type of patient and existing condition;

- vi. The level of training and experience of the person who will be administering the product;
- vii. Whether the person administering can be appropriately trained to administer the product;
- viii. The level of monitoring required during and after administration;
- ix. The training and experience of the administrator to provide adequate monitoring; and
- x. The potential risks (as identified in 2(a) above) involved with administration.

This clause relates to specific veterinary involvement. A client not able to administer a tablet to a dog or cat, or a client not able to administer an injection of antibiotic intramuscularly to a calf, does not necessarily mean veterinary involvement is required.

- i. Where a veterinary medicine is deemed suitable to be administered by a lay person, the veterinarian has a responsibility to appropriately advise and train the administrator.

3. Understanding Section 3

- a. The NZFSA document “*Veterinarians Recognised (under s 62, ACVM Act) to Issue a Valid Authorisation for Purchase and Use of restricted Veterinary Medicines Requiring Veterinary Authorisation ACVM Performance and Technical Standards No 1*” (<http://www.nzfsa.govt.nz/acvm/publications/other-standards/pts-vet-authoriser1209.pdf>) sets out NZFSA expectations under the ACVM Act regarding the standards to be maintained by veterinarians recognised to authorise the purchase and use of restricted veterinary medicines (RVMs) that (under their conditions of registration) require veterinary authorisation. Veterinarians are expected to know and comply with the requirements detailed in this document.
- b. In addition to the NZFSA’s requirements this code identifies further ethical 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 ethical requirements that apply.
- c. This code identifies the expectation that 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 below). An alternative option to consultation but which is only likely to be suitable in certain limited circumstances would be through the use of Veterinary Operating Instructions (see Understanding Section 4). These two options define the only two processes by which veterinarians can authorise RVMs.
- d. A consultation is a specific interaction between the veterinarian and client usually involving an animal(s) that the client is responsible for. There are several components to a consultation (see COPC glossary for definition). For a more detailed breakdown of what is expected in terms of these components see - www.vetcouncil.org.nz/documentation/VCNZ_CompentencyStandardsAndPerformanceMeasuresForVeterinarians.pdf - in relation to obtaining, recording and analysing information. The aim 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 an interview and usually involve an examination

of the animal(s) and or their environment. The resulting course of action can involve any or all of but is not limited to: collection of further information through diagnostic testing; treatment with a veterinary medicine; treatment using a veterinary procedure; advice or recommendations; referral to another veterinarian; ongoing monitoring and follow-up.

- e. The requirement for veterinary authorisation is removed where the use of a restricted veterinary medicine is allowed according to an operating plan that has been approved under section 28 of the ACVM Act.

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 restricted veterinary medicines, 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 restricted veterinary medicines, and removes the requirement for veterinary authorisation.

Operating plans approved under section 28 of the ACVM Act are not the same as veterinary operating instructions. These are discussed under section 4 of these explanatory notes.

- f. 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. Taking into account the generally accepted standard of care that exists for this set of circumstances in practice, what actions or decisions would another veterinarian with the same training and experience reasonably make or take in the same circumstances?
- g. VCNZ may from time to time publish guidance setting out what is considered reasonable for specific circumstances. An example is the *Standard Relating to Sufficient Information* setting out the minimum requirement in order to prescribe dry cow therapy.
- h. When restricted veterinary medicines 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 necessarily the individual animals within the herd or flock.
- i. There is a strong ethical expectation that veterinarians will obtain an owners consent before proceeding with treatment. This is discussed in detail in the client relationships section of the Code, and that section's explanatory notes.
- j. 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 (see 3a), 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 provision for emergency care in case of technical failure, adverse events or unexpected complications.

Expecting that the veterinarian must “make provision” allows the veterinarian to 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.

- k. 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, the authorisation of a veterinary medicine for a client by a veterinarian who is employed in the same local practice (i.e. a co-worker in the practice) where the co-worker works in the same area of practice as the client’s usual veterinarian, and where the usual veterinarian would have otherwise authorised the veterinary medicine because they have recently seen and therefore do have personal knowledge of the health condition / status of the animal(s).

It is expected that there are few situations where not seeing or examining the animals would be acceptable.

