AVMA American Veterinary Medical Association

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

Re: Docket No. 2007N-0114, Electronic Distribution of Prescribing Information for Prescription Drug Products; Reopening of Comment Period

Dear Sir or Madam:

The American Veterinary Medical Association (AVMA) was established in 1863 and is the largest veterinary medical association in the world. As a not-for-profit association established to advance the science and art of veterinary medicine, AVMA is the recognized national voice for the veterinary profession. The association's more than 75,000 members represent approximately 85% of U.S. veterinarians, all of whom are involved in a myriad of veterinary medical practice including private, corporate, academic, industrial, governmental, military, and public health services.

The AVMA is appreciative that FDA questioned animal drug needs and reopened the comment period on a previously human health care-centered proposal on the distribution of electronic prescribing information. The FDA seeks to garner views on the feasibility of establishing an efficient process for industry to electronically distribute prescribing information contained in the package insert to dispensers.

Overall, the provision of electronically available, searchable label information including prescribing information is beneficial to veterinary medicine because it increases accessibility to the most current drug information. However, given that the FDA Center for Veterinary Medicine is challenged by insufficient resources, advancement of the proposal should not be allowed to negatively impact the review and approval of needed new animal drugs.

In the background of the proposal, FDA identified that in human healthcare settings the package insert is often not readily accessible by the prescribing physician and consequently electronic information could be helpful. However, in veterinary medicine, veterinarians are often the prescribers and dispensers of animal drugs. Hence, the paper package insert is readily accessible to practicing veterinarians. The provision of the paper drug insert currently remains critically important even if electronic information is supplemented.

If animal drug labels and prescribing information are displayed electronically, they should appear on a web-based, publicly available, centralized site via a searchable database. We contend that the FDA CVM web site is the ideal location for a searchable database of up-to-date animal drug labels. Veterinarians provide medical care for a wide range of

terrestrial and aquatic animal species. Each has numerous medical conditions requiring unique drugs, dosages, and dosage forms. These medical conditions cause animal pain and suffering. Since an insufficient number of FDA approved drugs exist to adequately treat all these animals and their conditions, veterinarians may legally prescribe drugs in fashions other than described on drug labels. Such extralabel drug use must occur within a veterinarian-client-patient relationship in order to relieve animal pain and suffering and be conducted in compliance with strict regulations designed to ensure protection of animal and public health. Since animal owners viewing publicly available, searchable, web-based prescribing information might not be aware of this fact, it is imperative that a disclaimer appear on each page. The disclaimer should explain the need for extralabel drug use in veterinary medicine and redirect any animal owner with questions to their veterinarian.

In addition to these overarching comments, the AVMA has furnished answers to the specific questions posed by FDA in the October 22, 2007 reopening of the comment period:

A. General

(1) Currently, who uses and benefits from the prescribing information?

Veterinarians primarily benefit from the prescribing information, using the information to prescribe drugs to patients within a veterinarian-client-patient relationship. Clients (animal owners) also benefit if the information has been featured in a client information sheet or if the label is currently available via the Internet. Researchers and veterinary teaching institutions also benefit from the information. Additionally, product labels are assembled into drug compendia.

(2) How can electronic distribution and access of the prescribing information be accomplished?

Firstly, the creation of electronically available prescribing information should not supplant the paper package inserts which currently accompany animal drugs.

Electronic prescribing information may be even more up to date and consequently is of additional value. Ready access is important; hence the posting of prescribing information on a web site is beneficial. The prescribing information could be displayed via individual drug sponsor web sites or via the FDA web site, with the FDA site being superior for reasons of centralization, searchability, and prompt access to approved label changes.

Additionally, a voluntary, free, email subscription service could distribute label updates. If this service were pursued, it would be helpful if veterinarians could choose parameters that would customize the information they receive.

However, we wish to share that the North American Compendiums, Inc, according to company information, offers an annual web subscription to over 4,950 pharmaceutical, biological, diagnostic, feed additive and parasiticide product monographs. Users of the Compendium of Veterinary Products may view or print full label text of all products. The resource is updated regularly. Also, the AVMA subscribes to the electronic Compendium and makes the resource available free to AVMA members via the AVMA web site at www.avma.org.

