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Search Policy

Go


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Issues

Issues > Policy > Compounding

AVMA policy

Compounding

(Oversight: COBTA; EB approved 11/00; revised 03/05; 04/09)

Compounding is the manipulation of a drug, other than in accordance with the FDA approved label, to make a different formulation of the drug to meet the needs of a specific patient.

Veterinarians need to be aware that compounding, including formulation in a novel drug delivery system (e.g. transdermal), may impact the absorption and depletion of a drug. This may result in drug concentrations that are above or below the therapeutic range and lead to the development of an adverse drug event, including therapeutic failure. In order to minimize the risk of adverse events associated with compounded drugs, the following actions are recommended:

1. The decision to use a compounded drug should be veterinarian (not pharmacist) driven, based on a veterinarian-client-patient relationship. Whenever possible the veterinarian should make that decision utilizing evidence-based medicine.
2. Compounding must be implemented in compliance with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Compliance Policy Guide 608.400 titled Compounding of Drugs for Use in Animals. Use of compounded drugs in food animals is accompanied by food safety concerns that preclude their use unless information exists to assure avoidance of illegal tissue residues.
3. Use of a compounded drug should be limited to:
 - a. Those drugs for which both safety and efficacy have been demonstrated in the compounded form in the target species;
 - b. Disease conditions for which response to therapy or drug concentration can be monitored; or
 - c. Those individual patients for which no other method or route of drug delivery is practical.
4. Use of a compounded drug should be accompanied by the same precautions followed when using an approved drug, including counseling of the client regarding potential adverse reactions and attention to the potential for unintended human or animal exposure to the drug.

One element in evaluating the quality of a compounding pharmacy is whether the pharmacy is accredited by an independent accreditation body. For example, the Pharmacy Compounding Accreditation Board (PCAB) offers accreditation to compounding pharmacies that meet high quality and practice standards. Further information and a listing of PCAB-accredited pharmacies are available at www.pcab.org. Be aware that independent accreditation is different from association or professional training center memberships that may lack quality assurance programs and inspections.

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