

Submission to the Ontario College of Pharmacists

Draft Providing Pharmacy Services for Animals Policy and Supplemental Guidance

Thank you for the opportunity to provide feedback on the draft *Providing Pharmacy Services for Animals Policy* and accompanying Supplemental Guidance.

As an Ontario pharmacist with substantial experience dispensing commercially available medications and preparing compounded medications for animal patients, I support the College's objective of establishing clear expectations for pharmacy professionals providing services to animals.

Appropriate regulation is important to protect animal health, clarify professional responsibilities and ensure that pharmacy services are provided safely.

At the same time, the final policy should preserve access to veterinary pharmacy services provided by pharmacists who are willing and have developed appropriate knowledge and expertise. Pharmacist and pharmacy participation can improve access to medications, provide animal owners with greater choice, promote competition and affordability, and provide an additional source of medication expertise.

The key principle underlying this submission is that veterinary pharmacy should be treated as an area of specialized pharmacy practice.

Professional authorization to dispense a veterinary prescription should not, on its own, be interpreted as establishing competence to do so. Conversely, pharmacists who have developed appropriate veterinary expertise should not be prevented from practising in this area because veterinary pharmacy is not routinely practised by all pharmacists.

The final policy should therefore preserve access while establishing clear expectations around competence, professional responsibility and collaboration.

1. Veterinary pharmacy requires appropriate knowledge and competence

Pharmacists should continue to be permitted to dispense, sell and compound medications for animal patients. However, veterinary pharmacy should not be treated as an area in which every pharmacist is necessarily competent solely by virtue of being licensed.

Veterinary pharmacotherapy involves considerations that may differ materially from human pharmacy practice, including:

- significant physiological differences between species;
- species-specific dosing and toxicity;
- differences in metabolism and drug elimination;
- species-specific risks associated with excipients;

- unique dosage-form and administration requirements;
- extra-label drug use;
- compounded preparations;
- food-producing animal considerations; and
- veterinary-specific drug information and reference resources.

Pharmacists choosing to provide veterinary pharmacy services should therefore have sufficient knowledge, education, practical experience and veterinary-specific resources to safely assess the pharmaceutical aspects of veterinary prescriptions.

A mandatory certification program should not necessarily be required. Competence may be developed through formal education, continuing professional development, mentorship, practical experience and focused veterinary pharmacy practice.

However, the expectation should be more meaningful than simply possessing access to a veterinary reference.

The final policy should clearly state that pharmacy professionals must be able to demonstrate sufficient knowledge and competence for the veterinary services they choose to provide.

Where that competence is lacking, the pharmacist should not provide the service and should make reasonable efforts to facilitate referral to another pharmacist, pharmacy or appropriate provider with the necessary expertise.

This approach appropriately protects animal patients without unnecessarily restricting pharmacists who have developed specialized veterinary competence.

2. Clearly distinguish therapeutic decisions from pharmaceutical decisions

One of the most important areas requiring clarification is the division of responsibility between the veterinarian and pharmacist.

I agree the veterinarian should remain responsible for assessing the animal, establishing the veterinarian-client-patient relationship, diagnosing the condition and determining the appropriate course of treatment.

The pharmacist is responsible for assessing the pharmaceutical aspects of the prescription, safely dispensing or compounding the medication, identifying medication-related concerns and communicating with the veterinarian where clarification or intervention is necessary.

These roles are complementary but distinct.

A useful principle for the final policy would be:

The veterinarian is responsible for the therapeutic decision. The pharmacist is responsible for the pharmaceutical assessment and dispensing decision.

Both professionals must exercise judgment and communicate when concerns arise, but neither profession should be required to unnecessarily duplicate the other's assessment.

3. The veterinary therapeutic decision cascade should remain primarily a prescribing responsibility

The draft policy requires pharmacy professionals dispensing or selling a drug for extra-label drug use to follow the same decision-making cascade as veterinarians.

This requirement in its current wording seems flawed and will create uncertainty about professional responsibility.

