Technician **ce lesson**



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Target Audience

Pharmacy technicians in community-based practice.

Program Goal

To serve as an introduction to companion animal medications in the pharmacy setting

Learning Objectives

- Upon completion of this program, the technician should be able to: 1. Describe the animal medicine drug approval process and corresponding federal oversight agency
- 2. List the three categories of animal products
- 3. Identify the three pet medication sub-categories when triaging pet products for pet-patient owners
- 4. Describe state and federal animal laws to assist in obtaining legal prescriptions for pet-owner clients

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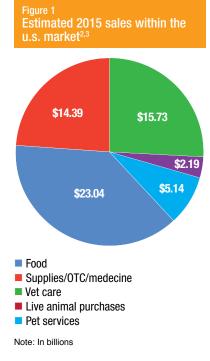
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Technicians and their pet patients: companion animal medication dispensing

INTRODUCTION

According to a recent Federal Trade Center 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 were estimated to surpass \$60 billion, with \$14.39 billion alone spent on supplies and medications.²⁻³

Recent reports suggest this market growth trend as 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-be-



ing.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 that, 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 online pet medication pharmacies 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.⁵⁶ Thus, technicians play an important role in assisting their pharmacist colleagues to work with local veterinarians and 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 towards 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 (table 1) does not differ from that of animal drug. There is, however, an additional category called veterinary drugs, which 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.

Three Federal agencies are responsible for the oversight of animal drug products:

Table 1 Drug and veterinary drug definitions

DRUGS	VETERINARY DRUG
"articles intended for use in the diagnosis, cure, mitiga- tion, treatment or preven- tion 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) & (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

- 1. <u>Center for Veterinary Biologics⁸⁻¹⁰</u> a branch of the U.S. Department of Agriculture Animal and Plant Health Inspection Service, which 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. <u>Center for Veterinary Medicine^{8,11-12}</u>: 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.
- Environmental Protection Agency⁸, ¹³⁻¹⁶: 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 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, abbreviated NADA, or a conditional approval (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. CVM is composed of six offices that coordinates together to approve NADs and conducts monitoring once the product is on the market. CVM's Office of New Animal Drug Evaluation (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 idea that 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 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, where they agree on information required in order to get the drug approved.

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 consists of 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 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.¹⁹The generic approval process mirrors that of humans in which the drug sponsor will:

- 1. 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:
 - a. Active ingredient, strength, dosage regimen and dosage form
- The pharmaceutical company also must show that the generic copy is:

 a. Consistently made from batch to batch, including identity, strength, purity and qual

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 (ANDA	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)	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).	
Freedom of Information Summary (FOI)	Document made available to the public that details safety and ef- ficacy data that supports CVM's approval of a new animal drug	

ity as the brand name drug b. Bioequivalent to the approved brand name drug 1. Absorption and in therapeutic effect

4. 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 and, therefore, require medications from time to time to treat and prevent illness. Since pets are increasingly looked at like family members, their health and wellbeing are a major priority for pet owners.⁴ Three categories of animal products are available for use in the United States:

- <u>Veterinary Biologics</u>^{7, 9-11}: 1. 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 is typically more affordable than treating the 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. <u>Pesticides^{11, 13-16}</u>: are mostly used in pets for the treatment of fleas, ticks and ear mites (and internal parasites like heartworm). Flea bites not only are irritating to a pet, but in some cases can cause flea allergy dermatitis (leading 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. Numerous products are available for pet owners to choose from in a variety of dosage

forms (tablets, sprays, dips, shampoos, powders and spot-treatments among others)

<u>Pharmaceuticals^{12, 17}:</u> includes a variety of animal medications, such as pain, antibiotics, heartworm preventatives, antiarrhythmics, hypertension, anesthetics, etc. Pharmaceuticals are used with the intended purpose of eradicating or managing disease/disorders in animals.

COMPANION ANIMAL DRUG METABOLISM

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. (2008), a breed is considered a group of animals with common ancestry and certain distinguishable characteristics developed by artificial selection and maintained by controlled breeding. Therefore, as we individualize therapy to humans, companion animals also require specific care. As a result, it would be inappropriate to treat all dogs that have an infection the same way.²⁰

There is significant variability between animal species with respect to drug metabolism. While technicians are not expected to be able to identify these differences, it is useful to be aware of certain cases when assisting pharmacists. For example, acetaminophen is used in humans widely and can result in liver toxicity when the metabolic pathway is over worked.21 Notably, acetaminophen is rarely used in dogs, and contraindicated in cats. The non-prescription medication diphenhydramine is not dosed in companion animals the way it is in humans. In fact, companion animals often require doses that exceed what are approved in humans.

