

The Growing Number of Over-the-Counter Medications Influencing Prescribing Practices

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ABSTRACT

Over-the-counter (OTC) medicines play a major role in the management of the most common illnesses, such as heartburn and allergy. Self-managing these conditions can potentially eliminate the need for medical office visits and prescription medications. This can result in an overall change in health care costs and prescribing patterns. When an ingredient formerly available only as prescription becomes available for nonprescription use it is referred to as an “Rx-to-OTC” switch. The most recent Rx-to-OTC switch approvals by the United States Food and Drug Administration include second-generation antihistamines, proton pump inhibitors, and intranasal steroids. Studies have examined how these switches impact the consumer and health care provider.

Keywords: allergy, GERD, OTC, Rx-to-OTC switch, self-care

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INTRODUCTION

Self-care is defined as “taking charge of the responsibility of one’s personal well-being through self-diagnosis and self-recognition of emergent signs and symptoms with the use of conventional and alternative medical modalities (ie, over-the-counter medications, dietary supplements, herbals, etc) and the implementation of appropriate life-style changes.”^{1(p228)} It is estimated that, in 2015, over-the-counter (OTC) medication sales in the United States were approximately \$40 billion, which represents a 2.8% increase since 2014.² OTC medications offer timely and convenient treatment for mild to moderate conditions, such as the common cold, headaches, pain, allergies, heartburn, and fungal infections. According to the Consumer Healthcare Products Association (CHPA), OTC medications provide value by expanding access to treatment for the most frequent and common illnesses. Although consumers may only visit their health care provider 3 times a year, trips to a pharmacy to purchase OTC products may occur approximately 26 times a year.² It is estimated that, of the 240 million people who utilize OTC medications, 60 million would not

have sought treatment if those products were not available.² Approximately every dollar spent by a consumer on OTC medications saves \$6-\$7 for the US health care system, with an annual cost savings of \$102 billion.³ This financial savings may be due to eliminating the need for visits to a health care provider, avoiding unnecessary diagnostic testing, less time missed from work, and the cost of a potential prescription medication. There are > 300,000 OTC medications and 80 therapeutic categories available on the market and many of these became available through what is known as switching from prescription (Rx) to OTC status.⁴

THE RX-TO-OTC SWITCH

The Nonprescription Drugs Advisory Committee is a committee within the US Food and Drug Administration (FDA) charged with reviewing and evaluating the safety and effectiveness of all OTC products. This committee also monitors what is referred to as the “Rx-to-OTC switch.” This is when an ingredient formerly available only as prescription becomes available for nonprescription use. The first status

switch took place in 1976 when brompheniramine and chlorpheniramine, both first-generation antihistamines, became available without a prescription.³ Considerations that determine whether a switch takes place include the drug's safety, effectiveness, labeling, and self-selection.^{4,5} From the safety perspective, switching an ingredient to OTC status must outweigh the risks associated with the product and there should be a low potential for misuse or abuse. From the consumer perspective, they must understand the product warnings, be able to use the medication without the supervision of a health care provider, and must be able to self-diagnose the condition for which the product is intended.^{5,6} In the last 10 years there have been approximately 20 FDA Rx-to-OTC switch approvals. The most common drug categories during this time frame included intranasal steroids, proton pump inhibitors (PPIs), and second-generation antihistamines (SGAs) (see Table).²

Table. Most Recent and Common Rx-to-OTC Switches

Category	Generic Name	Brand Name	Approval Date
Intranasal steroids	Budesonide	Rhinocort Allergy Spray	March 2015
	Fluticasone	Flonase Allergy Relief	July 2014
	Triamcinolone	Nasacort Allergy 24HR	October 2013
PPIs	Esomeprazole	Nexium 24HR	March 2014
	Omeprazole/sodium bicarbonate	Zegerid OTC	December 2009
	Lansoprazole	Prevacid 24HR	May 2009
	Omeprazole	Prilosec OTC	June 2003
SGAs	Fexofenadine	Allegra	January 2011
	Cetirizine	Zyrtec	November 2007
	Loratadine	Claritin	November 2002

OTC = over the counter; PPI = proton pump inhibitor; SGA = second-generation antihistamine.

PRESCRIBING PRACTICES AND OTC SWITCHES

For years there has been a debate over expanding access to nonprescription medications. As previously noted, the perceived benefits of switching prescription ingredients to OTC status include improvement of health by enhancing access to medications and reducing health-related costs by reducing the amount of visits to the health care provider. However, the inappropriate use of OTC medications, potential for misdiagnosis of the medical condition to be treated, and out-of-pocket costs for the patient continue to be a concern.

One area that has been reviewed is the impact of OTC switches on the utilization of physician services and effects on medication prescribing patterns. Gurwitz et al. investigated the utilization of physician services and prescribing patterns within a health maintenance organization (HMO) after the OTC switch of vaginal fungal products took place in 1991.⁷ They concluded that, by 1 year after the introduction of OTC products to treat vaginal candidiasis, physician visits were reduced by 0.66 per 100 members of the HMO, and the number of prescriptions dispensed was reduced by 6.42 per 100 members. An overall cost savings of approximately \$42,500 was identified within the HMO, which included medication costs and the costs for laboratory testing. Although there was a significant savings to the health care company, the study does make mention of the cost shift to the patient to purchase the OTC product and the potential for misdiagnosis leading to inappropriate treatment and delay in a cure. It has also been suggested that, although the number of prescriptions dispensed would decrease because of OTC access, the change in the number of medical office visits may be related to the specific medical condition being treated.⁸ For example, conditions that can be self-treated, such as vaginitis, have seen a downward trend in office visits, whereas a condition such as gastroesophageal reflux disease (GERD) has seen little change in the number of office visits.⁸ Since 2003, > 10 Rx-to-OTC switches took place for self-treating common conditions, including GERD, allergy, and allergic rhinitis. According to a survey by the CHPA, 98% of primary care physicians either recommend or have no reservations recommending nonprescription medications to patients.³

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