By the time a pharmacist receives a veterinary prescription, the veterinarian has already assessed the patient and selected a course of therapy. The pharmacist will generally not have access to all of the clinical information underlying that decision.

For example, when a veterinarian prescribes a compounded preparation, the pharmacist may not know whether:

- another veterinary drug was previously attempted;
- an approved veterinary product was considered but clinically unsuitable;
- an available human medication was inappropriate;
- the animal could not tolerate a particular dosage form;
- excipients created a species-specific concern;
- a particular route of administration was necessary;
- previous treatment had failed; or
- other patient-specific clinical factors influenced the decision.

Requiring the pharmacist to independently reconstruct or repeat that assessment risks transferring part of the prescribing responsibility from the veterinarian to the pharmacist.

The therapeutic decision cascade should therefore guide veterinary prescribing rather than require pharmacists to independently repeat the veterinarian's clinical decision-making process.

The pharmacist should instead assess the prescription within the limits of veterinary pharmacy competence and consult the veterinarian where a concern exists.

The policy should also avoid presenting the therapeutic decision cascade as an inflexible sequence where professional judgment is more appropriate. Availability, clinical suitability, evidence, safety, tolerability and the individual needs of the animal may all influence the appropriate treatment.

4. “Available” should mean reasonably available and clinically appropriate

The terms “available,” “not available” and “not possible” play an important role in the proposed policy but require clearer definition.

A medication may technically exist in Canada but not be practically available to the dispensing pharmacy.

Examples include medications that are:

- on backorder;
- unavailable through pharmacy wholesalers;
- subject to restricted veterinary distribution channels;
- discontinued but still listed as authorized;
- obtainable only after an unreasonable delay; or
- otherwise inaccessible to the dispensing pharmacy through ordinary lawful channels.

More importantly, availability should not be confused with clinical suitability.

A veterinary or human product may technically be obtainable but still be inappropriate for a particular animal because of:

- strength;
- dosage form;
- route of administration;
- inability to accurately measure the required dose;
- excipients or flavouring agents;
- species-specific toxicity;
- administration difficulties; or
- other patient-specific considerations.

The policy should therefore use a standard based on whether a medication is reasonably available and clinically appropriate for the animal, rather than merely whether an authorized product exists.

5. Pharmacists should retain professional judgment when selecting compounding ingredients

The draft policy proposes that compounded preparations be prepared first from a drug approved for veterinary use, then from a drug approved for human use, and only if those options are not possible from an active pharmaceutical ingredient.

This requirement should be revised.

Once the veterinarian has appropriately determined that a compounded preparation is therapeutically required, selection of the appropriate starting material becomes an important pharmaceutical decision.

Using a manufactured tablet, capsule or other commercial dosage form is not inherently safer or pharmaceutically preferable to using an appropriate quality API.

Commercial products can introduce:

- fillers;
- coatings;
- dyes;
- flavours;
- preservatives;
- binders;
- lubricants;
- insoluble material; and
- other excipients that may affect compatibility, stability, dose uniformity or suitability for a particular species.

Using an appropriate API may provide the pharmacist with greater formulation control and may, depending on the preparation, represent the more scientifically appropriate approach.

The final policy should therefore permit pharmacists to select the appropriate starting material based on recognized compounding standards, Health Canada requirements, formulation science, ingredient quality, animal safety and professional judgment.

The therapeutic decision to use a compounded medication belongs primarily to the veterinarian.

The pharmaceutical decision regarding how that preparation should be compounded should remain within the pharmacist's area of expertise.

6. The existence of a commercial drug should not automatically preclude compounding

The final policy should clearly recognize legitimate patient-specific reasons for compounding even where a commercially manufactured product exists.

Examples may include:

- an unavailable strength;
- an extremely small or unusual dose;
- inability to swallow the commercial dosage form;
- inaccurate or impractical tablet splitting;
- a required alternative route of administration;
- species-specific concerns with excipients;
- a need to remove an unsuitable ingredient;
- administration or adherence challenges; or
- the need for a dosage form that can reasonably be administered to the animal.

