

Feedback – Draft Policy Providing Pharmacy Services to Animal Patients

Feedback on the Policy

Lines 23-27

It is unclear why compounding for animal patients is characterized as extra-label drug use (ELDU) when human compounding is not similarly classified under Ontario's controlled acts or human health regulatory frameworks. Greater clarification is needed regarding the regulatory basis for this distinction.

Lines 38-44

The statement that pharmacy professionals require an exemption under the Veterinary Professionals Act (VPA) to compound, dispense, and sell drugs pursuant to a veterinary prescription warrants further explanation.

Pharmacists already possess authority to dispense legally authorized prescriptions within their scope of practice. Both the federal Food and Drugs Act and the Drug and Pharmacies Regulation Act (DPRA) define a drug as a substance intended for use in humans, animals, or fowl. As a result, dispensing veterinary prescriptions falls within pharmacists' existing professional authority.

The Policy should clarify why an exemption under veterinary legislation is necessary when pharmacists are already authorized under pharmacy and federal legislation to dispense veterinary prescriptions.

Lines 57-64

The requirement that pharmacists follow the same decision-making cascade as veterinarians for ELDU raises significant concerns.

The veterinary "cascade" was developed as a prescribing framework and does not align with established pharmacy compounding principles. From a compounding perspective, the hierarchy proposed in the Policy may result in the unnecessary manipulation of commercial products containing excipients, coatings, dyes, fillers, and other ingredients that can affect compatibility, stability, and dose uniformity.

In most circumstances, compounding from a quality pharmaceutical-grade API provides greater control over formulation, consistency, and stability than compounding from a commercial dosage form. The Policy should recognize the pharmacist's professional judgment in selecting the most appropriate starting material rather than mandating adherence to a veterinary prescribing framework that is currently under review/revision.

Lines 65-70

The expectation that pharmacists assess whether a prescribed quantity or frequency is "reasonable" should be reconsidered.

Veterinary prescribing patterns vary widely depending on the nature of the practice and patient population. Pharmacists generally do not have access to the clinical information necessary to determine what constitutes a reasonable quantity within a specific veterinary practice. Responsibility for determining the appropriateness of quantity and frequency should remain with the prescriber.

Lines 76-78

The reference to the CAHI decision cascade should be removed or substantially revised. Decisions related to prescribing and decisions related to compounding involve different professional competencies and responsibilities, each falling within the expertise of the respective practitioner.

Pharmacists must retain professional discretion to select the most appropriate formulation and starting material in accordance with recognized compounding standards.

The requirement to prioritize veterinary-approved and human-approved products before considering an API conflicts with established compounding principles. Starting material selection should be based on professional judgment, available evidence, recognized standards, and the specific requirements of the preparation. In most cases, a quality API is preferable because it avoids the excipients, coatings, fillers, dyes, and manufacturing variability associated with commercial dosage forms which can all effect the final safety, quality and stability of the compounded preparation.

Health Canada's POL-0051 recognizes compounding from either an authorized drug or an appropriate API, while USP standards assign responsibility for ingredient selection to qualified compounding personnel. The Policy should reflect these principles and preserve pharmacists' professional discretion in selecting the most appropriate starting materials.

Lines 83-92

This section does not adequately address office-use prescriptions.

For office-use orders, the veterinarian is both the prescriber and the immediate recipient of the preparation. The pharmacist cannot reasonably know in advance which individual animals may ultimately receive treatment within the practice. Consequently, requirements for patient-specific information are often not applicable at the time of dispensing.

The decision to obtain a preparation for office use rests with the veterinarian, who is responsible for establishing and maintaining the veterinarian-client-patient relationship (VCPR) and documenting subsequent use within the practice. The pharmacist remains responsible for assessing whether the preparation may appropriately be supplied and for ensuring quality, record keeping, and traceability.

The Policy should clearly distinguish between patient-specific prescriptions and office-use prescriptions. Requirements such as animal name, species, client information, group size, or withholding times are appropriate for patient-specific prescriptions but may not be available or relevant when dispensing for office use.

Similarly, requiring species information on a prescription label may not be necessary in all circumstances. While this information should be maintained in the patient record where applicable, finite label space should be reserved for information that directly supports safe use.

