A Veterinarian's Guide to Compounded Medications

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Abstract

Compounded medications are often needed in veterinary medicine. However, the regulations governing the art and science of compounding are unclear, and the U.S. FDA's attempted clarifications frequently change. This, combined with the profit potential of compounding, can lead to the various interpretations being difficult to navigate, often influenced by bias of the entity offering advice. Consequently, veterinarians are left to sort through often-conflicting information to select appropriate compounds and guide clients to high-quality pharmacies.

Take-Home Points

- Compounded products should be prescribed only if the patient cannot be appropriately treated for the diagnosed condition with a currently marketed FDA-approved, conditionally approved, or indexed product.
- The FDA perceives a compounded product to be an unapproved drug and a greater risk to the patient than an approved finished dosage form; there is no guarantee that a compounded product will provide the correct dose.
- Both the prescribing veterinarian and the compounding pharmacist have responsibility for determining if a prescribed compound is likely to be safe and effective.
- Pharmacist knowledge regarding veterinary patients and compounding varies greatly according to whether the pharmacist has received additional education and experience in those areas.
- Availability of some compounded products has been shifted by the requirements stipulated in the Center for Veterinary Medicine Guidance for Industry #256 and changes to the U.S. Pharmacopeia compounding General Chapters that have led to stricter requirements that compounding pharmacists must follow.
- Veterinarians should critically evaluate compounding pharmacies and develop a working relationship with a pharmacy with which confidence can be built.

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Compounded medications can be crucial for meeting a patient's medical needs. Examples of why they are needed include the following:

- The patient cannot be medicated with approved dosage forms.
- Available products may be too or insufficiently concentrated, contain an allergen or other toxic agent, or are not available in the United States. For example, piroxicam is commonly dosed at 0.3 mg/kg to treat transitional cell carcinoma in dogs. However, the lowest strength approved by the U.S. FDA is a 10-mg capsule. Therefore, there is no way to obtain an accurate dose for a small dog without compounding.

However, compounded products have their pitfalls, and the approach to their regulation is complex, changes frequently, and is applied differently according to whether the product is compounded from a finished approved dosing form or a bulk drug substance (BDS). Compounded drugs for non–food animals are regulated differently than those for food animals; the major driving force behind the differences is public safety. This article answers questions frequently asked by veterinarians when prescribing compounded medications.

Q: Why should FDA-approved medications be chosen over compounded medications?

FDA-approved products carry less risk than compounded products. Compounded drugs are legally allowed only when an approved, currently marketed product cannot be used to safely and effectively treat the patient.

The Animal Medicinal Drug Use Clarification Act (AMDUCA) legalizes extra-label drug use and indicates when it is appropriate.[1] Because compounded products are not FDA approved, their use is considered a form of extra-label drug use and AMDUCA requirements must be met. AMDUCA stipulates that compounding should be considered only when approved products (or conditionally approved or indexed drugs) are not appropriate for treating the patient's condition. What constitutes "appropriate" may not be clear, but neither cost nor convenience alone is appropriate reasons for using a compounded product.

For approved products, safety and efficacy have been demonstrated for the labeled use; the manufacturing process and facility have been approved; the labeling has been approved; the product is made the same way every time; stability until the expiration date has been proven; and the final product is tested for potency and, if applicable, sterility. In contrast, compounded products are not required to go through the same formulation and end-product testing. Potential consequences are that compounded products may contain more or less drug than indicated on the label, lack safety (e.g., may contain toxic ingredients, may lead to adverse events or lack of drug sterility when required), or lack efficacy for the intended use (e.g., may lack bioavailability). There may or may not be research studies supporting probable efficacy of various compounded formulations. However, each pharmacy may make the compound differently, which can affect product quality, safety, and efficacy.

Therefore, when selecting a medication, use an FDA-approved product (on or off label) if feasible, and if an approved product cannot be used to get the appropriate drug at the appropriate dose into the patient reliably, then a compounded drug might be considered. However, there is no guarantee that a compounded product will provide the correct dose. Do not reach for a compounded product only because it is less expensive or because it is preferred by the client.

