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Target Audience

Pharmacists in community-based practice.

Program Goal

To guide the pharmacist in identifying key factors to consider when providing pet medications in the community pharmacy.

Learning Objectives

Upon completion of this program, the pharmacist should be able to:

1. Describe the animal medicine drug approval process and corresponding federal oversight agency.
2. Compare and contrast the three categories of animal medicines.
3. Assess differences in major animal species metabolism to make appropriate drug therapy recommendations.
4. Identify reputable animal drug product information resources to verify drug dosing of major animal species.
5. Evaluate state and federal animal laws to obtain legal prescriptions for pet owner clients.

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Companion animal medication dispensing: Pharmacists and their pet patients

INTRODUCTION

According to a recent Federal Trade Center, or FTC, report, approximately 65% of U.S. households own a pet.¹ Of these pet homes, the most frequently owned animals are cats and dogs, which account for approximately 80 million homes. Americans are spending more on their pets — including food, supplies, veterinary care, prescription and non-prescription medications and other pet services and products.²⁻³ In 2015, pet expenses are estimated to surpass \$60 billion with \$14.39 billion alone spent on supplies and medications.²⁻³

Recent reports suggest this market growth trend is largely being driven by a change in attitude by Americans about their pets.³⁻⁴ About 63.2% of pet owners categorize their pet as a family member and, as such, are willing to spend more than ever before on their health and well-being.³ Traditionally, pet owners have purchased all of their pet medications directly from their veterinarians. This pet medication market was a result of almost all large manufacturers who, until recently, only sold their animal medicine products directly to licensed veterinarian offices or authorized distributors who then sold to veterinarian offices.¹

In the last few years, increased access has become available to pet

owners through pet medication pharmacies online, and traditional brick-and-mortar community pharmacies giving pet owners more options. The increased availability of pet medications has not been without controversy as safety concerns have been registered by veterinarians across the country.⁵⁻⁶ Thus, pharmacists, as medication experts, are positioned to work with veterinarians and assist pet owners to obtain and use pet medications safely.

ANIMAL DRUG PRODUCT REGULATION

A considerable amount of time and effort is dedicated every year to the development of new and innovative products. While the spending is equivalent to about one-fortieth of human drugs, it is still a considerable amount of money directed toward the health and well-being of pets.⁷

Like drug products for humans, animal medicines also are subjected to a drug approval process and strict regulation. The definition of drug (see Table 1) does not differ from that of animal drug. There is however, an additional category called veterinary drugs that are specific to animals and may not be used in humans. All approved drugs in the United States are subject to regulation, and animal medicines are no exception.

There are three federal agencies re-

Table 1
Drug and veterinary drug definitions

DRUGS	VETERINARY DRUGS
“Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals.” (Section 201(g)(1)(B) and (C) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. 321(g)(1)(B) & (C)])	A drug that is restricted by federal law to use by or on the order of a licensed veterinarian, according to section 503(f) of the Federal Food, Drug and Cosmetic Act.

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sponsible for the oversight of animal drug products:

1. Center for Veterinary Biologics, or CVB⁸⁻¹⁰: The branch of the U.S. Department of Agriculture Animal and Plant Health Inspection Service that regulates veterinary biologics (vaccines, diagnostic kits and other products of biological origin) to ensure that the veterinary biologics available for the diagnosis, prevention and treatment of animal diseases are pure, safe, potent and effective.
2. Center for Veterinary Medicine, or CVM^{8,11-12}: The branch of the Food and Drug Administration that reviews and regulates the approval of all animal drugs to ensure that they are safe and effective in animals, have the highest quality standards and are not harmful to humans.
3. Environmental Protection Agency, or EPA^{8, 13-16}: The agency works closely with the FDA to regulate the use of flea, tick and parasite products. Additionally, the EPA develops safety guidelines focusing on the prevention of harm to humans and non-targeted species.

ANIMAL DRUG PRODUCT APPROVAL

The drug approval process for animal medicines is analogous to human drugs in that animal pharmaceutical companies are required to provide safety and efficacy data prior to approval status.¹⁷ Additionally, these companies also must demonstrate to CVM that they can consistently manufacture quality drug products to the approved specifications.

