

Veterinary medicines

Veterinarians must exercise sound professional judgement when authorising, dispensing, recommending, selling and using veterinary medicines.

1. When using or selling any unrestricted veterinary medicine or dispensing a restricted veterinary medicine, a veterinarian must:
 - (a) Ensure effective product management (storage, reporting adverse reactions, maintaining the integrity of product, labelling, security, safety of handling); and
 - (b) Meet statutory requirements imposed under the Agricultural Compounds and Veterinary Medicines, Animal Products, Hazardous Substance and New Organisms, Health and Safety in Employment, Medicines, Misuse of Drugs, Fair Trading and Consumer Guarantees Acts and other relevant legislation.

2. When using or recommending any unrestricted veterinary medicine or authorising any restricted veterinary medicine a veterinarian must:
 - (a) Consider the implications of its use with regard to risks to public health, trade in primary produce, agricultural security, animal welfare, occupational health and safety and the environment, and act accordingly to avoid or mitigate significant risks;
 - (b) Be satisfied that the choice of product is justified, and that use is appropriate to achieve the intended effect and ensure the welfare of the animal;
 - (c) Provide appropriate advice on the management of residues and withholding periods in food producing animals;
 - (d) Determine and provide the appropriate level of veterinary involvement (if any) required during and after administration in order to manage the risks; and
 - (e) Determine and provide the appropriate level of advice and training (if any) to:
 - administer the veterinary medicine safely and appropriately; and
 - monitor the effects of treatment on the animals and make provision for veterinary intervention in the case of adverse effects.

3. When using or authorising restricted veterinary medicines, the veterinarian must comply with the requirements and expectations of NZFSA in relation to authorisation, as set out in their published performance and technical standards (<http://www.nzfsa.govt.nz/acvm/publications/other-standards/pts-vet-authoriser1209.pdf>). Additionally the veterinarian must:
 - (a) Comply with all of the points in 2 above;
 - (b) Obtain sufficient information to assist risk assessment and to support the choice of that veterinary medicine through either:
 - i. Veterinary consultation as defined in the glossary, or
 - ii. Issuing Veterinary Operating Instructions as detailed in paragraph 4
 - (c) Create and maintain appropriate records detailing the decision and the action taken;
 - (d) Honour requests for written authorisations in lieu of dispensing.

4. When issuing Veterinary Operating Instructions, a veterinarian must comply with the requirements and expectations of NZFSA in relation to VOI, as set out in their specific published guidelines (<http://www.nzfsa.govt.nz/acvm/publications/other->

[standards/veterinary-operating-instructions-guidelines1209.pdf](#)). Additionally the veterinarian must:

- (a) Tightly define the specific treatment circumstances in which each restricted veterinary medicine is authorised to be used under VOI.
 - (b) Only authorise use of restricted veterinary medicines under VOI where there is no reasonable expectation that either veterinary judgement or a veterinary diagnosis would be needed in order to ensure that the use of the product in the specific case is appropriate and justified.
 - (c) Be able to provide evidence that the process for developing and issuing VOI has been followed appropriately prior to implementation of the instructions.
 - (d) Be able to provide evidence that they have identified the specific competencies required of personnel authorised in the VOI and be able to provide appropriate detail of the training and assessment of the personnel in relation to those competencies.
 - (e) Make it a requirement of the VOI that specific records are kept in relation to every instance of use of the restricted veterinary medicines by VOI specified personnel, documenting sufficient information to permit easy assessment of compliance with the terms of the VOI.
 - (f) Be able to provide evidence of sufficient monitoring that allows the veterinarian to be confident that the terms of the VOI are being complied with.
 - (g) Review the competency of the personnel annually by personally assessing the use of the restricted veterinary medicines by the user.
 - (h) Withdraw the VOI immediately in situations of non compliance.
5. When using or authorising human medicines or the discretionary use of registered veterinary medicines “off label”, the veterinarian must:
- (a) Comply with all of the points in 2 and 3 above;
 - (b) Consider if there is a registered veterinary medicine that will adequately achieve the intended effect and ensure the welfare of the animal and, if appropriate, choose the registered veterinary medicine in preference; and
 - (c) Not supply any Medsafe approved human medicine for use as a veterinary medicine, or any registered veterinary medicine off label unless the additional risks can be justified.
6. When using or authorising a preparation that has been compounded, the veterinarian must:
- (a) Comply with all of the points in 2,3 and 4 above;
 - (b) Consider, (in situations where there is no appropriate registered veterinary medicine) if there is a Medsafe approved human medicine which will adequately achieve the intended effect and ensure the welfare of the animal and if indicated choose the human medicine in preference to a compounded product;
 - (c) Ensure that compounded products do not contain prohibited or restricted substances as defined by NZFSA;
 - (d) In situations where the product is compounded personally, be competent in all aspects of formulation and manufacturing and take full responsibility for the product including its preparation, packaging and labeling;
 - (e) Be satisfied that a third party contracted to do the compounding is competent, issue a compounding order specifying the product, quantity, packaging and labeling and retain full responsibility for the product;

