



Statement on the Discretionary Use of Human and Veterinary Medicines by Veterinarians

1. Introduction

The Agricultural Compounds and Veterinary Medicines (ACVM) Act provides a legislative basis for preventing or managing the risks associated with the use of agricultural compounds (which include veterinary medicines), in the management of animals or plants.

The risks to be managed are:

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

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

The Act also requires that consumers are provided with sufficient information about agricultural compounds.

The Act defines veterinary medicine as "any substance, mixture of substances, or biological compound used or intended for use in the direct management of animals".

It is an offence under this legislation to import, manufacture, sell or use a veterinary medicine that is not specifically registered as a trade name product, or exempted as a defined group.

It is also an offence for a veterinarian to knowingly fail to provide a client with information to prevent the occurrence, in any primary produce from any animal treated with an agricultural compound, of residues of that compound which contravene any requirements of the Animal Products Act 1999, or the Food Act 1981 or any regulations or notices in force under those Acts or successive legislation.

Veterinary discretionary use includes use of:

- Human medicines (including non-prescription medicines)
- Specially compounded medicines
- "Off-label" use of registered veterinary medicines.

Schedule 2 of the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 identifies the groups of agricultural compounds which are exempt from registration under the ACVM Act. This schedule also sets out the relevant conditions that apply when compounds from these groups are used.

As well as complying with the ACVM Regulations, veterinarians must meet the requirements of the Veterinary Council of New Zealand's (VCNZ) Code of Professional Conduct for Veterinarians (COPC).

a) Human Medicines (including non-prescription medicines):

Preparations scheduled as medicines under the Medicines Act 1981 and used on animals as veterinary medicines are identified as exempt under the 2011 Regulations with the following conditions:

- (i) Must not be used on animals except under the direct care or with the authorisation of a veterinarian.
- (ii) Must not be advertised for sale for use on animals
- (iii) Certain conditions of the Regulations apply including the need for the product to be fit for purpose. These conditions include in particular (but are not limited to) that when used as recommended the product will not:
 - Be toxic to animals treated or exposed to the compound to an extent that causes unnecessary or unreasonable pain or distress, and,
 - Fail to reduce or eliminate pain or distress to animals treated with the compound where the elimination of pain or distress is a stated purpose of the product.

b) Specially compounded medicines:

Preparations scheduled as “Compounded Veterinary Preparations used by Veterinarians” are also identified as exempt under the 2011 Regulations with the following conditions:

- (i) Must not be used on animals except under the direct care or with the authorisation of a veterinarian.
- (ii) May only be used on animals specified by the compounding veterinarian, or animals of a type specified by the compounding veterinarian.

c) Off-label use of registered veterinary medicines:

Off-label use of registered veterinary medicines is permitted, provided the products do not have a condition of registration specifically prohibiting such use. Where discretionary use is not approved, that product may be used only as specified in the current approval (which includes label directions and registration conditions).

Most over-the counter (OTC) veterinary medicines will have a generic condition of registration stating “*Any person using the product on any animal or in any manner other than as specified in the approved product and manufacturing specifications must, before using the product, seek advice from an appropriately qualified source and confirm that the intended use is not likely to cause unnecessary or unreasonable pain or distress in the animal treated.*” If in the professional judgement of the veterinarian it is appropriate to do so, veterinary medicines registered as OTC products may be used in a discretionary manner. Where the veterinarian is unsure, they should seek appropriate advice. While the additional consultation, prescribing and record keeping required for discretionary use of human, veterinary and compounded medicines are not required for registered OTC products, it is strongly advised that veterinarians, when recommending off-label use, keep records of the advice provided.

The product stewardship expectations set out in section 2 of the Veterinary Medicines section of the COPC apply to the recommendation, sale and use of OTC products and to off-label use.

The rest of this statement applies only to discretionary use of restricted veterinary medicines, human and compounded medicines.

Before discretionary use of restricted veterinary medicines, human medicines or specially compounded medicines, there must be a veterinary consultation in regard to discretionary use as described below, and the requirements as listed must be met. VCNZ’s expectations around veterinary consultation are set out in the COPC glossary.

Veterinarians should note that failure to comply with the COPC in relation to using veterinary medicines may result in a complaint being laid before VCNZ and/or a Ministry for Primary Industries (MPI) investigation under the ACVM Act or the Animal Welfare Act.

Civil liability may also be a consequence as a result of losses incurred by a client through inadequate advice or service. In addition veterinarians are responsible for any consequence(s) of the improper compounding of unregistered veterinary medicines used in a discretionary manner.

