

NONFOOD

SN SPECIAL REPORT


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Switch Hitters

Recessionary pressures and demand for health care reform make for a fertile climate for new entries into the Rx-to-OTC switch field

By **CHRISTINA VEIDERS**

After a relatively quiet period in the Rx-to-OTC arena, supermarkets can prepare for the next new wave of drugs to go over the counter in the near future.

Those who follow the over-the-counter segment say the current economic and political environment, with its emphasis on containing health care costs, favors the need for more costly prescription drugs to change status to less expensive OTCs for the self-care market.

In 2008, the U.S. Food and Drug Administration listed no new OTC drug approvals. This follows previous years when a few to a handful of prescription drugs changed to the OTC market.

Since 1976, 84 ingredients, dosages or indications have made the switch from prescription to OTC status. Additionally, 15 medications were introduced during that time directly to the OTC market without having been prescription first, reports the Consumer Healthcare Products Association.

More than 700 OTC medicine products today use ingredients and

dosages that were available only by prescription less than 30 years ago, according to the association.

The recent fall-off in the number of new OTC medications simply signifies the ebb and flow of the process and is not any indication the pharmaceutical industry is holding back on moving prescription drugs to the self-medication market or that the FDA is taking a more stringent approach on the approval process.

"It is a little bit of a wave phenomenon," explained Jim Wisner, president, Wisner Marketing Group, Libertyville, Ill.

"We had a year or two where you didn't have a lot of OTC switches, but we did have some big ones."

According to a report ("Rx to OTC Switches 2009") by Kalorama Information, a division of MarketResearch, the U.S. market for Rx-to-OTC switches was worth just over \$6.7 billion in 2008, up 3.8% from 2004's \$5.8 billion. Gastrointestinal and other product categories contributed to the growth with increases of 6.8% and 14.4%, respectively.

The market is forecast to increase 8% to nearly \$9.6 billion in 2013.

Growth is expected to continue for several segments, with other drug categories responsible for the highest growth of 25.6% and gastrointestinal drugs providing growth of 9.6%, primarily due to the approval earlier this year of Prevacid 24-HR (Novartis Consumer Healthcare), a heartburn remedy in the proton pump inhibitor class.

These segments are followed by allergy, cough, cold and sinus products with 5.7% growth, analgesics with 5.6% growth, anti-infectives with 2.2% and smoking cessation with 2%, according to the Kalorama report.

Laura Mahecha, industry manager, health care, Kline & Co., Little Falls, N.J., noted that new OTCs coming to market are more-complex medications and therefore carry more weight in gaining FDA approval.

Such drugs are either new categories or new types of medications for which Kline forecasts more switch applications and approvals in the next three years.

"I think the majority of those will occur in the antacids area with PPIs [proton pump inhibitors] like Prevacid and Zegerid. You may see additional switches as a competitive response to Zyrtec [allergy medication]," she said.

"Claritin [Shering-Plough] got pretty hard hit with Zyrtec [McNeil Consumer] and private-label competition so it's possible that Shering may launch the Clarinex product

in the next couple of years to bolster their franchise in allergy and steal some of the newness from Zyrtec," she said.

This illustrates the market share battles and strategic thinking pharmaceutical companies employ to extend product life and protect and grow their market share. Drug companies generally submit products for OTC approval once the product's market exclusivity is about to expire. A company can then gain another three-year exclusivity once the product is approved for the OTC market.

While the federal regulatory process is predicated on a product's safety and efficacy, among other factors, the recession and concerns to cut health care costs have set the momentum in favor of more prescription drugs winning FDA approval, said industry observers.

"While the FDA is cautious [in granting switches], they do want to be aggressive as they reasonably can because it is good health care policy [to curbing the rising cost of health care]," said Wisner.

WEDGE AGAINST SOARING COSTS

Consumer use of OTCs is seen as one way to help bring down escalating health care expenditures in the country because it cuts down on visits to the doctor, and insurance organizations generally don't cover OTCs.

Growth in national health expenditures in the United States is expected to significantly outpace economic

NEW DRUG CLASS

The passage of the Combat Methamphetamine Epidemic Act of 2005 unofficially created a new classification of drugs — those sold without prescription from behind the counter (BTC). The regulation, which passed in 2006, placed cold medications containing pseudoephedrine, also used to make the addictive stimulant methamphetamine, behind the counter. The emergency contraception, Plan B, which went over the counter in 2006, also is sold BTC.

The U.S. Government Accountability Office has decided to reexamine the viability of BTC as a drug class and update a 1995 report on the topic. In doing so, it looked at five countries where nonprescription drug availability has increased by altering nonprescription classes or reclassifying some drugs into less restrictive classes.

Proponents are supporting the move to improve public health through increased availability on nonprescription drugs and greater use of pharmacists' expertise. Opponents are concerned that a BTC drug class might become the default for drugs switching from prescription to nonprescription status, thus reducing consumer access to drugs that would otherwise become available OTC. They also argued pharmacists might not be able to provide the support counseling services needed for patients using the drugs.

Jim Wisner, president of Wisner Marketing Group, Libertyville, Ill., sees the BTC movement growing. He said if statin drugs that lower cholesterol go over the counter, they have a good chance of being sold BTC. "Such drugs need a small measure of reliable health care oversight that pharmacists are more than capable of doing. From a medication management standpoint, pharmacists get a lot more training than doctors," Wisner said.

The movement of drugs to BTC status would help to change pharmacists' role in a good way, he added. "When their activity is primarily confined to dispensing, they're probably being underutilized in the health care community. These are well-trained, very professional people who do understand medication management, and BTC drugs would enable pharmacists to have a more positive and proactive influence on what's going on with their patients' health."

— C.V.

growth in 2008 and 2009 due to the recession, according to a report issued by the Centers for Medicare & Medicaid Services (CMS). In 2008, national health expenditures were projected to rise 6.1%, as health spending increased from \$2.2 trillion in 2007 to \$2.4 trillion in 2008, while growth in the economy, as measured by the gross domestic product (GDP) was expected to be 3.5%. This year, health spending is projected to increase 5.5% while the GDP is expected to decrease 0.2%. By 2015, total U.S. health care spending is expected to reach \$4 trillion

and 20% of the GDP.

Meanwhile, OTC sales continue to grow. Manufacturer sales were up 2.4% to \$18.3 billion in 2008, according to a Kline report on the nonprescription drug market in 2008. Not surprisingly, private-label OTC medicines were up 8.2% over the same time period, in which antacids and allergy medicines posted the highest growth last year, driven primarily by increases of private-label omeprazole (Procter & Gamble's Prilosec) and cetirizine (Johnson & Johnson's Zyrtec).

In a new soon-to-be-re-

leased Kline report, "Impact of Recessions on the U.S. OTC Market," there is clear evidence that private label grows at significant rates during a recession, Mahecha said. "We saw that last year the overall OTC market climbed 2.4%, but private label was up 8%. Consumers did trade down to private label but by the same token, switch products like MiraLax still did really well." Mahecha said consumers are still willing to pay extra if they feel the product is superior or innovative and offers them more relief. **SN**