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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 00D-1632
Guidance for Industry #117
Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)-VICH GL24

Dear Sir or Madam:

The American Veterinary Medical Association, on behalf of its 65,000 members, wishes to comment on the draft guidance document that describes a system for the management of adverse event reports following the use of marketed veterinary medicinal products.

The objective of the AVMA is to advance the science and art of veterinary medicine, including its relationship to public health, biological science, and agriculture. The Association provides a forum for the discussion of issues of importance to the veterinary profession, and for the development of official positions. The Association is the authorized voice for the profession in presenting its views to government, academia, agriculture, pet owners, the media, and other concerned publics.

The AVMA recognizes the importance of adverse event monitoring and strongly encourages harmonization of terminology and systems to facilitate collection, analysis, and dissemination of product knowledge back to product users. Credible reporting protects the health of animals and the public. To enhance the value of the proposed adverse event monitoring system, the AVMA recommends the following actions:

Broaden scope of covered products

Section III.1 of VICH GL24 defines "Veterinary Medicinal Product (VMP)" as "any medicinal product with approved claim(s) to having a protective, therapeutic or diagnostic effect or to alter physiological functions when administered to or applied to an animal. The term applies to therapeutics, biologicals, diagnostics and modifiers of physiological function." The AVMA believes the document should cover any product that has labeling (approved or otherwise) indicating use on or in animals, to include

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pesticides and nutritional supplements. Furthermore, the document should create a system where adverse events associated with human drugs used in animals are effectively reported.

Create single system to facilitate reporting

It is common in veterinary medicine for adverse events to be associated with more than one product, and in the United States for these products to be regulated by differing regulatory authorities. In these situations, first-hand reporters must report their observations to either multiple marketing authorization holders (companies) or multiple regulatory authorities. This negatively impacts the willingness of concerned people to report. The AVMA believes this document should create a single system to receive adverse event reports from concerned people. The single system would then disseminate reports to the marketing authorization holders (companies) for further submission to the regulatory authorities.

Create standard analysis system

The document lacks a system for analysis of received reports. It is important that the document include a standard analysis system to determine when reports of an unusual number or severity have been received, for a brand of product and across a common active ingredient or antigen. 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 made, and a standardized method of analysis intended to determine when reports of an unusual number or severity have been received.

Prevent inappropriate clustering of adverse events in single report

Section III.2 of VICH GL24 defines "Adverse Event" as "any observation in animals, whether or not considered to be product-related, that is unfavorable and unintended and that occurs after any use of VMP (off-label and on-label uses). Included are events related to a suspected lack of expected efficacy or noxious reactions in humans after being exposed to VMP(s)." The AVMA strongly supports the components of this definition.

An "Adverse Event Report" is "a direct communication from an identifiable first-hand reporter that includes at least the following information: an identifiable reporter, and identifiable animal(s) or human(s), an identifiable VMP, one or more adverse events." The AVMA believes the definition of the adverse event report should be clarified to prevent a single direct communication of separate concerns from being recorded as a single adverse event report. The AVMA is concerned that under the proposed definition,

the communication of events involving dissimilar animals treated with dissimilar products and exhibiting dissimilar symptoms could inappropriately be lumped into a single adverse event report following a single, direct communication. This would confound the collection, analysis, and sharing of medically relevant data. This document should clearly provide for subdivision of the complex communication into multiple adverse event reports.

Share information with the VMP user

Section IV.1 of VICH GL24 illustrates the information flow of the pharmacovigilance system, i.e. it demonstrates how a VMP user can make an adverse event report directly to the regulatory authority, or indirectly through the marketing authorization holder. The described system lacks a means to inform VMP users of 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 make future adverse event reports. The document should create a mechanism to disclose to interested parties (veterinarians and animal owners) medically relevant information that can be determined from the number or severity of the received reports.

Facilitate communication

To heighten communication on this important subject, the AVMA is filing 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 International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH). Thank you for this opportunity to comment.

Respectfully,

Bruce W. Little

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BWL/ECG