2. Veterinary Consultation In Regard To Discretionary Use

a) General requirements of veterinarians

All the following steps must be performed before discretionary use. Veterinarians should document the consultation process (e.g. in clinical records).

- (i) Veterinarians must meet all of the requirements of consultation (as set out in the COPC) including being given and accepting responsibility for the ongoing health and welfare of the animals to be treated. They must have obtained sufficient information about the animal or group of animals, to judge that treatment with a veterinary medicine is justified.
- ii) The process of reaching a decision about which product to use can be compared to a linear cascade (see Figure 1). If there is a registered veterinary medicine that can be used in compliance with the label and registration conditions (or an exempted veterinary medicine) to achieve the intended clinical effect, it should be considered first.
- iii) If there is no such suitable product, but there is a registered or exempted veterinary medicine available, which can be expected with discretionary (off-label) use, to meet the treatment and welfare needs of the animal(s) and manage the risks identified in the ACVM Act, it can be considered as an alternative treatment option.
- iv) If no registered or exempt veterinary medicine is available which, even with discretionary use, meets the treatment and welfare needs of the animal(s) a "human medicine" or preparation specially compounded by or for a veterinarian may be used, provided the risks identified in the ACVM Act can still be managed.
- v) In all cases the decision for discretionary use must balance the negative effects of the drug with its benefits to the animal.
- vi) If there is no alternative treatment available, and the animal's need justifies it, veterinarians may apply to the MPI ACVM Group to import a veterinary medicine for alleviation of an immediate welfare need of an animal under their care provided certain conditions are met. Contact the MPI ACVM Group for information.

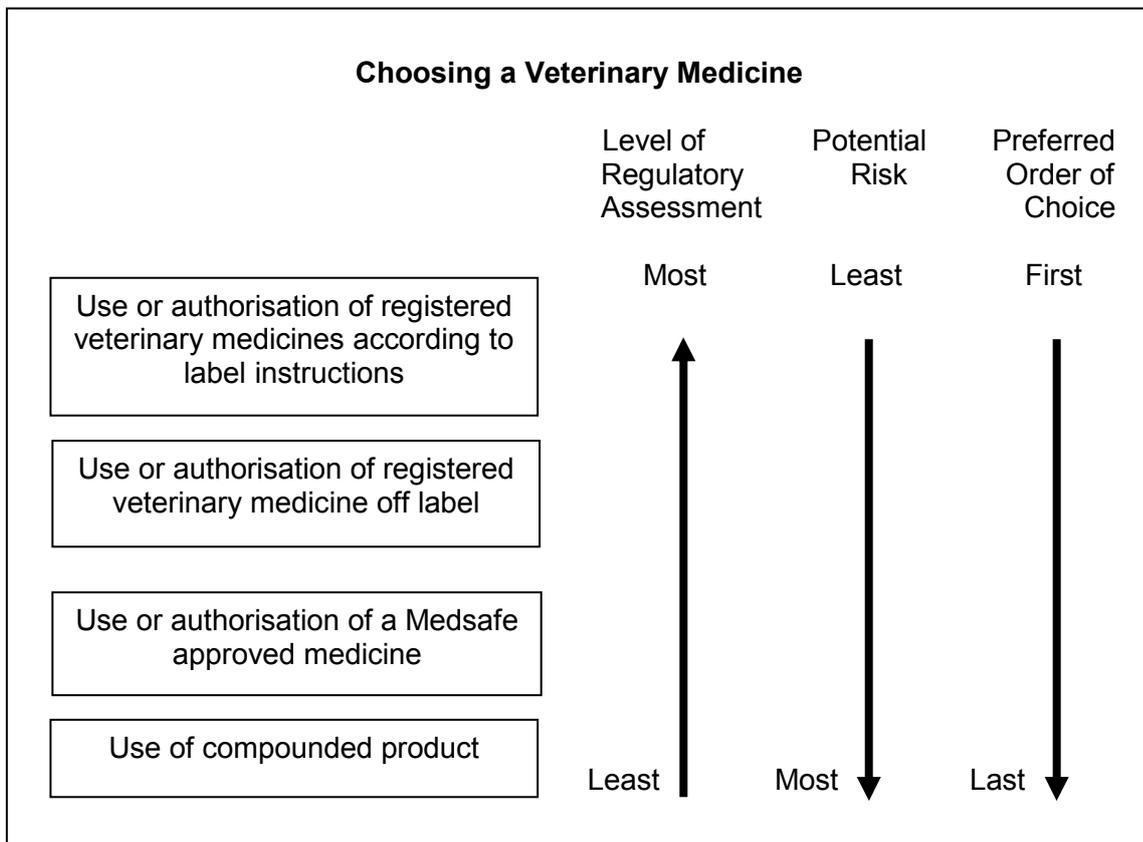


Figure 1: *The decision making cascade is described as a linear process. Veterinarians are expected to have consciously worked through each step before deciding the type of product they will actually use. The cascade is not meant to restrict veterinarians' choices but to facilitate good decision making by effectively managing the risks associated with the type of product used. Ultimately the type of product used is at the discretion of the veterinarian as long as they are able to justify their decision.*