COMPANION ANIMAL MEDICATION PROCUREMENT

Technicians may find themselves responsible for procuring pet medications with the

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 her veterinarian gave a prescription for fluoxetine to assist with Rascal's anxiety. Hazel wants to know why she couldn't fill this prescription at her vet's office? She is worried that she won't know what to expect with the medication since it won't be coming from her vet and her dog is very small.

Discussion

The technician can ease Hazel's concerns by explaining that the medication her veterinarian wrote is a human medication that can be prescribed for animals by a licensed veterinarian. Veterinarians are not able to dispense human medications and, therefore, she must fill the prescription at a pharmacy. The technician also can take this opportunity to ease the pet owner's concerns by explaining that the pharmacist will be available to discuss the medication with her before she leaves. This way she will be comfortable with how to administer the medicine and know what to expect.

expanding market and increased access. It is important for technicians to recognize that the three categories of animal products discussed above can be further subdivided when considering access at a local pharmacy:

- 1. <u>Human Prescription Medications</u>: Medications that already have gone through the drug approval process for human consumption. Additionally, these medications may be prescribed by a licensed veterinarian for use in companion animals (ex. furosemide).
- 2. <u>Non-Prescription Medications</u>: Traditionally over-the-counter medications that do not require a prescription by a licensed veterinarian (ex. diphenhydramine).
- 3. <u>Pet-Specific Medications</u>: Medications not approved for human consumption that may or may not require a prescription by a licensed veterinarian. These medications often are not stocked in a human pharmacy (ex. Rimadyl®).

All of the above medication categories are going to require different approaches by the pharmacy technician. For example, a human medication that is approved for use in a dog may only require a written prescription from a licensed veterinarian and then can be processed like a routine prescription. In most cases, a non-prescription medication should only be recommended by a pet owner's veterinarian or after a pharmacist has consulted with the veterinarian. As discussed above, companion animals have variability in their metabolism and certain OTC products may not be appropriate with other medications a pet may be using. Petspecific medications are most likely where technicians will see the greatest variability in process, depending on organization capabilities. Some pharmacies may not carry pet-specific medications, have limited options or have a completely separate online pet pharmacy. Therefore, it is important for pharmacy technicians to be familiar with their company policy and procedures, as well as access routes for pet owners.

REQUIREMENTS FOR OBTAINING LEGAL PRESCRIPTIONS FOR PET OWNERS

Veterinarians are required to establish a Veterinarian-Client-Patient Relationship in order to diagnose and treat a client's animal.²² In general, a VCPR is considered to be established if the following items have been met: ²³⁻²⁴

- "The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the patient, and the client has agreed to follow the veterinarian's instructions."
- 2. "The veterinarian has sufficient knowledge of the patient to initiate at least a general or preliminary diag-

ANIMAL SCENARIO 2

Blake comes into the pharmacy today and wants to know how he can get a prescription for his cat's flea prevention. He saw a flyer in the newspaper that said this pharmacy has an online pharmacy that could ship the medicine to his home. He explains that he lives on a large farm about 30 miles from the nearest pharmacy and it is inconvenient for him to go to town for the necessary medication. He said his veterinarian has never written a prescription for him to take somewhere else and is not sure what to do.

Discussion

The pharmacy technician should reassure Blake that they will be able to assist him in obtaining a prescription. The tech should explain to the pet owner that they will have the pharmacist call the veterinarian for the patient, but will need to know some additional information. The tech should ask the owner about his pet's last veterinarian visit and obtain the pets information, as well as the veterinarian's information. Once the pharmacist is able to legally obtain the prescription, the prescription should be processed following company policy and procedures, state and federal laws.

nosis 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."