There is an important distinction between inappropriate duplication of a commercially available drug and legitimate patient-specific compounding undertaken to meet a therapeutic need.

A commercially available product should not automatically be considered therapeutically suitable simply because it exists.

7. Preserve appropriate pharmacist discretion regarding interchangeable products

The draft policy states that a drug must be dispensed exactly as prescribed and specifically includes the brand of drug among the elements that cannot be modified without veterinarian approval.

This requires clarification.

Changing the manufacturer of a therapeutically equivalent or legally interchangeable product does not necessarily constitute a change in therapy.

Where the:

- active ingredient;
- strength;
- dosage form;
- prescribed dose; and
- directions

remain unchanged, product selection is fundamentally part of the dispensing process.

Requiring veterinarian authorization solely to change a manufacturer could create unnecessary delays, particularly during shortages or backorders, while adding administrative burden for both pharmacists and veterinarians.

At the same time, veterinary dispensing requires additional judgment because inactive ingredients may have species-specific relevance.

The policy should therefore preserve pharmacists' existing authority to substitute interchangeable products where permitted by law, while requiring the pharmacist to assess whether differences in excipients, formulation or other characteristics are appropriate for the animal.

A more appropriate expectation would be:

The prescription must be dispensed as prescribed except where substitution is permitted under applicable legislation and is appropriate based on the pharmacist's professional judgment, including consideration of species-specific formulation and excipient concerns.

8. Office-use orders require a realistic division of responsibility

The continued ability of pharmacies to provide commercially available and compounded medications to veterinarians for legitimate office use should be preserved.

The draft policy states that the quantity and frequency supplied must be reasonable for the veterinarian-client-patient relationship.

This expectation requires clarification because the dispensing pharmacy generally does not have sufficient visibility into the veterinarian's practice to independently determine what quantity is reasonable for the underlying VCPRs.

A pharmacy may not know:

- the veterinarian's active patient population;
- case mix;
- frequency of particular treatments;
- seasonal demand;
- number of practice locations;
- anticipated clinical needs; or
- future patients who may require treatment.

The veterinarian is responsible for establishing and maintaining the VCPR and for determining the clinical need for medications maintained within the practice.

The pharmacist should still exercise appropriate oversight. This can include assessing:

- historical ordering patterns;
- quantity ordered;
- frequency of orders;
- anticipated use;

- beyond-use dates or expiry;
- unusual ordering behaviour; and
- other circumstances that reasonably raise a concern.

Where an order appears unusual or excessive, clarification should be sought.

However, the standard should be whether the order appears reasonable based on information reasonably available to the pharmacy, rather than requiring the pharmacist to independently validate the veterinarian's underlying VCPRs.

The policy and Supplemental Guidance should also clearly distinguish between patient-specific prescriptions and office-use orders. Information that is appropriate and available for an individual animal prescription may not exist at the time an office-use preparation is supplied because the veterinarian may not yet know which specific animal will ultimately receive the medication.

9. Pharmacists have an important counselling role

The final policy should more clearly acknowledge the pharmacist's role in counselling animal owners within the pharmacist's area of competence.

The veterinarian remains responsible for diagnosis, treatment selection and veterinary clinical management.

However, appropriately trained pharmacists possess expertise that can add value regarding:

- medication administration;
- dose measurement;
- storage;
- handling;
- beyond-use dates;
- medication interactions;
- missed doses;
- disposal;
- compounded dosage forms;
- formulation characteristics; and
- identification of circumstances where the veterinarian should be contacted.

A collaborative model should recognize the expertise of both professions rather than unnecessarily assigning all medication-related counselling to one profession.

10. Pharmacists who do not provide veterinary services should facilitate continuity of care

Not every pharmacist or pharmacy will choose to provide veterinary pharmacy services, nor should every pharmacist be expected to do so.

A pharmacist who does not possess the necessary veterinary knowledge, competence or resources should not be required to provide a service outside their area of competence.