Q: Who is responsible for assessing the risks and benefits of a compounded product?

Both the prescribing veterinarian and the compounding pharmacist have a responsibility to assess, to the best of their professional ability, whether a compounded product is likely to deliver the active pharmaceutical ingredient to the patient safely and effectively (**BOX 1**). The best outcome for patients results from interprofessional collaboration in conjunction with the client.

When determining the likelihood that a compounded medication will be safe and effective for the patient, the veterinarian and pharmacist both contribute valuable knowledge. When considering use of a compounded medication, perform due diligence to determine if a compound will likely be safe and effective, educate the client on the pros and cons of

using a compound, and collaborate with the pharmacist to select the best formulation regarding patient safety and efficacy.

Q: Are pharmacists educated well enough to meet veterinary practitioners' compounding needs?

Pharmacists' veterinary pharmacology knowledge may be limited. Pharmacists often assume that veterinarians have at least anecdotal evidence that the chosen compounded product is supported. Pharmacists also often have limited access to resources to search primary veterinary literature. Veterinary pharmacy is not a required component of pharmacy education. Therefore, most pharmacists have very

BOX 1
Compounding Responsibilities of the Veterinarian and Compounding Pharmacist

The veterinarian is responsible for:

- Determining whether an animal-approved or conditionally approved or indexed human drug is available to appropriately treat the patient
- Educating the pharmacist, as appropriate, regarding the health of the patient as it might affect the use of the drug to help assess the likelihood of safe and effective delivery of the compounded product
- Determining, in consultation with the client, the best alternative product that might be compounded to meet the patient's medical needs
- Considering evidence of safety and efficacy publications, such as peer-reviewed research articles, about a compounded product. However, these reports are relevant only for the compounding recipe used in the publication. Experiences of a specialist reporting success are supportive. Less ideal are anecdotal reports and especially "testimonials" provided on pharmacy websites.
- Closely monitoring the patient for evidence of effectiveness or adverse events (including therapeutic failure). In most circumstances, evidence of quality, safety, or efficacy will be lacking for a compounded product being used for your patient. In such instances, identifying a measurable outcome will help determine therapeutic efficacy or safety.
- Reporting adverse events to both the compounding pharmacy and the U.S. FDA
- Assuring client-informed consent, which includes ensuring that the client understands what a compounded product is and is not and its potential benefits and risks
- Recommending an appropriate compounding pharmacy

The pharmacist is responsible for:

- Determining the need for compounding by helping to identify if an approved formulation is available that might meet the patient's needs
- Determining when a bulk drug substance (BDS) must be used in lieu of an approved finished dosage form for the compounding
- Ensuring that the criteria for using a BDS have been met when compounding a product for individual patient use or for office stock
- Ensuring that state requirements for use of office stock are being met
- Determining an appropriate beyond-use date
- Determining the most appropriate excipients to be used to deliver the active pharmaceutical ingredient safely and effectively up to the assigned beyond-use date
- Evaluating the potential for quality, safety, and efficacy of the product as prescribed by the veterinarian
- Suggesting the most appropriate flavor and dosage form options based on what is available
- Consulting with the prescribing veterinarian regarding the potential risks and benefits of using the compounded product, given the chemistry of the active pharmaceutical ingredients and the excipient and whether the product is likely to deliver the active pharmaceutical ingredients safely and effectively to the patient
- Recommending the most appropriate packaging and storage condition
- Ensuring appropriate labeling, including directions and applicable warnings and precautions
- Counseling the client about appropriate storage and beyond-use date
- Advising the prescribing veterinarian regarding the potential for adverse events and how to report them
- Reporting adverse events, if they occur, to the appropriate regulatory authority
- For controlled drug substances, helping ensure that all Drug Enforcement Agency regulatory requirements are met

little, if any, exposure to the practice of veterinary pharmacy and will look to the prescribing practitioner for validation of dosing regimens. Doses of some drugs are markedly different (e.g., levothyroxine), and preparation of some formulations may be foreign to pharmacists (e.g., feline transdermal products, using desmopressin nasal spray as an eye drop). Gastrointestinal tract differences between animals and humans can lead to profound differences in oral bioavailability. Pharmacists' knowledge regarding unsafe doses of some drugs may be limited. Therefore, when something looks odd to a pharmacist, they may default to assuming that that is just what is done in veterinary medicine and assuming that the veterinarian prescribing the compound has learned from experience that it will work. For those and other reasons, nurturing a close working relationship with a compounding pharmacist helps justify the confidence the veterinary client expects.