- (f) Compound only enough product to manage short-term requirements and not store product in anticipation of future needs;
 - (g) Not advertise or promote compounded products as veterinary medicine trade name products or display them for sale to the general public; and
 - (h) Not import compounded veterinary medicines without approval from NZFSA.
7. When decanting or breaking down a trade name product the veterinarian must ensure that:
- (a) the product is not altered in any material way other than to change the original packaging and labeling;
 - (b) no additional hazards are introduced through careless or inappropriate procedures during decanting or breaking down;
 - (c) the choice of alternative packaging does not jeopardise the quality of the product;
 - (d) all the crucial information about the product is provided to the client, as well as the veterinarians contact information and additional instructions;
8. When providing a dispensing service for restricted veterinary medicines authorised by any veterinarian outside the practice a veterinarian must:
- (a) Have the appropriate NZFSA recognition to trade in restricted veterinary medicines;
 - (b) Ensure that the veterinary medicine is supplied only to a person who has the appropriate authorisation;
 - (c) Be satisfied that the authorisation is bone fide and the person requesting the veterinary medicine is the one authorised to purchase it;
 - (d) Give effect to the instructions of the authorising veterinarian if it is a veterinary authorisation; and
 - (e) Keep a record of the transaction with a copy of the authorisation.
9. For a generic chemical to be used as a veterinary medicine the veterinarian must;
- (a) Recognise that there has been no regulatory assessment of the chemical for that purpose, or any regulatory control of the quality and fitness for purpose for treatment of animals, and address the risk management in an adequate manner; and
 - (b) Make the client aware of the situation and provide adequate risk management advice.
10. Veterinarians must not authorise, dispense, recommend or sell restricted veterinary medicines with a condition of registration requiring administration only by a veterinarian, and must keep them locked in a controlled drug cabinet, with veterinary access only.
11. Veterinarians must not use, recommend or authorise the use of veterinary medicines, prescription medicines, pharmacy only medicines or restricted medicines (as defined in the Medicines Act 1981) for use on humans.
12. Veterinarians must not advertise or display restricted veterinary medicines where such action has the potential to influence the end users expectation about the necessity to use a specific product.

Glossary

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

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

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

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

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

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

Veterinary medicine: Any substance, mixture of substances or biological compound used or intended for use in the direct management of an animal.

Veterinary consultation

A veterinary consultation must include the veterinarian:

1. Collecting and recording sufficient information relevant to the individual circumstances to ensure the proposed course of action (including treatment) is appropriate and meets the needs and best interests of the animal(s) and the client;
2. Obtaining appropriate consent to the proposed course of action;
3. Being given and accepting responsibility for the ongoing health and welfare of the animal(s) concerned in relation to the consultation. This includes arranging emergency care taking into consideration the circumstances and the potential for adverse effects from, or failure of the agreed course of action;
4. Determining and providing the appropriate level of advice and training in order to be satisfied that the agreed course of action can occur as planned; and
5. Interviewing the client (or a legitimate and authorised representative of the client).

In most cases consultation will involve the animal(s) having been seen by the veterinarian at the time of the consultation, or recently or often enough for the veterinarian to have sufficient personal knowledge of the condition/health status of the animal(s) in order to be able to propose the particular course of action/treatment.

Veterinary authorisation

An instruction, in an appropriate documented form, from a veterinarian authorising:

1. the use of a restricted veterinary medicine by the specified person in accordance with the authorising veterinarian's instructions;
2. the holding of a relevant restricted veterinary medicine by a person who is neither a recognised trader nor a veterinarian;
3. the sale from a person recognised to sell restricted veterinary medicines to a person specified in the authorisation.

Advertise

To publicise to the community or to any section of the community using any words, whether written, printed, spoken, or in any electronic form, or of any pictorial representation or design or device used to promote the sale of any agricultural compound; and 'to advertise' has a

corresponding meaning (ref: section 2 ACVM Act). Advertising does not include general information transfer about animal health, animal welfare, or food safety status or management.

Compounded preparation

A preparation prepared by a veterinarian or by a person on behalf of a veterinarian for use or sale as a veterinary medicine without regulatory assessment or approval.

Compounding

Combining ingredients (some of which may be generic chemicals or biological compounds and others may be trade name products) to prepare a medication to be supplied to a person to treat an animal. To prepare means not only the process of combining ingredients in an appropriate manner for the intended purpose but also placing the medication into appropriate packaging with appropriate labelling to allow it to be supplied to and used by a person other than the veterinarian who compounded it.

Generic Chemical

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

Off Label Use

Off label use is using a registered veterinary medicine (OTC or restricted) product for a purpose not assessed by ACVM.

Veterinary Operating Instruction (VOI)

A set of instructions from an authorising veterinarian (AV) to a non-veterinarian to hold restricted veterinary medicines (RVM) in anticipation of their use, and to use RVMs only in accordance with the AV's instructions in circumstances in which the AV will not be carrying out a case-specific consultation.