Behind-the-Counter Availability of Certain Medications

Background

Currently, medications in the U.S. are available either as prescription or non-prescription (“over-the-counter”). On November 14, 2007 the Food and Drug Administration (FDA) held a public hearing on the possibility of making certain medications available “behind-the-counter”. The purpose of the meeting was to solicit information and views from the public regarding specific issues associated with behind-the-counter (BTC) availability, including the impact on patient access to safe and effective medication products, patient utilization, and patient compliance. FDA also sought public comment on the appropriate regulatory framework for such medications and criteria for BTC availability.

The general concept of BTC is to make certain medications available behind-the-counter at the pharmacy without a prescription and require the intervention of a pharmacist before dispensing. Arguments in favor of a BTC category of medications include pharmacist education of and increase interaction with patients helps to ensure safe and effective use of medications, and increased patient access to medications that might otherwise be underutilized, particularly by patients without health insurance. Variations of BTC status are in effect in other countries, including Australia, Canada, France, New Zealand, United Kingdom, Denmark, Germany, Italy, Netherlands, Sweden, and Switzerland.

APhA Position

APhA's support of the availability of certain drugs without a prescription, but only after an intervention by a pharmacist, is based upon four key principles:

1. A pharmacist-patient clinical intervention is essential;
2. FDA must base its BTC categorization decisions on science;
3. Processes for drug availability without a prescription must be uniform; and
4. Pharmacists must be able to bill and be paid for the clinical services provided.

Summary of APhA’s Comments to FDA (November 2007)

APhA recommended that the Agency move forward with its BTC initiative because the program offers the potential to provide several major benefits to patients and our nation’s public health, including:

- Expanded consumer access to formerly prescription-only medications;
- Increased patient adherence;
- Enhanced patient safety;
- Improved health outcomes;
- Increased identification of other untreated conditions and referrals to physicians; and
- Cost savings for both consumers and the health care system.
Specifically, APhA stated:

- APhA fully supports FDA’s effort to establish a BTC program. Although APhA does not take a position on which specific products would be most suitable for BTC status, the Agency should consider as candidates those products that would not only meet its designated BTC criteria but would also provide a significant public health benefit.
- In deciding whether and how to design a BTC process, FDA should ultimately be guided by what is best for the patient.
- Pharmacists are fully qualified to provide the clinical interventions FDA contemplates for BTC products and, in fact, have already provided similar interventions to millions of patients on a range of prescription medications.
- FDA should establish a standardized, objective, and science-driven process for determining when a product is eligible for BTC status. Its decisions must be based on clinical evidence of efficacy and patient safety in actual use, whereby select medications that otherwise would have been available only by prescription are stored behind the pharmacy counter and made available without a prescription only after an FDA-required clinical intervention by a pharmacist.
- FDA should clearly define a standardized process whereby the pharmacist implements the required clinical intervention and other key program requirements in order to achieve the anticipated gains in patient access, adherence, safety, cost savings, and outcomes.
- FDA must work with all stakeholders to develop standardized administrative processes to ensure successful implementation and operation.
- FDA should provide significant consumer education prior to approving each product for BTC status, especially the first product.
- Pharmacists must be able to bill, via a standardized mechanism, and be fully paid for the clinical services FDA would require. Otherwise, a BTC program would likely not be financially feasible.
- FDA should collaborate with professional associations, schools of pharmacy, and others in the pharmacy education infrastructure to provide the content for BTC-specific training and education that we would provide pharmacists and pharmacy technicians.

Congressional Request for GAO Report on BTC Drugs
In January 2008, Representatives Dingell (D-MI) and Stupak (D-MI) requested that the United States General Accountability Office (GAO) update a 1995 report entitled: *Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated* (GAS/PEMD-95-12). The study examined existing variations in BTC systems in Australia, Canada, Denmark, France, Germany, Italy, the Netherlands, Sweden, Switzerland, the United Kingdom, and the European Union. At the time, the only comparable United States system existed in the state of Florida under the Pharmacist Self-Care Consultant Act of 1985. The 1995 report concluded that little evidence exists to support the establishment of a pharmacy or a pharmacist class of drugs in the United States (at that time), either as a fixed or a transition class.

Specifically, the report made the following observations:

- The European Union has not imposed any particular drug distribution system because it has not found any superior system.
- Patients typically had appropriate access to medications to treat symptoms even without a pharmacist-only option because other nonprescription medications exist for the same purpose.
- No evidence suggests that a pharmacist-only class of drugs reduces misuse or
The report stated that the “reality of pharmacy practice diverges from the theory” and that pharmacist counseling, while appropriate, is often incomplete or inconsistent to provide consumers with valuable information related to appropriate use and side effects.

- The Florida model was not successful. Pharmacists rarely prescribed the medications and recordkeeping requirements were not followed.

Chairman Dingell (D-MI) and Representative Stupak’s (D-MI) request included a thorough examination of recent data and reports developed since the original study to provide a comprehensive overview of the situation. The request also discouraged an “on-the-ground” investigation of other country’s systems and encouraged an examination of United States resources and the need for a BTC system.

In April 2008, APhA submitted comments with suggestions for the proposed GAO examination. The comments noted that some recent OTC switches require consumers to make a more informed risk/benefit analysis and pharmacists can help consumers by providing professional input. APhA urged a review of recent data about the current role of pharmacists in patient care and not simply focus on existing systems that may or may not be relevant to a United States BTC system.

APhA Statements

The following documents are available on the APhA Government Affairs Web site at www.pharmacist.com/GA:

- 4/11/2008 APhA Comments to Representatives Dingell and Stupak Regarding Request for GAO report on BTC
- 11/14/2007 APhA Statement at FDA Public Meeting on BTC
- 12/17/2007 APhA Comments to FDA on Behind-the-Counter Availability of Certain Medication
- 12/17/2007 APhA Comments to FDA on Behind-the-Counter Availability of Certain Medications (Executive Summary)

Resources

- APhA House of Delegates: www.pharmacist.com/HoD
- APhA Government Affairs Resources www.pharmacist.com/GA