AAVPT-USP Workshop to Address Issues Associated with Solubility of Veterinary Medicines

Feedback Needed on New USP Standards in Development for Animal Drugs

Rockville, MD (PRWEB) September 25, 2012 -- To help shape the direction of the first public standards specific to the solubility criteria of veterinary medicines, the American Academy of Veterinary Pharmacology and Therapeutics (AAVPT) and the U.S. Pharmacopeial Convention (USP) are co-sponsoring the workshop, Solubility Criteria for Veterinary Products, November 7-8, 2012, in Rockville, Md.

Solubility of a drug substance is critical to ensuring that a drug has the ability to be absorbed. Some substances are poorly soluble, and must be specially formulated to allow the patient to receive the full benefit of the medication. Due to differences in the gastrointestinal tracts of humans and animals, veterinary medicines require a different approach when setting criteria for solubility. In response to this need, USP is initiating plans to develop a new informational general chapter (to be numbered above 1000) titled Solubility Criteria for Veterinary Drugs, which will be included in the United States Pharmacopeia and National Formulary (USP–NF). The purpose of the AAVPT-USP workshop is to seek to establish the framework around which to establish USP solubility assessments and to develop the specific sets of criteria for “fully soluble” drugs for certain veterinary species.

“A drug’s solubility defines the ability of that compound to go into solution and how it will behave in the body,” explained Sanja Modric, Ph.D., D.V.M., president of AAVPT and pharmacologist/Veterinary medical officer in the Office of New Animal Drug Evaluation, U.S. Food and Drug Administration (FDA). “When a drug is taken by mouth, it passes through various parts of the gastrointestinal tract with different physiological and anatomical characteristics that are important in determining the solubility of a drug. Currently, there are no standard solubility criteria used in veterinary drug development. Establishing the criteria that reflect the unique physiologic and anatomic characteristics for each veterinary species will be used to help define factors that can influence in-vivo product dissolution, which in turn will be invaluable for predicting those variables that can influence the behavior of a compound as it traverses the gastrointestinal tract. This is a first step in predicting the clinical performance of an orally administered veterinary medicinal formulation. Given the unique anatomic and physiologic characteristics of various animal species, prediction of in-vivo performance of medications using human solubility criteria (Biopharmaceutics Classification System) may not be correct. By identifying the solubility characteristics of a drug, we can better identify the pivotal questions to ask both during product development and during the regulatory review process for new animal drugs.”

“If a medication is not absorbed appropriately in the body, it will not have its intended effect,” said V. Srinivasan, Ph.D., executive vice president of global science and standards for USP. “The challenge in veterinary medicine is that the current criteria for classifying drug solubility are based on human gastrointestinal physiology, which is not appropriate. Despite this, human medications are sometimes prescribed for animals simply in smaller or larger doses, depending on the size of the animal. These drugs may not work, or could lead to potentially adverse effects in animal patients. This is why establishing this standard is critical.”

Major differences between the human and animal gastrointestinal tracts that are important in terms of drug dissolution include pH in different parts of the tract, temperature, fluid volume and gastrointestinal transit time. “With different characteristics that will impact dissolution, it is important that those parameters be specifically...
identified for veterinary species,” noted Dr. Modric.

Given the many different species in which veterinary drugs may be used, establishing standards for solubility can be far more complex an activity than for drugs used by humans. In developing the new standards, USP will initially focus on oral dosage forms for dogs and cattle, as these are the most common companion animal and food animal veterinary patients, respectively. The ultimate goal is to expand the general chapter to include criteria for other species such as cats, swine and poultry.

The rationale for the new general chapter and how USP may proceed was detailed in a Stimuli article published in Pharmacopeial Forum (PF) 38(4) [July-August 2012], the online vehicle through which USP proposes new and revised standards, and accepts public comment on its proposals. This will form the basis of workshop discussions.

Based on feedback received at the workshop and via PF, USP will develop the initial version of the general chapter. The workshop will feature presentations from FDA, pharmaceutical companies and academia.

Scientists and others involved in the development and manufacturing of veterinary products, those involved in the early stages of development of human use pharmaceutical products, those responsible for considering the types of data that may be needed to support biowaivers for veterinary pharmaceuticals, and anyone who wishes to achieve an appreciation of the interspecies differences in gastrointestinal physiology that can influence product performance would all benefit from the workshop.

The registration fee for association/academia/government and industry participants is $200.

Registration, a full agenda and more information is available at www.usp.org/meetings-courses/workshops/solubility-criteria-veterinary-products. USP will also host a Veterinary Drugs Stakeholder Forum on November 9 in conjunction with the workshop to consider the broader needs of the veterinary medicines’ community.

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Contact Information
Francine Pierson
U.S. Pharmacopeial Convention
http://www.usp.org
301-816-8588

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