

## Introduction

With some restrictions under the *Poisons and Therapeutic Goods Act 1966* and the *Stock Medicines Act 1989* (most notably in relation to food producing species), the supply options for a veterinarian in NSW include a registered medication for that animal species, a registered medication for use in another animal species or humans (off label use) or an unregistered medication compounded by either a compounding pharmacy or the veterinarian.

Compounding refers to the extemporaneous preparation and supply of a therapeutic product that is not commercially available as a registered medication. The term is generally used to refer to a single 'unit of issue' of a therapeutic product intended for supply for a specific patient in response to an identified need.<sup>1</sup>

Veterinarians have indicated that compounded medications provide a number of potential benefits for veterinarians, animal owners and animal welfare. Compounded medications may:

1. Increase the range of available therapeutic agents to veterinarians
2. Allow more precise dosing of some animals
3. Improve animal owner compliance

## Purpose

The purpose of this guideline is to clearly define the circumstances in which the use of a compounded medication is considered appropriate and compliant with various pieces of legislation including particular emphasis on the *Veterinary Practice Regulation 2013* (sch 2) Veterinary Practitioners Code of Professional Conduct (Code).

## Policy

1. Veterinarians intending to prescribe a compounded medication must ensure they are aware of their legislative requirements including requirements under agriculture and veterinary chemicals legislation, poisons and therapeutic goods legislation, stock medicines legislation and veterinary practice legislation.
2. When prescribing compounded medication veterinarians should collaborate with a pharmacist who has been educated, and completed sufficient training, in the compounding of medication for the treatment of animals.
3. Compounded medications are not subject to the same efficacy, safety, and quality assurance testing of registered medications and hence the potential for harm to animals and animal carers is greater when compounded medications are prescribed.
4. Compounded medication should only be used for treating individual animal patients or a group of animals (not food producing species) when there is no registered medication available for that animal species, another animal species or registered human medication.
5. Compounded medication is considered acceptable if a registered medication is available but an appropriate method for dosing or dose concentration does not exist and a practical alternative does not exist.
6. Compounded medication must be dispensed by a pharmacist directly to a client or supplied directly to the veterinarian who has physically examined the animal for the purpose of supplying to the client. A veterinarian must not mark-up, apply a dispensing fee or label a compounded medication supplied by a pharmacist.
7. Cost is not considered to be an acceptable justification for prescribing a compounded medication.

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<sup>1</sup> Pharmacy Board of Australia 2015, Guidelines on compounding of medicines, Updated content issued August 2017, Pharmacy Board of Australia.

### Application of the Code

1. Veterinarians must carry out professional procedures in accordance with current standards and must base professional decisions on evidence-based science or well recognised current knowledge and practice or both (cl 4):
  - a. The veterinarian must assess the patient's condition, based on history, clinical signs, and physical examination in order to establish a therapeutic need prior to prescribing a compounded medication
  - b. The veterinarian must ensure that a registered medication is not available either for that species or for another species (human or animal) or if available, that the registered medication does not have an appropriate method for dosing or dose concentration
  - c. For production animal species, only a single animal on the property may be treated at any time using a compounded medication
2. Veterinarians must where appropriate consult with or offer referral to colleagues who may have greater skills, knowledge and experience in the use of a particular compounded medication (cl 5).
3. Veterinarians must, where it is practicable to do so, obtain the informed consent of the person responsible for the care of the animal before prescribing a compounded medication (cl 7). When prescribing a compounded medication the client must be made aware that the medication is not registered and has therefore not undergone efficacy, safety and quality assurance procedures subjected to registered medication; the reasons why a compounded medication is required; and the role of the pharmacist (if applicable) and veterinarian in the event of a concern or complaint.
4. When prescribing a compounded medication for treatment the veterinarian must ensure he or she is available for the ongoing care of the animal or if he or she is not available make arrangements for another veterinarian to take over the care of the animal (cl 8). If a pharmacist is involved in compounding the medication the veterinarian should ensure a pharmacist is also available for consultation if required.
5. Veterinarians must ensure that all persons assisting in the provision of veterinary services to animals have the skills, knowledge and equipment to enable them to perform any required duty according to current standards except in the case of an emergency (cl 13). Accordingly, veterinarians should collaborate with pharmacists who have been educated, and completed sufficient training, in the compounding of medications for the treatment of animals.
6. Veterinarians must maintain knowledge of and obey any code or rules of an animal sporting organisation unless they are inconsistent with legislation or other legal requirements (cl 14). It is vital to ensure the compounded medication does not contain any substances prohibited under the rules of the relevant animal sporting organisation.
7. Veterinarians must ensure that a copy of the prescription for the compounded medication is retained for at least 3 years (cl 15):
  - a. The record must specify that a compounded medication was prescribed, the reason for its use and discussions with the client in relation to informed consent
  - b. If additional written information is provided, a copy of this must be retained in the record
  - c. Where applicable, the record must note any possible adverse reaction to the compounded medication and any possible adverse reaction must be reported to the compounding pharmacist
  - d. If the record is altered the alteration must be clearly identified in the record as such.
8. Before prescribing a compounded medication the veterinarian must provide an estimate of costs, if any, for this prescription and any freight charge if the veterinarian will be collecting the compounded medication on behalf of the client (cl 16):
  - a. A prescription fee or freight charge calculated as a percentage of the cost of the compounded medication is considered to be a mark-up.
9. A veterinarian may supply restricted substances (Schedule 4 or Schedule 8 in the Poisons List) only for the care of an animal he or she has physically examined or has under his or her direct care and only in respect of that animal (cl 20):

- a. A veterinarian may prescribe a compounded medication if the veterinarian has performed a physical examination on the animal and based on history, clinical signs, physical examination and further diagnostic testing as appropriate and, in accordance with current standards, has established a therapeutic need for the compounded medication
  - b. A therapeutic need for a compounded medication includes establishing that there is no registered medication available or, if available, that the registered medication does not have an appropriate method for dosing or dose concentration
  - c. Animals are considered to be under the direct care of a veterinarian if the veterinarian has visited the property where these animals are kept, is fully aware of husbandry and management conditions and has physically examined sufficient animals from this property in order to establish a therapeutic need for supplying restricted substances to an animal from this property in accordance with current standards. A compounded medication may be prescribed for a group of animals at this property if compliant with this guideline and if the animals are not classified as food producing species
10. A veterinarian must not prescribe a compounded medication to a client for an animal or animals if this service is accompanied by any payment or other inducement to the veterinarian (cl 21).

**Monitoring**

1. The Board may request a copy of all records relating to the use of compounded medications including patient records and copies of prescriptions
2. The Hospital Inspector will consult with veterinarians at licensed premises and with veterinarians operating from unlicensed premises (as indicated in the Annual Return) in order to monitor compliance with this guideline.
3. The Board will liaise with other veterinary boards in Australia to establish and implement a consistent approach where possible to the regulation of compounded medication.
4. The Board will consult with the profession, veterinary, and other regulatory bodies as required regarding this guideline.

**Conflict of Interest**

Members of the Board must comply with the Code of Conduct for Board members in relation to decisions regarding this guideline.

**Review**

This guideline shall be reviewed annually or as required to ensure that it remains in line with current standards of practice, appropriate to the operations of the Board and compliant with the relevant legislation.