EQUINE VETERINARY COMPOUNDING GUIDELINES

The American Association of Equine Practitioners recognizes the importance of a sound relationship between the equine veterinarian and their pharmacist. Because of the valid role of pharmacy compounding in equine veterinary medicine, the AAEP Drug Compounding Task Force has compiled the following guide to aid the veterinarian in making responsible decisions involving the use of compounded medications.

Veterinarians must understand the differences between the following:

I. FDA Pioneer Drug: A drug that has undergone the scrutiny of blinded controlled studies to demonstrate safety and efficacy in accordance with federally mandated Good Laboratory Procedures (GLP). The active ingredient and product were manufactured under federally mandated Good Manufacturing Practices (GMP) in federally inspected plants. Therapeutic consistency, product quality, accurate drug shelf life and scientifically substantiated labeling are all federally mandated on these products.

II. Generic Drug: A generic drug is bioequivalent to a brand-name drug in dosage form, efficacy, safety, strength, route of administration, quality and intended use. Generic drug labels display an ANADA # or ANDA # signifying FDA approval of a generic animal drug or human drug, respectively. Generic drugs and their active ingredients also must be manufactured under GMP in federally inspected plants.

III. Compounded Drug: Any drug manipulated to produce a dosage form drug (other than that manipulation that is provided for in the directions for use on the labeling of the approved drug product).

The veterinarian must realize that the use of bulk drugs in preparation of compounded medications is, under strict interpretation of the Federal Food Drug and Cosmetic Act, illegal because it results in the production of an unapproved new animal drug. Preparation, sale, distribution, and use of unapproved new animal drugs is in violation of the Act. The preparation of compounded medication from bulk drugs may be permissible in medically necessary situations when there is no approved product available or the needed compounded preparation cannot be made from an FDA-approved drug. Therefore legal compounding can only begin with FDA-approved drugs in compliance with federal extra-label drug use regulations. International AAEP members should adhere to the rules and regulations set forth by the appropriate governmental regulatory bodies that pertain to the country or province where they practice.

Legal compounding requires a valid veterinarian-client-patient relationship. The veterinarian should limit the use of compounded drugs to unique needs in specific patients and limit the use of compounded drugs to those uses for which a physiological response to therapy or systemic drug concentrations can be monitored, or those for which no other method or route of drug delivery is practical. The prescribing veterinarian should remember that compounded drugs have not been evaluated by the FDA approval process for safety, efficacy, stability, potency and

consistency of manufacturing. One should not assume compounded drugs are consistent from one batch to another, contain the stated amount of drug substance or the desired drug substance, or are safe and efficacious for the intended use.

Consider that veterinary compounding pharmacies currently operate in a very dynamic regulatory situation and laws, regulations and guidelines regarding veterinary compounding may vary widely from state to state. Ensure that the pharmacy you use is licensed in the state in which you practice. Proactively seek to educate yourself on regulations concerning compounded medications. Be wary of pharmacies using trademarked brands in the literature to promote "look-alike" compounded products. Be wary of firms that appear to disregard federal, state and local laws, regulations and guidelines concerning disposition of compounded drug products. Be aware that compounding drugs to mimic licensed, FDA-approved drugs is illegal. Assuming there is an FDA-approved product that is in the appropriate dosage form that can be used for the specific patient indication, veterinarians cannot use compounded "look-alikes" as substitutes. The decision to use the products, in lieu of the FDA-approved product, is illegal and potentially jeopardizes the patient and the veterinarian's liability insurance. In the long term, this practice by veterinarians discourages new product development by pharmaceutical companies.

Veterinarians are encouraged to contact their state pharmacy boards concerning the re-selling of compounded products. Some state pharmacy boards reportedly require compounded drugs to be dispensed at cost and some allow regular mark up.

The prescribing veterinarian should consider the legal, ethical and clinical ramifications when making recommendations concerning the use of compounded medications for their patients. They should provide information about the benefits and risks of compounded drugs as it is important to an owner's decisions about therapy. They should understand the concept of "Standard of Care": One acts below the standard of care when he/she fails to exercise the level of care, skill, diligence and treatment that is recognized as the standard of acceptable and prevailing veterinary medicine.

The prescribing veterinarian should understand that his/her professional liability policy may or may not respond to allegations of negligence arising from the use of compounded drugs. Veterinarians insured with the AVMA-PLIT may review comments at www.avmaplit.com.

Do not miss the opportunity to form a relationship with a pharmacist experienced in compounding who, when medical necessity exists for a specific patient, can produce the best possible compounded product and discuss related product expectations.