



February 14, 2003

Dr. Claudia Okeke
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852

RE: Revisions to Proposed General Chapter <1265>, *Pharmacopeial Forum*, Written Prescription Drug Information — Guidelines

Dear Dr. Okeke:

I am writing on behalf of the Pharmaceutical Printed Literature Association (PPLA) with regard to USP's request for comments on revisions to proposed General Chapter <1265>, *Written Prescription Drug Information – Guidelines*. Specifically, the PPLA endorses and applauds USP for taking a proactive approach toward a standard that clarifies and improves written prescription drug information for consumers. Since its inception, PPLA has worked diligently to advance its members' position that written drug information is fundamental to an informed, and thereby better protected, medication consumer base.

USP's initiative to improve and clarify prescription drug information empowers those who rely on Rx medications but, lacking advanced degrees in pharmaceutical sciences, may be unable to decipher crucial information about drug products. The USP recommendations represent a new and critical level of protection against potential adverse effects from the very medications consumers need and trust.

PPLA Background

The PPLA is a not-for-profit association chartered in 2001 to serve as the voice of pharmaceutical printed package information manufacturers, and provide a forum for members to promote and improve delivery of information for protection of patients. To do so, the PPLA works to support health care professionals, and advocates use of printed literature to legislative, regulatory and other decision-making bodies. Additionally, PPLA acts as an educational resource for strategic partners and the public.

As a relatively new association, PPLA's core initial goal is to help the pharmaceutical industry help consumers benefit from existing and new drugs - a return on investment of billions of research and development dollars - by taking those drugs as prescribed, with instructions, precautions and risk data clearly understood. The desired outcome is a win-win-win situation: consumers enjoy better health, the healthcare system operates at lower total cost, and drug manufacturers report higher sales.

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As a result of the evolution of the Food, Drug and Cosmetic Act of 1938, the carefully regulated content of printed literature provided by pharmaceutical manufacturers has been the primary means for communicating to physicians and pharmacists how and when patients should take drugs correctly, and how to avoid mistakes. But despite this history, there is still no guarantee that patients will get accurate information directly from the manufacturer each time they have a prescription filled. And today, consumers are playing an increasing role in identifying medications and specifically requesting that their doctors write prescriptions for one drug instead of another.

This trend has already caused liability concerns in at least one state, New Jersey, where the state's supreme court has abolished the "learned intermediary" defense for pharmaceutical manufacturers who engage in DTC advertising. One of the functions of the PPLA, therefore, is to offer input to FDA, Congress, and other governmental agencies on how to provide reliable, detailed, and controlled information for healthcare professionals and consumers in the age of direct-to-consumer and Internet information. Working together, PPLA members are confident that we will be able to achieve each of these goals.

PPLA Concerns

In the section subtitled "Accessibility Guidelines," the recommendations call for producing prescription drug leaflets in English and Spanish. PPLA notes that standards already in place in the European Union mandate that leaflets also be available in five languages: German, French, Italian, English and Spanish. Moreover, the norm in printed instructional information in the United States, which is embraced by American consumers, includes French with English and Spanish in instructions. The position of the PPLA is that written prescription information must be translated from English into Spanish and French to be consistent with wider consumer-product labeling norms and to be inclusive of wider consumer populations.

Conclusions

The goals of USP and PPLA clearly are synergistic. PPLA therefore would welcome the opportunity to support USP's written prescription drug initiatives more directly. It is PPLA's wish to be considered a resource to USP, and to be included in committees or task forces that seek to advance our common objectives.

Sincerely,

Peter G. Mayberry
Executive Director