

# Draft Explanatory Notes to the Code of Professional Conduct (COPC)

## Introduction

These explanatory notes to the COPC have been written to:

1. provide a greater level of detail around the Veterinary Council's (VCNZ) expectations of veterinarians' ethical conduct;
2. explain the use of terms not already covered in the COPC glossary;
3. identify other resources which some of the COPC requirements are based on;
4. explain how the COPC might be applied by VCNZ or a VCNZ Complaints Assessment Committee (CAC) in cases where concerns about possible breaches have been identified.

The explanatory notes are complemented by other guidance as identified in the text. In the future further guideline material may be developed by VCNZ in conjunction with organisations such as New Zealand Veterinary Association (NZVA), the New Zealand Food Safety Authority (NZFSA), Massey University or other Industry groups. This guidance may provide specific examples of the application of the COPC, templates for use when applying the COPC or set out in further detail VCNZ's position on a particular issue.

## Professional Judgment

A fundamental principle of the Code of Professional Conduct is the exercise of sound professional judgment by veterinarians in all their professional endeavours.

Veterinarians are educated to evaluate clinical situations and make appropriate treatment decisions. Similarly VCNZ expects veterinarians to evaluate situations (whether in relation to a clinical matter or not), apply established ethical criteria and make a competent and sensible decision about the most appropriate course of action taking into account the individual circumstances and the best potential outcomes for the animal, the client and the profession. This is exercising sound professional judgement.

VCNZ accepts that there is usually not just one right decision in every given set of circumstances, and the COPC purposely does not set out to be prescriptive in defining how every situation must be managed.

## 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](http://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. 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 the VCNZ's Competency Standards and Performance Indicators for Veterinarians - 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.
- b. Consultation is a specific ethical requirement in order that a veterinarian may authorise or use a restricted veterinary medicine. However, the requirement for a consultation and 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 (R) 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 3i of these explanatory notes.

- c. 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?
- d. 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.
- e. 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.
- f. 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.

- g. 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:
- i. Provision of a particular service (e.g. artificial breeding programme) to geographically widespread clientele, where the veterinary medicine is necessary for a particular programme of treatment that will personally involve the veterinarian.
  - ii. 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).
  - iii. Where animal welfare issues arise that over-ride this expectation – e.g. supplying dog vaccinations for immunising a particular litter of puppies in a geographically isolated area where the risk of Canine Parvovirus is high, and it is not practical or in the welfare interest of the puppies to transport them to a veterinarian to be physically examined. While the particular puppies in these circumstances may not have been examined by a veterinarian there will still need to have been a consultation with the owner regarding the vaccination of these specific animals. Avoiding the cost of the consultation would not be considered an acceptable animal welfare reason to circumvent this expectation.

It is expected that there are few situations where not seeing or examining the animals would be acceptable. In these situations the authorising veterinarian needs to have collected sufficient information through interview to be satisfied that the risks associated with product use are satisfactorily managed.

- h. 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.

- i. Veterinary Operating Instructions (VOI) are a recognised and specific set of veterinarian endorsed instructions and records relating to the administration of restricted veterinary medicines by authorised non-veterinary persons to animals under the care of that veterinarian. VOI must only be created following a consultation regarding the specific animal(s)/herd/flock to be treated. VOI must not be used to authorise the use of restricted veterinary medicines in circumstances where the veterinarian has not carried out a consultation in relation to those animal(s).

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.

VOI have specific relevance where use will be carried out by a non veterinarian at a time when the veterinarian will not be present to make the decision to use the product on the specific animal. Significant potential risks are associated with the use of a variety of types of restricted products. VOI provides a tool that helps veterinarians manage and control risks more effectively in circumstances when they are not present to have a direct influence.

In every case the veterinarian will need to be satisfied that the clinical variables associated with use have been sufficiently defined so that the presence of a veterinarian is therefore not required in the particular identified circumstances in order to decide whether the authorised products should be used. The veterinarian must also be satisfied that the person(s) specified in the VOI is adequately trained and experienced in the use of the specified veterinary medicine, and is able to safely and effectively carry out the instructions as documented.

The requirement for VOI to be directly linked to a consultation is an ethical obligation defined by this Code of Professional Conduct. It is an additional requirement to that defined by NZFSA. NZFSA requires veterinarians when issuing VOIs to exercise their professional judgement to support their roles as persons recognised under section 62 of the ACVM Act to authorise the sale and use of registered restricted veterinary medicine trade name products. This does not necessarily require a consultation. Veterinarians must be aware that they need to meet both the NZFSA requirements for authorisation of restricted veterinary medicines and the Code of Professional Conduct's requirements.

