### Overview of Veterinary Pharmacy: Tips for Pharmacists

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### Who Am I?

- Pharmacist with over 25 years of experience in veterinary pharmacy
- I developed and instruct online courses in veterinary pharmacy with University of Florida
- Teach pharmacology to veterinary students in the Caribbean (Grand Cayman Island) using distance education methods from my home in the US
- Previous regulatory affairs/regulatory compliance consultant to veterinary drug distributors
- Pharmacist who has filled many veterinary prescriptions over the years

#### **Educational Objectives**

Discuss factors influencing veterinary prescribing and dispensing

• Review the applicable legal and regulatory constructs of drugs used in animals including FDA-approved uses and extra-label use

• Outline the veterinary drug information resources that can be used to support a pharmacist in the safe and accurate filling of pet prescriptions

### Why learn about this topic?

- Any pharmacist who works in a retail/community pharmacy environment will eventually be presented with an animal prescription.
- Retail pharmacies are offering more veterinary products to pet owners. Large retailers, grocery outlets, mass merchandisers and online pharmacies are providing many chronic and preventative meds for pets. All cash business.
- Rx's indicated in the medical treatment of pets are not exempt from the definition of "prescription drug" at the state level and thus require the same level of safety, competency and focus on regulatory requirements as human Rx's.

Veterinary Pharmacy Education Resolution 110-5-14. National Association of Boards of Pharmacy. May 30, 2014. Acessed December 20, 2021. <u>Veterinary Pharmacy</u> <u>Education (Resolution 110-5-14) - National Association of Boards of Pharmacy (nabp.pharmacy)</u> Ken Niedziela. Today Veterinary Business. August 2019. Accessed December 20, 2021. <u>Veterinarians sell 74% of pet medications - Today's Veterinary Business</u>

(todaysveterinarybusiness.com)

### Discuss factors influencing veterinary prescribing and dispensing

- The scenario of companion animal medications only being available from the prescribing veterinarians office has changed.
- Veterinarians are increasingly seeking to decrease the amount drug inventory as a cost saving measure.
- DVMs generally want to focus on clinical services, not drug provision.

Shawn P. Messonnier, DVM. Pharmacy challenges: Present and future. DVM 360, December 14, 2021. Accessed December 20, 2021. Pharmacy challenges: Present and future (dvm360.com) (dvm360.com) Pet Medications. Costco.com Accessed December 20, 2121. Costco Rx - Pet Medications

### Discuss factors influencing veterinary prescribing and dispensing

- Veterinarian dispensing incident to practice has been recognized as a declining part of veterinary revenue. Pharmacies have entered the market and are here to stay.
- Owners want convenience and price competitiveness.
- Manufacturers of some topical flea/tick products, generic heartworm preventatives, NSAIDs, recognize the value of supply chain logistics that exist in human pharmacy wholesale distribution.

Emily Shiver, CVPM. DVM 360. Fighting online veterinary pharmacies ... and winning. May 17, 2020. Accessed December 20, 2021. Fighting online veterinary pharmacies...and winning-dvm360 Winning-dvm360 Pet Medications. Costco.com Accessed December 20, 2121. Costco Rx - Pet Medications

# Review the applicable legal and regulatory constructs of drug use in animals

- In 1994, Congress amended the Federal FDC Act that give veterinarians the legal ability, with certain restrictions, to use approved human and animal drugs in an extra-label manner. This is called extra-label drug use. In short, ELDU is the use of a drug in way/manner that is different from the federal label.
- FDA's requirements for ELDU in animals is to limit this use to situations where an animal's health is threatened or where the animal may suffer or die without treatment.
- In companion (non-food-producing) animals, a DVM can prescribe an approved human drug for an extra-label use even if an approved animal drug is available. This is not the case for food-producing animals. For these animals, FDA's requirements for extra-label drug use prohibit the DVM from prescribing an approved human drug if there's a drug approved for food-producing animals that you can prescribe instead. For example, if a drug approved for chickens is available, the DVM must first use that drug to treat a sick cow before reaching for a drug approved for people.

