SWITCHING FROM RX TO OTC

BY CYNTHIA BORDA

COUNTER MEASURES

Switching products from prescription to nonprescription status can be a viable life-cycle management strategy, **ONE THAT IS EXPECTED TO BE USED MORE FREQUENTLY, ALBEIT SLOWLY**, as patents expire and as pharmaceutical companies face increasing pricing pressures.

CONSUMERS ARE INCREASINGLY COMFORTABLE MANAGING THEIR OWN HEALTHCARE. They want easy access to low-cost, effective, safe, and easy-to-get products, which has led to an increase in self-medication. Many of the off-the-shelf products that consumers are now using once had life as prescription brands.

Through August 2006, more than 90 ingredients or dosage strengths have made the switch from prescription to OTC status or have been newly approved since 1976, according to the Consumer Healthcare Products Association (CHPA), a member-based association representing the leading manufacturers and distributors of nonprescription, OTC medicines, and nutritional supplements. More than 700 OTC products on the market today use ingredients or dosages that were available only by prescription 25 years ago.

Switching safe prescription medicines to nonprescription status has been a long-held life-cycle management strategy for certain drug classes, such as gastrointestinal and allergy medica-

Bill Martineau
Freedonia Group

THE FASTEST GROWING OTC SEGMENTS ARE the antiseptics and topical antifungals, both of which have an annual growth rate of about 8.4%.

tions. Industry leaders say although there are fewer drugs eligible for switching, because many of the easier switches have already occurred, there are still opportunities for a number of reasons, including government pressure to reduce healthcare costs, regulatory policy changes, expansion of indications for OTC products, and patent expirations.

Industry experts say products most likely to be switched are those that resolve an acute condition that patients themselves could detect. Strong switch candidates include: Prevacid, marketed by TAP Pharmaceutical Products Inc. for treating gastroesophageal reflux disease; Protonix, marketed by Wyeth Pharmaceuticals Inc. also for the treatment of gastroesophageal reflux disease; Zyrtec, marketed by Pfizer Inc. for treating allergies; and an OTC version of Xenical, which would be marketed by Johnson & Johnson after securing the rights from GlaxoSmithKline.

"In the acid reflux disease category, AstraZeneca's Prilosec has paved the way," says Laura Mahecha, industry manager, healthcare, for Kline & Company Inc. "In the allergy category, Zyrtec is another expected switch, which follows the successful Schering-Plough OTC positioning of Claritin."

Asthma and lifestyle products, such as erectile dysfunction, obesity, and oral contraception, are also possible candidates for U.S. OTC switches, says Andy Tisman, senior principal, consumer health, IMS Management Consulting.

A survey conducted in 2005 by Business Insights found that companies anticipated future switches to be made in the upper respiratory, gastrointestinal, and analgesia therapeutic categories. Researchers at Business Insights also say switches are expected in the anti-inflammatory, cardiovascular, allergy, dermatology, and CNS therapeutic categories.

More than 90 ingredients or dosages have made the switch to OTC status since 1976.

CHPA

SUCCESS STRATEGIES

For many manufacturers, switching to OTC status is an element of life-cycle management, Mr. Tisman says.

"Looming patent expirations are an impetus to extend the life of the product," he says. "The ideal time to consider a switch strategy is while the product is in Phase III clinical development, when trials also can be conducted for different dosages and indications in anticipation of OTC use. Unfortunately, this forward-thinking approach often won't yield results for 15 years, and many companies are focused on the current prescription blockbuster."

A switching strategy can offer dual opportunities, says Michael White, president and founder of PharmaKinnex Inc.

"If the brand has done well as a prescription product, the company can leverage that equity," he says. "If the brand had some issues in terms of efficacy or side effects, switching the product to an over-the-counter brand affords the company the opportunity to reposition the product through renaming, decreasing the dose to minimize side effects, or redirecting the message. This strategy was employed by the manufacturer of Naprosyn, which was competing with the COX-2 inhibitors just reaching the market. The company decreased the dose to reduce the risk of bleeding, changed the name to Aleve, and thus created a 'new' product."

Successful Rx-to-OTC switches, Ms. Mahecha says, depend on when the product comes onto the marketplace, the uniqueness of the product, and how well it was known when it was a prescription product.

"An example would be Advil compared with Nuprin," she says. "Advil is one of the leading OTC brands, in part because of its market-

TOP 10 SWITCHED OTCs

PRODUCT	MARKETER	2005 RETAIL SALES
Advil	Wyeth	$384
Prilosec	AstraZeneca	$380
Claritin	Schering-Plough	$322
Nicorette	GlaxoSmithKline	$227
Motrin	McNeil	$203
Monistat	McNeil	$176
Aleve	Bayer	$171
Pepcid	Merck/J&J	$164
Zantac	GlaxoSmithKline	$122
Nicoderm CQ	GlaxoSmithKline	$111
TOTAL		$2.26 billion

* Note: Dollars are in millions
Source: The Freedonia Group, Cleveland.
For more information, visit freedoniagroup.com.

ing message. Nuprin is basically nonexistent because the marketers did not make the product unique."