Feedback on the Supplemental Guidance

Lines 69-71

This section requires clarification regarding acceptable ingredients for compounding.

NAPRA's compounding standards permit the use of APIs and ingredients that comply with recognized pharmacopoeia standards and Health Canada's POL-0051. There are numerous pharmacopeial-grade APIs available through Canadian suppliers that have established safety and efficacy in specific animal species despite not appearing in the Drug Product Database or Prescription Drug List. The Guidance should explicitly recognize these circumstances.

Lines 102-103

This statement requires correction.

The Guidance broadly suggests that a Drug Establishment Licence (DEL) is required for the importation of veterinary APIs. However, Health Canada's Guidance Document on Drug Establishment Licences (GUI-0002) specifically states an exemption for pharmacists and practitioners. They are allowed to import API without a DEL. With respect to importation, a pharmacist only requires a DEL if they are importing API specifically listed on Health Canada's List A: Certain Antimicrobial Active Pharmaceutical Ingredients.

The Guidance should clearly distinguish between List A antimicrobial APIs and all other veterinary APIs to avoid creating unnecessary confusion regarding regulatory requirements.

Lines 129-144

This section contains several inaccuracies regarding the sale of narcotic, controlled substances & targeted substances to veterinarians.

The cited federal regulations do not establish "emergency use" as a prerequisite for sale to a veterinarian. Rather, veterinarians, as practitioners, may obtain these substances pursuant to the requirements outlined in the relevant federal regulations. Certain transactions may be authorized based on either written or verbal orders. See Food and Drug Regulations G.03.003.

The Guidance should be revised to accurately reflect the applicable federal regulatory framework and avoid creating restrictions that do not exist in legislation.

Lines 145-159

The Guidance's characterization of compounded preparations as inherently presenting greater risk than manufactured products should be revised.

Risk is determined by multiple factors, including formulation, starting materials, preparation methods, quality controls, testing, storage conditions, and intended use. Manufactured products may themselves present challenges related to strength, dosage form, excipient content, availability, stability after manipulation, or product defects and recalls.

Rather than asserting that all compounded preparations carry inherently greater risk, the Guidance should focus on professional standards that support safe and effective compounding.

This section also appears to place responsibility on pharmacists to assess operational aspects of veterinary practices that are more appropriately within the prescriber's scope of responsibility.

Lastly the example provided creates a negative depiction of compounding suggesting non-compliance with regulations (duplication of a commercial product). This should be removed or revised.

Lines 166-172

The reference to "dispensing volume" should be removed.

The term is not defined and may vary considerably between veterinary practices. Instead, office-use compounding should continue to be supported by evidence of routine prescribing patterns and anticipated clinical need, consistent with POL-0051. Undefined dispensing volume should not determine the legitimacy of office-use prescribing.

The recommendation that pharmacists encourage the use of patient-specific prescriptions in place of office-use prescriptions should be removed. Office-use prescribing is a longstanding component of veterinary practice. The Guidance should acknowledge and support this established practice rather than introducing measures that could have the effect of limiting its appropriate use without a demonstrated safety benefit.

Feedback on the Consultation Webpage

The consultation materials should clearly state that this Policy does not require pharmacists to provide veterinary pharmacy services if they do not possess the necessary knowledge, competencies, or resources. Several comments published during the consultation appear to reflect a misunderstanding on this point.

The materials should also clarify that pharmacists already possess the authority to provide pharmacy services to animal patients. This Policy does not represent an expansion of scope. Many pharmacies have safely and effectively provided veterinary compounding and dispensing services for decades.

Overall Comment

The final Policy should preserve pharmacists' professional authority to select appropriate starting materials, including quality APIs; maintain veterinarians' ability to obtain office-use preparations; and ensure that veterinary prescribing decisions remain the responsibility of veterinarians.

Incorrect or misleading information should be removed or revised.

The individuals most affected by these changes are those who work with veterinary prescriptions and compounded preparations every day. Their practical experience should play a larger role in shaping the final Policy. As drafted, several provisions may unintentionally limit access to treatment options, increase burdens on practitioners and animal owners, and complicate patient care without a demonstrated corresponding benefit to safety or quality.