

# 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 intended condition.

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



## Definition

**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, 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 the veterinarian:

1. Only prescribes a drug in an extra-label manner within an existing veterinarian-client-patient relationship (VCPR), 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 a veterinarian has the responsibility to ensure safety, efficacy and, if appropriate, food safety when prescribing extra-label drug use.
4. Prescribes a drug approved for veterinary use as the first drug treatment option where available. Alternatively, prescribes a drug approved for human use. When no approved drug exists and where a therapeutic need has been established, prescribes 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.
5. Meets the requirements of federal and provincial legislation when prescribing or dispensing an extra-label drug 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 Health Canada does not recommend extra-label drug use with antimicrobials of Very High Importance in human medicine which are listed as Category I Antimicrobials.<sup>2</sup>

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

<sup>2</sup> 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.

## Guide to the Standard

A separate *Guide to the Professional Practice Standard: Extra-Label Drug Use* has been developed by the College and can be found on the Colleges' website [www.cvo.org](http://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 can be found at the College's website at [cvo.org](http://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: Use of Compounded Drugs in Veterinary Practice*
6. *Guide to the Professional Practice Standard: Use of Compounded Drugs in Veterinary Practice*
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:

1. Health Canada Policy on Extra-Label Drug Use (ELDU) in Food Producing Animals
2. Health Canada Categorization of Antimicrobial Drugs Based on their Importance in Human Medicine Health Canada, Extra-Label Drug Use (ELDU) in Animals
3. 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.