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No Time to Delay

Getting your drug approved is only half the battle. It's how and when you launch that makes all the difference to the bottom line.

By Tim Noffke

The early bird gets the worm. It's an adage that means whoever arrives first has the best chance of success. But for pharma companies, launching a new drug is about more than just a taste of victory—it also means the loss or gain of billions of dollars, and avoiding harm to patients awaiting the arrival of a potential cure.

Some causes of delay are unanticipated—for example, receiving a regulatory approval letter later than expected—but other roadblocks are a result of poor planning. There is so much focus and energy on the regulatory submission that preparation for launch takes a backseat in the process. And given the high stakes and competitive landscape of the pharma industry today, a delay in launch can cost a company an average of $15 million per drug, per day (see "All in a Day's Work"). But regardless of a drug's revenue potential, delaying launch reduces a firm's ability to recoup its investment in R&D, wastes precious time in a product's patent life, and can leave the door open for competitors to usurp market share—or even a first-to-market position.

Why, then, do delays occur? Higher-priority products may divert a company's focus and take precedence, or financial constraints may limit a company's ability to launch. However, many delays are unintentional and can be prevented with foresight and proper planning. What do product managers need to know in order to successfully react to challenges that may arise when launching a drug in time? Here's a look at how three different companies used dynamic project management to get their products to market quickly, despite less-than-stellar conditions.

All in a Day's Work

	2005 Global Sales (in billions) (Source: IMS MIDAS, MAT)	Average Daily Sales (in millions) (Source: IPM)
Lipitor (Pfizer)	$12.9	$35.3
Plavix (BMS)	$5.9	$16.2
Nexium (AstraZeneca)	$5.7	$15.6
Advair (GSK)	$5.6	$15.3
Zocor (Merck)	$5.3	$14.5
Norvasc (Pfizer)	$5	$13.7
Zyprexa (Lilly)	$4.7	$12.9
Risperdal (J&J)	$4	$10.9
Prevacid (TAP)	$4	$10.9
Effexor (Wyeth)	$3.8	$10.4
Total	**$56.9**	**$155.9**

Expect the Unexpected

The time a company takes from receiving an approval letter to making its commercial debut can range anywhere from a few short days to many long months (see "Across the Spectrum," page 2). So what enables a company to hit the ground running right after approval? It takes detailed planning and disciplined execution, but more than anything, it takes the ability to act effectively when things go wrong.

The most crucial step is to develop a robust launch plan. An obvious first move, but launch planners often act before vital questions have been answered. To ensure success from the first step, the company should ask questions like: "What are the critical tasks?" "What problems might we encounter?" and "How will we deal with these challenges, should they occur?"

Here are some general principles to help guide a product team through effective launch planning:

- **Start early and work backwards** Launch planning should start as soon as the company knows it has a clinically viable product. For a drug, that could be at the beginning of Phase III. It's also crucial to construct the launch plan working backwards—from the earliest conceivable approval date—to ensure the company is in a position to act if the agency moves quicker than expected.
- **Document it** Each team needs to provide input on the time and effort they anticipate will be required for launch. Use that data to develop a project plan that identifies roles, responsibilities, and timelines.
- **Stay focused and bucket activities** Identify the 20 or so critical tasks that are truly essential to the success of your launch, and keep them front and center. Gather activities into two groups: those required to prepare for the launch date, and those that are triggered by approval.
- **Don't over- or under-do, but prepare for the worst** Construct detailed plans and schedules for each team and each person—but be careful: Getting mired in the minutiae can be just as confusing as insufficient instruction. Brainstorm anything and everything that might go wrong: Review lessons learned from your company's previous launches and research the challenges other companies have faced under similar circumstances. Create "what if" flowcharts. Assess the likelihood and magnitude of each risk to fully grasp the impact of various scenarios.
- **Develop Plan B...and C and D** Using the information you've collected, determine and document the actions you would take to manage each potential problem. What's most important is to anticipate what's ahead and know how to handle it so that the launch stays on track.
- **Make someone "it"** Designate one manager to be responsible for the entire launch effort. He or she is not obliged to any one functional department, but provides a bridge across functional silos, facilitates problem-solving, and ensures everything gets done. Not only must this person excel in leadership and organizational skills, but be a consummate diplomat as well.

