



THE COLLEGE OF
VETERINARIANS
OF ONTARIO

PROFESSIONAL PRACTICE STANDARD

Use of Compounded Products 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 products 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 product 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 he or she compounds 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 product may compound and dispense the product him or herself, issue a prescription for a specific compounded product, or dispense from stock a product 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.

Definition

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 product in an appropriate form for dosing. It can involve raw materials or the alteration of the form and strength of commercially available products. 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. [Health Canada, *Policy on Manufacturing and Compounding Drug Products in Canada*]

Practice Expectations

A veterinarian meets the *Professional Practice Standard: Use of Compounded Products in Veterinary Practice* when he/she:

1. Prescribes and dispenses 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. Prescribes and dispenses a compounded formulation that contains a controlled drug in accordance with the College's *Professional Practice Standard: Management and Disposal of Controlled Drugs*.
3. Understands the risks associated with compounding, and establishes appropriate risk mitigation processes to ensure pharmaceutical safety in animal care.
4. Obtains informed consent from the client for the use of a compounded formulation for the animal(s) 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.
5. Uses 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. Records 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. Understands that he or she may issue a prescription for a quantity of a compounded formulation in the absence of an identified need in a patient for maintaining an inventory of

the compounded formulation for in-office use that is reasonably expected to be used before the beyond use date.

8. Understands that he or she is 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 product.
9. Provides a beyond use date of a compounded formulation that is based on known stability data. If a veterinarian purchases a compounded product from a compounding pharmacy, the pharmacy will provide a beyond use date.
10. Understands that prescribing a compounded product instead of an approved drug should not be done solely for economic reasons for the veterinarian.
11. Understands that he or she requires 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. Understands 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 Products in Veterinary Practice* has been developed by the College. See the Resources tab on the College website at www.cvo.org.

Legislative Authority

Veterinarians Act, R.S.O. 1990, s. 7(1)9
Food and Drugs Act, RSC 1985, c F-27, s. 3, 8, 9, 11
R.R.O. 1990, Reg. 1093: General s. 23-33 (*Veterinarians Act*)

Other References:

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

Guide to the Professional Practice Standard: Use of Compounded Products in Veterinary Practice

Professional Practice Standard: Medical Records

Guide to the Professional Practice Standard: Medical Records

Professional Practice Standard: Informed Client Consent

Guide to the Professional Practice Standard: Informed Client Consent

Professional Practice Standard: Prescribing a Drug

Professional Practice Standard: Dispensing a Drug

Professional Practice Standard: Extra-Label Drug Use

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

Resources:

USP Chapter 795: http://www.pharmacopeia.cn/v29240/usp29nf24s0_c795.html
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)

The following can be found on the College's website at www.cvo.org:
Sample Informed Client Consent to Dispense Compounded Product
Sample Informed Client Consent to Dispense Compounded Product for Food Producing Animals and Poultry

College publications contain practice parameters and standards which should be considered by all Ontario veterinarians in the care of their patients and in the practice of the profession. College publications are developed in consultation with the profession and describe current professional expectations. It is important to note that these College publications may be used by the College or other bodies in determining whether appropriate standards of practice and professional responsibilities have been maintained. The College encourages you to refer to the website (www.cvo.org) to ensure you are referring to the most recent version of any document.