US Food and Drug Administrations, Center for Veterinary Medicine. The Ins and Outs of Extra-Label Drug Use in Animals: A Resource for Veterinarians. Updated January 16, 2020. Accessed December 20, 2021. The Ins and Outs of Extra-Label Drug Use in Animals: A Resource for Veterinarians | FDA

# Review the applicable legal and regulatory constructs of drug use in animals

- FDA recognizes that in some situations a drug compounded from bulk drug substances may be the only appropriate treatment option for a particular animal.
- Pharmacists who compound animal drugs from bulk drug substances (for non-food animal patients) generally will not receive regulatory action from the FDA. New GFI #256 Compounding Animal Drugs from Bulk Substances.
- Animal drugs compounded from bulk drugs (or API's) do not undergo review by FDA, they are not proven to be safe or effective.
- FDA has the right to prohibit extra-label uses of certain drugs in animals. Certain human and animal drugs, families of drugs, and substances are prohibited from ELDU in all food-producing animals. Chloramphenicol, vancomycin, metronidazole, DES, antivirals, etc.

CVM GFI #256 - Compounding Animal Drugs from Bulk Drug Substances CVM GFI #256 - Compounding Animal Drugs from Bulk Drug Substances | FDA

US Food and Drug Administrations, Center for Veterinary Medicine. The Ins and Outs of Extra-Label Drug Use in Animals: A Resource for Veterinarians. Updated January 16, 2020. Accessed December 20, 2021. <u>The Ins and Outs of Extra-Label Drug Use in Animals: A Resource for Veterinarians | FDA</u>

#### Define a valid veterinarian-client-patient (VCPR) relationship

- FD&C Act allow extra-label drug use (ELDU) only on the lawful order of a licensed veterinarian in the context of a valid veterinarian-client-patient relationship (VCPR). A valid VCPR relationship has three parts:
  - The DVM has the responsibility for making medical judgments about the health of an animal, or animals, and the need for medical treatment. In turn, the client (the owner or other animal caretaker) has agreed to follow your instructions;
  - The DVM has sufficient knowledge of the animal, or animals, to develop a general or preliminary diagnosis of the medical condition; and
  - The DVM is readily available for follow-up in case of adverse drug reactions or treatment failure.
  - Such a relationship can exist only when the DMV has recently seen and are personally acquainted with the keeping and care of the animal or animals. This includes recently examining the animal or animals, made "medically appropriate and timely visits" to the premises (usually the case for food-producing animals), or done both.

US Food and Drug Administrations, Center for Veterinary Medicine. The Ins and Outs of Extra-Label Drug Use in Animals: A Resource for Veterinarians. Updated January 16, 2020. Accessed December 20, 2021. The Ins and Outs of Extra-Label Drug Use in Animals: A Resource for Veterinarians | FDA

#### Define a valid veterinarian-client-patient (VCPR) relationship

- What to do when an animal owner asks you to recommend an OTC drug for use in their pet?
  - Veterinarians are the only person who can authorize ELDU
  - A pharmacist *does <u>not</u>* have the legal right to initiate/recommend ELDU in animals
  - DVM's can direct a pet owner to go to a pharmacy to get an OTC drug
  - A pharmacist can assist a pet owner in finding the correct product/dosage form of an OTC drug based upon instructions from a veterinarian. Example diphenhydramine
  - Consult a trusted veterinary drug reference to verify dosages/indications

US Food and Drug Administrations, Center for Veterinary Medicine. The Ins and Outs of Extra-Label Drug Use in Animals: A Resource for Veterinarians. Updated January 16, 2020. Accessed December 20, 2021. <u>The Ins and Outs of Extra-Label Drug Use in Animals: A Resource for Veterinarians | FDA</u> Plumbs Veterinary Drugs. Drug Monographs. Updated continuously. Accessed December 20, 2021. <u>Plumb's (plumbs.com)</u>

#### **ELDU Examples**

- Levothyroxine for hypothyroidism in dogs
- Diazepam to treat seizure disorders in dogs and cats
- Alprazolam or trazodone to treat anxiety or noise phobias such as thunder storms and fireworks
- Ciprofloxacin or levofloxacin in dogs for infectious diseases
- Human label eye drops for treatment of glaucoma in dogs and cats
- Human label insulins for treatment of diabetes mellitus in dogs and cats
- Gabapentin for behavior management or pain in dogs or cats
- Tramadol for pain management in dogs and cats

Veterinary drug information resources that can be used to support a pharmacist in the safe and accurate filling of pet Rx's

- When a pharmacist needs to verify indications, dosages, contraindications or guidance for patient counseling, consult a trusted veterinary drug reference or resource.
- Best piece of advice that I can give to pharmacists filling pet prescriptions in retail/community settings.