(3) Would electronic distribution and access of the prescribing information improve the public health?

Again, the AVMA does not recommend supplanting the paper package inserts with electronically available prescribing information as we believe that would negatively impact animal and public health.

Additional electronic access could improve animal and public health. It could heighten awareness of drug information and provide veterinarians with the most up to date information. In turn, this could potentially reduce drug adverse effects and drug residues.

The electronic provision of prescribing information would be very useful from a teaching perspective. Having an electronic on-line form of the package insert accessible 24/7 would facilitate teaching veterinary students in clinic settings and non-clinic settings. Compendia (books and CDs) of product labels do exist, but faculty may not have the resource or their version may not be the most up to date.

Due to the ready accessibility of an electronic format, veterinary students would become more familiar with accessing and using this information source. Students would see such things as the legal restrictions that appear on individual drug products and this would complement their study of pharmacology and medicine. Eventually the information could be used to enhance teaching of not only veterinary students but practitioners.

The provision of legitimate drug information could educate consumers beyond some of the drug misinformation that can be found on the web and in that way improve animal and public health.

(4) Would electronic distribution and access of prescribing information improve prescribing habits? If so, how?

Electronic distribution has the potential to improve prescribing in the following ways: electronic information is the most current, electronic information could be available if the paper insert was not available, and most importantly, *searchable (by keyword)* electronic information could allow veterinarian to seek out pertinent information, thereby improving their case management.

(5) How might we ensure that changes in the distribution and access of the prescribing information will not negatively affect current users?

It is imperative that the electronic information not supplant the paper package inserts.

It is also imperative that a disclaimer addressing the need for veterinary supervision and the validity of extralabel drug use accompany the publicly available electronic prescribing information.

The disclaimer should encourage animal owners to consult their veterinarian regarding medical treatment of animals. Attending veterinarians have a veterinarian-client-patient relationship which makes them knowledgeable of the specific medical history of individual patients. This knowledge causes veterinarians to customize drug recommendations when indicated.

The disclaimer should also identify that veterinarians treat animals with drugs in ways other than displayed on the approved label because an insufficient number of drugs are approved to treat the myriad conditions of all animal species. Extralabel drug use is legal and may be in the best interest of animal welfare and the public health when conducted according to federal regulations. It would be very easy for an animal owner to unnecessarily become concerned that their dog was treated with

a "cat drug" or their bird was treated at a dose very different than that labeled for dogs. Therefore, disclaiming language must encourage animal owners to discuss their questions with their animal's veterinarian.

(6) Would an increase in electronic access to prescribing information affect prescribers, pharmacists, clients and patients? If so, how?

Electronic access heightens the availability of information and consequently, through increased awareness, could benefit the prescribing of drugs by veterinarians and the use of drugs by owners/patients. Pharmacists could benefit from the information, but again, the information is available to pharmacists via the paper package insert.

(7) Are there any issues particular to the prescribing information for animal drugs that are dissimilar or distinct from those associated with human drugs and that might affect the feasibility of electronic distribution of labeling?

Yes. Unlike the human health care model, the majority of animal drugs are prescribed and dispensed by veterinarians, not pharmacists. Thus, the veterinarian has the paper drug insert available to him/her when prescribing or dispensing the drug.

Unlike physicians, veterinarians care for numerous animal species, including pets, livestock, poultry, horses, zoo animals, wildlife and others. Since FDA approved drugs do not exist for all the animal species and all the conditions within a species, veterinarians must use drugs in an extralabel manner. They do so by applying scientific medical information to relieve animal suffering and complying with federal FDA regulations designed to protect the public.

B. Logistics

(1) Generally and without focusing on vendor-specific methods, how can electronic distribution of prescribing information be accomplished?

The generation of searchable, electronic prescribing information starts with the drug sponsor. Firms would need to use a standardized template and harmonized software in order to produce similarly arranged labels for FDA approval. In order for this to happen, after consulting industry, FDA would need to provide clear guidance on the formatting and submission parameters of the electronic prescribing information. Assembled information should be searchable, publicly available, and updated easily and promptly. Information should redirect animal owners with questions to their veterinarians and inform the public of the concept of extralabel drug use.

