



THE COLLEGE OF  
VETERINARIANS  
OF ONTARIO

# PROFESSIONAL PRACTICE STANDARD

## Extra-Label Drug Use

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### Introduction

Extra-label drug use refers to the use of a drug that is not in accordance with the approved label or the package insert of the drug licensed by Health Canada. Extra-label drug use encompasses a broad range of activities. Extra-label drug use can be a significant component of a veterinarian's practice, and can be essential for certain animal species.

As a drug used in an extra-label manner has not undergone the drug review process at Health Canada that ensures that a drug product has received rigorous scientific scrutiny and satisfies all requirements and criteria that are prescribed by the *Food and Drug Regulations*, a drug used in an extra-label manner does not have proven safety or efficacy characteristics based on its intended use. According to Health Canada, extra-label drug use presents a number of potential public health and food safety risks, including violative drug residues being present in food products derived from ELDU-treated animals, the emergence and/or aggravation of antimicrobial resistance, and potential adverse reactions to an animal or group of animals since these products may not have been tested appropriately for the new condition of use.

Veterinarians must ensure that they meet the practice expectations when prescribing and dispensing a drug in an extra-label manner.

### Definitions

**Extra-Label Drug Use:** Extra-label drug use (ELDU), also referred to as "off-label use", refers to the use or intended use of a drug approved by Health Canada in an animal in a manner not in accordance with the label or package insert with respect to species, indication, dose, duration,

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and route of administration. It also includes the use of all unapproved drugs, including unapproved bulk active pharmaceutical ingredients (APIs) and compounded drugs.<sup>1</sup>

## Practice Expectations

A veterinarian meets the *Professional Practice Standard: Extra-Label Drug Use* when he/she:

1. Only prescribes a drug in an extra-label manner within an existing veterinarian-client-patient relationship, and in keeping with the *Professional Practice Standard: Prescribing a Drug* and the *Professional Practice Standard: Dispensing a Drug*.
2. Obtains informed consent from the client when prescribing a drug in an extra-label manner.
3. Understands that he or she has the responsibility to ensure safety, efficacy and, if appropriate, food safety when prescribing extra-label drug use.
4. Recommends a drug approved for veterinary use as the first drug treatment option where available. Alternatively, recommends a drug approved for human use. When no approved drug exists and where a therapeutic need has been established, recommends that a drug be compounded from a drug approved for veterinary use, a drug approved for human use, or (if neither is possible) from an active pharmaceutical ingredient. Understands that prescribing a compounded product instead of an approved drug should not be done solely for the economic benefit of the veterinarian.
5. Meets the requirements of federal and provincial legislation when prescribing or dispensing an extra-label product for food-producing animals including, but not limited to, banned substances (C.01.610.1), medicated feeds (C.08.012) and violative residues in the *Food and Drug Regulations*.
6. Understands that extra-label drug use in food-producing animals is not recommended by Health Canada with antimicrobials of Very High Importance in human medicine which are listed as Category I Antimicrobials in the Health Canada Categorization of Antimicrobial Drugs Based on their Importance in Human Medicine.
7. Prescribes in an extra-label manner in keeping with current research and evidence for a specific species.

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<sup>1</sup> Health Canada, Extra-Label Drug Use (ELDU) in Animals

## Legislative Authority

R.R.O. 1990, Reg. 1093: General (*Veterinarians Act*)

## References

The following can be found on the College's website at [www.cvo.org](http://www.cvo.org):

*Professional Practice Standard: Use of Compounded Products in Veterinary Practice*

*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 Policy on Extra-Label Drug Use (ELDU) in Food Producing Animals  
Health Canada Categorization of Antimicrobial Drugs Based on their Importance in Human Medicine

Health Canada, Extra-Label Drug Use (ELDU) in Animals

Alberta Veterinary Medical Association Council Guidelines regarding Prescribing, Dispensing, Compounding and Selling Pharmaceuticals

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](http://www.cvo.org)) to ensure you are referring to the most recent version of any document.