The Federal Food, Drug and Cosmetic Act specifies that no new animal drug (Table 2) may be sold into interstate commerce unless it is the subject of an approved New Animal Drug Application, or NADA, abbreviated NADA or a conditional approval, or CNADA, in effect pursuant to the code.¹⁸ Unapproved investigational animal drugs may be exempt from this requirement and may be shipped in interstate commerce to qualified experts to study safety and efficacy if exemption status is met pursuant to the code.¹⁹

As mentioned earlier, the FDA's Center for Veterinary Medicine approves and regulates new animal drugs, or NAD. CVM is composed of six offices that coordinate together to approve NADs and conducts monitoring once the product is on the market. CVM's Office of New Animal Drug Evaluation, or ONADE, is primarily responsible for reviewing the information submitted.¹⁸⁻¹⁹

It is a common misconception that the new animal drug approval process begins with CVM. Instead, the process actually begins with the drug sponsor who has an

Table 2
Animal drug approval terms and definitions

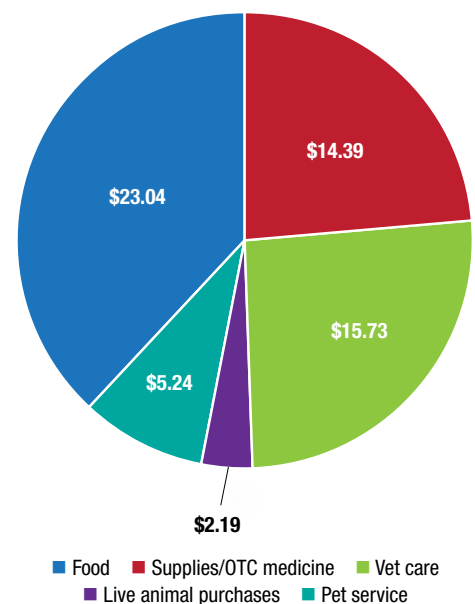
DRUG APPROVAL TERM	DRUG APPROVAL DEFINITION
New animal drug (NAD)	Defined, in part, as any drug intended for use in animals other than man, including any drug intended for use in animal feed but not including the animal feed, the composition of which is such that the drug is not generally recognized as safe and effective for the use under the conditions prescribed, recommended or suggest in the labeling of the drug (21 U.S.C. § 321(v)).
New animal drug application (NADA)	Application to obtain approval of a new animal drug and includes any subsequent supplemental applications made to an approval.
Abbreviated new animal drug application (ANADA)	Application to obtain approval of a generic NAD and includes any subsequent supplements to an approved ANADA. A generic NAD is a copy of an approved new animal drug for which patents or other periods of exclusivity are near expiration.
Conditional new animal drug application (CNADA)	Application for conditional approval allows a drug sponsor to legally market a new animal drug intended for a minor use or a minor species after proving it is safe under 21 U.S.C. § 360b(d), but before collecting all the necessary effectiveness data. The drug sponsor can keep the product on the market for up to five years, while collecting effectiveness data required by 21 U.S.C. § 360b(d), if FDA approves the sponsor's annual renewal requests.
Drug sponsor	Entity responsible for collecting all the information about a new animal drug and submitting this information to CVM for review (any person or organization can be a drug sponsor)
Office of New Animal Drug Evaluation (ONADE)	Lead office of CVM that is primarily responsible for reviewing new animal drug applications
Freedom of Information Summary (FOI)	Document made available to the public that details safety and efficacy data that supports CVM's approval of a new animal drug

idea they wish to investigate about a new compound. Open communication with ONADE is necessary for a drug sponsor to successfully bring a new animal drug to the marketplace. As a result, most drug sponsors will first submit an investigational new animal drug, or INAD, file to CVM to assist in corresponding throughout the process. CVM then will collect a fee from the drug sponsor, and a development plan is created between CVM and the drug sponsor, in which they agree on information required in order to get the drug approved.

There are five major components to the new animal drug approval process:¹⁹

1. Target animal safety: The drug sponsor must show that the investigational drug is safe in its target animal. Safety is commonly established through clinical studies in which side effects and the drug's margin of safety are identified in healthy animals.
2. Effectiveness: The drug sponsor then will try to establish that the drug is effective for the target species when used according to the label. The most common

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way efficacy is established is through a field study in which only animals with the intended disease or condition are given the investigational drug. The drug sponsor's goal is to demonstrate that the drug will do what it is intended to do under normal conditions when used according to the label.