(2) What are the costs associated with the successful implementation of electronic distribution and access to prescribing information, including startup and maintenance expenses? Please breakdown costs per healthcare sector.

We recommend the FDA consult the animal drug industry for costs involved in assimilating and submitting the prescribing information for display and search on the FDA web site.

(3) Is the technology and infrastructure currently available to accomplish electronic distribution and access? If so, what is available? If not, what is needed?

The technology exists for FDA to display a centralized, searchable database of FDA approved drug product labels.

The generation of searchable, electronic prescribing information starts with the drug sponsor. Firms would need to use a standardized template and harmonized software in order to produce similarly arranged labels. In order for this to happen, after consulting industry, FDA would need to provide clear guidance on the formatting and submission parameters of the electronic prescribing information. Assembled information should be searchable, publicly available, and updated easily and promptly. Information should redirect animal owners with questions to their veterinarians and inform the public of the concept of extralabel drug use.

(4) What are other potential barriers to accomplishing the electronic prescribing information?

Several barriers exist in regards to accomplishment of implementing an electronic prescribing information database. The barriers impact the animal drug industry and the FDA. First, there is a need for adequate human capital in development and implementation of standardized, electronic files with labeling information, which would then be held in a centralized, searchable database. The database must be updated as product label changes are approved by FDA. Finally, an important consideration is that appropriate resources for performing these roles must be identified.

(5) How can we ensure that electronic prescribing information is accessible to those who need the information?

It is paramount that maintenance of labeling information be pursued in paper form as well as in electronic form, to ensure ready veterinary access to such information. In addition to the need for paper labeling, access to web-based labeling should be free and readily available on the FDA site. Web-based labeling information should also be easily searchable using search engines on the Internet.

(6) How do we meet the needs of those who do not have electronic capability?

Continuation of labeling in paper form will ensure prescriber access to such information, particularly for those without electronic capability. Proper veterinarian-client-patient relationships must be encouraged to facilitate sharing of drug information from veterinarians to animal owners.

(7) In case of emergency or when a computer system is down, what might be the backup?

If paper labeling is continued, no backup will be required given an emergency shutdown of the electronic labeling system. Promotion of information sharing within a veterinarian-client-patient relationship will ensure continuity of information under emergency circumstances.

(8) How should electronically disseminated prescribing information be regularly updated and remain current?

Labeling changes that are approved by the FDA should be updated in "real time" on the FDA electronic prescribing information, to ensure that accurate information is relayed to the public. Whether the website is government-owned or contracted, the website coordinator must be provided with, and must post, new labeling information automatically. Updates that are posted to the centralized site should also be shared with stakeholders, in order for the update notifications to be shared promptly with a wider audience of professionals and their clients.

(9) What are the roles for the involved parties manufacturers, third-parties, health professionals, FDA, and consumers)?

The first step is for the FDA to develop a universal electronic labeling process with which manufacturers will comply. Success of an electronic prescribing database not only includes development and implementation of the site, but in addition, the public must be knowledgeable on accessibility to such a system, for the public to gain such product information. Subscriber services could help. The electronic labeling information process should be iterative, such that a subgroup of stakeholders should be included in a verification or reassessment process to assure efficiency and accuracy. The FDA should be the central resource for labeling information collection and sharing.

(10) Should all products have electronic prescribing information or are there some products or classes of products that should continue to have paper prescribing information accompany the product?

All drug products should continue to be provided to the public in paper form.

(11) If electronic prescribing information were to be used instead of paper inserts, then how should electronic prescribing information be implemented? Should electronic prescribing information be phased in? If so, over what time period? Which products should use electronic prescribing information first?

The AVMA opposes the sole usage of electronic prescribing information and the discontinuation of paper prescribing information. Animal drug prescribing information must be provided in paper form.

The AVMA appreciates the opportunity to share its thoughts on the matter of electronic distribution of prescribing information for prescription animal drug products.

Respectfully,

for W. Ron DeHaven, DVM, MBA
Executive Director

WRD/ECG