Pharmacists also may not have strong compounding skills. Although compounding is taught to some extent in pharmacy schools, it is not covered extensively and often the time is devoted primarily to sterile compounding, which is common for the human hospital setting. Therefore, many compounding pharmacists learn the nonsterile compounding tricks of the trade through working in a compounding pharmacy and seeking additional training in this area. Although additional training can improve pharmacists' formulation quality and understanding of veterinary nuances and efficacy concerns (such as with transdermal formulations), available data on many compounds regarding stability and oral bioavailability are still lacking. Theories and estimates can be based on species and drug knowledge, but these aspects require scientific studies for definitive proof.

Do not assume that a pharmacist makes only compounds that are likely to be safe and effective or that all pharmacists have extensive knowledge of compounding. Critically consider the appropriateness of the compounds you are requesting.

Q: What is limiting my ability to get the compounds I used to get?

Updates to the United States Pharmacopeia (USP) compounding General Chapters 795, 797, and 800 as well as the Center for Veterinary Medicine Guidance for Industry (GFI) #256 have changed what compounding pharmacies are allowed to use as active ingredients, prescription requirements, and beyond-use (expiration) dating.

The implications of GFI #256 can be explained by the fact that compounded products can be made from 2 sources.

- The first source is an FDA-approved manipulated product (e.g., tablets crushed to make a suspension). AMDUCA legalizes compounding only when commercial products are manipulated as the source of the active drug.
- The second source is BDS. Allowing unrestricted use of bulk chemicals raises 2 concerns, both associated with the ease with which compounding is improved when using a BDS.
  - The first concern is that using a BDS circumvents the drug approval process by disincentivizing drug companies from obtaining FDA approval if a cheaper, compounded drug is being widely used.
  - The second concern is that widespread use of a drug compounded from a BDS means that many patients may be treated with a medication that is neither safe nor effective.

However, compounding a product from a BDS may be necessary when:

- An FDA-approved product is not commercially available in any version
- The approved product cannot meet the patient's medical needs (e.g., contains an undesirable ingredient; is available only in concentrations too high or low; requires a formulation dependent on the absence of excipients [i.e., inactive vehicles], such as injectable products or transdermal gels)

To explain its approach to regulating AMDUCA, the FDA releases guidance documents. The most recent guidance document on this topic is GFI #256, which delineates the circumstances under which the FDA will not regulate products compounded from a BDS (it will apply discretion).[2] For regulatory discretion to apply, the guidance includes lists of active pharmaceutical ingredients and compounded preparations that can or cannot be compounded into office stock from a BDS. When a BDS is being used to prepare patient-specific prescriptions as well as office stock, GFI #256 requires additional documentation from both the veterinarian

(medical justification) and the compounding pharmacist,[2] which has limited pharmacists' ability to prepare some of the office stock products that were previously available. However, these compounded products may still be available pursuant to use of a finished dosage form, whether for a patient-specific prescription or office stock, if the criteria delineated in AMDUCA are met.

There have also been recent updates to the USP General Chapters that apply to compounding for human and veterinary patients. Some of the most limiting ones affect requirements for preparing sterile compounds and how long compounded products are good after they are prepared (i.e., beyond-use dates).[3] The additional restrictions have caused the need for formulation and workflow changes in pharmacies, which has affected the cost, beyond-use dates, and/or availability of some compounded products.