Marketers need to target their messages and have insight about their consumer audiences, Mr. Tisman says.

"The challenge for marketers is to change behavior and get a consumer to go from being a patient who visits the physician and receives a prescription to being an educated consumer," he says.

Bill Martineau, a senior healthcare consultant at The Freedonia Group Inc., says changing behavior involves changing the perception that a prescription product is better than an OTC product.

Mr. White concurs, citing that one of the biggest challenges is to leverage the brand efficacy, particularly when the OTC version has a lower dose than the prescription product.

"Consumers question whether the brand is still as effective at a lower dose," he says. "Since the physician is now out of the scenario, there needs to be an effective marketing plan to address consumer issues."

"Claritin and Prilosec were successful switches because they were marketed as new and improved treatments," Mr. Tisman says. "The ingredients for a successful switch include drugs that have less complex indications or that are applicable for an acute diagnosis or a recurrent diagnosis where the patient can recognize the symptoms and know what he or she is suffering from. One of the reasons that simvistatin, an anticholesterol medication (marketed as Zocor in the United States by Merck), was unsuccessful as an OTC in the United Kingdom was that the marketing was targeted to young, healthy adults with mildly elevated cholesterol. The patients didn't buy into the message. High cholesterol is a chronic, asymptomatic condition, and the consumer does not get a feeling of relief when taking the medication."

Pharmacy-only medicines account for 24% of OTC sales in the U.K.

IMS

Laura Mahecha
Kline & Company

COMPANIES NEED TO PROVE THAT A DRUG IS SAFE ENOUGH to take without the help of a physician or a pharmacist and the dosing instructions are simple enough for all consumers to understand.

THE OTC MARKET

According to analysis by The Freedonia Group, U.S. shipments of OTC products in

A LOOK AT THE PLAN B SWITCH

WE ARE COMMITTED TO RESPONSIBLE EDUCATION and making sure people know that Plan B is an emergency contraceptive and not RU-486 (the "abortion pill"). The sooner the product is taken, the better that it works. Education is absolutely critical.

Amy Niemann
Barr Pharmaceuticals

In November, Barr Pharmaceuticals Inc.'s subsidiary Duramed Pharmaceuticals Inc. launched Plan B (levonorgestrel) emergency contraceptive OTC/Rx product to customers.

Approved Aug. 24, 2006, the Plan B OTC/Rx dual-label product is available as an OTC product to consumers 18 years of age and older and as a prescription-only product for women 17 years old and younger. It replaces the Plan B prescription-only product that has been marketed in the United States since 1999. Because Plan B remains a prescription product for women younger than 17, it is sold only in retail pharmacy outlets from behind the pharmacy counter and under the supervision of a pharmacist.

According to Amy Niemann, senior VP of proprietary marketing at Barr, timely access to the product was the impetus for taking Plan B over the counter versus being available only through a prescription.

"There is a 72-hour window during which this product is effective," Ms. Niemann says. "For many women, it can be challenging to obtain a prescription and have it filled in that short timeframe. We proposed that Plan B be available over the counter for all ages. The agency approved Plan B OTC for consumers 18 years old and older."

Taken within 72 hours of unprotected intercourse, Plan B has been shown to reduce the risk of pregnancy by 89% after a single act of unprotected sex. Plan B is more effective when taken in the first 24 hours after intercourse; effectiveness declines as the interval between intercourse and the start of Plan B increases.

The company also has implemented an educational program called CARE (Convenient Access, Responsible Education) that provides information to pharmacists, physicians, other healthcare providers, as well as consumers.

"A comprehensive educational program was necessary because Plan B is being dispensed under a dual-label," Ms. Niemann says. "This is a totally new approach — one product dispensed in two different ways for different patient populations."

Because there is such an important need to make sure all of the stakeholders understand the labeling, she says the marketing dollar mix has shifted.

"More of our educational and marketing dollars have been moved to cover pharmacist education," she says. "We want to make sure pharmacists clearly know the guidelines for dispensing and that a government-issued ID has to be checked before purchase."

The company's salesforce of 350 is distributing materials to ob/gyn offices and clinicians that clarify that the prescription requirement is still intact for women 17 years old and younger.

Andy Tisman
IMS Management Consulting

THE CHALLENGE FOR MARKETERS IS TO CHANGE BEHAVIOR and get the consumer to go from being a patient who visits the physician and receives a prescription to being an educated consumer.

2005 topped $29 billion and are expected to reach $37 billion by 2010.

