

Use of Compounded Drugs in Veterinary Medicine

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Introduction

Unlike licensed veterinary drugs that undergo a strict legislated approval process by the federal Veterinary Drugs Directorate, compounded drugs are not tested or approved by Health Canada and their use may be associated with greater risk to animal care and outcomes. A veterinarian who engages in the preparation of a compounded drug assumes the same responsibility for the quality, stability, safety, efficacy, potency, and any adverse reactions of the compounded product that a pharmaceutical company assumes for its approved drugs. This accountability exists whether a veterinarian orders compounded drugs through a compounding pharmacy or when they compound independently.

Compounding is extra-label drug use. In Ontario, no individual other than a licensed veterinarian or pharmacist may dispense a compounded drug for administration to animals. Compounding is an accepted veterinary practice and, in certain circumstances, and for some species, may be the most appropriate and effective method of dispensing a drug. A veterinarian wishing to prescribe a compounded drug may compound and dispense the drug themselves, issue a prescription for a specific compounded drug, or dispense from stock a drug that was purchased from a compounding pharmacy for in-office use.

Using a question-and-answer format, this *Guide to the Professional Practice Standard: Use of Compounded Drugs in Veterinary Practice*



addresses questions and offers suggestions on how to apply the *Professional Practice Standard* in situations that arise in veterinary practice.



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Frequently Asked Questions about General Expectations

1. What constitutes a compounded drug?

Compounded drugs are created by any of the following means:

- Manipulating an approved drug to produce a dosage, form, or concentration other than that which is provided for in the directions for use on the labeling. This may be achieved by:
 - Combining two or more drugs to create a new drug;
 - Diluting a drug other than according to the instructions on the label;
 - Mixing to administer by a different route than is recommended on the label or directions for use;
 - Converting an approved medication into a different form (e.g. tablet to liquid, splitting one capsule into two capsules)
 - Adding an unapproved non-drug substance (e.g. flavour base)

2. When is compounding appropriate?

Compounding is appropriate if there is a therapeutic need for a drug and there is no approved drug in the appropriate form for dosing.

3. Who is responsible for the efficacy of a compounded drug?

In the absence of Health Canada regulatory controls, a veterinarian must be aware that, when prescribing a compounded drug, they are responsible for both its potency and purity, as well as for all outcomes, including adverse events (which may include lack of effect).

4. Where an ingredient in a compounded drug includes a controlled drug, is the compounded drug considered a controlled substance?

Yes, where the ingredients in a compounded drug include a controlled substance, the compounded drug is deemed to be a controlled drug, and all relevant regulations apply, including, but not limited to, storage, record keeping, refills and label requirements.

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5. When is compounding not appropriate?

Compounding is not appropriate:

- For the purpose of growth promotion or performance enhancement;
- Where there is an equally appropriate drug available, without a comprehensive informed consent discussion about the risks involved;
- To circumvent legitimate drug-approval processes;
- When a component of the compounded drug is banned for use in food producing animals for which the compounded drug is prescribed and dispensed;
- To sell to third parties
- where the compounding activity constitutes “manufacturing” according to Health Canada, unless the veterinarian is licensed to do so. See Health Canada’s [“Policy on Manufacturing and Compounding Drug Products in Canada” \(POL-0051\)](#) for details.

6. Is a veterinarian required to report adverse reactions to compounded products?

There are no regulations requiring a veterinarian to report adverse drug reactions. Health Canada encourages veterinarians to monitor and report adverse reactions to the Veterinary Drugs Directorate when a compounded product is implicated.

7. How is compounding distinct from manufacturing?

Health Canada’s Policy 0051, Manufacturing and Compounding Drug Products in Canada, describes the circumstances differentiating compounding and manufacturing. Manufacturing includes: preparation of product beyond the usual needs of a practice, preparation of drug product in the absence of an established veterinarian-client-patient relationship, and resale of a compounded drug to third parties, including other veterinarians or pharmacies.

Frequently Asked Questions about Informed Consent

8. What are the expectations that a veterinarian must meet to achieve informed consent when prescribing, dispensing or administering a compounded drug?

A veterinarian must document that the client provided informed consent when a compounded drug is prescribed or administered by the veterinarian or dispensed for administration by the client. At a minimum, the client should be advised of the following:

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- The drug has not been federally approved (i.e., has not gone through the government approval process);
- The efficacy of the drug is not necessarily known;
- Any risks that may be incurred when handling the drug; and
- Any commonly expected side effects that the animal may demonstrate

9. Are there situations when client consent is not required when dispensing or administering a compounded product?

Procedures that routinely utilize compounded drugs for analgesic and anesthesia purposes (such as IV ketamine/diazepam, for the induction of general anesthesia; diluted narcotics, for pain control; diluted dexamethasone, for diagnostic tests; and combinations of a tranquilizer plus a narcotic, for balanced sedation) are generally accepted practices within the profession. In these situations, separate client consent is not required as long as their use is in accordance with published data in refereed journals, veterinary textbooks, or recommendations from recognized experts.

Frequently Asked Questions about In-Office Use

10. Can a veterinarian dispense compounded drugs that they have obtained for in-office use?

A veterinarian may compound or obtain a compounded product from a pharmacist for use within their accredited veterinary facility. In these cases, the prescription and product label should state that it is for clinic use. Practitioners may re-dispense these products to individual animals or groups of animals, where a veterinarian-client-patient relationship exists, as long as a record is made noting the original pharmacy that prepared the product and the prescription number. This will allow for trace-back to the original pharmacy and batch in the event of concerns arising with respect to the product.

Legislative Authority

Food and Drugs Act and Regulations (Federal)

Feeds Act and Regulations (Federal)

Controlled Drugs and Substances Act and Regulations (Federal)

Drug and Pharmacies Regulation Act and Regulations (Provincial)

Drug Interchangeability and Dispensing Fee Act (Provincial)

Veterinarians Act (Provincial) Regulation 1093, s. 1, 18, 23-33 (Veterinarians Act) (Provincial)



Resources

The following can be found at their links or at the College's website at cvo.org:

1. [Policy on Extra-Label Drug Use in Food Producing Animals](#), Health Canada, 2015.
2. [Position Statement: Extra-label Drug Use \(ELDU\)](#), Canadian Veterinary Medical Association, 2021
3. [Veterinary Oversight of Antimicrobial Use – A Pan-Canadian Framework of Professional Standards for Veterinarians](#), Canadian Veterinary Medical Association
4. *Professional Practice Standard: Prescribing a Drug*
5. *Guide to the Professional Practice Standard: Prescribing a Drug*
6. *Professional Practice Standard: Dispensing a Drug*
7. *Guide to the Professional Practice Standard: Dispensing a Drug*
8. *Professional Practice Standard: Extra-Label Drug Use*
9. *Guide to the Professional Practice Standard: Extra-Label Drug Use*
10. *Professional Practice Standard: Use of Compounded Drugs in Veterinary Practice*
11. *Professional Practice Standard: Management and Disposal of Controlled Drugs*
12. *Guide to the Professional Practice Standard: Management and Disposal of Controlled Drugs*
13. *Professional Practice Standard: Informed Client Consent*
14. *Guide to the Professional Practice Standard: Informed Client Consent*
15. *Professional Practice Standard: Medical Records*
16. *Guide to the Professional Practice Standard: Medical Records*
17. *Professional Practice Standard: Establishing, Maintaining and Discontinuing a Veterinarian-Client-Patient Relationship (VCPR)*
18. *Guide to the Professional Practice Standard: Establishing, Maintaining and Discontinuing a Veterinarian-Client-Patient Relationship (VCPR)*

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