THE COLLEGE OF VETERINARIANS OF ONTARIO

GUIDE TO THE 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 intended condition.

Using a question and answer format, this *Guide to the Professional Practice Standard: Extra-Label Drug Use* addresses questions and offers suggestions on how to apply the Professional Practice Standard in situations that arise in veterinary practice.

Frequently Asked Questions about General Expectations

What constitutes extra-label drug use (ELDU)?

ELDU is 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, or route of administration. It also includes the use of all unapproved drugs, including unapproved bulk active pharmaceutical ingredients (APIs) and compounded drugs.

Must I always prescribe a drug approved for veterinary use over a drug approved for human use (and an approved drug over a compounded drug?)

When determining which drug to prescribe, a veterinarian uses their clinical judgment to recommend the most appropriate course of treatment for an animal or animals, taking into consideration the following:

- The availability of any approved veterinary drugs for the species in question and condition (on-label use)
- The availability of veterinary drugs or approved human drugs (extra-label use)
- The need for a compounded drug where no approved drug exists, and a therapeutic need is established
- Current research and evidence of available treatments
- Considerations such as side effects, risks, and benefits

Do I have to obtain client consent before undertaking ELDU?

Yes. A veterinarian undertaking ELDU is required to obtain informed consent within an existing veterinarian-client-patient relationship.

A veterinarian is permitted to use their professional discretion when determining the threshold for informed consent. Oral consent may be acceptable in cases of lower risk. However, it is recommended that written consent be sought in cases of higher risk.

Do I have to obtain informed client consent each time I undertake ELDU for the same drug?

A veterinarian has an ongoing responsibility to consider both the client and circumstance, as well as the level of risk, when determining whether or not informed client consent is required each time the same extra-label drug is prescribed.

I wish to use an extra-label drug in a livestock herd but I am unaware of the appropriate withholding time – what should I do?

In these circumstances, a veterinarian should consult the Canadian Global Food Animal Residue Avoidance Database (cgFARAD) to obtain the required residue avoidance information.

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)

References

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

Professional Practice Standard: Prescribing a Drug
Guide to the Professional Practice Standard: Prescribing a Drug
Professional Practice Standard: Dispensing a Drug
Guide to the Professional Practice Standard: Dispensing a Drug
Professional Practice Standard: Extra-Label Drug Use
Guide to the Professional Practice Standard: Extra-Label Drug Use
Professional Practice Standard: Use of Compounded Drugs in Veterinary Practice
Guide to the Professional Practice Standard: Use of Compounded Drugs in Veterinary Practice
Professional Practice Standard: Management and Disposal of Controlled Drugs
Guide to the Professional Practice Standard: Management and Disposal of Controlled Drugs
Professional Practice Standard: Informed Client Consent
Guide to the Professional Practice Standard: Informed Client Consent
Professional Practice Standard: Medical Records
Guide to the Professional Practice Standard: Medical Records
Professional Practice Standard: Veterinarian Client Patient Relationship
Guide to the Professional Practice Standard: Veterinarian Client Patient Relationship

Additional References:

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