

**30 September 2026**

**Ontario College of Pharmacists**

**483 Huron Street**

**Toronto, ON M5R 2R4**

**Re: Summit Veterinary Pharmacy Ltd. Submission on the “Draft Providing Pharmacy Services for Animals Policy” and its “Supplemental Guidance Document”**

To Whom It May Concern:

Summit Veterinary Pharmacy Ltd. supports clear standards that protect animal patients and allow pharmacists and veterinarians to work effectively together. We bring approximately 25 years of experience devoted to veterinary compounding, including both patient-specific prescriptions and office-use prescriptions. Based on that experience, we believe the draft Policy and Supplemental Guidance require substantial revision before they are finalized. As written, they would create practical barriers without demonstrating a clear patient safety benefit and could delay treatment, reduce access to needed medications and adversely affect animal patients. Our principal concerns are:

- **Veterinarian Autonomy:** Shifting clinical and treatment decisions away from licensed veterinarians and onto pharmacists.
- **Office-Use:** Treating office-use orders as though they were patient-specific prescriptions and requiring pharmacists to second-guess the veterinarian’s choice of office-use.
- **Starting Material Hierarchy:** Forcing a commercial-product-first rule before allowing the use of API starting materials when compounding.

### **Veterinarian Autonomy**

The proposed treatment cascade must not become a mandate for the pharmacist. Applying it in pharmacy practice conflicts with established international standards governing compounding and starting material selection. The veterinarian examines the animal, establishes the veterinarian-client-patient relationship, diagnoses the condition, selects the treatment and determines whether a compounded medication is required. When the prescription reaches the pharmacy, the pharmacist’s role includes assessing pharmaceutical and formulation appropriateness, compatibility, stability, dosing feasibility and whether a suitable compounded medication can be produced. Requiring the pharmacist to oversee the veterinarian’s treatment cascade compliance (directly or indirectly) blurs these responsibilities, delays care and places the pharmacist in the position of monitoring decisions that belong to the prescribing veterinarian. OCP’s Board materials recognize that the veterinarian is responsible for deciding when a compounded preparation is appropriate. The Policy must preserve this division of responsibility.

For the same reason, using the CAHI veterinary decision cascade as a requirement for pharmacists does not align with good pharmacy practice and appears to prioritize a commercial-product-first approach over consistency, safety and reliability in compounded preparations. It imports a veterinary prescribing tool into pharmacy practice and risks diminishing pharmacists’ expertise in compounding while exposing them to accountability for decisions outside their role. Pharmacists’ formulation decisions should not be made subordinate to a framework developed for veterinary prescribing rather than pharmacy compounding. Veterinarians and pharmacists have distinct areas of professional expertise and accountability, and a veterinary prescribing framework should not override the pharmacist’s professional judgment in matters of formulation and compounding. This requirement should be removed or, at minimum, should remain subject to the pharmacist’s professional discretion.

### **Office-Use**

The decision to obtain a preparation or commercial drug for office-use belongs to the veterinarian. Establishing the veterinarian-client-patient relationship (VCPR) is likewise the veterinarian’s responsibility. The pharmacist

remains responsible for determining whether the order can be appropriately supplied and for the quality, records, and traceability of the chosen preparation. The pharmacist should not be required to “assess the need for, and intended purpose of, orders for office use,” by questioning the veterinarian’s choice, evaluating future patient needs or supervising the subsequent clinical use of the preparation. Where the pharmacist can appropriately supply an office-use prescription, the veterinarian’s direction should be respected as for any other prescription dispensed by the pharmacist.

The Policy and Supplemental Guidance treat patient-specific prescriptions and office-use prescriptions too similarly, even though they are fundamentally different. An office-use preparation is ordered by a veterinarian for use within the practice in anticipation of treating or dispensing to animals (based on their history of practice), when the need arises. At the time of the order, a specific patient is not usually known. However, the prescription requirements beginning at line 82 call for information such as the animal’s species and name, or information identifying a group and number of animals, the client’s name and withholding time, together with related labelling requirements. Much of this information is not available when an office-use prescription is issued, and many office-use prescriptions can be used across multiple species. Doxapram for example shows 11 dosing groups of animals in Plumbs, including dogs, cats, horses, swine, rabbits, birds, reptiles, etc. The Policy should therefore state clearly that these patient-specific requirements apply only to patient-specific prescriptions and are not required for office-use prescriptions.