3. Human food safety: The drug sponsor must show that food products made from treated animals are safe. There are four components to human food safety — toxicology, residue chemistry, microbial food safety and regulatory method — that are targeted with the goal of preventing harm to humans and antibiotic-resistant bacteria from entering the food supply in treated animals.
4. Chemistry, manufacturing and controls: The drug sponsor describes the plan for creating the drug. The plan must include the drug ingredients, procurement of the ingredients, location of drug manufacturing, process for making the drug, packaging, storage and length of time for storage.
5. Environmental impact — The National Environmental Policy Act, or NEPA, requires that CVM assess how the environment will be impacted. As a result, CVM requires all drug sponsors to submit an environmental assessment that describes the amount of drug expected to get into the environment and its potential impact. CVM then will assign the product into two categories "Finding of No Significant Impact," or FONSI, or an "Environmental Impact Statement," or EIS. A waiver may be granted by CVM in certain cases where the drug product is being used in a single companion animal — such as a dog or cat where impact to environment is minimal — or a slight modification to an already approved drug.

There are three additional minor sections required:¹⁹

1. All other information: Includes "all information about the drug that was not part of the five major technical sections." Drug sponsors typically collect this information from scientific literature, foreign experience, medical experience in humans and studies that were conducted by the drug sponsor but not included in the major technical sections.
2. Product labeling: "Labeling" includes all information on the immediate container, package insert, outer packaging, shipping label and the client information sheet.
3. Client Information sheet, or CIS: The equivalent of a human medication

guide that provides additional information about side effects, and what to expect when giving the drug to an animal. It should be noted that not all approved animal drugs have a CIS.

Once all of the necessary information has been submitted with the proper application, a diverse team of CVM personnel reviews the NADA. This diverse team of CVM personnel includes a variety of experts including, but not limited to, veterinarians, biostatisticians, microbiologists, toxicologists and pharmacologists. If an approval is granted, the final step required is called a Freedom of Information Summary, or FOI, in which a detailed explanation of safety and efficacy that supports CVM's approval is made available.

Generic animal drugs

Once an animal drug product has been approved and is on the market for a specific number of years, another drug sponsor can get approval for a generic copy.¹⁹ The generic approval process mirrors that of humans:

- The drug sponsor will submit an Abbreviated New Animal Drug Application to CVM.
- Information in the ANADA must show that the generic copy is identical to the approved brand name drug in active ingredient, strength, dosage regimen and dosage form.
- The pharmaceutical company also must show the generic copy is:
 - Consistently made from batch to batch including identity, strength, purity and quality as the brand name drug; and
 - A bioequivalent to the approved brand name drug in absorption and therapeutic effect.
- Labeling of generic copy must match approved brand product labeling, although trade name can be different.

ANIMAL DRUG PRODUCTS

Our pets, like humans, are not immune to illness; therefore, they may require medications from time to time to treat and prevent illness. Since pets increasingly are looked at as family members, their health and well-being is a major priority for pet owners.⁴ There are three primary categories of animal products that are available for use in the United States:

1. Veterinary biologics, or VB:^{7, 9-11} Work through the stimulation of the immune system (i.e., vaccines) and are administered in animals to aid in the prevention of disease. Similar to humans, routinely vaccinating animals typically is more affordable than treatment of disease, prevents transmission of communicable organisms and

minimizes animal suffering. Companion animals, such as dogs and cats, commonly receive vaccinations for distemper, rabies and hepatitis.

2. Pesticides^{11, 13-16}: Are mostly used in pets for the treatment of fleas, ticks and ear mites, as well as such internal parasites as heartworm. Flea bites are not only irritating to a pet, but in some cases can cause flea allergy dermatitis that leads to skin problems; anemia; and rarely even death. Tick bites also are not without harm, as they can lead to Lyme disease and expose their human companions to risk of infection. There are numerous products available for pet owners to choose from in a variety of dosage forms (tablets, sprays, dips, shampoos, powders and spot-treatments, among others).
3. Pharmaceuticals^{12, 17}: Includes a variety of animal medications, such as pain, antibiotics, heartworm preventives, antiarrhythmics, hypertension, anesthetics, etc. Pharmaceuticals are used with the intended purpose of eradicating or managing diseases/disorders in animals.

