Introduction

The College’s *Professional Practice Standard: Use of Compounded Products in Veterinary Practice* describes the expectations that a veterinarian must meet when prescribing or dispensing a compounded product. Compounded products have an associated risk factor for both animals and humans. Veterinarians are expected to maintain current knowledge of the benefit of such products and prescribe and dispense in keeping with best evidence related to animal and human health. In general, practitioners must ensure they assess the risk of harm, including the potential for drug interactions, potency reduction, and residues entering the food chain when making their prescribing decisions.

Using a question and answer format, this guide addresses questions and offers suggestions on how to apply the Professional Practice Standard in situations that arise in veterinary practice.

Definition

Compounding is the combining or mixing together of two or more ingredients (of which at least one is a drug or pharmacologically active component) to create a final product in an appropriate form for dosing. It can involve an Active Pharmaceutical Ingredient (API) 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 labeling material. [Health Canada, *Policy on Manufacturing and Compounding*]
**Frequently Asked Questions About Compounding in Veterinary Practice**

**How does a veterinarian determine whether or not to prescribe a compounded product?**
When approved veterinary products administered following the manufacturer's direction are not available or are not appropriate for a particular animal(s), the use of a compounded product may be indicated. The Canadian Veterinary Medicine Association (CVMA) has developed a decision cascade (Therapeutic Decision Cascade for Animal and Public Safety) that veterinarians must consider when deciding whether or not it is appropriate to use a compounded product for a specific animal.

1. Approved veterinary drug (DIN): label instructions
2. Approved veterinary drug (DIN): extra-label drug use (ELDU)
3. Approved human drug (DIN): ELDU
4. Compounded product: from approved veterinary drug (DIN): ELDU
5. Compounded product: from approved human drug (DIN): ELDU
6. Compounded product: from active pharmaceutical ingredient (API) : ELDU

**When is it not appropriate for a veterinarian to prescribe or dispense a compounded product?**
Veterinarians sometimes receive requests from clients for compounded products for purposes other than lack of availability of an approved product. Veterinarians should not prescribe or dispense a compounded product in the following situations:
- for growth promotion or performance enhancement;
- when the cost difference between an approved product and a compounded product drives the decision;
- to circumvent legitimate drug-approval processes;
- when a component of the compounded drug is banned for use in food-producing animals; or
- to sell to third parties.
What are the expectations that a veterinarian must meet to achieve informed consent when prescribing, dispensing or administering a compounded product?

Veterinarians must document that the client provided informed consent when a compounded drug is prescribed or administered by the veterinarian or dispensed for administration by the client. At a minimum, the client should be advised of the following:
- the drug has not been federally approved (i.e., has not gone through the government approval process);
- the efficacy of the drug is not necessarily known;
- any risks that may be incurred when handling the product; and
- any commonly expected side effects that the animal may demonstrate.

Are there any situations when client consent is not required when dispensing or administering a compounded project?

Procedures that routinely utilize compounded drugs for analgesic and anesthesia purposes (such as IV ketamine/diazepam, for the induction of general anesthesia; diluted narcotics, for pain control; diluted dexamethasone, for diagnostic tests; and combinations of a tranquilizer plus a narcotic, for balanced sedation) are generally accepted practices within the profession. In these situations, separate client consent is not required as long as their use is in accordance with published data in refereed journals, veterinary textbooks, or recommendations from recognized experts.

Are there special circumstances to be considered when a veterinarian prescribes a compounded product that includes controlled substances?

Where the ingredients in a compounded product include a controlled substance, the compounded product is deemed to be a controlled substance. In this situation, all regulations relevant to the use of controlled substances in veterinary practice apply including, but not limited to, storage, record keeping, refills and label requirements.

What are the factors that a veterinarian should take into account when prescribing a compounded product to food producing animals?

Health Canada notes that a valid veterinarian-client-patient relationship is a necessary condition for use of compounded products in food producing animals and the use of such products should be conducted under the supervision of a licensed veterinarian. Decisions to prescribe a compounded product should only be undertaken in accordance with the Food and Drugs Act and its regulations.

How is compounding distinct from manufacturing?

Health Canada’s Policy 0051, Manufacturing and Compounding Drug Products in Canada, describes the circumstances differentiating compounding and manufacturing. Manufacturing includes: preparation of product beyond the usual needs of a practice, preparation of product in the absence of an established veterinary-client-patient relationship, and resale of compounded product to third parties, including other veterinarians or pharmacies.
Can a veterinarian re-dispense compounded product?
Veterinarians may compound or obtain a compounded product from a pharmacist for use within their accredited veterinary facility. In these cases, the prescription and product label should state that it is for clinic use. Practitioners may re-dispense these products to individual animals or groups of animals, where a veterinarian-client-patient relationship exists, as long as a record is made noting the original pharmacy that prepared the product and the prescription number. This will allow for trace-back to the original pharmacy and batch in the event of concerns arising with respect to the product.

Is a veterinarian required to report adverse reactions to compounded products?
There are no regulations requiring veterinarians to report adverse drug reactions. Health Canada encourages veterinarians to monitor and report adverse reactions to the Veterinary Drugs Directorate when a compounded product is implicated.
Legislative Authority

Veterinarians Act, R.S.O. 1990, s. 7(1)9
Food and Drugs Act, R.S.C. 1985, c F-27, s. 3, 8, 9, 11
R.R.O. 1990, Reg. 1093: General s. 31 (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: 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

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
Canadian Veterinary Medical Association, Guidelines for Legitimate Use of Compounded Drugs in Veterinary Practice, 2006

Resources

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.