



Behind-the Counter Drugs¹

The Academy of Managed Care Pharmacy (AMCP) supports the establishment of a class of drugs that would allow consumers, with the intervention of a pharmacist, to purchase certain medications without a prescription. While several other countries currently have a version of a behind-the-counter (BTC) class of drugs, the FDA is unclear if it has the authority to establish a BTC classification of medications. The establishment of a BTC class of drugs could help improve patient care by removing potential barriers to access.

AMCP supports the establishment of a third class of BTC drugs if the following conditions are met:

- **Medications selected for BTC status must provide a benefit to the public.** Making certain drugs available BTC should provide access to treatment regimens for patients who may have difficulty seeing a primary care physician.
- **Decisions about the drugs selected for BTC status must be based on clinical effectiveness and safety.**
- **Standardized processes for ordering and dispensing of BTC drugs must be established.**
- **Pharmacists must be required to perform clinical evaluation and interventions before dispensing BTC drugs.** If a drug is determined to be appropriate for a patient, the pharmacist should counsel the patient on safe use and monitor the drug therapy for continued safe and effective use for an appropriate amount of time.
- **Patient health information must be protected.**
- **Program oversight requirements must be developed.** The decision to move such a drug from BTC or OTC status to a more restrictive category could be triggered by a clinical finding that impacts patient safety negatively or raises questions about its effectiveness for a medication's approved indication(s).

October 2011

The Academy of Managed Care Pharmacy (AMCP) is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to assist patients in achieving positive therapeutic outcomes. The Academy's 6,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit. More news and information about AMCP can be obtained on its website, at www.amcp.org.

¹ See AMCP's *Where We Stand on Behind the Counter Drugs*, available online at <http://www.amcp.org/Tertiary.aspx?id=8725>.