COMPANION ANIMAL DRUG DISPOSITION

Companion animals, like their human counterparts, have evolved over a millennia, resulting in physiological and anatomical differences.²⁰ Like a human ethnicity, these differences have resulted in unique breeds. According to Fleischer et al, a breed is considered a group of animals with common ancestry and certain distinguishable characteristics developed by artificial selection and maintained by controlled propagation. Therefore, as is necessary in tailoring therapy to humans, companion animal breeds also require individualized treatment. As a result, it would be inappropriate to generalize pharmacodynamics, or PD, and pharmacokinetic, or PK, properties based upon a nonspecific term, such as "dog."²⁰

Drugs, in most cases, are treated as xenobiotics in companion animal species in which the priority is to metabolize and eliminate the drug as quickly as possible.²⁰ There is significant variability between species with respect to drug metabolism and phase I and II reactions. The Cytochrome P-450 system is present in companion animals, and nomenclature is based on the amino acid sequence of the CYP enzymes compared with function as in humans. It is important to note that a fully named CYP enzyme is specific to one species since the amino acid sequence can only be derived from one species.²⁰ For example, the common CYP isozyme CYP3A4 can only be found in humans, while the comparable enzyme, or ortholog, in dogs is CYP3A12. Furthermore, CYP families can share similar sequence properties but have very

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different substrate specificities and enzyme regulation between two species. This makes species extrapolation amongst CYP450 very challenging, as a drug could be metabolized by two different CYP enzymes.²⁰ Species variability also can result from environmental and genetic factors that cause polymorphisms. Beagles, due to a polymorphism, are known to have high propofol hydroxylase activity due to significant activity of CYP2B11.^{20,22} Furthermore, these polymorphic differences have been observed to exist in sub-populations of beagles where about 45% are fast metabolizers of celecoxib.^{20,23}

Glucuronidation is an important phase II metabolic pathway that promotes efficient elimination into urine and/or bile while making a drug unsuitable for reabsorption. Glucuronidation enzymes are found in humans in the primary sites of drug metabolism (i.e., liver, kidney and intestinal mucosa).²⁴ In fact, humans alone express 19 different glucuronidation isoforms classified into two families and three subfamilies — UGT1A, UGT2A and UGT2B.²⁵ Deficient glucuronidation is one of the oldest abnormal pharmacologic reactions observed in cats.^{24, 26} Early reports suggested that this reaction does not take place in all glucuronidated drugs. Instead, the deficiency has been linked to compounds with planar phenolic structures, which are primarily metabolized in the liver by UGT1A6 and UGT1A9.^{24, 27-29} Cats appear to only express two different isoforms of UGT1A — 1A1 and 1A2 — providing some evidence for why cats poorly metabolize some drugs that undergo glucuronidation.³⁰

Acetaminophen is used in humans widely and can result in hepatotoxicity when the metabolic conjugation pathway is saturated.³¹ Notably, acetaminophen is rarely used in dogs and is contraindicated in cats. There have been several mechanisms proposed for the increased sensitivity of acetaminophen in cats, including the lack of N-acetyltransferase, or NAT, isoform 2. McConkey et al propose a cycle in erythrocytes among dogs and cats that require deacetylation of acetaminophen and then reacylation back to acetaminophen by NAT2. The by-product p-aminophenol is proposed to accumulate in dogs and cats since they both lack NAT2.

REPUTABLE ANIMAL DRUG PRODUCT INFORMATION RESOURCES

In recent years, pharmacists assisting pet owners in drug therapy decisions have not been without controversy. In the state of Ohio, the pharmacists' role in pet medication recommendations has been debated heavily.⁶ The board of pharmacy and the Ohio Vet Association have been working closely to ensure that recommendations pharmacists make to their pet patients is

Table 3
Description of general USP-NF general chapters <797> and <795> for human and animal compounding

USP-NF GENERAL CHAPTER	CHAPTER DESCRIPTION
<797>	"Provides procedures and requirements for compounding sterile preparations. Describes conditions and practices to prevent harm to patients that could result from microbial contamination, excessive bacterial endotoxins, variability in intended strength, unintended chemical and physical contaminants, and ingredients of inappropriate quality in compounded sterile preparations."
< 795>	"Provides guidance on applying good compounding practices in the preparation of non-sterile compounded formulations for dispensing and/or administration to humans or animals."

sound and safe. Pharmacists must take care of their pet patients in the same way they do their human patients. This means that for every prescription, the pharmacist should consider the "five rights" of medication use: right patient, right drug, right time, right dose and the right route for their pet patients. These rights generally are considered the standard for safe medication practices. However, pharmacists must be diligent and aware that the five rights are not all encompassing with respect to safety of medication administration. For example, trailing zeros, poor handwriting and ambiguous drug labels, among others, can contribute to medication safety failures.³³

In order to make competent recommendations and evaluate the appropriateness of drug therapy, reputable resources need to be sought out. As is common practice with humans and their physicians, reaching out to the pet patient's veterinarian should occur when drug therapy concerns arise. To assist in a meaningful conversation, there are several additional resources that are available to verify drug dosing of companion animals (not all inclusive).

