



American Pharmacists Association
Improving medication use. Advancing patient care.

January 4, 2005

Cathy Groupe
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5630 Fishers Lane, Room 1093
Rockville, Maryland 20857

Dear Ms. Groupe:

The American Pharmacists Association (APhA), the national professional society of pharmacists, is interested in presenting at the January 13th-14th Joint Meeting of the Non-Prescription Drugs Advisory Committee and the Metabolic Drugs Advisory Committee. Jan Engle, PharmD, Former President of APhA, will present on APhA's behalf.

We request approximately 5 minutes to present information related to the pharmacist's perspective on the use of over-the-counter (OTC) statin drugs. Specifically, APhA's comments will focus on the pharmacy profession's approach to OTCs distributed only in outlets with a pharmacy. This "Pharmacy Care OTC" approach would not only provide patients with access to the medications without a prescription, but would also ensure that patients have access to a consultation with a pharmacist if they so choose. The attached draft report, which was developed by a task force convened by APhA, provides additional information on "Pharmacy Care OTCs". A revised report will be issued in early January and will be presented by Dr. Engle at the meeting.

Correspondence on this issue should be directed to Susan Bishop, APhA's Associate Director of Regulatory Affairs, at the American Pharmacists Association, 2215 Constitution Avenue, NW, Washington, DC 20037.

Please contact Susan Bishop with any questions about this request. She may be reached at 202-429-7538 or sbishop@aphanet.org.

Thank you for your time and consideration.

Sincerely,

John A. Gans, PharmD
Executive Vice President



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APhA Pharmacy Care OTC Task Force Report of Opening Meeting

The movement of products from prescription to over-the-counter (OTC) status is a reality of our health care environment, a reality intended to increase consumer access to safe and effective medications. In the past few years, a non-sedating antihistamine, a full strength H₂ receptor antagonist, and a proton-pump inhibitor have made this transition to OTC status. With the support of consumers, manufacturers, and regulators, all indications point to even more products making the move — including products for asymptomatic conditions like osteoporosis or high cholesterol. As a component of these discussions, the American Pharmacists Association (APhA) is exploring the concept of enhancing the role of pharmacy through increased encouragement of consumer-pharmacist interaction and distributing some OTCs exclusively in outlets with a pharmacy, creating a new category of these products: Pharmacy Care OTCs. Consumers seeking input from the medication expert on the health care team—their pharmacist—would have ready access to that advice.

In August 2004, the American Pharmacists Association convened a Task Force to discuss these issues and develop recommendations for incorporating additional OTC products into pharmacy practice and implementing the Pharmacy Care OTC category. Task Force members (identified in Attachment A) include representatives from independent and chain community pharmacy practice, managed care, academia, and pharmacy management. Pharmacy Care OTCs are a sub-category of non-prescription medicines available only in pharmacies to facilitate interaction between consumers and pharmacists. These medications may be used for chronic, asymptomatic conditions or other conditions where consumers would benefit from additional interaction with their pharmacist. Pharmacy Care OTCs can provide significant benefit to consumers, who may also benefit from the expertise of pharmacists to help them effectively utilize these products. This category presents an opportunity for pharmacists to play a greater role in consumer medication use, and help deliver the public health benefits expected from expanded consumer access to important medications.

Task Force Mission Defining a “Pharmacy Care OTC” Category

Moving products from prescription to OTC status affects pharmacy practice in many ways, including pharmacists’ efforts to coordinate and monitor medication use, the need to prepare pharmacy personnel for the product shift, and the financial impact of the shift. OTC products designated as Pharmacy Care OTCs will require additional thought and planning on the part of the manufacturer, pharmacists and facility staff. The Task Force mission included providing advice to the profession of pharmacy and other stakeholders on helping consumers make the best use of Pharmacy Care OTC medications.

Objective

The task force discussed this new category and developed guiding principles for implementation of the category. The task force made recommendations on issues such as:

- ✓ Necessary training and education of pharmacy personnel and facility staff to support pharmacist/consumer interaction, including providing consumer education materials.
- ✓ Considerations in selling such products, including access to pharmacy personnel, product placement, and support services such as in-pharmacy point-of-care testing.

The following recommendations are issued for comment. Please provide your comments to APhA at TaskForce@APhAnet.org by December 1st. The Task Force will consider your comments and issue a final report in early 2005.

Recommendations

The APhA Task Force on Pharmacy Care OTCs recommends manufacturers, pharmacists and pharmacies consider the following when choosing to provide Pharmacy Care OTCs. Task Force recommendations are meant to be flexible, allowing for individualization within a specific pharmacy practice setting.

Management of the Pharmacy Care OTC Category

- **Products in this category should demonstrate a proven health benefit.**
- **Guidelines for patient identification and risk assessment should be available.**

Supporting Consumer/Pharmacist Interaction

- **Product placement and promotion should support direct interaction with the pharmacist.**
Pharmacy Care OTCs present an opportunity for consumers to easily access important medicines and ask questions of their pharmacist. To facilitate that interaction, consumers must have direct access to pharmacists, access that is supported by product placement and promotion. Pharmacies should establish workflow and staffing patterns to support the interaction, as well as business models that support providing these services. Marketing approaches (e.g., print ads, shelf-talkers, etc.) should direct consumers with questions to their pharmacist. Methods to provide access to counseling and education when the pharmacist is not present should be developed, including alternatives to face to face approaches, such as use of the telephone and the internet. Appointment systems should be considered if the product requires lengthy consultations or if the pharmacy environment is not always conducive to consumer/pharmacist interaction.
- **Facility staff should be educated about Pharmacy Care OTCs.**
When the pharmacy is one component of the facility (e.g., a grocery store or mass merchandiser), appropriate non-pharmacy staff should be educated generally about Pharmacy Care OTCs, including information about the availability of pharmacists for consultation and where such products are located.
- **Education about Pharmacy Care OTCs and specific products included in the category should be provided through the media, marketing, pharmacists, and pharmacies.**

Scope of Consumer/Pharmacist Interaction

- **Pharmacy staff should be educated and trained about the product and the appropriate population for product use.**
Pharmacists are responsible for responding to consumer inquiries. Pharmacists, student pharmacists, technicians and others working in the pharmacy should be educated about the product and condition being treated, risks, appropriate monitoring, and follow-up, as well as procedures for responding to consumer inquiries.
- **Pharmacist/consumer interaction includes:**
 - **identifying consumers who should use the medication,**
 - **identifying consumers who should be referred to another health care professional, and**
 - **providing appropriate support.**Consumer/pharmacist discussion may encompass screening activities as well as consultation at the point of purchase. Recommendations for consumer use should be consistent with product labeling and clinical guidelines, where available. For consumers using Pharmacy Care OTCs for chronic

conditions, the consumer/pharmacist interaction should include ongoing support, such as compliance monitoring and monitoring for therapeutic endpoints.

Other Services

- **Support services should be available or referral information provided.**
Some Pharmacy Care OTCs may require point-of-care testing to identify appropriate consumers and monitor consumer progress.
- **Documentation of Pharmacy Care OTCs in the patient profile is encouraged.**
Pharmacy Care OTCs facilitate documentation of product use, supporting drug/drug interaction screening, protection against drug/disease contraindications, and outcome monitoring. Consumers should report use of Pharmacy Care OTCs to their pharmacist and their doctor or other prescriber. Pharmacists who sell Pharmacy Care OTCs should recommend and request consumer approval to add these products to their medication profile. Consumers and pharmacists share in the decision-making for communicating information about their use of Pharmacy Care OTCs with the primary physician providing their healthcare.