ANIMAL HEALTH INSTITUTE

Proposal for a concept paper of VICH Bioequivalence Guideline for the Registration of Animal Health Products

The registration requirements for animal health products vary widely. This variation between countries is apparent in a number of regulatory activities including the type and scope of registration guidelines. Bioequivalence (BE) is an example of a testing requirement where existing guidelines have a high degree of variability between countries. Japan, the EU and the USA have developed BE guidelines to accommodate product registrations that may not require a full data package if there is sufficient evidence that the product adequately meets efficacy, safety and quality requirements for food producing and non-food producing animals. However, there is a potential for inconsistency in the registration requirements to demonstrate bioequivalence in these countries, as well as in Canada and Australia.

Sound BE guidelines must provide assurance of efficacy and safety to a standard that would enable the bioequivalent products to be interchangeable in the market place. To prove that they are interchangeable, the animal health products under evaluation need to have the same bioavailability and effect in the animal. This is on top of the assurance that they have sufficiently similar composition of active and inactive ingredients and route of administration. The need for bioequivalence becomes increasingly important when it relates to the metabolism and excretion of compounds in food animals.

Bioequivalence uses a set of methodologies that were initiated for human drug products more than two decades ago. Over this period of time there has been considerable contribution by regulatory authorities, academia and industry to develop different types of BE studies as well as the statistical models that are applicable to different formulations and products to determine if a candidate product or new formulation is interchangeable with the pioneer product. Consistent guidance is needed to ensure that the right studies are done and that waivers (criteria for which BE studies are not required) are only in place for products or formulations (and routes of administration) where it is clearly unnecessary to run BE studies.

A BE guideline is not available from VICH; therefore, we request the development and creation of a harmonized process to develop a BE guideline to be used in the registration of animal health products. The ultimate goal of this effort is to create guidance that assures that animal health products are safe and efficacious, meet global quality standards, and contribute to the production of a safe global food supply and the well-being of all animals.