For instance, the "Merck Veterinary Manual," first published in 1955, is a comprehensive reference available without charge. Since its creation 50 years ago, the MVM provides detailed guidelines for diagnosis, treatment and prevention of animal disorders and diseases.³⁴ For example, if a pet owner brought in a prescription for a thiazide diuretic for their dog, the MVM could be used to research the common indications for this medication, as well as the recommended dosing range. Furthermore, in the clinical use section, the MVM describes how thiazide diuretics have a relatively low potency in dogs and cats, and thus are used as rescue diuretics in companion animals that are resistant to furosemide.³⁵ This rescue use of thiazide diuretics is generally not seen in humans, and thus reinforces the importance of properly researching the in-

tended use and pharmacologic action of the drug in companion animals before making recommendations.

Drugs.com's Veterinary Product Database, or VPD, is available free of charge to healthcare providers and contains more than 5,000 "pharmaceutical, biological, diagnostic, feed medications and parasiticide product monographs categorized by treatment type."³⁶ A particularly useful feature of this online database is that it allows for browsing by specific species. For example, a pet owner's question about whether their recently acquired Rimady[®] prescription also could be used for their cat could easily be answered by searching for the product monograph that clearly informs the healthcare provider that it is not approved for use in cats.³⁷

The "FDA Approved Animal Drug Products," also known as the "Green Book," has been published since 1989 when the Generic Animal Drug and Patent Restoration Act was signed into law by the president of the United States.³⁸ The law has three requirements:

1. That all drug sponsors provide certain information about approved animal products;
2. That the information be made available to the public; and
3. That it be updated on a monthly basis.

This reference has eight different sections and is primarily used by drug sponsors and animal pharmaceutical companies. However, it also can assist pet owners in determining whether an animal product is FDA approved.

A traditional pharmacy resource already in use is the "United States Pharmacopeia," or USP. This resource has a veterinary medicine section that can be consulted for drug monographs.³⁹ Additionally, the five general compounding sections of the USP-NF may be consulted for veterinary compounding; chapters <797> and <795> are the most utilized for sterile and non-sterile product compounding guidelines (Table 3).⁴⁰

If the pharmacy has a substantial animal population that is regularly served, a

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ANIMAL SCENARIO 1

Hazel is a pet owner of a small 8-lb. female chihuahua named Rascal. She explains that Rascal was recently adopted from a shelter; and shortly after Hazel brought her home she began to experience diarrhea and vomiting. Rascal was taken to her local veterinarian and prescribed metronidazole and a suspension that says “amoxicillin trihydrate and clavulanate potassium” for her giardia infection. Hazel is worried that her dog was prescribed a human medication and is worried about the adverse effects Rascal may experience as a result. The pharmacist is concerned because they have never heard of metronidazole being used in dogs. What counseling points should the pharmacist provide to Rascal’s pet owner?

Discussion

The pharmacist should inform the patient that they are going to research the use of metronidazole in canines before making any specific recommendations. A quick search using the Merck Veterinary Manual for giardia leads the pharmacist to a general overview of giardiasis. This overview confirms that giardia spp is a chronic protozoal infection that is found in up to one-third of shelter animals’ fecal samples. Furthermore, there are no approved treatments in the United States for giardia. There is, however, evidence to support the extra-label (or off-label) use of metronidazole in dogs at a 25 mg/kg BID for five days with approximate 65% eradication. Metronidazole also has been shown to cause acute symptoms of anorexia and vomiting, so Hazel should be counseled to make sure that Rascal eats and drinks regularly while using metronidazole. Furthermore, if Rascal begins to experience difficulty walking, the veterinarian should be notified right away as ataxia is a rare side effect. Finally, the pharmacist should inquire as to whether Hazel has any other pets within the household, as Rascal’s infection can be spread easily to her other pets. Special care should be taken to make sure Rascal’s feces are removed right away and the area where defecation occurs should be avoided for at least a month as it is impossible to disinfect the grass area of all giardia cysts.

traditional veterinary drug information resource may prove useful to keep on hand. “Plumb’s Veterinary Drug Handbook” is a drug information resource that comes in a variety of options, including online, pocket handbook, paperback and via an app to assist animal healthcare providers in drug therapy-related decisions.⁴¹

REQUIREMENTS FOR OBTAINING LEGAL PRESCRIPTIONS FOR PET OWNERS

Veterinarians are required to establish a veterinarian-client-patient relationship, or VCPR, in order to diagnose and treat a client’s animal.⁴² In general, a VCPR is considered to be established if the following items have been met:⁴³⁻⁴⁴

1. The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the patient, and the client has agreed to follow the veterinarians’ instructions.
2. The veterinarian has sufficient knowledge of the patient to initiate at least a general or preliminary diagnosis of the medical condition of the patient. This means that the veterinarian is personally acquainted with the keeping and care of the patient by virtue of a timely examination of the patient by the veterinarian, or medically appropriate and timely visits by the veterinarian to the operation where the patient is managed.
3. The veterinarian is readily available for

follow-up evaluation, or has arranged for veterinary emergency coverage, and continuing care and treatment.