• Free and subscription based options.

#### **Subscription Based Reference**

- Plumb's Veterinary Drugs (electronic subscription) or Plumb's Veterinary Drug Handbook (text for purchase).
- Written in monograph format, with additional reference tables and appendices
- Called "the virus" in veterinary medicine
- Peer-reviewed drug informatics resource that can support pharmacists in real time in their efforts to safely dispense pet prescriptions, verify dosages, check indications, access medication guides for patient counseling.

#### Plumb's VETERINARY DRUG HANDBOOK

**10TH EDITION** 

James A. Budde Dawn M. McCluskey This reference is called "the virus" in veterinary medicine because it is everywhere.

WILEY Blackwell

#### They took the print version and made it better!!

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	Acetohydroxamic Acid > P Acetyldysteine > R S	Overdosage / Acute Toxicity Drug Interactions	<ul> <li>Often used in combined dosage forms with codeine, tram hydrocodone; see the codeine, tramadol or hydrocodone monographs for more information.</li> </ul>	Antibiotic, Antiparasitic (Systemic Drug) Doses Dosage Forms Drug Interactions Adverse Effects
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products. See also the Trimeprazine Ta with Prednisolone monograph. Note: Although separate entities, prednisone and prednisolone are ofter	Acetazolamide		hydrocodone and tramadol monographs for more informati use of acetaminophen combination preparations. A case report of adjunctive treatment for pain usine oral ace	Adverse Effects: Neurologic disorders, lethargy, veskness, neutropenia, hepatotoxicity, hematuria, anorexia, nausea, vomiting, & diantea.     Very bitter, metronidazole benzeate may be more palatable when compounded.     Uses / Indications     () () () () () () () () () () () ()
considered bioequivalent; most specie	Al Drugs Appendix New & Updated Notes	-	MacBook Air	Although there are no veterinary-approved meteonidazele products; the drug has been used extensively in the treatment of Giordie in both dogs and acts. It is also used disclaring in small animals for the treatment of the pravatises (frictionssis and Balontidium coli) as well as treating both enteric and systemic anaerobic infections. It is commonly employed as a perioperative
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#### Free Online Reference

Merck Veterinary Manual

Merck Veterinary Manual (merckvetmanual.com)

Veterinary Content> Pharmacology

Resources> Tables, Reference Guides or Infographics

#### Basics of PK and PD

#### \*\*\*\* A cat is not a small dog. A dog is not a small person.\*\*\*\*

- Metabolism significant differences in cats. They are deficient in glutathione, glucuronyl transferase making glucuronidation conjugation difficult and therefore can not metabolize drugs like people or other small animals.
- GI transit time faster in monogastrics versus ruminants. Dogs>people. So, caution with some of the prolonged release, once a day cardiac drugs, theophylline SR.
- Do not extrapolate doses outside of species such as a rodent vs. large mammal. Or a ruminant to monogastric. Or a reptile to a mammal. Use BMR as a guide.
- Some animals have more/different receptors than others. Cattle have large number of α-2 receptors in their CNS making them very sensitive to alpha agonists. Xylazine
- Some species are more affected by GABA inhibition than others horses.