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 client 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 client could and would comply before authorising the product(s). The veterinarian would most likely not be responsible for the client'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.

- j. Examples of situations where the use of VOI would be considered compatible with the expectations within this code:
- (i) VOI written by a veterinarian authorising a veterinary nurse employed in a veterinary clinic to administer premedication drugs to an in-patient prior to general anaesthesia where that patient has been recently examined by a veterinarian and a consultation has taken place with the owner regarding the proposed anaesthesia and treatment.
  - (ii) VOI written by a veterinarian authorising a veterinary nurse to administer a sedative to a cat for the purposes of grooming the cat where there has been a consultation by the veterinarian with the owner of the cat regarding the proposed treatment.
  - (iii) VOI written by a veterinarian authorising a veterinary nurse to administer a general anaesthetic to an in-patient without the veterinarian present at the time in order that the patient can be prepared for surgery, and where there has been a consultation with the owner of the patient with regards to the proposed anaesthesia and surgery.
  - (iv) VOI written by a veterinarian authorising a technician employed by a veterinary practice using local anaesthetic and/or xylazine in order to disbud calves without the veterinarian present (where the owner of the calves is a client of the practice and where there has been a consultation with a veterinarian in relation to the disbudding).
  - (v) VOI written by a veterinarian authorising a farmer client to administer intramammary cerates to cows in the herd with mastitis where a consultation has taken place with the farmer regarding the proposed management of mastitis as a clinical problem within that herd.
  - (vi) VOI written by a veterinarian authorising a farmer to administer xylazine and local anaesthetic to a stag for the purposes of removing velvet, where the farmer is a client of the veterinarian and there has been a consultation with the farmer regarding the proposed treatment.
- k. Examples of situations where the use of VOI would not be considered compatible with the expectations within this code:
- (i) VOI written by a veterinarian authorising a veterinary nurse employed in a veterinary clinic to administer premedication drugs to an in-patient prior to general anaesthesia where a veterinarian has not had a consultation with the owner regarding the proposed anaesthesia and treatment e.g. a cat or dog dropped off at a clinic

for a desexing operation where that animal has never been to the clinic before and has never been examined by a veterinarian before.

- (ii) VOI written by a veterinarian authorising a non veterinarian to administer vaccine to dogs or cats where there has not been a consultation by the veterinarian previously in relation to those particular animals.
- (ii) VOI written by a veterinarian authorising a technician employed by a veterinary practice using local anaesthetic and/or xylazine in order to disbud calves without the veterinarian present where the owner of the calves is a not client of the practice and where there has not been a consultation with the veterinarian in relation to the disbudding.
- (vii) VOI written by a veterinarian authorising a farmer to administer xylazine and local anaesthetic to a stag for the purposes of removing velvet, where the farmer is not a client of the veterinarian and/or where there has not been a consultation with the farmer regarding the proposed treatment.

I. 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. 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.

m. 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. 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.

## 5. Understanding Section 5

- 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.
- b. 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.

## 6. Understanding Section 6

- 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.

## 7. Understanding Section 7

- 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 must apply to NZFSA for individual formal recognition under section 62. Veterinarians who are recognised to operate a veterinary pharmacy must know what kind of authorisation is required for each one (c.f. Performance and Technical Standards for persons recognised to sell restricted veterinary medicines).
  - 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.

#### **8. Understanding Section 8**

- 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

#### **9. Understanding Section 9**

- 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 8 are self explanatory.

#### **10. Understanding Section 10**

- 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.

#### **11. Understanding Section 11**

- a. Veterinarians may advertise or promote (including offering purchasing incentives) restricted veterinary medicines to end users where advertising or promotion is not likely to jeopardise the risk management role of the prescribing veterinarian. For example, advertising would be acceptable if the veterinarian's risk management involvement is in relation to how or when the product should be used (e.g. oestrus synchrony products) rather than deciding if a particular product should be used (e.g. disease treatment products). In all cases, the person must emphasise that end users should discuss treatment options with their veterinarian. The overriding concern is that advertising must not be used to affect the decision to authorise the use of the product.
- b. For trade name veterinary medicine products that must not be advertised to end users (e.g. antibiotic products and anabolic steroids), the ACVM Group will expressly state that prohibition in a condition on the registration. This means that 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.