4. The veterinarian provides oversight of treatment, compliance and outcome.
5. Patient records are maintained.

A VCPR cannot be established online, over the phone or via email. Typically, the VCPR is created through an in-person visit and maintained through regular visits afterward.⁴² If regular visits afterward do not continue, the VCPR would be invalid, and any further treatment — including writing and/or dispensing prescriptions — would be unethical and, in some states, illegal.⁴³⁻⁴⁴ Each state has a Veterinary Practice Act that outlines the requirements of the VCPR, and further specific information may be accessed with the State Veterinary Medical Board. Furthermore, the American Veterinary Medical Association also includes the VCPR as a requirement in their Principles of Veterinary Medical Ethics.⁴³

Pharmacists are already familiar with the doctor-patient relationship requirement that is essential for obtaining legal prescriptions and dispensing of human medication in their regular practice. Obtaining legal prescriptions for the purpose of dispensing to pet owners also must fulfill the VCPR requirement. Failure to do so would be unethical and potentially illegal, depending on the individual State Pharmacy Practice Acts. If a pharmacist suspects that the VCPR has not been properly established or may be invalid, the pharmacist should

reach out to the owner’s veterinarian to discuss their specific concerns. Special care should be exercised in evaluating VCPR requirements, as they could vary from state to state. Each state’s Veterinary Medical Board can be consulted for more detailed, state-specific dispensing practice laws (i.e., length of time between visits).

In addition to traditional commercially available drug products, pharmacists also may be called upon to compound medication for pet owners. It is necessary for all pharmacists to ensure they are following all state and federal regulations required for veterinary compounding. In most instances, the rules for compounding in humans mirror those for use in non-food animals. For example, pharmacists may compound only when the animal drug product needed is not commercially available only for individual pet patient use.⁴⁵ Compounding in bulk to sell to veterinarian offices is strictly forbidden, and would be considered manufacturing and subject the pharmacist(s) and pharmacies to legal consequences.

In addition to state and federal regulations, it also is necessary for pharmacy teams to be familiar with their individual company Policy and Procedures, or P&P, with respect to obtaining and dispensing of animal medications. A traditional brick-and-mortar pharmacy may be able to provide medications to all pet owners, under specific circumstances or not at all based upon the companies individual P&P. The entire pharmacy team should be educated and knowledgeable to take care of their pet-owners’ needs with respect to pet medications.

With the advent of online pharmacies, it may be necessary to counsel pet owners on how to find a reputable pharmacy if their current pharmacy does not dispense medications intended for animal use. The National Association of Boards of Pharmacy has a program called Veterinary-Verified Internet Pharmacy Practice Sites, or Vet-VIPPS, which accredits online pharmacies that “dispense prescription drugs and devices for companion and non-food producing animals.”⁷⁴⁶ The program also assures owners that “they are purchasing drugs and devices from an online pharmacy that is properly licensed and complying with state and federal laws and regulations.” Vet-VIPPS pharmacy sites display the Vet-VIPPS seal on their websites. The seal serves as a basic way for consumers to evaluate the business practices of that online pharmacy and to access verified information about the pharmacy. Every pharmacy that displays the Vet-VIPPS seal has fully complied with the Vet-VIPPS criteria, which includes “a customer’s right to privacy, authentication and security of pre-

ANIMAL SCENARIO 2

Blake comes into the pharmacy today and requests to speak with the pharmacist. He explains that he lives on a large farm about 30 miles from the nearest pharmacy, and it is inconvenient for him to have to come to town for flea prevention for his cat. He informs the pharmacist that a friend recommended an online pharmacy called Doctors Foster and Smith, and he wants to know if it is safe to order his cat's medication from there. His cat is his beloved companion on the farm and he does not want to order from a company that is not reputable.

