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American Pharmacists Association

Improving medication use. Advancing patient care.

July 25, 2005

Division of Drug Information (HFD-240)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Docket No. 2005D-0169

Dear Sir/Madam:

Thank you for the opportunity to comment on the draft guidance document "Useful Written Consumer Medication Information (CMI)." The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 53,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

The quality of written information distributed to consumers is of obvious interest to the Association and our members. Pharmacists are committed to improving patient health through the appropriate use of both prescription and over-the-counter medications. To ensure the safe and effective use of medications, pharmacists help patients manage their medications with patient education activities including providing written information and oral consultation. Written consumer medication information (CMI) is one method pharmacists use to provide their patients with information on the proper use of their medications, possible side effects, adverse reactions, and general information.

Recognizing the importance of CMI as an adjunct to oral counseling, APhA participated in the 1996 Steering Committee that developed the Action Plan for the Provision of Useful Prescription Medicine Information. The Action Plan's goal was to improve the quality and availability of useful information that is provided to consumers.¹ The Action Plan and the included "Keystone" criteria were successful in serving as a step towards improving the appropriate use of medications. The private sector and the pharmacy profession have made great improvements in providing patients with better information about their drug therapy, including written CMI, since the development of the Action Plan. In 1992, less than 25% of patients received written patient information other than the prescription label and associated cautionary or advisory stickers. By 1995 that number had increased to more than 55%. The most impressive increase was announced by the Food and Drug Administration (FDA) in June 2002 when the

¹ Action Plan for the Provision of Useful Prescription Medicine Information. December 1996: pg. 5.

Agency released the results of its study that found that almost 90% of patients received CMI.² It is clear that pharmacy has taken the charge of distributing CMI very seriously and has achieved a significant increase in the distribution of CMI since Public Law 104-180 was passed in 1996.

APhA and the pharmacy community, however, recognize the need for improvement in the quality of CMI distributed. The results of the 2002 study found that the quality of information distributed varied and did not meet the criteria evaluating “usefulness” a majority of the time. In an effort to facilitate the improvement of CMI, APhA joined the National Council on Patient Information and Education (NCPPIE)-coordinated CMI Initiative. For the past three years, APhA has been an active participant in the CMI Initiative and has worked to educate CMI developers and vendors on the need to improve the quality of CMI.

The Association appreciates the Agency’s release of the draft guidance document on useful CMI. The Agency developed the guidance in response to the FDA Drug Safety and Risk Management Advisory Committee’s recommendation that the FDA take a more active role in advising and encouraging the private sector to meet the 2006 target goal of 95% distribution of quality CMI.³ APhA supported the Advisory Committee’s 2003 recommendation – APhA had requested that the FDA provide guidance on quality CMI in 2002 and again in 2003. We requested guidance on the Agency’s general expectations for “quality CMI”, how the quality of CMI will be measured, and how the 2006 assessment will be conducted.

The draft guidance recently released by the Agency does provide some insight into these areas, and the guidance will likely serve as a catalyst to further advance private sector efforts to improve the quality of CMI in order to meet the 2006 goals. However, we are dismayed with the timing of the guidance’s release. The Action Plan was released in December 1996, was accepted by the Secretary of the Department of Health & Human Services in January 1997, and was the topic of discussion at FDA meetings to discuss the private sector’s progress in 2002 and 2003. However, several years passed before the guidance was released. Had the guidance been issued sooner, the private sector would have had more time to incorporate the guidance into their efforts and respond to the Agency’s recommendations. With the release of the guidance so close to the 2006 deadline, it will be very difficult for the private sector to meet the targeted deadline.

APhA offers the following comments on the draft guidance as published in the May 26, 2005 *Federal Register* Notice.

III. Applying the Action Plan Criteria for CMI

A. General Considerations

Lines 144-147: The draft guidance states that information will be considered useful when the most recent FDA-approved professional labeling or package insert (PI) “serves as the source document for the information contained in the CMI.” It is not clear if the Agency intends the professional labeling or PI to be the only source of information contained in the CMI, or if the professional labeling or PI can be supplemented by other sources of material. APhA recommends that the Agency clarify that other sources of information can be included in CMI. Information from widely-accepted research studies and information on off-label indications should be eligible for inclusion in CMI.