- l. Veterinarians should carefully consider the circumstances in which they use electronic means for authorising. Writing a veterinary authorisation based, for example, on an internet consultation is only likely to be considered acceptable by VCNZ in certain circumstances. Veterinarians authorising the use of veterinary medicines via electronic means are expected to provide their animal patients with the same standard of care and comply with the same ethical expectations around consultation regardless of the communication method or service delivery mechanism used. Therefore, in circumstances where the veterinarian considers it appropriate to use electronic means for an authorisation they must be confident that adequate consultation has been carried out before providing the authorisation. Where authorisation follows, for example, an internet consultation it is expected that the veterinarian will have recently seen or examined the animal(s) and should only proceed if they are confident that a physical examination would not add critical information about the management of the case.
- m. There are statutory requirements under the ACVM Act and potentially the Misuse of Drugs Act 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. The COPC identifies the ethical expectation that records must be kept and maintained in relation to treatment with veterinary medicines.
- n. Where there has been a consultation and a veterinarian has proposed treatment with a veterinary medicine, the client is entitled to request from the veterinarian a written authorisation to take away and have the product dispensed by a different trader rather than have the consulting veterinarian dispense it. The consulting veterinarian is ethically obliged to comply with that request. **The expectation is**

that this would apply in every situation where the veterinarian would have otherwise dispensed 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 (e.g. because 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 and that except in exceptional circumstances this would be within 24 hours.

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 COPC.

The veterinarian is entitled to charge a reasonable fee for writing the authorisation, however, it would be unethical for the veterinarian to demand that the client should meet a different standard of consultation in order to be entitled to a written authorisation as compared to the standard of consultation that would normally be required if the veterinarian was dispensing the product, e.g. 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.

4. Understanding Section 4

- a. Veterinary Operating Instructions (VOI) are a set of instructions from an authorising veterinarian to a non-veterinarian to hold a restricted veterinary medicine (RVM) in anticipation of use, for use 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, and where all matters requiring consideration by the veterinarian have been addressed in the instructions.
- b. The two NZFSA documents "*Veterinarians Recognised (under s 62, ACVM Act) to Issue a Valid Authorisation for Purchase and Use of restricted Veterinary Medicines Requiring Veterinary Authorisation ACVM Performance and Technical Standards No 1*" (<http://www.nzfsa.govt.nz/acvm/publications/other-standards/pts-vet-authoriser1209.pdf>) and "*Veterinary Operating Instructions ACVM Guidelines No 65*" (<http://www.nzfsa.govt.nz/acvm/publications/other-standards/veterinary-operating-instructions-guidelines1209.pdf>) set out NZFSA's expectations in relation to VOI. The latter document also provides a template for developing VOI. The NZFSA documents stipulate that compliance with the guidelines for VOI is not mandatory. However, in order to demonstrate compliance with the ethical expectations required in this code veterinarians are strongly advised to follow those guidelines and to meet the minimum suggested requirements.
- c. Additional to the NZFSA's requirements this code identifies further ethical expectations that apply to veterinarians when issuing VOI. There is a strong expectation that veterinarians will exercise sound professional judgement when developing and issuing VOI, and that they must adhere to both the legal and ethical requirements that apply.