When a pharmacy is no longer able to compound a product that has been previously available and the issue is because the prescription is for office stock using a bulk chemical not on the "list," it may help to discuss with the pharmacist the options for compounding for an individual patient. If an appropriate medical rationale cannot be provided, the compounding pharmacist may still be limited but should be able to help the practitioner assess compounding options.

Q: What should a veterinarian expect of a quality compounding pharmacy?

Ideally, 503B facilities (outsourcing) are used for office stock compounds and 503A pharmacies (traditional compounding pharmacies) are used for patient-specific compounds.

503B: Because 503B facilities are required to follow current Good Manufacturing Practices, the risks associated with potency, stability, and sterility are greatly decreased.

503A: When looking for a quality 503A compounding pharmacy, a veterinarian should expect the pharmacy to meet certain criteria (**BOX 2**). There are several ways to evaluate the quality of a compounding pharmacy, and ideally information from several of the following should be combined to generate a full picture:

- Website review to gain an understanding of the type of compounding and potentially the training/background of those doing the compounding and to determine if there are products advertised that are known to be inappropriate for the reasons stated above
- Licenses and certifications
- FDA warning letters, recalls, and 483s (i.e., FDA inspection findings)
- Compounding pharmacy accreditation from the Accreditation Commission for Health Care's Pharmacy Compounding Accreditation Board (achc.org/pcab-compounding-pharmacy), which is an optional accreditation available to human and veterinary compounding pharmacies
- Pharmacy tour to get a feel for the quality of the

BOX 2

What to Expect From a Quality 503A Compounding Pharmacy

- Does not duplicate FDA-approved products (unless back-ordered)
- Follows applicable USP chapters and state and federal (e.g., GFI) guidance and regulations
- Critically evaluates requests for new drug/dosage form combinations by considering the legal implications as well as the clinical implications as described in other sections
- Supports beyond-use dates that are longer than USP defaults with stability-indicating studies of the exact formulation being prepared
- Has pharmacists (and ideally technicians) with veterinary compounding training (because formulations prepared, active ingredients used, and toxicity concerns associated with inactive ingredients often differ between human and veterinary patients)
- Has not recently received FDA warning letters or actions by the state Board of Pharmacy where the compounding pharmacy is located or where they are shipping medications
- Has pharmacists who are willing to work with veterinarians and their clients to find solutions
- Has a system in place for collecting and tracking reported adverse effects

GFI=Guidance for Industry; USP=United States Pharmacopeia

process (e.g., cleanliness of compounding spaces, types of equipment used, workflow that supports pharmacist oversight and verification, quality checks throughout the compounding process)
- Conversation with the Pharmacist in Charge
- Word-of-mouth reports from colleagues

However, when short on time, the author asks 2 questions to gain a basic understanding of legal compliance and clinical considerations. The exact drugs and formulations questioned can be adjusted based on what has been seen in practice and what the veterinarian has found concerning.
- Will you compound cyclosporine 100-mg capsules?
- Do you think compounded transdermal enrofloxacin is an appropriate option for feline patients that are difficult to medicate?

The first question looks at legal compliance with not duplicating FDA-approved products. There are both veterinary and human cyclosporine 100-mg capsules available; therefore, compounding duplicates will not be tolerated unless they are back-ordered or the patient cannot tolerate an inactive ingredient.

The second question looks at clinical considerations. Enrofloxacin is a fluoroquinolone antibiotic that is classified by the World Health Organization as a medically important antimicrobial drug.[4] With the current concerns about antimicrobial resistance, increased oversight is warranted to ensure use is appropriate. Many drugs are not effectively absorbed by the transdermal route, and use of a fluoroquinolone antibiotic would be especially concerning because limited absorption would not only cause poor efficacy but also has the potential for increasing antibiotic resistance. In addition, 1 study showed lack of enrofloxacin transdermal absorption.[5]

Proactively evaluate a couple of compounding pharmacies to identify go-to sources and advise clients of the importance of using a high-quality pharmacy.

Summary

Compounded medications are essential for effectively treating veterinary patients. However, compounds are not without risk; therefore, the quality and oversight of the products being used should be understood before the products are being prescribed to patients. TVP

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