



Statement on Compounding Veterinary Medicines

This statement should be read in conjunction with:

- Paragraph 6 of the Veterinary Medicines section of the VCNZ Code of Professional Conduct and related explanatory notes
- MAF Guidance on Developing a Documented System to meet conditions of exemption from registration for Compounded Veterinary Preparations under the ACVM (Exemption) Regulations 2011

Definitions

Compounding means to combine ingredients (for example, generic chemicals or biological compounds or trade name products) to prepare a medication to be dispensed 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 dispensed to and used by a person other than the veterinarian who compounded it.

Practices that are also included but do not strictly fit the above definition of compounding are:

- decanting and breaking down trade name products into smaller quantities when there is no change in the product itself
- reconstituting trade name products, and
- preparing medications to be used immediately by the veterinarian who prepares the medication.

Prescribing in this document means to make a decision about the choice of a particular veterinary medicine as the most appropriate under the circumstances and to convey that decision to the person requesting the advice. It is not used in the context of authorising the use of veterinary medicines that have conditions of registration that restrict who can sell or use the products. To convey the latter meaning the word 'authorisation' would be used.

Dispensing means to supply or sell a veterinary medicine.

General requirements for Compounding

Compounded veterinary medicines are either compounded by a veterinarian or by a manufacturer or compounding pharmacist on behalf of that veterinarian. The practice of compounding and dispensing compounded veterinary medicines is authorised via an exemption from registration in Schedule 2 of the ACVM (Exemption) Regulations 2011. The exemption only applies to veterinarians. Veterinarians must comply with all of the conditions of exemption from registration (refer to Regulations 7, 10, 12 and 14)

If the compounding is to be carried under a veterinarian's direction, the compounding order (equivalent to the manufacturing specifications, such as formulation, packaging and labelling) must be the instructions of the veterinarian to the person who will compound the veterinary medicine.

Compounded veterinary medicines are not assessed by MAF, so there is no external review of information to support their use as veterinary medicines. Nevertheless, they may be used as such when a veterinarian accepts full responsibility for their use and takes due care to manage risks. Apart from any other risks, the ones relevant to the ACVM Act are:

- trade in primary produce
- agricultural security
- animal welfare and
- public health not related to those managed under the HSNO Act.

Veterinarians must have a documented system in place for compounded veterinary preparations and must implement this in accordance with Regulations 7, 10, 12 and 14. Under these Regulations veterinarians must provide adequate labelling and, if the compounded product is to be used on a food-producing animal, must provide sufficient advice to avoid residues that do not comply with New Zealand food residue standards.

Prohibition on promotion and advertising

Compounded veterinary medicines must not be advertised or promoted as veterinary medicine trade name products.

They must not be displayed for sale to the general public.

Selling

Compounded veterinary medicines must be sold only in the context of a veterinarian providing professional services associated with an adequate consultation for particular animals under his/her care. They must not be offered for sale as trade name products.

Prescribing

Compounded veterinary medicines must be prescribed only after a veterinary consultation and only for animals under the care of the prescribing veterinarian. The veterinarian must conclude that there is no alternative product that has already been authorised under the ACVM Act (ie registered or specifically exempt from registration).

Compounding

Veterinarians must be competent in all aspects of formulation and manufacturing commensurate with the type, complexity and potential hazards of the preparations they are compounding. In the first instance, it is up to the compounding veterinarian's judgement as to whether or not he/she is competent to compound a particular medication. However, the veterinarian must be able to defend that judgement successfully in light of common practice of the veterinarian's peers.

Veterinarians must have a documented system in place governing their compounding.

Veterinarians must not use or specify an ingredient that is prohibited from use as an agricultural compound or specify an ingredient or use that is inconsistent with limitations on a similar veterinary medicine trade name product. The most current list of prohibited/restricted substances can be obtained from MAF.

