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Editorial

Nonprescription Drug Safe Use Regulatory Expansion

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The process used for switching a prescription-only medication to over-the-counter status (Rx-to-OTC) in the United States may be headed for a change in 2013. In 1976, the latest version of this process was introduced by the US Food and Drug Administration (FDA). Since that time, over 90 ingredients, indications, or dosage strengths have been switched from prescription to nonprescription status.[1] In general, the consumer has benefited from the wider and easier access to formerly prescription-only medications such as diphenhydramine, ibuprofen, sodium naproxen, cetirizine, loratadine, fexofenadine, nicotine, omeprazole, and lansoprazole.[1-3] However, the financial burden for the purchase of these medications has shifted from the health insurance industry to the consumer. Some consumers are saving money and making their self-care more convenient, whereas other patients may not complete therapy because of the lack of insurance coverage for the medication.[4,5]

Two reports by Francesco International have taken a look at the Rx-to-OTC switch process. Both of these reports discuss the potential for Rx-to-OTC switches for the treatment of hypertension, hypercholesterolemia, diabetes, incontinence, and chronic obstructive pulmonary disease.[6,7] Switching some of these medications and others may be worth billions of dollars in sales.[7] The first Rx-to-OTC switch in these therapeutic areas occurred in January 2013; oxybutynin transdermal system 3.9 mg/day (*Oxytrol for Women*) became the first OTC treatment for overactive bladder in women and will be available for purchase in September 2013. However, the formulation intended for the treatment of men will remain a prescription-only product.[8]

The new initiative by the FDA is entitled Nonprescription Drug Safe Use Regulatory Expansion (NSURE).[9,10] There are limitations related to the current process used for Rx-to-OTC switches: The consumer must be able to make a purchasing decision based on information in product labeling and the principal display panels of its packaging; other conditions for marketing are not considered (eg, technology); and prescription and nonprescription products for the same indication, population, and dose are not allowed.[9-11] It may be possible to use new technologies and information systems to overcome some of these issues. To address these and other issues related to the Rx-to-OTC switch process, the FDA is conducting public hearings and seeking input from consumers, regulated industry, insurers, and health care providers to gain insight on how this process could be performed without compromising patient safety.[9-12]

The key questions related to safety and effectiveness of moving a medication from prescription-only status to OTC status are the same as they have been in the past[1-3,7,10]:

- Can the patient adequately self-diagnose their medical condition?
- Can the medical condition be successfully self-treated with an OTC product?
- Is self-treatment with an OTC medication safe and effective under the conditions of actual use by the consumer?

Through the use of technology and pharmacists, we hope that some of these issues can be overcome and more medications made available to consumers as OTC products. No matter what happens, pharmacy needs to be prepared to help consumers with this transition and to ensure that all of these medications are used correctly and patient safety is not compromised.

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