- (vii) Human or compounded medicinal preparations must not be offered for general sale, and must not be imported without MPI approval. When compounding is carried out by another person, veterinarians must provide a written prescription or a compounding order. Legal responsibility for compounding (including formulation, manufacturing, quality control, packaging and labelling) rests with the prescribing veterinarian.

b) Specific requirements for discretionary use in food-producing and non food-producing animals

This section lists the requirements of veterinarians on each occasion of discretionary use of veterinary medicines or human medicines or specially compounded preparations.

Requirements for discretionary use in production and companion animals are listed separately. The principal difference is the need to apply withholding periods in animals used for producing food for human use.

i) Discretionary use in food-producing animals

Veterinarians are required to:

- Ensure there is no specific ban precluding the medicine under consideration from being used on the intended species or in the intended way. Contact MPI or its food safety [website](http://www.foodsafety.govt.nz/) (<http://www.foodsafety.govt.nz/>) if there is doubt.
- Ensure the discretionary use will not jeopardise or hinder any official regulatory control programme or pest management strategy, or any other aspect of agricultural security. Contact [MPI](http://www.mpi.govt.nz/) if there is doubt (<http://www.mpi.govt.nz/>). If there is significant risk to agricultural security, veterinarians must not proceed with the intended discretionary use.
- Assess the scientific data available so as to reasonably predict the efficacy of the intended use, and that unnecessary pain or distress will not result from the discretionary use.
- Assess from the information available, including the pharmacology of the medicine, the probability of residues of the medicine occurring in food, and provide advice for withholding times that are sufficiently long to ensure that no violative residues result. If the medicine is a registered veterinary medicine, the registering company may hold relevant information. If there is insufficient information on which to establish a withholding time, the default withholding time set by MPI should apply:
 - Birds meat 63 days, eggs 10 days
 - Ruminants (including deer) meat 91 days, milk 35 days
 - Camelids meat 63 days
 - Lagomorphs (rabbits, hares) meat 63 days
 - Monogastrics (pigs, horses) meat 63 days
 - Fish, crustacean, molluscs meat 35 days

(These times do not apply to sustained release formulations because the withholding period must apply to the time after the release period, not after administration.)

- Advise the animal's owner/agent of the withholding time.
- As for restricted veterinary medicines, there is a requirement to keep, for at least five years, auditable records for veterinary, human or compounded medicines used in a discretionary manner. Ensure that the following

information is conveyed to the animal's owner or agent, in writing, and that a record is kept by the prescribing veterinarian:

- Name of owner or owner's agent;
 - The identity of the animal/group to be treated;
 - The trade name of the drug, the active ingredient if compounded, and the concentration;
 - The dose rate and frequency of treatment;
 - The route and method of administration;
 - The duration of treatment;
 - The withholding time;
 - The date of treatment;
 - The name of the prescribing veterinarian and the name, address and contact phone numbers of that veterinarian's practice.
- Ensure that the following information is conveyed to the animal's owner or agent:
 - Any special considerations in regard to operator safety;
 - Specific advice that adverse reactions should be reported immediately to the prescribing veterinarian or in the absence of that veterinarian to other veterinarians in the practice.

ii) Discretionary use in companion animals and other animals not kept for food production

Discretionary use may involve prescribing or dispensing of medicine, or administration to the animal within the veterinary clinic in the course of treatment.

The nature of the information conveyed to the owner differs in the two situations.

