

Consumer Value And Professional Opportunity In Nonprescription Drug Therapy

Self-care with nonprescription (also referred to as over-the-counter [OTC]) drugs is deeply embedded in American society and the American health care system. Consumers are seeking higher levels of ownership and more active roles in assisting in the management of their own health care. Further, consumers are becoming intellectually empowered with more and better health information via the print and electronic press. The new “Drug Facts” label format facilitates consumer understanding of core facts about nonprescription drug therapy.

Approximately 100,000 nonprescription drugs and combinations of drugs are utilized to manage or assist in the management of over 450 medical conditions. Many of these conditions (e.g., headache, fever, heartburn, constipation, diarrhea, the common cold, allergic rhinitis [seasonal and perennial], acne, superficial wounds, dysmenorrhea, sunburn, athlete’s foot, vaginal candidiasis, head lice, motion sickness) occur millions of times each year. All of these conditions, if not treated, can produce significant discomfort, impair quality of life and decrease workplace productivity.

Consumer beliefs, attitudes and actions demonstrate confidence in nonprescription drugs. The FDA has added to that confidence with the approval (“switch”) of drugs that were formerly prescription-only to nonprescription status. Among formerly prescription drugs that have been converted to nonprescription status are Advil, Afrin, Drixoral, Aleve, Pepcid AC, Zantac 75, Nicorrete, Rogaine, Lamisil (topical), Claritin, Claritin D and Prilosec OTC. Historically the FDA has moved products from prescription-only to nonprescription status at a fraction of the dose most commonly prescribed. However, the last three FDA “Rx to OTC” switches have been at the most commonly utilized prescription dose. These products include Prilosec OTC (omeprazole, 20 mg), Claritin, (loratidine, 10 mg) and Pepcid AC Maximum Strength (famotidine, 20 mg).

Nonprescription drugs, in addition to meeting FDA criteria for safety and effectiveness, frequently create consumer value by relieving society of the economic burden associated with unnecessary medical office visits and overtreatment of many self-limited clinical conditions with unnecessary and much more expensive prescription drugs.

Nonprescription drugs frequently cost less than an insured patient’s copayment for a prescription drug, and in many cases the nonprescription drug will produce an equivalent or superior therapeutic effect over certain prescription drugs. The underinsured and uninsured are particularly dependent on cost-effective nonprescription drug therapy for the appropriate management and symptomatic relief of scores of medical conditions.

A variety of health care issues cannot be addressed adequately by the “Drug Facts” label or self-help information available in print or via the Internet. There are many situations surrounding prudent use of nonprescription drug therapy that require the acquisition and assessment of patient information; analysis regarding proper nonprescription drug selection and use (e.g., contraindications, warnings/precautions, adverse effects, drug interactions); and clinical judgment regarding the appropriateness of either

Published in:

The International Journal of Pharmacy Education

Fall 2003, Issue 2

nonprescription drug therapy or referral for further medical evaluation. Issues surrounding patient comorbidity and polypharmacy are virtually infinite. There is no label, treatment protocol, or algorithm that can address issues that require clinical judgment. This reality necessitates access to a “learned intermediary.”

That “learned intermediary” is most logically the community-based pharmacist. The pharmacist is the only health professional who receives formal education and training in nonprescription drug therapy. The pharmacists’ professional role in self-care is upon fostering the safe, appropriate, effective and economical use of nonprescription drugs.

The pharmacist possesses knowledge and skill that can greatly assist patients in diagnosing self-treatable conditions, guiding nonprescription drug selection, use and monitoring and/or triaging the patient for further medical evaluation. In the practice domain of nonprescription drug therapy, the pharmacist often functions as a primary care practitioner or “gatekeeper.” Community-based pharmacists often serve as the portal-of-entry into the health care system. Also, patients often have several health care encounters with pharmacists between physician office visits.

As a self-care “gatekeeper” or primary care practitioner, pharmacists have the opportunity to provide vital pharmaceutical care services. The pharmaceutical care process in managing nonprescription drug use involves four (4) key steps. These are:

- Gathering and evaluating patient information
- Developing a care plan
- Implementing a care plan
- Monitoring and follow-up

In *gathering and evaluating patient information*, pharmacists must realize that they have a responsibility to physically assess or “diagnose” the self-medicating patient. This does not involve a hands-on diagnostic process, but does involve a physical assessment utilizing clinical observation and interview. This informed diagnostic “search for clues” by the pharmacist with a good knowledge of pathophysiology and pharmacotherapy will generally allow the differentiation of self-treatable conditions from those requiring medical evaluation. The pharmacist can then advise and counsel the patient on the proper course of action (e.g., nondrug approaches to symptom management, self-treatment with one or more nonprescription products, or referral to a physician or other caregiver).

In *developing a care plan*, referral for medical evaluation by the pharmacist is highly appropriate if symptoms are severe, symptoms are progressively worsening and not amenable to nonprescription drug therapy, symptoms return repeatedly and worsen over time, the patient's health status is vague or the patient's overall health status is fragile due to age, coexisting disease and/or complexity of drug therapy. In developing a care plan, if self-treatment is deemed appropriate, nondrug approaches (e.g., dietary, lifestyle) to patient management should be considered. If nonprescription drug therapy is warranted, OTC drugs should be selected based on symptoms and other patient variables (e.g., pediatric, geriatric, pregnancy, breast feeding, comorbidity, concurrent Rx, OTC or herbal therapy).

In *implementing a care plan*, information provided to the patient should include the following:

- The reason the OTC drug was selected
- The intended use and expected action of the OTC drug
- How the OTC drug is to be consumed
- Probable side effects, warnings and precautions to observe while taking the OTC drug.
- How to self-monitor for an appropriate clinical response

Adherence to the "Drug Facts" label should be encouraged. Finally, it is very important for the pharmacist to validate patient understanding and allow time for the patient to ask questions or express concerns.

In the *monitoring and follow-up* phase of the pharmaceutical care process, efforts should be made to assure the patient used the nonprescription drug correctly and determine whether the patient received an effective therapeutic response. Queries regarding any prescription or nonprescription drug problems (e.g., adverse effects, allergies, drug interactions) are strongly encouraged. Guidelines for proper drug use should always be reinforced. Alternative medication(s) or medical referral should always be a consideration in the monitoring and follow-up phase of providing pharmaceutical care.

Nonprescription drug therapy has traditionally been a profit center for American pharmacy, but is becoming significantly more important to pharmacy because of various market forces (e.g., the "baby boomer" bubble, shrinking reimbursement and profit margins on prescription drugs, excellent gross profit margins on both private label and national brand OTC drugs). Further, payment for nonprescription drugs is "first-party." There are negligible third party constraints on nonprescription drug sales.

In the realm of self-care and pharmacotherapy with nonprescription drugs, most consumers would benefit substantially from a meaningful interface with a pharmacist committed to the provision of value-based, patient-focused, health outcome oriented

Published in:

The International Journal of Pharmacy Education

Fall 2003, Issue 2

pharmaceutical care. Opportunities for community-based pharmacists to provide higher levels of diagnostic and pharmacotherapeutic self-care interventions are vast. Additional initiatives are needed by the profession of pharmacy and individual pharmacists to serve the self-care interest of the public. Such an opportunity, when acted upon, provides both clinical and economic dividends for individual patients and the professional and business interests of the profession of pharmacy.