However, where reasonably possible, the pharmacist should assist the animal owner in identifying another pharmacy or provider capable of safely providing the requested service.

This protects both principles:

- pharmacists should never be pressured to practise outside their competence; and
- animal owners should not encounter unnecessary barriers to filling a valid veterinary prescription simply because the first pharmacy approached does not provide veterinary services.

11. Access, affordability and consumer choice should remain important policy considerations

Veterinary pharmacy services provided by appropriately qualified pharmacists can offer meaningful benefits to animal owners.

Independent access to pharmacy services can:

- improve medication accessibility;
- provide additional professional medication expertise;
- increase consumer choice;
- improve convenience;
- promote competition;
- reduce medication costs in some circumstances; and
- help owners continue treatment where affordability may otherwise become a barrier.

These benefits should be considered when evaluating regulatory requirements that could unnecessarily limit pharmacy participation.

Animal safety must remain the primary consideration, but restrictions should have a clear safety rationale and should be proportionate to the risk being addressed.

Creating administrative barriers that delay treatment or discourage capable pharmacies from providing veterinary services may have the unintended consequence of reducing access without improving animal safety.

12. Expectations should be aligned between pharmacy and veterinary regulators

The final policy should clearly align the expectations of pharmacists with the corresponding responsibilities of veterinarians.

In particular, there should be consistency regarding:

- responsibility for the therapeutic decision;
- extra-label drug use;
- use of compounded preparations;
- professional discretion;
- office-use medications;
- communication between professionals; and
- responsibility for the VCPR.

Where two regulated professions are expected to collaborate in providing care, regulatory expectations should complement rather than contradict each other.

Clear, jointly understood boundaries will reduce unnecessary veterinarian-pharmacist communication for administrative matters while encouraging consultation where there is a genuine clinical or medication-related concern.

Conclusion

Appropriately qualified pharmacists should continue to be permitted to dispense, sell and compound medications for animal patients.

Veterinary pharmacy should not be viewed as a service that every pharmacist is automatically prepared to provide. It is an area of specialized practice that requires appropriate knowledge, experience, resources and professional judgment.

At the same time, the fact that some pharmacists have not developed veterinary expertise should not justify restricting pharmacists who have.

The final policy should preserve a clear division of professional responsibility:

The veterinarian is responsible for the therapeutic decision. The pharmacist is responsible for the pharmaceutical and dispensing decision.

Both professionals remain responsible for recognizing concerns, communicating with one another and acting in the best interests of the animal patient.

The College is therefore encouraged to:

1. establish a meaningful competency expectation for pharmacists choosing to provide veterinary pharmacy services without unnecessarily requiring a single mandatory certification pathway;

2. clarify that pharmacists who lack appropriate competence should not provide the service and should make reasonable efforts to facilitate referral;
3. clarify that application of the veterinary therapeutic decision framework is primarily the responsibility of the prescribing veterinarian;
4. define medication availability in terms of both reasonable access and clinical appropriateness;
5. preserve pharmacists' professional judgment in selecting appropriate starting materials for compounded preparations;
6. expressly recognize legitimate patient-specific reasons for compounding despite the existence of a commercial product;
7. preserve appropriate pharmacist authority regarding interchangeable products while requiring consideration of species-specific formulation differences;
8. clarify the limits of pharmacy responsibility when assessing veterinarian office-use orders and VCPRs;
9. clearly distinguish office-use orders from patient-specific veterinary prescriptions;
10. recognize the appropriate medication counselling role of pharmacists with veterinary expertise;
11. consider access, affordability and consumer choice when evaluating restrictions on pharmacy participation; and
12. ensure that pharmacy and veterinary regulatory expectations are aligned and clearly define the respective responsibilities of both professions.

A strong regulatory framework should protect animal patients while allowing qualified pharmacy professionals to contribute their expertise.

The most effective policy will therefore be one that establishes meaningful expectations for competence and safety while preserving professional judgment, collaboration, access and appropriate consumer choice.

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