#### Basics of PK and PD

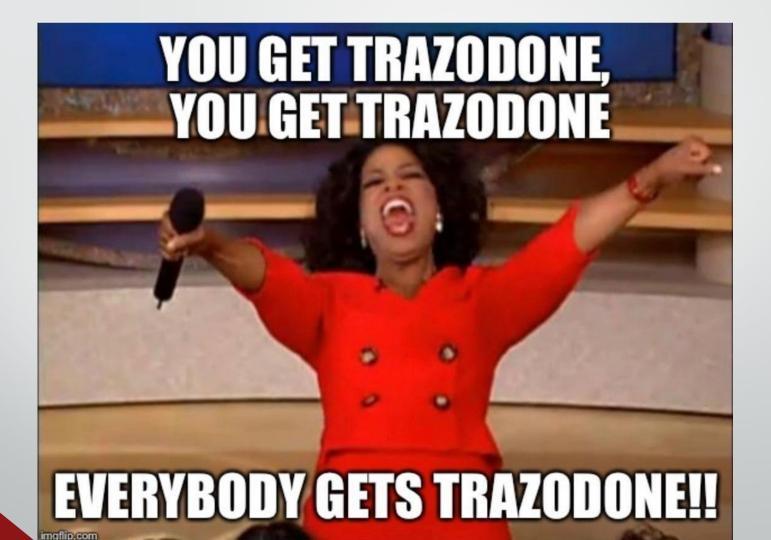
- Prednisone is a prodrug. Cats and horses lack the enzyme necessary to convert prednisone to prednisolone. Therefore, administer prednisolone to those species.
- Opiates will cause predictable sedation in dogs but can cause CNS excitation in horses and cats.
- Dogs and cats metabolize benzodiazepines faster than people.
- Xylitol is toxic to dogs, results in massive release of insulin=hypoglycemic.
- Certain drugs approved for use in cattle will kill other mammals (tilmicosin).
   Certain drugs can be used in dogs and horses but are not well tolerated in cats (lidocaine).

 Acetaminophen is toxic to cats. NSAIDs such as naproxen and ibuprofen are not indicated for use in dogs or cats due to a very narrow therapeutic window.

 The sig abbreviation "SID" means once-a-day in veterinary medicine. It can be misread by pharmacists as five times a day resulting in overdoses.

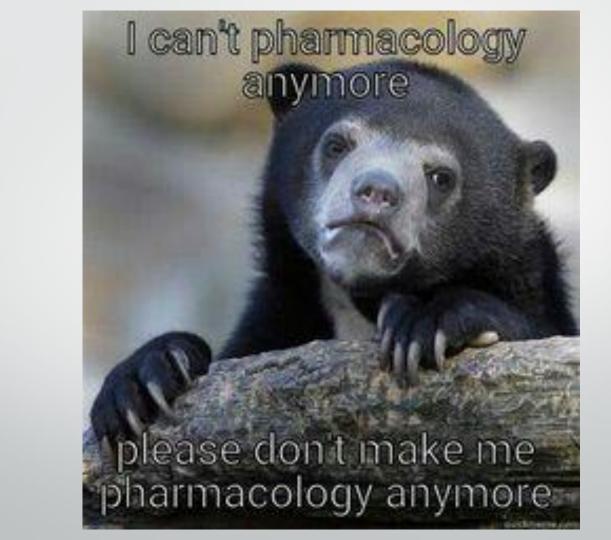
Chocolate is toxic to dogs specifically, theobromine.

- The dose of levothyroxine for hypothyroidism in dogs is 4-5 times that of humans and will always be dosed twice a day (BID).
- Diazepam can be used to treat seizure disorders in dogs and cats. Dog dosing is ~1mg/kg PO or rectally, 120# St. Bernard = 54mg.
- Trazodone can be used to treat anxiety or noise phobias such as thunder storms and firework noise. Everybody gets trazodone!!
- Human ciprofloxacin can be used in large breed dogs needing extended therapy because it can be less expensive than veterinary enrofloxacin (a prodrug to ciprofloxacin).



- NPH and Levemir can be used to treat DM in dogs. Lantus is used to treat diabetes in cats. Insulins are not interchangeable/substitutable for use in dogs and cats.
- Gabapentin and tramadol are frequently being used in conjunction with veterinary label non-steroidal drugs such as carprofen for pain management.
- The liquid formulation of gabapentin should never be dispensed to dogs because it contains xylitol as a sweetener and is toxic to canines. Watch OTC drug solutions, sugar free candy and peanut butter, other foods and gum.

- Piroxicam can be used for anti-tumor activity in animals with cancer.
- Veterinarians are not eligible for National Provider Identifier (NPI) numbers.
- The American Society for the Prevention of Cruelty to Animals (ASPCA) sponsors the Animal Poison Control Center (APCC). 888-426-4435.
- ASA use in dogs for ~>7 days, guaranteed a GI bleed.
- OTC Kaopectate and Pepto-Bismol contain bismuth subsalicylate an ASA derivative



#### Conclusion

• Questions? Let me know if I can do anything to assist.

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