We appreciate that the Supplemental Guidance expressly recognizes preparation in anticipation of prescriptions, consistent with POL-0051. We expect that this established practice will remain available based on documented prescription history and professional judgment to ensure adequate supply to meet a practitioner’s needs.

### **Starting Material Hierarchy**

The starting material hierarchy for compounding raises significant concerns. The draft Policy (lines 76-78) directs pharmacies to begin by using a drug approved for veterinary use, then a drug approved for human use, and to use an API only as a last option. A pharmacist must be able to select the most suitable starting material using professional judgment, recognized compounding standards, reliable literature and the specific requirements of the preparation. In most cases, a quality API is the best option for a compounded preparation. Crushing or manipulating a commercial dosage form introduces excipients, coatings, fillers, dyes and manufacturing variables that can affect compatibility, stability, concentration and dose consistency. Those concerns are particularly important for very small doses, unusual dosage forms; such as transdermal gels, and species that cannot tolerate particular excipients. Requiring the use of a commercial product can create unpredictable stability problems, increase costs for animal owners and carry into the compounded preparation the dosage variability permitted in commercial dosage units. This increases the risk of subpotent or superpotent preparations, which can be more effectively controlled by using a quality API as the starting material.<sup>1</sup>

Experienced compounding experts and support organizations, including PCCA and MEDISCA, provide member pharmacies with formulas and technical information based on the use of APIs. Relegating APIs to a last resort would therefore leave compounders with fewer reliable formulation options and substantially limit their ability to rely on the scientific literature and technical resources developed for API-based compounding.

This is more than a matter of preference. Dr. Loyd V. Allen Jr., a recognized authority in pharmaceutical compounding, often advised pharmacists that commercial dosage forms can introduce lot-specific potency variation, excipients and other formulation characteristics into a compounded preparation. In [“Compounding with Commercial Drug Products Can Cause Errors!” \(2012\)](#), he described how calculations based only on labelled strength, rather than considering the actual drug content in a commercial product, can produce compounding errors. His analysis reinforces why the pharmacist must retain responsibility for selecting the most appropriate starting material.

The governing standards reinforce a quality-based approach to component selection rather than a commercial-product-first hierarchy. Health Canada's POL-0051 states that a compounded preparation should be produced "from an authorized drug or from an API used in an authorized drug for use in Canada or listed in a recognized pharmacopoeia" listed in Schedule B of the Food and Drugs Act. USP <795>, section 6.2.1, assigns responsibility for component selection to the designated compounding personnel. For APIs, it requires compliance with an applicable USP–NF monograph where one exists and a certificate of analysis containing specifications and test results demonstrating requisite quality. It also requires manufacture by an FDA-registered facility in the United States or compliance with the applicable regulatory jurisdiction outside the United States. NAPRA's Guidance Document for Pharmacy Compounding of Non-Sterile Preparations similarly focuses on quality, sourcing, traceability and storage, and section 6.3.2 permits APIs that meet appropriate quality requirements. These standards establish how a quality API is selected and verified; as such, they do not support using APIs as a last resort. Requiring compliance with these standards while imposing a conflicting decision hierarchy as a policy requirement undermines a clear and coherent approach to starting material selection. The final Policy must leave selection of the starting material with the pharmacist, in consultation with the prescriber, as necessary.