- d. The concept of VOI has evolved from the human medical use of Standing Orders. Doctors can write Standing Orders allowing designated persons with identified competencies to use specified prescription medicines to treat human patients without involving the doctor at the time. In the same way VOI are seen as a strategic tool allowing the optimal use of available skills in the workforce through the delegation of treatment roles that do not need to be specifically undertaken by a veterinarian to a less highly but still appropriately trained person.
- e. VOI authorise that specified RVMs can be held by designated persons in anticipation of use. In all cases when people working under VOI use the RVMs, they are not prescribing or authorising them, but rather administering or supplying them and only pursuant to the documented instructions of the authorising veterinarian.
- f. VOI do not have to be linked to a case-specific veterinary consultation in relation to the animals being treated. Under the VOI, the specified person can only use the authorised RVM on the identified animals (or class of animals) in the defined circumstances. As long as the specified person complies fully with the conditions of the VOI, they are not limited to only using the RVMs on animals belonging to the veterinarian's clients. Neither are they limited to using the products following a consultation between the veterinarian and the owner of the animals. Consequently there is not necessarily a vet-client relationship between the veterinarian issuing the VOI and the owner or the person in charge of the animals being treated under the authority of the VOI.
- g. Understanding Section 4(a) and (b):
- i) VOI must be developed in such a way as to tightly define and ring-fence which animals can be treated, the precise types of treatment situations applicable and the decision making process expected of the user leading up to use. In every case when issuing VOI, the veterinarian must be satisfied that all of the clinical variables associated with the case have been sufficiently defined and managed so that the presence of a veterinarian is therefore not required in the particular identified circumstances in order for the user to decide whether or how the authorised products should be used.
 - ii) VOI can only be considered an appropriate option in situations where there is no need for a veterinarian to make a clinical diagnosis in order to ensure the use authorised by the VOI is appropriate and justified, and also where there is no requirement for a veterinarian to exercise their professional judgement in relation to the decision to use the particular product.
 - iii) For the purposes of illustrating how VOI might be used, it is likely that most animals treated under VOI will fit into one of three groups:
 1. Prophylactic treatment of healthy animals for the purpose of preventing disease. Examples might include:
 - Vaccinating a dairy herd for leptospirosis.
 - Vaccination of animals admitted to a shelter organisation for the purposes of adoption.
 2. Chemical restraint of healthy animals to facilitate the performance of a procedure or manipulation. Examples might include:
 - Use of local anaesthetic/xylazine for disbudding calves

3. Treatment of an animal(s) identified to have a particular condition or state of health, where the presence of that condition or state is so obvious that a veterinarian is not needed to diagnose it under the particular circumstances in order to justify the authorised treatment.

Examples might include:

- Sedation of an agitated horse by a groom on an export flight.
- Euthanasia by injection of a seriously injured stray animal by an SPCA officer.

- iv) There would be very few exceptions where veterinary diagnosis and judgement would not be considered a requirement in order to justify the appropriate use of antibiotics. Therefore, VOI are unlikely to be considered an appropriate way to authorise the use of these products.

- h. Understanding section 4(c).

This section should be self explanatory. Veterinarians must always have developed the particular VOI before use of the RVMs.

- i. Understanding Section 4(d)

The veterinarian must be satisfied that the person(s) identified in the VOI is adequately trained and experienced in the use of the specified veterinary medicine, and is able to safely, reliably and effectively carry out the instructions as documented. The issuing veterinarian must identify and document the particular competencies required in relation to using the specified restricted veterinary medicines in accordance with the VOI, and document how the specified person is recognised as being in possession of those competencies (either by the specific training provided by the veterinarian, or relevant qualifications).

- j. Understanding Section 4(e)

Veterinarians are required to keep careful records detailing their own use of restricted veterinary medicines associated with consultations. It is expected that similar records will be kept by the person specified in the VOI that detail how, when, where and on whose animals RVMs were used and in what circumstances. Those records should document: date of use; name and address of person in charge of the animals; identity of the animals (or herd or flock), the identity of the person using or providing the restricted veterinary medicine; volume or amount of product used; method of administration; reason for use; adverse reactions or events and sufficient details to allow immediate stock reconciliation.

- k. Understanding Section 4(f)

Veterinarians must use their professional judgement to determine the level of monitoring/auditing that is required on a case by case basis in order that they can be confident that the conditions and terms of the VOI are complied with.

As part of this monitoring, the records of use must be examined in order that the veterinarian can be satisfied the treatment decisions of the specified person are valid and in compliance with the terms of the VOI. The frequency the records should be examined is reliant on the judgement of the veterinarian for the particular circumstances.

Reconciliation of all restricted veterinary medicine purchases and disposals, against the record/register must also be conducted frequently enough for the veterinarian to be confident that product use remains in compliance with the VOI.

The veterinarian is expected to use their judgement when deciding how often these records should be checked in order to have confidence. However, it is expected that auditing will take place at least every 6 months, or at the conclusion of the term of the VOI if that is a shorter period.