Because prescribing a compounded veterinary medicine must be restricted to those cases in which there is no suitable alternative, the veterinarian should not compound any more of the preparation than would be needed to meet his/her short-term requirements. The prescribing veterinarian must take full responsibility for the product, its preparation, packaging and labelling.

The veterinarian should not store quantities of compounded veterinary medicines in anticipation of future needs beyond the short term. The veterinarian must be satisfied that, if the veterinary medicine is stored at all, it will continue to meet the compounding specifications.

Third parties compounding preparations under a compounding order

When a prescribing veterinarian contracts the compounding to a third party, the veterinarian retains full responsibility for the medication. The veterinarian must ensure that the third party is competent and reliable to carry out the preparation. The veterinarian must issue a compounding order specifying the product, quantity required, packaging and labelling.

It is recognised that specialist compounding pharmacists may have more detailed and current information than veterinarians regarding formulation specifications, manufacture and quality control. It is acceptable practice for veterinarians and specialist compounding pharmacists to collaborate in the specification and manufacture of preparations. It is also acceptable practice to include human medicines approved for sale in New Zealand or a veterinary medicine trade name product that has been registered under the ACVM Act without specifying its full formulation. However, there must be sufficient information to judge that, even without the full formulation information, the medicine or veterinary medicine can safely be considered fit for the purpose, and can be mixed with the other ingredients with no adverse consequences.

Proprietary ingredients of the compounding pharmacist that have not been registered or approved for sale in New Zealand and for which the pharmacist refuses to disclose the formulation should not be acceptable to the veterinarian issuing the compounding order.

The quantity of the compounded veterinary medicine should be only what is necessary and sufficient to meet the prescribing veterinarian's short-term requirements. If the veterinarian intends to do the packaging and/or labelling personally, the compounding order must specify this. The veterinarian must consider how long the preparation could be kept, depending on the stability of the preparation and the need by the current cases being treated.

The third party compounding a veterinary medicine in accordance with a compounding order should follow the instructions of the veterinarian and prepare no more than was specified in the compounding order. However, the veterinarian will be held responsible for any adverse consequences.

Where the specification of the formulation has been a collaborative effort, the acceptance by the veterinarian of any lack of disclosure must be apparent. The acceptability of a lack of disclosure must be based on the professional judgement of the veterinarian issuing the compounding order. However, the veterinarian must be able to defend that judgement successfully in light of common practice of the veterinarian's peers.

The veterinarian must ensure that the compounding order is clear and complete in its instructions and limits the quantity to the amount that meets the short-term requirements. The third party is expected to keep records of compounding orders and be able to relate their preparations to specific compounding orders. It is also expected that the full quantity prepared is given to the veterinarian (or his or her agent) who issued the compounding order. The third party must not retain or hold any part of the order. However, if they do and they offer the preparation to another party or offer it for sale themselves, the exemption from registration will be nullified

and the action is likely to be illegal. The original veterinarian will not be held responsible for the action, if the veterinarian took no part in the action.

Importation prohibited

Compounded veterinary medicines must not be imported without approval from MAF.

Decanting and breaking down trade name products

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:

- the product is not altered in any material way other than to change from the original packaging and labelling
- no additional hazards are introduced through careless or inappropriate procedures during decanting or breaking down
- the choice of alternative packaging does not jeopardise the quality of the product
- all the crucial information about the product is provided to the client, as well as the veterinarians contact information and additional instructions.

Having breached the integrity of the trade name product, the veterinarian must take full responsibility for any adverse consequences.

Reconstituting trade name products

Trade name products must be reconstituted in accordance with the instruction for each product, using only appropriate diluents and careful procedures to avoid introducing additional hazards.

Preparing medication to be used immediately by the veterinarian who prepares the medication

At times, a veterinarian may have to compound a preparation for immediate use. The preparation will not be stored or dispensed to another person, so the requirements for packaging and labelling are irrelevant. However, the requirements for careful formulation and preparation still apply. The veterinarian must ensure that the resulting medication is fit for purpose and take full responsibility for any adverse consequences.