#### *Additional Points Requiring Clarification*

The Supplemental Guidance requires clarification regarding the importation of veterinary APIs. It states broadly that Health Canada requires and issues establishment licences for the importation of active pharmaceutical ingredients for veterinary use. However, Health Canada's Guidance on Drug Establishment Licences (GUI-0002) states that, **except for APIs for veterinary use set out on List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients, a drug establishment licence is not required** to import or compound a drug that is not commercially available in Canada, pursuant to a prescription, when the activity is undertaken by a pharmacist, a practitioner, or a person compounding under a practitioner's supervision. OCP's broader statement in the Supplemental Guidance (lines 102-103) could lead registrants to believe that a DEL is required in circumstances where the federal regulations provide an exemption. The final Guidance should clearly distinguish List A veterinary APIs from other prescription-based importation and compounding circumstances. [Ref: *Food and Drug Regulations*, C.01A.002(1)(b) and C.01A.002(3)].

The Supplemental Guidance's characterization of the risks associated with compounded preparations also requires correction. It states categorically that compounded preparations "inherently pose an incremental risk to the patient compared to a manufactured product." This statement is speculative and unsupported and should be removed. Risk depends on many factors: the preparation, formulation, starting materials, process, testing, and storage. A manufactured dosage form may be unsuitable because of its strength, excipients, dosage form, availability, or stability after manipulation, and manufactured products are subject to quality defects and recalls. The Guidance should address the controls that produce a high-quality preparation rather than asserting that every compounded preparation is inherently riskier.

Finally, the direction to dispense a drug "exactly as prescribed" should be clarified. Pharmacists dispense veterinary prescriptions as written, except when substituting an interchangeable drug in accordance with the Drug Interchangeability and Dispensing Fee Act (DIDFA). The final Guidance should distinguish permitted generic interchangeability from prescription adaptation and confirm that "exactly as prescribed" does not prevent pharmacists from complying with applicable interchangeability requirements.

The principal concerns identified above should be resolved clearly in the Policy itself, rather than left to interpretation or addressed only through Supplemental Guidance after approval. These revisions should be made before finalization. The Policy must keep veterinary prescribing decisions with veterinarians; protect veterinarians' right to obtain and use office-use preparations in their practices; and preserve pharmacists' authority to select quality APIs. The final documents should also correct the importation guidance and

unsupported statements regarding the risks associated with compounded preparations, and clarify the direction to dispense exactly as prescribed. When the VPA was being developed, OCP advised its Board that it had been consulted and had received assurances that the status quo for pharmacists would be preserved.<sup>2</sup> The final Policy and Guidance should be consistent with that stated intention and should not introduce unnecessary restrictions on established pharmacy practice.

OCP should undertake further meaningful consultation with pharmacists who have substantial experience in veterinary compounding and with veterinarians who rely on office-use preparations before approving the Policy. Proceeding without these changes risks reducing access to needed treatments, increasing costs and delaying care for animal patients without a demonstrated safety benefit over current veterinary practice.

Thank you for your consideration of these matters through this consultation.

Sincerely,

**Summit Veterinary Pharmacy Ltd.**

## **Authorities Referenced**

[Ontario College of Pharmacists, June 15, 2026 Board Meeting Agenda Materials, Agenda Item 9, “Providing Pharmacy Services to Animal Patients – Draft Policy for Review”](#)

[Drug Interchangeability and Dispensing Fee Act, R.S.O. 1990, c. P.23](#)

[Health Canada, Guidance on Drug Establishment Licences \(GUI-0002\)](#)

[United States Pharmacopeia, General Chapter <795>, Pharmaceutical Compounding—Nonsterile Preparations, section 6.2.1](#)

[NAPRA, Guidance Document for Pharmacy Compounding of Non-Sterile Preparations, sections 6.3.2 and 6.3.3](#)

<sup>1</sup> [Lloyd V. Allen Jr., “Compounding with Commercial Drug Products Can Cause Errors!” Science and Technology for the Hospital Pharmacist, vol. 2, issue 4 \(May 16, 2012\)](#)

<sup>2</sup> [Ontario College of Pharmacists, July 8, 2024 Board Meeting Agenda Materials, “Bill 171, Enhancing Professional Care for Animals Act, 2024”](#)