- i. Understanding Section 4(g)
The NZFSA guidelines set out expectations regarding review of the VOI. Additionally under this code, and as part of the review process, if the VOI is to be extended, veterinarians must review the competencies that are needed to carry out the instructions, and meet personally with the user in order to reconfirm their confidence that the user is working effectively and safely under the VOI. Ideally this would involve personally viewing the user administering the products.
- m. Understanding 4(h)
VOI must be cancelled and withdrawn by the veterinarian in any situation in which he or she is not confident that the instructions are being complied with. Non compliance by the specified person with the instructions of the authorising veterinarian puts that person in breach of the conditions of registration of the product. As well as the ethical implications, if the veterinarian is aware of non compliance and takes no action to withdraw their authorisation, their status as a recognised person under the ACVM Act may be put at risk.
- n. Writing VOI does not exempt the veterinarian from ultimate responsibility for ensuring that the risks will be managed satisfactorily. If a veterinarian issues VOI with the intent and confidence that the specified person could and would comply with the instructions and use the restricted veterinary medicine only in accordance with those instructions, then the veterinarian has met the responsibilities in support of issuing a veterinary authorisation. If the specified person fails to comply with the operating instructions then it may not be the veterinarian's fault. However, what would be questioned is whether the veterinarian issued adequate instructions and used sound judgement in deciding that the specified person could and would comply before authorising the product(s). The veterinarian would most likely not be responsible for the specified person's behaviour if something went wrong, but could be held responsible for issuing inadequate instructions, or making a poor judgement about the capability and reliability of the client or continuing to authorise the supply in the face of doubt.

5. Understanding Section 5

- a. The Code of Practice entitled *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. This will not continue to be recognised as being approved under section 28 of the ACVM Act. It will be updated to reflect the current definitions for terms and the revised guideline will be maintained and made available by VCNZ in order to detail the expected standard of practice.
- b. Off-Label use of a registered veterinary medicine occurs when the use does not comply with approved claims. Off-label use may involve the route of administration, dose rate, duration of treatment, target species or the condition being treated. Veterinary medicines that can be used off-label have a condition placed on their registration allowing this. Not all registered veterinary medicines have this condition, and these products can only be used strictly according to their label directions.

The label includes all of the product proprietor information ACVM 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:

- i. the physical label attached to the product
 - ii. label information on product packaging
 - iii. additional loose material packed with the product
- c. 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 (the Act). The 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.
 - d. 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.
 - e. Where discretionary use (of either a human medicine or a registered veterinary medicine) is controversial or outside the mainstream standards of care, the veterinarian must obtain the informed consent of the client.
 - f. The expectation still exists that 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 discretionary use of a human medicine or the off label use of a veterinary medicine. It is accepted that there may be circumstances where the discretionary use may be chosen in preference. This is acceptable as long as the decision can be justified and it is the exception rather than the rule.

6. Understanding Section 6

- a. NZFSA 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 compounded preparations have avoided the usual regulatory assessment, and so expose the veterinarian, animals treated; people involved with treatment and the public interest to potential risks (see 2(a)). Being able to compound veterinary medicines is a privilege granted to the veterinary profession that carries particular responsibilities. The ethical expectations around compounding are identified in section 5 of the Veterinary Medicines segment of the COPC. The details explaining the basis for these requirements are written in the guideline *Compounded Veterinary Medicines* published by VCNZ.
- a. Veterinarians may compound product under one of the three exemptions from registration of veterinary medicines that are specified in the ACVM regulations. A veterinarian, like anyone else, can also manufacture a trade name product that fits any of the defined product groups (based on scope of claims) specified in schedule 1 or 2 of the ACVM Regulations 2001. Veterinarians who manufacture or compound products become subject to ACVM requirements around manufacturing and it is important that they clearly understand those expectations.

Veterinarians are referred to the VCNZ guideline *Veterinarians and Manufacturing of Veterinary Medicine*, and the NZFSA for further details.