² Food and Drug Administration Talk Paper. “Success of Private Sector Patient Information with Prescription Medicines Assessed.” June 18, 2002.

³ 70 FR at 30469.

Lines 166-169: The guidance document includes the eight criteria that were used in the FDA-sponsored University of Wisconsin-Madison's 2001 evaluation of CMI. The document states that FDA believes the list provides the factors for determining if CMI is useful. The document continues to state that information that "substantially" satisfies each of the criterion will be deemed useful; however, the Agency fails to define the term substantially. When CMI is evaluated against the criteria what rating will indicate a "passing grade"? For example, must CMI be rated a four or five on a five-point scale (such as the scale utilized in the University of Wisconsin-Madison study) to "substantially" meet the criteria? Without a clear understanding of what success will look like in 2006, success will be challenging.

B. Specific Recommendations for Each Action Plan Criterion

Lines 185-187: The draft guidance states that unapproved indications can be included in CMI, but only if the CMI is customized for the individual patient. APhA appreciates the Agency's acknowledgement that information on off-label uses will be significant to a patient who has been prescribed the medication for an indication not currently approved by the Agency. However, restricting the inclusion of off-label uses to CMI that has been customized for a particular patient may present a barrier. Pharmacists may not know why a patient has been prescribed a particular medication – although including the intended use on prescriptions has been recommended as one method to decrease medication errors and improve appropriate medication use, prescribers often fail to provide it. Until prescribers are required to include the intended use on prescriptions, the FDA should allow the inclusion of common off-label uses on CMI so that patients who need the off-label information will have it.

Lines 219-222: Under the guidance, CMI would be required to include the following information: name, strength, dosage, and brief directions for use. APhA requests that the Agency clarify "brief directions for use." We assume that the Agency intends for the directions to include general information such as the route of administration (i.e. take orally by mouth), but not specific directions such as take one tablet orally twice a day. Because a medication will be used differently by each patient, it will be impossible to include specific directions for use in CMI. Patient-specific directions should continue to be included on the medication's package rather than through the CMI.

Lines 263-267: APhA is concerned that the guidance document recommends that CMI include all information on what patients should avoid while taking the medication, including drugs to avoid because of drug-drug interactions. While we agree that it is important for patients to be informed of other medications that may interact with their prescription, it may be impossible or unnecessary to list them all. For example, some medications have so many possible interactions that the sheer quantity may make it difficult to include them all in the CMI. It also may not be necessary to include all precautions because some are so rare that the chance of a patient experiencing an interaction is too small to warrant inclusion in the CMI. The Agency should clarify that common precautions must be included, and that less common precautions may be included at the provider's discretion.

Lines 284-287: The guidance suggests that medications that may carry risks when used during pregnancy, labor, or breast-feeding contain information on those risks. If the risks are unknown, the FDA suggests the following language, "Talk to your doctor if you are pregnant or breast-feeding. It is not known if the medicine will affect your baby." APhA supports the inclusion of such language as pregnant or breast-feeding mothers should generally check with a health care professional before using a medication. However, we recommend that the Agency revise the statement to direct the patient to "talk to your doctor or pharmacist." Pharmacists are the most accessible health care providers and the

medication experts on the health care team. Pharmacists can advise pregnant women and breast-feeding mothers of any potential risks with a medication. By including pharmacists in the CMI, it will increase the chance that patients will consult a health care professional before using the medication.

Lines 296-299: The draft guidance recommends that in addition to the most serious potential adverse reactions that appear in the *Warnings* or *Precautions* section of the PI, the guidance should also include a list of at least five to nine of the most common adverse reactions. APhA appreciates the Agency's specific direction in this section of the guidance document. By providing a number of adverse reactions that should be included (five to nine of the most common), the Agency has provided the developers of CMI with specific information they can use when working to improve the quality of their CMI. We also appreciate the FDA's recognition that it may be difficult to include all of a medication's potential adverse reactions. APhA recommends that the Agency consider adding specific suggestions for CMI developers on other components of the CMI such as contraindications and interactions (for example, the severity of interactions that need to be listed).

