Module 3: Regulatory and Ethical Issues in Veterinary Pharmacy

EDUCATIONAL OBJECTIVES

Upon completion of this activity, participants should be better able to:

1. Define the veterinarian–client–patient relationship that serves as the basis of providing care and medications for animals.
2. Discuss relevant statutes, regulations, guidance, and standards for drug use in non-human species.
3. Identify the federal and state agencies responsible for regulating the use of various veterinary products.
4. State important requirements for dispensing medications for use in animals.

Post-Test/Rationale

1. Choose the CORRECT statement regarding the regulatory status of marketed veterinary drugs:

   A. The marketing status of a veterinary product (prescription vs. OTC) is determined by the FDA based on whether it is possible to prepare “adequate directions for use” under which a layperson can use the drugs safely and effectively. ***
   
   B. Effective January 1, 2017, drugs intended to be added to feeds for food-producing animals will switch from prescription-only status to OTC and no longer will require a veterinarian’s order.
   
   C. Pharmacists may legally recommend the use of any human-approved OTC product in animals.
   

Correct Answer: A

Rationale: Over-the-counter drugs may be sold directly to laypersons only if the sponsor can prove to the FDA that the drug can be adequately labeled for safe use; legally, the drug must be used exactly according to FDA-approved labeling. Safe use includes safety to the animal, safety of food products derived from the animal, safety to the persons associated with the animal, and safety in terms of the drug's impact on the environment. Human OTC drugs are not labeled for use in any species other than humans, so federal law prohibits the use of a human OTC drug in an animal unless it is specifically pursuant to a prescription order by a licensed veterinarian with a valid veterinarian-client-patient relationship with that animal. Pharmacists should note well that recommending OTCs for use in non-human patients is illegal.

Located in Content Section: Categories and Regulation of Drugs Used in Animals; Food and Drug Administration; Over-the-Counter Drugs
2. Which of the following statements regarding the veterinarian–client–patient relationship (VCPR) is correct?

A. The veterinarian and client have entered into an agreement that the client is responsible for care of the animal patient.
B. The veterinarian must examine the animal at least once a year to maintain a valid VCPR.
C. The veterinarian agrees to be available to personally provide follow-up or make arrangements for patient follow-up.***
D. Licensed veterinarians employed by Internet pharmacies may legally authorize the use of drugs in animal patients.

Correct Answer: C
Rationale: The VCPR is legally defined as: (1) the veterinarian has assumed the responsibility for making medical 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 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) a timely examination of the patient by the veterinarian, or, (b) 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 the following: (a) veterinary emergency coverage, and, (b) continuing care and treatment. (4) The veterinarian provides oversight of treatment, compliance and outcome. And, (5) Patient records are maintained. There are no temporal conditions assigned to a valid VCPR.
Located in Content Section: The Veterinarian–Client–Patient Relationship

3. Which of the following drugs or drug classes is banned from use in racing animals?

A. Corticosteroids.
B. Injectable local anesthetics.
C. Oxyglobin.***
D. Procaine.

Correct Answer: C
Rationale: Oxyglobin is one of four drugs banned entirely for use in racing animals.
Located in Content Section: Food-Producing and Performance Animals; Performance Animals

4. Which of the following types of compounding is most likely to be subject to regulatory action by the FDA?

A. Compounding with bulk drug substances in food animals.***
B. Compounding outside valid medical need or where no VCPR exists.
C. Duplicating a commercially available product.
D. Compounding from bulk drugs for use in non-food animals.

Correct Answer: A
5. Which statement regarding regulatory enforcement authority of veterinary drugs is correct?