- "The veterinarian is readily available for follow-up evaluation or has arranged for the following: 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 afterwards.21 If regular visits afterwards do not continue, the VCPR would be invalid and any further treatment (including writing/ dispensing prescriptions) would be unethical and in some states illegal.23-24 Each state has a Veterinary Practice Act which 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.23

Just as pharmacists already establish that a doctor-patient relationship exists, in order to obtain a legal pet prescription a pharmacist must also ensure that the VCPR requirements have been met to dispense to pet owners. Failure to do so would be unethical and potentially illegal, depending on the individual State Pharmacy Practice Acts. If a technician is unsure or suspects that the VCPR has not been properly established or may be invalid, the technician should notify the pharmacist immediately to reach out to the pet owner's veterinarian. As with humans, technicians cannot verbally transcribe a new prescription for a pet patient or its owner.

In addition to state and federal regulations, it also is necessary for pharmacy teams to be familiar with their individual company Policy and Procedures 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 assist 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, (Vet-VIPPS) which accredits online pharmacies that "dispense prescription drugs and devices for companion and non-food producing animals."25 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 prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between customers and pharmacists."25-26 Once accredited, Vet-VIPPS sites 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.²⁷⁻²⁸ This national legislation was introduced in May of 2015 to make pet medications more affordable by giving owners the 'choice' on when and where to fill/pay for their pets prescriptions.²⁷ 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."²⁸

The American Veterinary Medical Association 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 guide on prescription requests (see table 3).²³

In contrast, proponents of the bill argue that veterinarians are only interested in profiting from filling prescriptions inhouse. 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."²⁹⁻³⁰ In addition, the FTC report found that the pet medication industry could become more competitive if: ³⁰⁻³¹

- 1. "consumers had greater access to 'portable' prescriptions" (or filled by an entity other than a veterinarian)
- "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"
- 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. Regard-

Table 3 Veterinary medical ethics principle II

PRINCIPLE II	PRINCIPLE II(B)
DESCRIPTION	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

less of the individual stakeholders' views, it is necessary for the pharmacy team 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 pharmacy teams 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.³¹ 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 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 patients, as well. Technicians can play an integral role in this process through assisting the pharmacist to ensure that all pet patients and their owners are taken care of.

PRACTICE POINTS

- Technicians play an important role in assisting their pharmacist colleagues to work with local veterinarians and pet owners to obtain and use pet medications safely.
- Like drug products for humans, animal medicines also are subjected to a drug approval process and strict regulation.
- In most cases, a non-prescription medication should only be recommended by a pet owner's veterinarian or after a pharmacist has consulted with the veterinarian.
- If a technician is unsure or suspects that the VCPR has not been properly established or may be invalid, the technician should notify the pharmacist immediately to reach out to the pet owner's veterinarian.

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Technician **ce lesson**

Learning Assessment

- 1. In 2015, what is the estimated amount of pet expenses for supplies and medications?
 - a. \$8 billion
 - b. \$10 billion
 - c. \$14 billion
 - d. \$17 billion
- 2. A recent change in American attitude about pets is responsible for the approximately 63% of pet owners who consider their pet a family member? a. True
 - b. False
- 3. Which of the following federal agencies is responsible for developing safety guidelines focusing on the prevention of harm to humans and non-targeted species, with the correct oversight responsibility of animal drug products?
 - a. Center for Veterinary Biologics
 - b. Center for Veterinary Medicine
 - c. Environmental Protection Agency
 - d. Centers for Disease Control and Prevention

- 4. The new animal drug approval process begins with the Center for Veterinary Medicine and requires the drug sponsor to submit an application to be considered for a New Animal Drug Approval.
 - a. True
 - b. False
- 5. The three primary categories of animal products available for use in the United States are:
 - a. Pesticides, antibiotics and vaccines
 - b. Pesticides, antibiotics and biologics
 - c. Pesticides, pharmaceuticals and vaccines
 - d. Pesticides, pharmaceuticals and biologics
- 6. Acetaminophen cannot be used safely in companion animals, such as cats and dogs.
 - a. True
 - b. False
- 7. An OTC product for a companion animal should be recommended to a pet owner only when a veterinarian

has recommended it or a pharmacist has consulted a veterinarian on the pet owner's behalf.

- a. True
- b. False
- 8. It is acceptable to dispense prescriptions for companion animals to pet owners who saw a veterinarian online. a. True
 - b. False
- 9. Technicians can call a veterinarian and obtain a legal prescription for a pet owner.
 a. True
 - b. False
- 10. 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.
 - a. True
 - b. False