

Sneezing



It's Asthma and Allergy Awareness Month and the seasonal allergies category is as congested as ever. But a slew of patent expirations poses a greater concern than the fierce competition. By **Ben Comer**

Season

Hay fever isn't the only thing causing brand-name prescription manufacturers' eyes to water this allergy season. Top-selling products for the treatment of allergic rhinitis (AR) went off-patent during 2007, giving rise to popular generic alternatives and subsequent losses of market share among staples in the category. The situation has caused allergy brand sales to dip to their lowest point in five years. Last year's sales were down 22% to \$5.2 billion from 2006.

The sniffing pharmaceutical companies invested in allergy relief will have to make tough decisions about where to put marketing dollars, whether transitioning to over-the-counter sales (Zyrtec), concentrating on replacement brands with fresh patents (Veramyst) or drumming up awareness for potential pipeline possibilities (Claritin/Singulair).

Due to the seasonal nature of allergy affliction, marketing efforts for AR products tend to focus on two peak seasons each year: spring (April, May and June) and fall (September and October).

The two most prominent categories for AR treatment are oral antihistamines (including combination antihistamines) and inhaled nasal corticosteroids (INCs). Antihistamines are widely available OTC and are relatively easy to use, although many physicians are recommending corticosteroids to patients. "Based on research we conducted last fall, there is a notable uptick in physicians prescribing INCs," says Sue Ramspacher, SVP, category business leader of respiratory, GfK Market Measures. "Inhaled nasal corticosteroids are becoming the first line of therapy and are being used to a much greater extent in terms of a physician's perspective. Veramyst is being prescribed, for example, because it addresses a broader range of symptoms."

New AR drugs like Veramyst, and Xyzal, in the antihistamine category, have the ability to move quickly into positive sales figures.

"The AR market is driven by sampling and detailing," says Ramspacher. "Literally weeks after the launch of Xyzal, there was a high level of awareness among allergists."

Ramspacher also mentions that the eagerly anticipated Claritin/Sin-



(Above) Nasonex remains one of the most recalled TV ads, due to its memorable bee campaign; (Right) Once a top-selling Rx allergy drug, Zyrtec's new OTC position comes after losing patent in 2007

gular pipeline compound is "at the top of the list in terms of physician awareness." The new compound was formed through a Schering-Plough/Merck partnership and is currently seeking approval from the FDA. "[AR] is a crowded category with lots of competitive players. Even though the market is crowded, there are still needs to be met, and areas where product attributes could differentiate themselves," she says.

Ramspacher cites long-term safety and the absence of rebound congestion as two examples of attributes that could provide differentiation. This should be encouraging for companies itching to enter the market. However, recent safety issues regarding Singulair may give pause to physicians. In March, the FDA announced an investigation into a "possible association between the use of Singulair and behavior/mood



changes, suicidality (suicidal thinking and behavior) and suicide.”

Approved in April 2007, GlaxoSmithKline’s Veramyst (fluticasone furoate) nasal spray is an emerging INC, which the company hopes will help to offset Flonase’s market share losses to generics. Flonase was once a leader of the category. “GlaxoSmithKline will not be advertising Flonase at all this season, on the consumer side or the professional side,” says Robin Gaitens, product communications manager for GSK. A Veramyst TV spot from September 2007 drew questions and commentary from viewers, who reacted to a seemingly odd line of copy seen in the ad:

“The way Veramyst works is not entirely understood.” Gaitens confirmed a 2008 DTC campaign in support of Veramyst, but declined to elaborate on campaign details.

In September 2006, UCB and Sanofi-Aventis entered into an agreement to launch and co-market the antihistamine Xyzal (levocetirizine dihydrochloride) in the US. Xyzal received FDA approval in May 2007 for tablets, followed by an oral solution in February 2008.

A DTC campaign featuring national TV spots, online and print ads launched in March, according to Scott Ellis, product director, UCB.

“As part of the 2008 public relations program, the Xyzal Challenge Your Course campaign was launched [in February], and is slated to run throughout the entire year. We have implemented a comprehensive, integrated consumer and professional awareness campaign for Xyzal as well, called X-Factor.” An X-Factor print ad contains copy reading: “Your indoor and outdoor allergies can itch, sneeze and run. But they can’t hide.” The Challenge Your Course (www.challengeyourcourse.com) program is a “collaborative partnership with the Asthma and Allergy Foundation of America (AAFA) and Jill McGill, an LPGA golfer who suffers from indoor and outdoor allergies,” explains Ellis. “The Xyzal website will incorporate the PR spokesperson Jill McGill as an ‘interactive guide,’ detailing her experience as a nasal allergy sufferer.” Agencies working on various aspects of the campaign include Ogilvy, HeartbeatDigital and PR agency Biosector 2.

Companies without new products immediately available for market are dealing with patent losses in other ways. Zyrtec (cetirizine HCl), the nation’s top-selling prescription allergy medicine, went off-patent in December 2007. Pfizer ceded OTC manufacturing and marketing rights to McNeil Consumer Healthcare in 2006. Zyrtec, an antihistamine, began its life as an OTC in January, with in-store displays created by Henschel-Steinau Inc.

After a branded Spring Wonderland Dome was erected in New York City’s Central Park last January, McNeil most recently announced a partnership with the Asthma and Allergy Foundation of America (AAFA) and actress/comedian Molly Shannon. The campaign, “Allergies Are No Laughing Matter,” represents “part of Zyrtec’s overall educational campaign,” according to McNeil spokesperson Peggy Ballman. Ballman declined to comment further on advertising for the brand.