Line 312: The Agency recommends that the name of the CMI's publisher be included in the CMI. It is unclear why the publisher's name will be of relevance to the patient. We request that the Agency remove this requirement. Information that does not relate to the medication or the patient's use of the medication should not be included in CMI. Including such general, and irrelevant, information in the CMI, only serves to clutter and lengthen the CMI – two factors that decrease the likelihood that patients will actually read the CMI.

Lines 320-327: The guidance calls for the addition of a general statement encouraging patients to discuss their medication with a health care professional, seek additional information about the medication, and obtain answers to their questions about the medication. APhA strongly supports this recommendation – directing patients to speak with a learned intermediary is one method to encourage the safe and appropriate use of medications. However, APhA urges the Agency to revise the suggested statement, “This leaflet summarizes the most important information about <insert medication name>. If you would like more information, talk with your doctor;” to talk “with your doctor or pharmacist”. As described in our comments on lines 284-287, pharmacists are the recognized medication expert and the most accessible health care provider and therefore should be included as a source of information.

Lines 332-334: Throughout the guidance document the Agency emphasizes that information contained in CMI should be consistent with or derived from the PI. APhA agrees that manufacturer-developed and FDA-approved information should be the main source of CMI information. The guidance also notes that CMI can depart from the PI when it is customized for individual patients. APhA is pleased that the FDA has recognized the need for customization in CMI. Patient information must be tailored to each patient and used to supplement information communicated by the pharmacist and other health care professionals. Pharmacists must be able to customize information specific to the particular drug and the particular patient.

Lines 352-385: The draft guidance contains explicit recommendations on the formatting and appearance of CMI. The recommendations include the size of the text, the type of font, the space between letters and lines of text, methods to highlight and draw attention to certain information, etc. APhA understands the need for CMI to be written on a level appropriate for the general public and presented in a clean and legible format. However, it may be difficult to include all of the information recommended in the draft guidance document in CMI and meet the formatting recommendations. CMI is usually generated by a

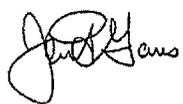
pharmacy's computer system. Any change to the length, content, or format of written CMI will likely require a change in the pharmacy's computer system and/or hardware such as printers. Such changes may affect a pharmacy's infrastructure and normal operating processes. For example, many pharmacies currently operate a system that only supports CMI of a one-page length. And for the small – and decreasing number – of pharmacies without a computer system, the problem is even more fundamental. To overcome this barrier, representatives from pharmacy and data vendors must work together to ensure that CMI that meets this guidance can be supported by systems currently in pharmacies.

As the Agency considers the comments it receives on the draft guidance and develops its final guidance, APhA recommends that the FDA consider additional materials that will help the private sector continue to move in the right direction. We recommend that the Agency consider including examples of quality CMI such as those included in Appendix G of the Action Plan. The Agency should also provide more information on how the 2006 assessment will be conducted such as what dispensing sites will be included. APhA recommends that the study be expanded to include all settings that provide medication – community, mail service, managed care, internet, and outpatient hospital pharmacies, long-term care facilities, physician offices, and others. Limiting the study to community pharmacies creates the impression that this sector of the health care community is solely responsible for ensuring the provision of useful information to patients – which is clearly not the case.

The Association appreciates the Agency's decision to work with the pharmacy community and the private sector developers to improve the quality of written CMI. We strongly support the FDA's efforts to improve the appropriate use of medication through patient education activities and we are committed to improving educational efforts of pharmacists and their patients. We are interested in working with the FDA as a partner to ensure that patients receive and use the medication information they need – through oral communications with their pharmacist and prescriber – and through the distribution of quality written CMI.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan K. Bishop, Associate Director, Regulatory Affairs, at 202-429-7538 or SBishop@APhAnet.org, or Susan C. Winckler, Vice President, Policy & Communications and Staff Counsel, at 202-429-7533 or SWinckler@APhAnet.org, with any questions.

Sincerely,



John A. Gans, PharmD
Executive Vice President

cc: Susan C. Winckler, RPh, Esq, Vice President, Policy & Communications and Staff Counsel
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