Discussion

The pharmacist can easily help ease Blake's concerns about the online pharmacy. The National Association of Boards of Pharmacy has a list of Vet-VIPPS accredited online pharmacies on its website. A simple search reveals that the Doctors Foster and Smith pharmacy is Vet-VIPPS accredited. Furthermore, the pharmacist can go to the pharmacy website and show Blake the Vet-VIPPS seal. If Blake clicks on the seal, he can review certified information about the pharmacy. Furthermore, the pharmacist can inform Blake that the seal also serves as a way to identify that Doctors Foster and Smith is reputable and take their pharmacy operations and pet wellbeing and health seriously with high quality standards.

Table 4
Veterinary medical ethics principle II

PRINCIPLE II DESCRIPTION	PRINCIPLE II(B) DESCRIPTION
A veterinarian shall provide veterinary medical care under the terms of a veterinarian-client-patient relationship (VCPR).	II(b): Veterinarians shall honor a client's request for a prescription in lieu of dispensing.

PRACTICE POINTS

- Pharmacists, as medication experts, are positioned to work with veterinarians and assist pet owners in obtaining and using pet medications safely.
- Like drug products for humans, animal medicines also are subjected to a drug approval process and strict regulation.
- Tailoring therapy for individualized treatment in companion animal breeds is just as important as in humans.
- Pharmacists must comprehend basic pharmacologic treatment differences between companion animals and humans prior to making drug therapy recommendations.
- If a pharmacist suspects that the VCPR has not been properly established or may be invalid, the pharmacist should reach out to the owner's veterinarian to discuss their specific concerns.

scription orders, adherence to a recognized quality assurance policy and provision of meaningful consultation between customers and pharmacists."⁴⁶⁻⁴⁷ Vet-VIPPS sites once accredited will complete an annual review and three-year accreditation.

Within the last year, S. 1200: Fairness to Pet Owners Act of 2015 was referred to a congressional committee for consideration.⁴⁸⁻⁴⁹ This national legislation was introduced in May of 2016 to make pet medications more affordable by giving owners the 'choice' on when and where to fill/pay for their pets prescriptions.⁴⁸ Thus a licensed veterinarian would be required to "provide a written copy of every prescription for a companion animal, whether or not their client needs or even wants it."⁴⁹

The AVMA argues that this prescription

mandate will "place undue regulatory and administrative burdens on veterinarians and small businesses." They further declare that clients already have the ability to fill a prescription at a pharmacy of their choice because AVMA encourages veterinarians to write them upon request in their Principles of Veterinary Medical Ethics and guide on prescription requests (Table 4).⁴³

In contrast, proponents of the bill argue that veterinarians only are interested in profiting from filling prescriptions in-house. AVMA denies this claim and cites a Federal Trade Commission report that "did not find evidence of veterinarians withholding written prescriptions from their clients and determined more information would be needed to understand the impact on consumers."⁵⁰⁻⁵¹ In addition, the FTC re-

port found that the pet medication industry could become more competitive if:⁵¹⁻⁵²

1. Consumers had greater access to "portable" prescriptions (or filled by other than a veterinarian);
2. Non-veterinary retailers had greater access to supplies of pet medications, which are currently restricted by exclusive distribution and exclusive dealing arrangements put in place by manufacturers of pet medications; or
3. Consumers had more low-priced generic animal drug options to choose from.

As mentioned above, the pet medication industry is rapidly growing and changing as a result of new opportunities. Regardless of the individual stakeholders' views, it is necessary for the pharmacist to put their pet owner first for the animal's health and well-being. While it is possible that resistance could occur when trying to obtain a legal prescription for a pet owner, the FTC report findings serve as a good reminder that just as pharmacists do, veterinarians too take an oath and put their clients well-being and health above all else. A pet owner may feel uncomfortable or even embarrassed to ask for a prescription related to affordability, but pharmacists can assist their patients as they always have in these instances.

The market growth of the pet medication industry stands to bring more pet owners into pharmacies.⁵² The importance of reaching out and working to develop relationships with local veterinarians cannot be understated. In doing so, a veterinarian may feel more comfortable recommending a pharmacy and/or pharmacist to serve their clients who request a prescription to be filled off-site.

CONCLUSION

The market for pet medications is expected to double in the coming years. With the changing opinion of companion animals as family members, owners are willing to spend more on their pet's health and well-being. This increased demand for services means that pharmacies may see increased traffic by pet owners and be required to serve not only human patients, but animal ones. As such, pharmacists should be aware of the drug approval process and state and federal laws. Additionally, pharmacists may be called upon to assist in verifying proper doses, and recognize the basic differences seen in drug disposition between species. As drug experts, pharmacists are in a unique position to develop relationships with local veterinarians to take care of companion animals to promote ultimate health and well-being.

