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APhA task force defines Pharmacy Care OTC category

New opportunities for pharmacists to impact patients' health

The pharmacist is the best health care professional to answer patients' questions about OTC drugs, especially at a time when more and more complex drugs are being switched to nonprescription status.

Several important prescription drugs have recently moved from behind the counter, including a proton pump inhibitor, a full strength histamine H₂ antagonist, and a nonsedating antihistamine. These Rx-to-OTC switches have given patients increased access to effective medications, something that consumers, manufacturers, and regulators all want. However, the easy availability of these medications can lead consumers to lose sight of the fact that each is a powerful drug, with side effects and potential interactions. Here is where the pharmacist can best help patients. But what if these medications are being sold in a gas station or convenience store? Who will a patient interact with then?

APhA task force

In August 2004, APhA convened a task force to discuss how to facilitate pharmacist–consumer relationships and also how to enhance the role pharmacists could play regarding a new category of OTC products. The group included members from independent and chain pharmacy practice, managed care, academia, and pharmacy management. In late October, the APhA Pharmacy Care OTC Task Force issued its recommendation for the creation of a new subcategory of drugs—Pharmacy Care OTCs—that would only be available in a pharmacy.

What it is, and isn't

According to the report, Pharmacy Care



OTCs would “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 OTC is a new category, not class, of products. (For more information about drug categories and classes, see “Should the U.S.,” page 14.) While the products would be sold only in a pharmacy, they would not be required to be located behind the counter or to be restricted-access. A product would become a Pharmacy Care OTC if its manufacturer asks for that designation when filing a New Drug Application with FDA. This would allow manufacturers to ensure that a qualified health professional would be at the point of purchase if the patient had any questions or concerns.

Specific recommendations

The task force made recommendations in four areas. First, the task force recom-

mended that products in the Pharmacy Care OTC category demonstrate a proven health benefit and that guidelines for patient identification and risk assessment should be available. In the area of supporting pharmacist–consumer interactions, the group recommended that products be placed in a spot that facilitates direct access to pharmacists (i.e., near the pharmacy). It also recommended that appropriate nonpharmacy staff should be generally educated about Pharmacy Care OTCs and should be able to provide information about when a pharmacist would be available for consultation.

Regarding pharmacist–consumer interactions, the task force recommended that pharmacy staff should be educated and trained about the products in the new category and about the appropriate population for each product. While student pharmacists, technicians, and others working in the pharmacy are included in the recommendation, the task force specified that pharmacists are responsible for responding to patient questions.

Pharmacist–consumer interactions include identifying consumers who should use a medication, identifying consumers who should be referred to another health care professional, and providing appropriate support. Other activities that constitute pharmacist–consumer interactions include screening activities, monitoring compliance (especially for people with chronic conditions), and consulting at point of purchase.

The task force also made recommendations for other services, including support services (such as point of care testing) and documenting Pharmacy Care OTC use in a patient’s profile.

Opportunity for pharmacists

The task force welcomes comments on its report. The full report may be accessed at www.aphanet.org, and comments can be submitted to taskforce@aphanet.org. The group will review all comments and revise its recommendations, as appropriate.

“This new category provides yet another opportunity for pharmacists to be advocates for patient health, helping consumers access and use important medications,” said John A. Gans, PharmD, executive vice president and CEO of APhA.

—Ann W. Latner