

Use of Compounded Drugs in Veterinary Practice

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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 drug 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 him or herself, 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.

Veterinarians must ensure that they meet the practice expectations for prescribing and dispensing a drug when compounding.



Definitions

Beyond Use Date: A beyond use date is the date after which a compounded preparation should not be used; determined from the date the preparation is compounded.

Compounding: Compounding is the combining or mixing together of two or more ingredients (of which at least one is a drug or an active pharmaceutical ingredient) to create a final drug in an appropriate form for dosing. It can involve raw materials or the alteration of the form and strength of commercially available drugs. It can include reformulation to allow for a novel drug delivery (e.g., transdermal). Compounding does not include mixing, reconstituting, or any other manipulation that is performed in accordance with the directions for use on an approved drug's labelling material.¹

Practice Expectations

A veterinarian meets the *Professional Practice Standard: Use of Compounded Drugs in Veterinary Practice* when they:

1. Prescribe and dispense a compounded formulation within an existing veterinarian-client-patient relationship, in keeping with the *Professional Practice Standard: Prescribing a Drug*, *Professional Practice Standard: Dispensing a Drug*, and the *Professional Practice Standard: Extra-Label Drug Use*.
2. Prescribe and dispense a compounded formulation that contains a controlled drug in accordance with the College's *Professional Practice Standard: Management and Disposal of Controlled Drugs*.
3. Understand the risks associated with compounding, and establishes appropriate risk mitigation processes to ensure pharmaceutical safety in animal care.
4. Obtain informed consent from the client for the use of a compounded formulation for the animal(s) or group of animals under care, which includes helping the client understand that the compounded formulation is not approved and that the efficacy of the formulation has not been tested by Health Canada.

¹ Health Canada, *Policy on Manufacturing and Compounding Drug Products in Canada*



5. Use a drug approved for veterinary use, or alternatively a drug approved for human use, rather than an active pharmaceutical ingredient, as the basis for compounding, when possible.
6. Record the information required for a prescription on the label of the compounded formulation when dispensed to a client, with the word “compounded” written on the container. If it is not feasible to include all of the information on the label due to the size of the packaging it must be included on a separate sheet or via a weblink.
7. Understand that they may issue a prescription for a quantity of a compounded formulation in the reasonable expectation of a formerly identified need in a patient or patient group for the purpose of maintaining an inventory of the compounded formulation for in-office use that is reasonably expected to be used before the beyond-use date.
8. Understand that they are solely responsible for establishing and advising the client of the appropriate withholding time when using compounded formulations in food animals. Withholding times should be at least as long as the withholding time recommended by the manufacturer of the drug or substance. Is aware that Canadian global Food Animal Residue Avoidance Databank (CgFARAD) will not provide advice on a withholding period for a compounded drug.
9. Provide a beyond use date of a compounded formulation that is based on known stability data. If a veterinarian purchases a compounded drug from a compounding pharmacy, the pharmacy will provide a beyond use date.
10. Understand that they require a Drug Establishment Licence to import into Canada active pharmaceutical ingredients that are considered medically important antimicrobials (found on List A of the Food and Drug Regulations) for the purpose of compounding. Understand that a veterinarian who imports, manufactures, or compounds an antimicrobial drug which contains antimicrobial active pharmaceutical ingredients contained on List A must submit annual sales reports to Health Canada.

Guide to the Standard

A separate *Guide to the Professional Practice Standard: Use of Compounded Drugs in Veterinary Practice* has been developed by the College and can be found on the Colleges' website www.cvo.org.



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 references informed the development of this *Professional Practice Standard*:

Health Canada, Health Products and Food Branch Inspectorate, Policy on Manufacturing and Compounding Drug Products in Canada, POL-0051, January 26, 2009
ABVMA Council Guidelines Regarding Prescribing, Dispensing, Compounding and Selling Pharmaceuticals

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

1. *Professional Practice Standard: Prescribing a Drug*
2. *Guide to the Professional Practice Standard: Prescribing a Drug*
3. *Professional Practice Standard: Dispensing a Drug*
4. *Guide to the Professional Practice Standard: Dispensing a Drug*
5. *Professional Practice Standard: Extra-Label Drug Use*
6. *Guide to the Professional Practice Standard: Extra-Label Drug Use*
7. *Professional Practice Standard: Management and Disposal of Controlled Drugs*
8. *Guide to the Professional Practice Standard: Management and Disposal of Controlled Drugs*
9. *Professional Practice Standard: Informed Client Consent*
10. *Guide to the Professional Practice Standard: Informed Client Consent*
11. *Professional Practice Standard: Medical Records*
12. *Guide to the Professional Practice Standard: Medical Records*
13. *Professional Practice Standard: Establishing, Maintaining, and Discontinuing a Veterinarian-Client-Patient Relationship (VCPR)*
14. *Guide to the Professional Practice Standard: Establishing, Maintaining, and Discontinuing a Veterinarian-Client-Patient Relationship (VCPR)*



The following additional resources are also applicable:

National Association of Pharmacy Regulatory Authorities - Model Standards for Pharmacy Compounding of Non-sterile Preparations <https://www.napra.ca/publication/model-standards-for-pharmacy-compounding-of-non-sterile-preparations/>

National Association of Pharmacy Regulatory Authorities – Guidance Document for Pharmacy Compounding of Non-sterile Preparations <https://www.napra.ca/publication/guidance-document-for-pharmacy-compounding-of-non-sterile-preparations/>

Plumb's Veterinary Drugs: www.plumbsveterinarydrugs.com

USP-NF Compounding Compendium: <http://www.usp.org/compounding/compounded-preparation-monographs>

Trissel's Stability of Compounded Formulations (print book)

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