## How would a Complaints Assessment Committee (CAC) apply the COPC expectations in the situation of a complaint?

After considering a complaint or referral and determining on the face of it that there is sufficient evidence that a veterinarian has breached the requirements of the COPC, the CAC needs to consider the action that it will be recommending to, or advising VCNZ of. The following points are likely to be considered by the CAC in reaching a decision on the recommendation:

1. How serious is a particular breach? The COPC identifies a series of expectations. Each of these in their own right, irrespective of any circumstances, can be considered to lie on a gradient of seriousness with some requirements being more serious and some less. For example, selling Class A registered veterinary medicines without a consultation would be considered very serious. Not reporting an adverse event in relation to a veterinary medicine where the consequences of the event were minor could be considered to have a relatively low level of seriousness.
2. Is this a competence, impairment or conduct (disciplinary) matter?
  - a. VCNZ defines a competent veterinarian as one who applies knowledge, skills, attitudes, communication and judgement to the delivery of appropriate veterinary services in accordance with their field of veterinary practice. The Competency Standards and Performance Indicators used by VCNZ are published on its website.
  - b. There are elements of this part of the COPC in relation to the use of veterinary medicines which could be considered to be either a competence or a conduct (disciplinary) matter depending on the circumstances. Breaches of parts of subsection 1(b), all subsections of 2, and subsections 3(b) and 3(c) could lead to the CAC recommending to VCNZ that a veterinarian's competence be assessed. But there are also elements in this part of the COPC which would likely be considered as a conduct or disciplinary matter, for example:
    - i. Providing veterinary medicines for use on humans
    - ii. Not honouring requests for written authorisations in lieu of dispensing;
    - iii. Part of the definition of consultation is "collecting and recording sufficient information relevant to the individual circumstances". If the information collected is believed to be insufficient or not relevant to the matter, this might raise a question about the veterinarian's competence. This may depend however on the nature of the veterinary medicine. The absence of a consultation in relation to the sale of a registered veterinary medicine, would likely be viewed as a conduct (discipline) matter.
    - iv. If a veterinarian's records in relation to a consultation are inadequate, then this could be considered to reflect on the veterinarian's competence. The circumstances of the consultation will always be considered in reaching an assessment. Altered records would be likely to be considered as a conduct issue, as would evidence that there were no records.
    - v. If the consent process has occurred but inadequately, this might be interpreted as a competence matter. However if the veterinarian has made no attempt to obtain consent, or there is sufficient evidence that

- the veterinarian has exploited the client through the consent process then these situations might become discipline matters.
- vi. Using and authorising the use of antibiotics without valid reason and inappropriately could be considered a competence matter.
  - vii. Authorising the sale of anaesthetic drugs to be used by people with inadequate training and without appropriate veterinary supervision would most likely be considered a conduct (disciplinary) matter.
- c. Despite sub sections a. and b. above, breaches may also be determined to be matters where a recommendation for disciplinary referral would be made, if there was evidence that the veterinarian showed:
- i. Reckless or willful disregard of their duty of care to the animals being treated and the public interest, and or;
  - ii. Reckless or willful disregard of the VCNZ's expectations and or;
  - iii. Unethical conduct (e.g. dishonest, fraudulent, exploitative, malicious) and or;
  - iv. Criminal conduct (i.e. breaches of legislative requirements)
3. What features may be viewed as increasing the seriousness of the potential breach?
- a. Does the complaint, after investigation, show evidence of more than one breach and how serious is it? A single breach of a serious nature may be sufficient for a CAC to take action on s43 of the Veterinarians Act. Alternatively a number of less serious breaches in combination may reach the threshold the CAC taking action.
  - b. What actions or decisions would other veterinarians with the same experience and training have reasonably taken or made in the same circumstances and how removed is that from the conduct of the veterinarian in this case?
  - c. Could the veterinarian be expected to have insight in this matter (previous recommendations from CAC or VCNZ)? Ignorance of the VCNZ expectations is not an acceptable defence, however, if the veterinarian should reasonably be expected to have gained prior insight into the requirements this could increase the likelihood that the CAC will consider a disciplinary referral;
  - d. Have there been harmful consequences (health and welfare, financial, biosecurity, etc) as a result of the breach to people, or animal patients, or the public interest;
  - e. Do the breaches bring the profession into disrepute;
  - f. Do the breaches involve matters which have particular relevance or importance in the eyes of the profession or public?
4. Are there mitigating circumstances which might reduce the potential seriousness of the conduct?
- a. Was the breach in any way justified or partly justified because of animal welfare considerations? The client not being able to afford the consultation, and therefore the veterinarian dispensing restricted

veterinary medicines without an adequate consultation would not be likely to be considered justifiable.

- b. Were there any distracting influences which may have affected the veterinarian's judgement?
- c. Did the veterinarian recognise the possibility of a breach and take steps which in their judgement would have adequately managed that risk in the given situation, e.g. seek advice on how to manage the situation and then follow that advice in good faith?
- d. Do the requirements of the COPC conflict with expectations of other legislation which would have otherwise allowed the action of the veterinarian to take place without consequences?