Pharmacist CE LESSON

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Learning Assessment

Successful completion of “Dispensing pet medications in the community pharmacy” (0401-0000-16-001-H03-9) is worth two contact hours of credit. To submit answers, visit our website at www.DrugStoreNewsCE.com. Please note: Assessment questions submitted online will appear in random order.

- In 2015, what was the estimated amount of pet expenses for supplies and medications?**
 - \$8 billion
 - \$10 billion
 - \$14 billion
 - \$17 billion
- A recent change in American attitude about pets is responsible for the approximately 63% of pet owners who consider their pet a family member.**
 - True
 - False
- Veterinary drugs may be used in humans, providing that the manufacturer submits human studies during the approval process, as well as veterinary studies.**
 - True
 - False
- Which of the following federal agencies has oversight to regulate veterinary biologics to ensure safety, potency and efficacy?**
 - Center for Veterinary Biologics (CVB)
 - Center for Veterinary Medicine (CVM)
 - Environmental Protection Agency (EPA)
 - Food and drug administration for veterinary products (FDAV)
- Which branch of the Food and Drug Administration reviews and regulates the approval of all animal drugs?**
 - Center for Veterinary Biologics (CVB)
 - Center for Veterinary Medicine (CVM)
 - Environmental Protection Agency (EPA)
 - Food and Drug Administration for Veterinary Products (FDAV)
- Which of the following federal agencies has oversight to develop safety guidelines focusing on the prevention of harm to humans and non-targeted species?**
 - Center for Veterinary Biologics (CVB)
 - Center for Veterinary Medicine (CVM)
 - Environmental Protection Agency (EPA)
 - Food and Drug Administration for Veterinary Products (FDAV)
- The new animal drug approval process begins with the Center for Veterinary Medicine, or CVM, and requires the drug sponsor to submit five major technical components to be considered for a New Animal Drug Approval, or NADA.**
 - True
 - False
- The three primary categories of animal products available for use in the United States are:**
 - Pesticides, antibiotics and vaccines
 - Pesticides, antibiotics and biologics
 - Pesticides, pharmaceuticals and vaccines
 - Pesticides, pharmaceuticals and biologics
- The same CYP Isozyme (CYP3A12) can be derived from multiple species.**
 - True
 - False
- Acetaminophen can be used safely in such companion animals as cats and dogs.**
 - True
 - False
- The USP can be used by pharmacists to assist in researching the following with respect to companion animals:**
 - Diagnosis
 - Treatment
 - Prevention
 - Veterinary compounding
- Pharmacists may dispense prescriptions for companion animals from pet owners who received a veterinarian consult online.**
 - True
 - False
- The National Association of Boards of Pharmacy, or NABP, provides a Vet-VIPPS seal for online pharmacies who:**
 - Meet specific criteria.
 - Pay a fee.
 - Are recommended by veterinarians.
 - All of the above
- Pharmacists should expect resistance from veterinarians when they try to obtain legal prescriptions for pet owners due to the Pet Owner Fairness Act currently being proposed in Congress.**
 - True
 - False
- A local veterinarian has developed a new drug for treatment of a somewhat rare condition that can develop in older cats. He is interested in expanding the use of the product. Which of the following is true?**
 - He must demonstrate that he can consistently manufacture the product.
 - He may ship the product to researchers for testing.
 - He must secure a NADA, abbreviated NADA or conditional NADA before selling the product.
 - All of the above
- A client information sheet is best defined as:**
 - Detailed instructions from the recent pet visit that prove the veterinarian has established a proper relationship before ordering medications.
 - The hours in which the veterinary site is open for business.
 - A document similar to a human medication guide.
 - None of these
- In animal medication development processes, manufacturers can copy any drug as soon as it has been approved to offer cost-saving generic alternatives quickly.**
 - True
 - False

Learning Assessment

18. A kennel cough vaccine often is required by animal boarding facilities. This pet medication is classified as:
- A required immunization (RI)
 - Pesticide
 - Pharmaceutical
 - Veterinary biologic (VB)
19. Which of the following is not a requirement outlined in the FDA Green Book?
- All drug sponsors provide specific information about approved products.
 - The information is available to the public.
 - The information is updated on a monthly basis.
 - Inter-species calculations are available for veterinarians.
20. Which of the following references was first published in 1955 as a comprehensive free reference for animal disorders?
- The United States Pharmacopeia
 - The FDA Green book
 - The Merck Manual
 - VPD