



APhA

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*The National Professional
Society of Pharmacists*

**Statement of the American Pharmaceutical Association (APhA)
to the Food and Drug Administration's
Nonprescription Drugs Advisory Committee and the
Gastrointestinal Drugs Advisory Committee
Over-the-Counter use of Prilosec® (omeprazole magnesium)
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Thank you for the opportunity to present the views of the American Pharmaceutical Association (APhA), the national professional society of pharmacists. I am Susan Winckler, a pharmacist and an attorney, and APhA's Vice President of Policy and Communications. My comments today will focus on the role of the pharmacist in helping consumers navigate the use of omeprazole magnesium in the over-the-counter (OTC) environment should the Agency choose to approve such availability.

In the interest of full disclosure, APhA frequently partners with Federal agencies, consumer groups, the pharmaceutical industry, and others to develop educational tools for pharmacists and consumers. The Association did not receive funding to participate in today's meeting, and the views I am presenting are solely those of the Association and its membership.

APhA's 50,000 members include pharmacist practitioners, pharmaceutical scientists, student pharmacists, and pharmacy technicians. APhA members provide care in all practice settings such as community pharmacies, hospitals, long-term care facilities, managed care organizations, hospice and the military. In each of these settings, we help consumers manage and improve their medication use—including the appropriate selection and monitoring of prescription and OTC products. Ensuring the public's health and safety, especially with respect to medication use, is the pharmacist's, and APhA's, highest priority.

APhA supports the transition of suitable prescription drug products to nonprescription status when supported by studies assessing the safety, efficacy, and appropriateness of such drug products for OTC use. In the application before the Agency for omeprazole magnesium, this proton pump inhibitor is being considered for OTC use for the treatment of frequent heartburn. Heartburn is a common gastrointestinal condition and may be one of the most common chronic conditions

affecting adults. More than 60 million Americans experience a heartburn episode at least once a month, and as many as 25 million experience daily heartburn.¹

Omeprazole magnesium would be the first proton pump inhibitor to be available without a prescription. A switch of omeprazole magnesium from prescription to nonprescription status may improve clinical outcomes by expanding consumer access to a drug therapy class that is considered “more effective in preventing and relieving heartburn” than alternative therapies such as histamine H₂-receptor antagonists.² To determine if the product should be switched from prescription to OTC status, the FDA should conduct a review of all existing therapies in the self-care market. If existing options for self-care raise questions of safety, effectiveness or product quality, the relative safety of the switch candidate increases and the risk-benefit analysis shifts in favor of OTC availability.

Pharmacists, other health care providers, and patients rely on the FDA to regulate the safety of medications and ensure that all products moved from prescription to OTC status follow the same or an equivalent process. Decisions to classify products as either prescription or nonprescription are best made by the Agency in consultation with the product sponsor, with the ultimate decision based on substantial evidence of safety and efficacy in actual OTC settings. The use of a drug product in the actual OTC setting is especially important in the uncontrolled, real-world setting of self-care. The number of products shifting from prescription to OTC status has increased markedly over the past several years, and consumers are increasingly making decisions regarding the self-diagnosis and treatment of health conditions. A challenge of this trend is ensuring that OTC products are appropriately selected and used by consumers. This is an area where pharmacists can help.

Let me explain. As pharmacists, we are in the ideal position to help consumers select an OTC medication when appropriate and help monitor their use. Pharmacists can—and do—play a role in helping consumers use OTC products for the prevention and treatment of frequent heartburn. We educate patients about heartburn and more serious conditions such as gastroesophageal reflux disease (GERD), ensure that patients are appropriate self-treatment candidates, assist patients with appropriate product selection, and refer patients with symptoms that may suggest a serious condition to a physician.³ We also work with patients to ensure that they understand how to use the product—how often to take the medication, what dose, and for what duration; and can suggest lifestyle modifications to help lessen the occurrence and severity of symptoms. We also monitor for interactions between OTC products, dietary supplements, and prescription medications, and for the development of adverse effects.

The dynamics of the same medication being available for one indication (frequent heartburn) in the OTC environment and other indications (gastroesophageal reflux disease, duodenal and gastric ulcers) as a prescription product will be challenging. This challenge, however, is not new. Histamine H₂-receptor antagonists have been available for years in both prescription and nonprescription form. As I described earlier, pharmacists assist patients in deciding whether

¹ “Strategies for the Self-Treatment of Heartburn.” American Pharmaceutical Association. 2001, pg. 1.

² DeVault KR, Castell DO. “Updated Guidelines for the Diagnosis and Treatment of Gastroesophageal Reflux Disease.” *Am J Gastroenterol*. 1999; 94: 1434-42.

³ “Strategies for the Self-Treatment of Heartburn.” American Pharmaceutical Association. 2001, pg. 1.

they should use a nonprescription product for short term relief of heartburn, or whether a consultation with a physician is warranted to determine if a more serious chronic condition exists. Similarly, non-steroidal anti-inflammatory medications, such as ibuprofen or naproxen, are available as both OTC and prescription products. Again, the pharmacist plays a valuable role in helping a consumer determine whether the use of these medications is necessary for the management of minor aches and pains or whether the pain requires a physician's attention.

Our ability to manage the use of omeprazole magnesium in a dual prescription and nonprescription environment, however, will be directly related to the amount of information available to pharmacists. The product sponsor must provide product labeling that clearly delineates when OTC use of the product is appropriate, and directs consumers to a health care professional when use of the product falls outside of labeled parameters. Additionally, an educational campaign to equip pharmacists with the proper tools to identify and select OTC therapies for frequent heartburn will be needed. As pharmacists, we will do our part as health professionals to work with consumers, physicians and other health care providers as a valuable partner in OTC drug therapy.

While most OTC products are purchased at the pharmacy,⁴ a recent survey showed that mass marketers such as supermarkets and discount stores without pharmacies are gaining a larger share of the OTC market.⁵ In these environments, consumers may make OTC decisions without the assistance of a health care professional—the pharmacist. The lack of access to a pharmacist or physician places even greater responsibility on the consumer for interpretation and understanding of drug labeling and appropriate use of medications. Two types of studies are particularly valuable in determining whether there is sufficient evidence to reclassify prescription products to OTC status—OTC label comprehension and actual use studies. It is our understanding that the product sponsors have conducted several label comprehension studies since the Agency first considered the switch in October 2000, and adjusted the labeling accordingly.⁶

In conclusion, APhA recommends that the Agency consider the real-world use of omeprazole magnesium in the OTC environment, existing OTC products available for heartburn, the risks and benefits of increasing access to the product, and the ability of consumers to appropriately select and use the product without a learned intermediary. APhA supports the transition of this product to OTC status, pending the outcome of this review by the FDA.

Thank you for the opportunity to present the views of the nation's pharmacists.

⁴ 61% of all respondents purchased OTCs at a chain or independent pharmacy. "Navigating the Medication Marketplace: How Consumers Choose," a joint survey from PREVENTION[®] Magazine and the American Pharmaceutical Association, 1997.

⁵ "Shift Away from Chain Drug Stores Continues" Chain Drug Review. June, pg. 27.

⁶ "NDAC to Reconsider OTC Prilosec 1 for Heartburn Prevention in June," Health News Daily. April 23, 2002.