Requirements of the veterinarian in prescribing or dispensing medicine for discretionary use

- Ensure there is no specific ban precluding the medicine under consideration from being used on the intended species or in the intended way. Contact [MPI](http://www.foodsafety.govt.nz/) or its website (<http://www.foodsafety.govt.nz/>) if there is doubt.
- Ensure the discretionary use will not jeopardise or hinder any official regulatory control programme or pest management strategy, or any other aspect of agricultural security. Contact [MPI](http://www.mpi.govt.nz/) if there is doubt. (<http://www.mpi.govt.nz/>)
- Assess the scientific data available so as to reasonably predict the efficacy of the intended use, and that unnecessary pain or distress will not result from the discretionary use.
- As for restricted veterinary medicines, there is a requirement to keep, for at least five years, auditable records for veterinary, human or compounded medicines used in a discretionary manner. Ensure that this information includes;
 - Name of owner or owner's agent;
 - The identity of the animal(s) to be treated;
 - The trade name of the drug, the active ingredient (if compounded for discretionary use) and the concentration;
 - The dose rate and frequency of treatment;
 - The route and method of administration;
 - The duration of treatment;
 - The date of treatment;
 - The name of the prescribing veterinarian and the name, address and contact phone numbers of that veterinarian's practice.
- As for any other treatment administered, dispensed or prescribed, advise the animal's owner or agent of any special considerations in regard to operator safety.

- As for any other treatment administered, dispensed or prescribed, advise the owner or agent to report any adverse reaction immediately to the veterinary practice.

Requirements of the veterinarian for discretionary use of medicines in clinic

- Ensure there is no specific ban precluding the medicine under consideration from being used on the intended species or in the intended way. Contact MPI or its website (<http://www.foodsafety.govt.nz/>) if there is doubt.
- Ensure the discretionary use will not jeopardise or hinder any official regulatory control programme or pest management strategy, or any other aspect of agricultural security.
- Contact MPI if there is doubt.
- Assess the scientific data available so as to reasonably predict the efficacy of the intended use, and that unnecessary pain or distress will not result from the discretionary use.
- Record and retain the following information for at least five years:
 - Name of owner or owner's agent;
 - The identity of the animal(s) to be treated;
 - The trade name of the drug, the active ingredient if compounded, and the concentration;
 - The dose rate and frequency of treatment;
 - The route and method of administration;
 - The duration of treatment;
 - The date of treatment;
 - The name of the prescribing veterinarian.
- Inform the animal's owner or agent that adverse reactions should be reported immediately to the veterinary practice;

3. Further Information

See:

- http://www.vetcouncil.org.nz/CPC/VetMed/CPC_VetMedicines.php
- VCNZ Statement on Prescribing and Dispensing Prescription Medicines, Restricted Veterinary Medicines and Controlled Drugs.¹ This includes detail on the period of supply for Prescription Medicines and Restricted Veterinary Medicines.

4. Definitions

Agricultural security

The ACVM Act defines agricultural security as "the exclusion, eradication, and effective management of –

(i) Pests

- a) includes any unwanted organism, including micro-organisms, pest agents, and any genetic structure that is capable of replicating itself (whether that structure comprises all or only part of an entity, and whether it comprises all or only part of the total genetic structure of an entity) that may affect plants, animals or raw primary produce; and
- b) includes any entity declared to be a pest for the purposes of this Act by order in Council made under subsection (2);
- c) does not include;
 - any human being or living organism that affects only human beings
 - any living organism declared not to be a pest for the purposes of this Act by order in Council made under subsection (2).

(ii) Unwanted organisms under the Biosecurity Act 1993.

¹ Still in draft form as at April 2013. Final version expected by July 2013

Authorisation: The process of a veterinarian creating a documented approval allowing a client to purchase a particular restricted veterinary medicine to administer to a particular animal(s) in accordance with the instructions of the veterinarian

Companion animal

Companion animals are considered to be cats, dogs and any other animals kept as pets, excluding ungulates. Where such animals are kept in a farming situation, for production of food they are not considered to be companion animals

Compounding Order

A compounding order is an instruction by a veterinarian to a third party to compound a product to be dispensed by the veterinarian

Discretionary use

The use by, or on the authority of, a veterinarian of:

- a registered veterinary medicine in a manner not specified in the conditions on registration for the product, or
- a human medicine scheduled under the Medicines Act 1981 and exempted from registration under the ACVM Act, or
- a preparation specifically compounded, by or on the authority of that veterinarian, for use on animals in that veterinarian's immediate care

In writing

Providing information "in writing" may involve including details on a label, invoice, receipt or by some other written means

Prescription

A prescription is an instruction issued to a third party to dispense, and, in the context of discretionary use, may include instructions regarding a product to be compounded. The documentation must meet the standard defined within the VCNZ Statement on Writing Prescriptions for Prescription Medicines and Restricted Veterinary Medicines

Unreasonable or unnecessary pain or distress

This is a professional but subjective assessment by the veterinarian of what is unreasonable or unnecessary pain or distress taking into account the veterinarian's knowledge of animal welfare and New Zealand society's current attitudes

Withholding time

The time that must elapse between the last treatment and sale for slaughter for human consumption or harvest of product to be sold for human consumption or use.