Schering-Plough is probably the most experienced in dealing with an OTC crossover in the allergy category. Claritin was approved for OTC back in 2002, and has continued to market its line of products. A new obstacle surfaced in 2006 when an article in the Patriot Act banned all OTC sales of products containing pseudoephedrine, a decongestant commonly used in combination with AR medications. Claritin-D, and now Zyrtec-D, are consequently held behind-the-counter (BTC), and represented on the drugstore shelf by placards urging consumers to “Take this tag to the pharmacy for purchase.” Commenting on the situation, Ramspacher explains that allergy medications are now classified into three groups: prescription, OTC and BTC. “A notable Schering-Plough ad for Claritin has a patient saying ‘Thank you for not changing your formulation,’ which is a direct statement on behind-the-counter medications.”

Marketing efforts for Claritin began targeting Zyrtec before it reached the shelves.

A Schering-Plough company release from November 2007 emphasizes Zyrtec’s listed side effects this way: “While Zyrtec is



Allergy Brand Sales 2003-2007 (in millions except where noted)

	2007	2006	2005	2004	2003
Zyrtec	\$1.63 billion	\$3.12 billion	\$3.35 billion	\$3.59 billion	\$3.88 billion
Nasonex	\$989,230	\$892,470	\$708,270	\$568,660	\$552,070
Fexofenadine HCL	\$722,590	\$829,280	\$256,630	\$579,150	\$1.36 billion
Fluticasone	\$523,670	\$527,780	N/A	N/A	N/A
Nasacort AQ	\$369,230	\$346,750	\$350,380	\$348,640	\$304,340
Clarinet	\$359,140	\$388,140	\$415,580	\$144,660	N/A
Astelin	\$271,240	\$233,180	\$174,260	\$144,660	\$123,270
Rhinocort Aqua	\$261,390	\$296,030	\$326,850	\$338,220	\$311,980
Xyzal	\$21,470	N/A	N/A	N/A	N/A
Flonase	\$43,030	\$76,390	\$342,250	\$1.21 billion	\$974,450
Total Market	\$5.19 billion	\$6.71 billion	\$5.93 billion	\$6.93 billion	\$7.51 billion

Source: IMS Health, IMS National Sales Perspectives, March 2008

approved for over-the-counter sale, consumers should be aware of its common side effects like drowsiness and fatigue. In fact, Zyrtec prescription labeling carries a caution about the occurrence of drowsiness and urges consumers to exercise caution when driving a car or operating dangerous machinery.” This passive-aggressive technique was augmented in January with Schering-Plough’s announcement of a sponsorship agreement with “Allergy Sufferer and NASCAR Sprint Cup Driver Carl Edwards.” In the release, Edwards says, “When I’m driving at 180

currently the most prescribed antihistamine in the nation, capturing 36.2% of the market share for that category, according to IMS Health.

One important factor catalyzing generic alternative usage is the “doctor’s offices vs managed care cost concerns,” says GfK’s Ramspacher. “Lots of generic competitors have been made available due to managed care professionals seeking the lowest cost alternatives.”

According to recent data from the American Academy of Allergy Asthma & Immunology, as many as 50 million people suffer from two forms of AR: seasonal and perennial. Seasonal allergies are caused by tree, grass and weed pollen. Perennial allergies are caused by frequent exposure to allergens like animal dander, mold spores and dust mites.

Many top-sellers in the antihistamine category are moving into old age, or at least middle age, in terms of patent life expiry. Meda Pharmaceutical’s Astelin (azelastine HCl) and Schering-Plough’s Clarinet (desloratadine) are both moving into the last couple of years of protection. However, most of the best-selling INCs are in good shape in terms of patent protection, with Flonase (fluticasone propionate) being the single exception to the rule – Flonase expired in 2004. Nasacort AQ, the third best-seller in 2007, expires in 2016, while Sanofi-Aventis’ Rhinocort Aqua, the fourth best-seller, expires in 2017. Rhinocort Aqua won a *MM&M* award in 2007 for its “Rhino Reader” campaign, created by Harte-Hanks. A Sanofi-Aventis spokesperson declined to comment on this year’s marketing effort. Generic Flonase was the second-best seller in 2007, according to research conducted by IMS Health.

Schering-Plough’s Nasonex, the nation’s best INC seller, will expire in 2014 at the earliest. “Nasonex sampling seems to be paying off. [The product] is holding its own against a large generic threat,” says Ramspacher. “Twenty-two percent of physicians overall prescribe [name brand] Nasonex compared with 20% prescribing generics.” Nasonex is known by many for its BBDO New York-created cartoon bee ads, which supersaturated consumer media outlets beginning in 2004. A 2007 TV spot from the campaign was listed as the fourth most-recalled ad by IAG Research. Despite criticism, the ads have weathered negative attention, and have been refreshed with new creative – still featuring the bee – for 2008. ■

Sanofi-Aventis’ Nasacort AQ, the third best-selling of the inhaled nasal corticosteroids, is not set to go off-patent until 2016

miles per hour, I can’t risk taking a medicine that makes me drowsy. That’s why I only use non-drowsy Clarinet to treat my worst allergy symptoms.” The Edwards sponsorship deal extends through the 2008 Sprint Cup racing season.

Competition from generics in the AR market will not subside any time soon. Sanofi-Aventis’s Allegra commanded 37% of the US antihistamine market in 2005, but has seen a steady decline – generic Allegra is