

I believe that standards should be clear and support both the health and safety of animal patients, and ensure that pharmacists can support veterinarians in their practice. The comments below focus on two parts of the draft that could affect how quickly and safely animals get treated: selling to veterinarians (lines 65-70) and the compounding rules (lines 57-64 and 76-78).

Selling to veterinarians (lines 65-70)

The draft states that it will allow pharmacists to sell to a veterinarian with a written order, in an amount and frequency that is “reasonable for the veterinarian-client-patient relationship.” If pharmacists must already keep records for two years, with no definition to the word ‘reasonable’ (as it may be based on a number of factors), makes this statement unnecessary. The written order and the records already let the College see what was sold and why, and the pharmacy should be able to prove through history what reasonable is.

A vet clinic can’t predict what will come through the door on a given day. Emergency situations do not wait; an animal with anaphylaxis, a seizure, or a serious injury needs treatment right away, not after a new order is placed and filled. Emergency, exotic, wildlife, and rural or mobile practices depend on having medication on hand and many rely on compounded medications to address the needs of their patients. They are the ones most at risk if “reasonable” is read too tightly. The wording is also hard to apply. It ties the amount to “the” veterinarian-client-patient relationship, but office stock is bought for animals the vet hasn’t seen yet. It isn’t clear which relationship the pharmacist is supposed to measure the amount against.

Many drugs used in animal patients are made and labelled for humans, in strengths and forms that don't suit the species or size of animal being treated. That's the whole reason pharmacist compounding and extra-label use exists: to take something that's available but not quite right and turn it into something safe and properly dosed. This is especially true for small or exotic animals, where there's often no commercial product made for that species at all. In those cases, compounding isn't a backup option; it's the only way to treat the animal safely. Cutting back on how much office-use stock pharmacies can supply doesn't make that need go away. It just pushes vets toward using human products as-is in the event of an emergency, or delaying treatment while a new order gets processed. Both are worse outcomes than having a correctly compounded product ready to go.

For example, consider a kitten that collapses from an allergic reaction. The epinephrine sold in Canada is made for people, and even the weakest available product is far too strong for an animal that small. The right dose is a tiny fraction of a millilitre, so the vet has to dilute the drug and measure it carefully while the kitten is in crisis. That takes time and risks a measuring mistake. A pharmacy can prepare it ahead of time at the right strength, but only if the vet can keep it on hand. Commercial supply can also run short, which leaves the clinic with nothing suitable on the shelf.

I am not asking the College to set a number on what is reasonable. A fixed number wouldn’t work, because pharmacies vary so much in size, volume and patient demographics. A pharmacy filling 2,000 prescriptions a day and one filling 20 will have very different ideas of what is reasonable, and both could be right for their own practice. A pharmacist also isn’t inside the vet’s clinic, so the veterinarian is the one who knows what their practice needs.

Line 47 already says pharmacists must practice within the limits of their knowledge, skills and judgment. Professional judgement has always been valued in the pharmacy profession as patient circumstances vary and

not all issues will be resolved in the same way. Similarly, not all pharmacy practices are the same, and a pharmacist should be able to judge whether they are knowledgeable enough to provide proper patient care within their knowledge; or direct the patient to another practice who can. It would be reasonable to expect a pharmacist to have taken steps to ensure they are able to provide adequate knowledge when providing care to animals; whether it be through additional training and resources, or through collaboration with the veterinarian before dispensing, and perhaps this is the issue that needs to be addressed.

I would ask the College to say that pharmacists can **support their quantities with records**, such as order history and the type of practice they supply, and to consider that a veterinarian will have needs for their practice that require them to order for 'office use'. Pharmacists are already bound by scope-of-practice limits regarding knowledge, skills, and judgment. Rather than restricting quantities via an undefined "reasonable" standard, the College should rely on existing practice standards and documentation requirements. Health Canada's POL-0051 already uses a similar idea. When pharmacies prepare drugs for anticipatory compounding, it looks at their documented prescription history instead of a vague word.

Compounding (lines 57-64 and 76-78)

I agree that approved products should be used when they suit the animal being treated. For compounding, though, lines 76-78 say a human-approved drug must be used before the raw drug powder (the active pharmaceutical ingredient, or API). This assumes the commercial product is the more reliable starting point. When it comes to accuracy, it often isn't.

Commercial products are allowed their own range of strength under USP standards, and some ranges are wide. A tetracycline capsule labelled 500 mg can legally contain anywhere from 450 mg to 625 mg. The pharmacist can't know where in that range a batch falls. Compounded products are also allowed a range of 90% to 110%, so the two uncertainties add up. A pharmacist can do every step correctly and still end up with a product outside the allowed range because of the starting material.

APIs usually have a much tighter range, often 98% to 102%. They also come with a lot-specific certificate showing a documented assay. Many commonly used drugs have no published USP standard at all, so the pharmacist has nothing to check the commercial product against. This matters even more in animals, where doses are based on weight and species and there is less room for error.

The draft also tells pharmacists to follow POL-0051 (lines 74-75). POL-0051 says compounded products should be made from an approved drug or from an API that meets a recognized standard such as the USP. It doesn't put one ahead of the other. The draft adds a ranking that Health Canada's policy does not have.

Commercial products do come with manufacturing quality checks that an API source may not always match. Accuracy and manufacturing quality are two different things, and the pharmacist should be able to weigh both for each preparation. The order of choices the draft relies on (footnote 10) was developed by veterinary and industry groups to guide drug selection. It wasn't built to decide which starting material gives the most accurate compounded product.

I would ask the College to remove the fixed order in lines 76-78 and let pharmacists choose an API when it is the more accurate source, as long as they document the reason. Where no approved product suits the

animal's species, size or dose, the "therapeutic need" in lines 63-64 should be treated as met. For small and exotic animals especially, compounding is often the only safe option.

Reference: Allen LV Jr. "Compounding with Commercial Drug Products Can Cause Errors!" International Journal of Pharmaceutical Compounding, Science & Technology for the Hospital Pharmacist, May 16, 2012.