THE UPTAKE

Launching a new pharmaceutical or biologic next year? Expect smaller sales than in years past and a gauntlet of more sophisticated payers, physicians and patients. The volatility around a successful launch is higher than ever, says **Mike Luby,** who offers a dose of reality based on six years of launch data

The pharmaceutical marketplace has changed considerably over the past five years. A series of challenging circumstances have converged, causing the greatest disruption of the past 30 years, if not longer. A major implication of this convergence and disruption is the effect that it now has on the launch of new pharmaceutical and biotechnology products.

An analysis of over 300 products by specialty launch curves, covering most major launches between 2002 and 2008, shows that, all things being equal, a product launched today is likely to achieve almost 50% less uptake in terms of market share than a product launched in a similar situation prior to 2006 (see chart). The effects are far worse for products that are close cousins of existing products, such as line extensions, isomers and extended-release versions, suggesting that the opportunity for a line extension to win marketplace acceptance like AstraZeneca's Nexium or Forest's Lexapro did is very remote.

Several factors are contributing to this new reality. First, patent expirations have meant there are now many relative "gold standard" products available in generic form, raising the bar for new product entries. In addition, the introduction of the Medicare Part D prescription benefit in January 2006 has increased the sophistication that payers are bringing to the management of their commercial managed-care plans, even for drugs without substantial Medicare populations. And healthcare providers (HCPs) and patients have become increasingly skeptical of new products, as market shocks such as the withdrawal of Merck's Vioxx or the publication of a meta analysis for GlaxoSmithKline's Avandia have called into question the safety of products that had very large bases of physician prescribers and patients. Increased intensity of FDA review has lengthened review times and lowered approval rates.

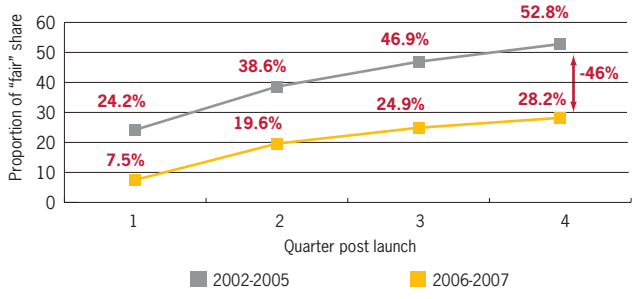
The last two contributing effects have been self-imposed. On the sales-force front, the industry was clearly over capacity, and many companies have moved to reduce sales-force sizes to be more in line with HCP needs. Finally, under the PhRMA DTC guidelines, which were implemented in late 2005, the industry trade organization encouraged member companies to hold off on DTC advertising for new products until such time as HCPs have been educated on the new product. This essentially removed a lever from the launch consideration set.

So, what are the implications for biopharmaceutical products launching today? The new reality dictates some new thinking in approaching launch planning and execution:

1. Assess the value proposition "trifecta" for physicians, payers and patients to determine optimal positioning. To identify a sweet spot that hits at the intersection of these three constituents, gain a clear understanding of the brand's value proposition relative to alternatives for each of these groups. In terms of targeting patient types, find an entry point that will provide compelling near-term uptake and that will lend itself to sequencing to the best long-term product opportunity. This could mean choosing a smaller patient segment, if it does not box you out from other targeted patient types over time. Then understand the relative weight each group will carry. This will vary in different market situations. For example,

Dose of Reality

Curves plot quarterly share for two launch periods and suggest a new uptake pattern, assuming share is a proxy for adoption.



Source: TargetRx analysis of claims databases for ~300 launch curves analyzed by physician specialty
Note: "Fair" share enabled comparison across categories (e.g., in a two-product market, fair share is 50%).

CURVE

a new formulation of a migraine product will likely have a different weighting for physicians/payers/patients than a new mechanism to treat type 2 diabetes.

2. Ensure that the forecast is reality based. Employ a hard dose of realism in launch assessment and planning, using independent consultants if necessary. There are many recent launch failures where it is clear that the assumptions prior to launch did not square up with current reality. The clarity around value proposition with physicians, payers and patients described previously should extend into assumptions around formulary adoption. Current reality suggests sales numbers will be smaller than they would have been in another time.

46% Given similar circumstances, your launch will be about this much smaller today than in 2005

Still, managers should resist the temptation to pump up the numbers, as this will only lead to disappointment and could mar the company's overall management credibility. Remember how different the current times are compared to the roaring '90s—there is no more Field of Dreams. It used to seem that a good product profile, coupled with a healthy dose of launch resources, would build a big brand. This no longer applies. Pfizer's Exubera is a great example of this (although there are many others), where an intriguing profile (inhaled insulin, no longer requiring injection) coupled with massive spending yielded very low output. While the drug met with safety concerns later on, the launch by any standard was an enormous disappointment.

3. Prime the marketplace. The new reality places a premium on getting HCPs comfortable with your product. Executing pre-launch activity to increase awareness, familiarity and prescribing comfort is critical. This is an area where, compared to the standard launch model, spending should be increased for many brand situations. If, through publications, presence at medical conferences, health science/medical liaisons and other appropriate/approved pre-launch market-conditioning efforts, you can shorten the time required for getting HCPs to the point that they are willing to prescribe your product, that is money well spent.

4. Based on your product's value proposition and a positioning that capitalizes on the brand's market opportunity, identify triggers that will accelerate uptake. Some of these are straightforward, such as the increasingly popular co-pay assistance programs ("co-pay cards"). Such a program can neutralize a reimbursement obstacle (tier 3 reimbursement status) and add ammunition to the sales pitch. It's also important to place some bets on long-shots, identifying a few opportunities that would have significant upside without heavy investment up front. An example could be petitioning US Pharmacopeia for category re-categorization if your delivery system is unique.

Deflated launch

It used to seem that a good product profile, coupled with a healthy dose of launch resources, would build a big brand or blockbuster. Not any more. Case in point: Pfizer's 2006-2007 failed launch of inhaled insulin Exubera (indicated to treat type 1 and type 2 diabetes). Data suggest that line extensions, isomers and extended-release formulations will also have a harder time gaining marketplace acceptance.

5. Execute a targeted, efficient marketing campaign. This may involve exercising some patience in the pursuit of patients. Nobody ever wants to be patient when it comes to the launch of a new product, but the new reality may dictate it. While marketing, planning and execution can address many obstacles, there are certain factors that are structural and that marketing cannot easily overcome. An example is securing Medicare Part D coverage. This process runs on an annual cycle, so if your product launches early in the year, it is highly unlikely Medicare coverage will be substantial in the first year on the market. If this is a critical segment for your product, uptake will be impacted significantly. This is why the positioning considerations for the trifecta of customers are so critical. Budgets and tactical plans then need to be developed to capitalize on your market opportunity.

Sequencing the spending to align with the market opportunity will make a big difference in the effectiveness of your spending. There is a tendency in launch situations to want to spend heavily early on. In many of today's scenarios, this will result in overspending, when the market forces are working against your success. This will put pressure on your organization, your team and your P&L. Pacing your investments to shape your market where possible, and introducing your product with the greatest odds for success, have never been more critical.

The launch environment for pharmaceutical and biotech products simply isn't what it used to be. The new reality is that a product launching today is going to be about half the size of one from five years ago, and the volatility around launch success has never been higher. This increases the import of planning and execution. It is a great time to be running a launch, though, as the stakes are high, and you never have to wonder if your efforts are making a difference. ■

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