- c. Compounding a veterinary medicine should be seen as a last resort and only undertaken because a product in the desired form or presentation is otherwise unavailable for animal treatment. The guiding principle should be that the compounded product improves the animal(s) welfare over and above anything else that is currently available and is therefore a more appropriate veterinary medicine to use.
- d. The process of reaching a decision about product 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 compounded medicine.
- e. The veterinarian must take full responsibility for the product whether they do the compounding personally or contract someone else to do it.
- f. Veterinarians should only compound sufficient material to satisfy their short-term requirements, and not in anticipation of future needs. Product should really only be compounded for a particular case. However, VCNZ recognises that there are situations where the practical reality is that more than what is needed for one case has to be prepared at the same time. However, it will be considered unethical if a veterinarian purposely sets out to compound so much product that it has to be stored in anticipation of future use, or is distributed to other traders thus circumventing the normal regulatory requirements expected of a registered veterinary medicine in routine use.
- g. Because the expectation is that compounding should only happen in order to provide a product for a particular case, compounded veterinary medicines should never be advertised, promoted, or displayed for sale.

7. Understanding Section 7

- a. 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. The veterinarian must ensure that:
 - (i) the product is not altered in any material way other than to change from the original packaging and labelling
 - (ii) no additional hazards are introduced through careless or inappropriate procedures during decanting or breaking down
 - (iii) the choice of alternative packaging does not jeopardise the quality of the product
 - (iv) all the crucial information about the product is provided to the client, as well as the veterinarians contact information and additional instructions.
- b. Having breached the integrity of the trade name product, the veterinarian must take full responsibility for any adverse consequences.

8. Understanding Section 8

- a. Veterinarians providing a dispensing service for restricted veterinary medicines have some particular responsibilities.
- b. NZFSA recognises all veterinarians with a current VCNZ practising certificate to authorise the purchase and use of restricted veterinary medicines requiring veterinary authorisation. Quite separate from recognition to authorise the purchase and use of restricted veterinary medicines requiring veterinary authorisation, veterinarians with current VCNZ practising certificates are generally recognised by NZFSA to sell such products as part of their own clinical veterinary services.

However, this recognition does not give the veterinarian the authority:

- (i) to dispense/sell any restricted veterinary medicine that requires authorisation only via an approved operating plan.
 - (ii) to fill veterinary authorisations issued by veterinarians that are not part of the same veterinary clinical practice.
- c. Some veterinarians may wish to operate a restricted veterinary medicine dispensing service (ie a veterinary pharmacy) to fill authorisation from:
 - (i) other veterinarians; or
 - (ii) other persons recognised by NZFSA to authorise the purchase and use of restricted veterinary medicines via approved operating plans.In order to do this the veterinarian have an operating plan approved by NZFSA governing the sale of restricted veterinary medicines. NZFSA should be contacted for guidance on the development of operating plans.
 - d. The accepted standard of practice for providing this dispensing service is detailed in the *ACVM Standard for Prescription Animal Remedy Veterinary Medicines*. This standard will no longer exist as an approved operating plan under section 28 of the ACVM Act, but will be maintained and published as a guideline by VCNZ in order to detail the standard expected.
 - e. The specific ethical expectations around providing a dispensing service are listed in the COPC and are self explanatory.

9. Understanding Section 9

- a. 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 e.g. zinc bacitracin, chloramphenicol etc
- b. The requirements in the COPC are self explanatory

10. Understanding Section 10

- a. There are currently no restricted veterinary medicines that have a condition of registration declaring that they can only be administered by a veterinarian. These are usually products that have sufficient risk to the safety and or welfare of people or animals that they should only be managed by an approved trader who supplies veterinarians, or a veterinarian. The requirements described in section 10 are self explanatory.

11. Understanding Section 11

- a. 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.
- b. 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) 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.

12. Understanding Section 12

- a. Veterinarians may advertise or promote (including offering purchasing incentives) restricted veterinary medicines to end users. However, they must explicitly state that the product is only available under veterinary authorisation. Ethically, a veterinarian should not advertise restricted veterinary medicines if it is likely to jeopardise the risk management role of the prescribing veterinarian. In all cases, the veterinarian should emphasise that end users should discuss treatment options with their veterinarian. The over-riding concern is that advertising must not be used to affect the decision to authorise the use of the product.
- b. Particular veterinary medicines will have a specific condition of registration that prohibits advertising to end users. 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.
- c. Restricted veterinary medicines should not be displayed in public view such that the products themselves or their labels might influence the purchasing decision.