A. The FDA is the federal agency responsible for enforcement of the Food, Drug, and Cosmetic Act, which governs the safety and effectiveness of “new animal drugs, vaccines, and biologics.”
B. The U.S. Department of Agriculture is responsible for ensuring that animal drugs and medicated feeds are safe and effective and that food from treated animals is safe to eat.
C. The state boards of veterinary medicine have primary regulatory authority over veterinary practitioners through relevant state veterinary practice acts.***
D. The Environmental Protection Agency regulates the manufacture, sale, and use of all pesticides, including rodenticides, insecticides, and germicidal preparations used systemically or topically on animals or systemically and topically on inanimate objects.

Correct Answer: C

Rationale: Veterinarians and pharmacists prescribing or providing drugs for use in animals are primarily regulated at the state level by state boards of veterinary medicine and pharmacy and their respective practice acts. The word “systemically” makes answer D incorrect.

Located in Content Section: Categories and Regulation of Drugs Used in Animals

6. Which statement regarding extra-label use of drugs in animals is correct?

A. “Extra-label” use also is referred to as “conditional” use.
B. Veterinary OTC products may legally be used by laypersons in an extra-label fashion.
C. Extra-label use of both animal and human drugs is permissible in or on animal feed.
D. By legal definition, the term “extra-label” means actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling.***

Correct Answer: D

Rationale: Extra-label use is defined in AMDUCA as actual or intended use of a drug in an animal in a manner that is not in accordance with the approved product labeling.

Located in Content Section: Evolution of Veterinary Drug Law; Animal Medicinal Drug Use Clarification Act of 1996

7. Which of the following veterinary products is **not** under FDA jurisdiction?

A. Shampoos for treatment of dermatological diseases.
B. Oral insecticides.
C. Skin conditioners.
D. Topically applied heartworm preventives.

Correct Answer: C
Rationale: Shampoos that make a medical claim for treatment of disease are under the jurisdiction of the FDA. Insecticides administered orally to animals are under the jurisdiction of the FDA; topically applied insecticides are under the jurisdiction of EPA. Heartworm preventatives are drugs and are not pesticides so even when applied topically they are under the jurisdiction of the FDA. Skin conditions that make no medical claims and contain no drugs are considered grooming aids and are not under the jurisdiction of FDA.

Located in Content Section: Categories and Regulation of Drugs Used in Animals; Food and Drug Administration

8. Which of the following statements is required to be included in the manufacturer's labeling of a veterinary prescription drug?

A. Rx Only.
B. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
C. Caution: Federal law prohibits dispensing this drug without secondary veterinarian authorization.
D. Caution: Federal law prohibits the use of this drug in humans.

Correct Answer: B
Rationale: “Rx Only” applies only to human labeled drugs. The federal veterinary prescription legend is stated in answer B.

Located in Content Section: Categories and Regulation of Drugs Used in Animals; Food and Drug Administration

9. In the Minor Use and Minor Species Act, the term “indexing” refers to:

A. Special incentives for companies to develop veterinary drugs for minor uses or minor species.
B. FDA authorization of drugs for use in minor species that are too rare or too varied to be the subject of adequate and well-controlled studies in support of drug approval.
C. The ability of companies to legally market a drug after proving that it is safe but before collecting all effectiveness data necessary for full approval, for a limited “index” time (e.g., 5 years).
D. The development of threshold numbers that specify the upper limit of minor use for major animal species.

Correct Answer: B
Rationale: The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index) is a list of drugs authorized by the FDA for use in minor species that are too rare or too varied to be the subject of adequate and well-controlled studies in support of drug approval.
10. A pharmacist who receives a prescription for an animal patient must verify that it represents a legitimate order from an appropriately licensed veterinarian. Which of the following may a pharmacist use routinely for verification?

   A. The veterinarian’s Drug Enforcement Agency registration number
   B. The veterinarian’s National Provider Identifier number
   C. The veterinarian’s state veterinary license number
   D. All of these sources may be used for routine verification

Correct Answer: C

Rationale: Veterinarians are not eligible for NPI numbers. The Drug Enforcement Agency strongly opposes the use of DEA registration numbers for any purpose other than the intended (i.e., to provide certification of DEA registration in transactions involving controlled substances).