"The fastest growing OTC segment is antiseptics and topical antifungals, both of which have an annual growth rate of about 8.4%," Mr. Martineau says. "Digestive and respiratory preparations also will provide favorable growth opportunities as both categories will continue to benefit from major Rx-to-OTC switched products."

U.S. retail sales for OTCs reached $15.1 billion (excluding sales from Wal-Mart) in 2004, according CHPA.

Recently, there has been a slow down in FDA Rx-to-OTC approvals, Ms. Mahecha says.

"Safety issues related to some prescription medications have had an impact on how the FDA evaluates switch candidates; consequently the FDA has become more conservative," she says. "Also, the applications have become more complex in terms of medications and conditions, for example high cholesterol. Companies need to prove that a drug is safe enough to take without the help of a physician or a pharmacist and the dosing instructions are simple enough for all consumers to understand."

ANOTHER CLASS OF DRUGS?

The approval of a nonprescription version of Plan B — the emergency contraceptive marketed by Barr Pharmaceuticals Inc.'s subsidiary Duramed Pharmaceuticals Inc. — has some experts talking about the possibility of establishing a new class of products that would be dispensed by the pharmacist, which in Europe is called pharmacy-only.

Approved in August 2006 and launched in November 2006, Plan B is a dual-labeled product. Plan B, which was approved for marketing in the United States in 1999 with a prescription for women of all ages, is now available on a nonprescription basis for women 18 years of age and older when dispensed under the supervision of a pharmacist. (For more information, please see box on page 30.) For consumers who are 17 years old and younger, Plan B still requires a prescription.

Some experts say this way of dispensing is similar to how some products are classified in the United Kingdom, where there are three classifications: Rx-only, pharmacy-only, and GSL (general sales list). Pharmacy-only products are medications that are kept behind the counter, and consumers requesting these products must discuss the medication with their pharmacists.

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>
> **CHPA**

One reason why more Rx-to-OTC switches are approved in the United Kingdom, where a behind-the-counter option exists, than in the United States is because the pharmacist is in a position to reassure and educate the consumer about the product, Ms. Mahecha says.

"Having the pharmacist control the dispensing provides a safety net, which makes the regulators' jobs easier," she says. "In addition,

Michael White
PharmaKinnex

One of the biggest challenges is leveraging brand equity. Since the physician is now out of the scenario, there needs to be an effective marketing plan to address consumer issues.

Europe has fewer mass-market outlets where drugs are sold than the United States, and pharmacies are smaller retail spaces. In the United States, OTC drugs are available in places where there are no pharmacies, such as gas stations, convenience stories, and warehouse clubs. There is also a smaller ratio of pharmacists to consumers in Europe."

Pharmacy-only as a category does not appear to be gaining traction in the United States, Ms. Mahecha says, because U.S. consumers are accustomed to having many options; a shift would require a cultural change.

> Many health regulatory agencies are focused on Rx-to-OTC switches as a way to help curb escalating prescription drug spending. At the same time, many major prescription drugs have lost or will soon lose patent protection. The market is ripe for new Rx-to-OTC switches and entirely new OTC categories.
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> **Kline & Company**

According to IMS data, sales of pharmacy-only medicines (those available for OTC sale but only under the supervision of a pharmacist) account for about 24% of the total value of the UK OTC medicines market. The market varies significantly between product categories: general pain relief accounts for 39%; cough remedies 30%; cold remedies 18%; and digestive products 7.5%.

Mr. Tisman says the general trend in Europe is for more products to be moved from the pharmacy-only classification to general sales. For example, ibuprofen (marketed outside the United States by Reckitt Benchiser under the brand name Nurofen) was relaxed from prescription status to pharmacy-only status and then some years later to general sales. The same scenario played out with the antifungal Canesten, which is a market leader in Europe for the treatment of dermatological and gynecological fungal infections. Canesten contains the original active ingredient clotrimazol developed by Bayer.

He says this trend is likely to continue, except in the cases where there are stronger formulations and/or larger pack sizes, which are reserved for pharmacy-only sale.

In much of the rest of Europe, Mr. Tisman says, the OTC market is essentially entirely pharmacy-only.

"There have been moves to liberalize OTC distribution by allowing mass-market sales of some OTC medicines in Germany, Poland, Portugal, and Italy," he says. "This would effectively reverse-engineer a pharmacy-only class."

The Netherlands, he says, relaxed its rules a number of years ago so that all OTC medicines could be sold by licensed druggists (with no pharmacist present).

"But over the last year or two there has been talk of re-establishing a pharmacy-only class," he says. "There are two main drivers behind this thinking: the possibility of future Rx-to-OTC switches, such as Zocor and Viagra, which authorities are not comfortable having available in mass-market outlets; and a pharmacist/physician lobby trying to reassert some medical control over OTCs, for example in the cases of some larger pack sizes of certain products currently available. It is not yet clear what the outcome will be, but it is notable that the arguments have aroused high public interest."✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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