Introduction to the bioequivalence theme issue

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This introduction provides an overview of the veterinary bioequivalence initiative and of the foundational goals and objectives of this theme issue.

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Back in 2009, we concluded that veterinary pharmacology was sorely in need of a bioequivalence initiative. Despite the pharmacological and statistical advances that have occurred since the early days of bioequivalence assessments, unresolved issues remain. While many of these issues are common to both human and veterinary medicine, there are also challenges specific to veterinary drug products.

To address this need, we constructed a four-pronged approach for facilitation of these complex issues:

a) The publication of a review article that detailed many of the challenges that need to be addressed through workshops and white papers. This work was published in 2011. (Martinez and Hunter, 2010).

b) The convening of a webinar that could be accessed by an international community and which provided the foundational history, pharmacokinetics, and statistical principles upon which many bioequivalence determinations are based (Marilyn Martinez, Presenter, Rob Hunter Cochair; May, 2011). The goal was to provide the basic information that could then serve as a springboard for further discussion.

c) The convening of the June 2010 AAVPT Bioequivalence Workshop, where participants had an opportunity to discuss complex bioequivalence issues (Martinez and Hunter, Co-chairs). The discussion topics included highly variable drugs, extended-release products, topical (nonsystemically absorbed) formulation, intramammary products, defining the appropriate analyte for the bioequivalence determination, and the bioequivalence assessment for Type A medicated articles. The key points from this workshop discussion have been published (Martinez et al., 2011).

d) The generation of a JVPT theme issue where experts have an opportunity to provide their perspectives on key topics. The objective of these publications is to provide a springboard for further focused discussion. Topics covered in this theme issue are as follows:

- Assessing product bioequivalence for extended-release formulations and drugs with long half-lives
- Should licking behavior be factored into bioequivalence evaluation of topical products
- Pharmacokinetics and pharmacodynamics of stereoisomeric drugs with particular reference to bioequivalence determination
- Establishing bioequivalence of veterinary premixes (Type A medicated articles)
- Estimating product bioequivalence for highly variable veterinary drugs
- Challenges associated with the demonstration of bioequivalence of intramammary products in ruminants
- How do you define equivalence of the API of biomass products?
- Challenges obtaining a biowaiver for topical veterinary dosage forms
- Solubility issues:
  - Establishing solubility criteria for veterinary species
  - Drug solubility classification in the dog
  - Drug solubility classification in the bovine
- Clinical endpoint bioequivalence trials
- Considerations for extrapolating in vivo bioequivalence data across species and routes
- International differences in bioequivalence criteria
In no case should any of these white papers be construed as guidance but rather should be viewed as perspectives that are being conveyed by one group of experts. Certainly, other perspectives may be equally appropriate and should be given consideration.

To this end, the AAVPT has kindly agreed to host a link where both members and nonmembers can post their comments on the published manuscript or on any other issue pertaining to the evaluation of bioequivalence for veterinary dosage forms. Address is Blog: Bioequivalenceforum.wordpress.com

http://bioequivalenceforum.wordpress.com/

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CONFLICTS OF INTEREST

M.N.M. declares no conflicts of interest and R.P.H. is employed by Elanco Animal Health which is a for-profit animal health pharmaceutical company.

REFERENCES
