



AMERICAN VETERINARY MEDICAL ASSOCIATION

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January 14, 2002

Docket No. 01D-0501
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

Re: Docket No. 01D-0501
Draft Guidance on Pharmacovigilance of Veterinary Medicinal Products: Management
of Periodic Summary Update Reports (PSUs)
VICH GL29

Dear Sir or Madam:

The American Veterinary Medical Association wishes to comment on the draft guidance addressing the management of adverse event reports following the use of marketed veterinary medicinal products. The AVMA comments pertain to VICH GL29 (Management of Periodic Summary Reports) and VICH GL30 (Controlled List of Terms).

The AVMA is a professional organization of more than 67,000 veterinarians dedicated to advancing the science and art of veterinary medicine. The Association supports the ongoing work of the International Cooperation on Harmonization of Technical Requirements for Approval of Veterinary Medicinal Products (VICH), and encourages it to strive for a set of harmonized guidelines that have a global perspective. The AVMA recognizes the importance of pharmacovigilance and strongly encourages harmonization of terminology and systems to facilitate collection, analysis, and dissemination of product information back to product users. Credible reporting protects the health of animals and the public.

The AVMA believes that reporting by veterinarians will be enhanced by a convenient pharmacovigilance system that returns clinically relevant information. We strongly encourage creation of a standard analysis system to determine when reports of an unusual number or severity have been received. A simple listing of recorded events is insufficient to provide proper guidance to practicing veterinarians and insufficient to evaluate whether regulatory action should be considered. A system for analysis of these reports should include, at minimum, a system to categorize the physiologic or anatomic systems involved, a controlled dictionary to record the clinical signs observed and diagnoses

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made, and a standardized method of analysis intended to determine when reports of an unusual number or severity have been received. It is imperative that veterinarians receive medically relevant information derived from adverse event reports. The sharing of such information is in the interest of animal and public health and serves as an incentive to veterinarians to make additional appropriate adverse event reports.

VICH GL30 "Controlled List of Terms"

The AVMA supports VICH document GL30 titled "Controlled List of Terms." The AVMA has intense interest in the analysis of adverse event reports, and this action is impossible without a controlled list of terms. While we support recommendation #6 that provides for categories of controlled lists of terms, little meaningful comment is possible until these lists of terms are developed and distributed for review.

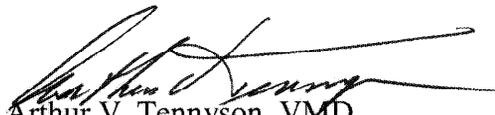
VICH GL29 "Management of Periodic Summary Update Reports"

The AVMA concurs that periodic summary updates (PSU) by manufacturers are highly useful, but we urge for one global PSU for a product, rather than different PSUs for every country or region where the product is approved. Post marketing surveillance systems benefit from information captured from the largest possible population of treated animals. Data from large populations facilitate the filtering of pertinent information and identification of rare events. We urge for a single set of harmonized PSU guidelines that have a global perspective.

The AVMA believes that clinically relevant information generated by PSUs should be shared with veterinarians in a transparent way. VICH GL29 proposes that manufacturers review adverse event reports within a time interval, analyze the reports, and submit the analysis to the government regulatory authority as a periodic summary report. We recognize that labeling updates may be implemented if the manufacturer or regulatory agency believes safety updates are needed. We believe the provision of an analysis or expert review of the submitted PSUs would allow for greater sharing of knowledge and enhance the safe use of medicinal products by veterinarians.

Thank you for this opportunity to comment. The AVMA encourages the ongoing work by the VICH on pharmacovigilance. To heighten communication of this important subject, the AVMA will share these comments with the U.S. Food and Drug Administration, the U.S. Department of Agriculture, the U.S. Environmental Protection Agency, the Animal Health Institute, and the VICH.

Respectfully,


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Assistant Executive Vice President

AVT/ECG



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