Understanding the unique characteristics of both your organization and your product helps determine launch-preparation strategy. Just because one methodology works for one company or even one product, doesn't mean it will work for an individual launch. In the following three cases, each company identified the unique strengths and shortcomings of its product to determine how to get the drug to market. There's no right or wrong way—but the scenarios illustrate there is a best way to successfully launch a drug.

Thinking Outside of the Box

The challenge A small US biotech company completed development of a new product with a larger partner, which was then headed for an initial European launch. In the end, the big firm decided to fully license its rights in the product back to the biotech, which left the small company to execute its first launch alone. Not only was there little European infrastructure and no commercial organization, but it was the holidays, a time when business in Europe comes to a virtual standstill. Under tight deadlines, the biotech was on its own.

Across the Spectrum

Drug	Approval Date	Est. Launch Date	Approval to Launch, in Days
Baraclude	March 29, 2005	Apr 8, 2005	10
Boniva 150mg	March 24, 2005	Apr 2005	30
Symlin	March 16, 2005	June 2005	90
Asmanex Twisthaler	March 30, 2005	Oct 2005	180
Xopenex HFA	March 11, 2005	Dec 2005	270

Source: 2005 Medco Health Solutions and company news releases

The winning approach After developing a project plan, the biotech was faced with two remaining hurdles, which it overcame with careful execution. One obstacle had to do with a language barrier—the company would be taking orders from customers from every European country, but it didn't have the customer service team capable to handle many languages. Not wanting to alienate new customers or delay launch, the biotech mobilized its country managers to field calls in their customers' native languages. From there, the order would be sent to another staff member for processing, to create a smooth flow.

With one obstacle out of the way, the company had to tackle one more issue—inventory. To manage the risk that European distributors might not replenish stock or ship product during the holidays, the biotech built a safety store of inventory in a second warehouse. This was an expensive move, but because the launch planner had identified and weighed all risks first, management concluded opening a second facility was the most prudent decision.

There was one flaw that the firm noted in hindsight—the planning group did not assign one point person to oversee the whole launch. Because the R&D group and the commercial group were busy with their own tasks, both teams did not communicate regularly with one another and a few hiccups occurred around timelines and hand-offs. A program manager would have developed an integrated plan, built relationships across teams, and asked for help from management to get the job done more efficiently.

Making It Seamless

The challenge A Big Pharma company was ready to launch its first biological drug. Not only was the drug a first-in-class for a particular indication, it also held significant revenue potential for treating additional conditions. There was just one problem—in-licensed from a small biotech company, the drug came harnessed to an ill-coordinated string of third-party contractors and consultants, hampering launch. To add more fuel to the fire, the FDA asked the company for additional data on product stability and purity. This added complexity to an already convoluted scenario and threatened to delay the product by a full seven months.

The winning approach A lot needed to get done, and fast, so the company implemented a precise project-management plan that included building effective communication structures; performing in-depth scenario analysis and risk assessment; and finding the right leader who would drive collaboration among the stakeholders.

Teams were divided into subteams that focused on critical tasks like process validation and supply-chain management. A senior executive, who had the clout to eliminate barriers, worked closely with functional-area experts to ensure everyone stayed on schedule and troubleshoot problems as they arose.

Because of the third parties involved, communication was specific and frequent to keep everyone on track. Egos also were set aside; important tasks that carried the most risk were allocated to those who could get the job done on time—regardless of rank.

The result? The delay was eliminated entirely, which was an unachievable goal when the project began. The product launched on time—and within 48 hours of regulatory approval.

Bridging the Divide

The challenge A small biotech had entered into a codevelopment/comarketing partnership with a global pharma company for its lead drug candidate. As one of its only products, the success of the molecule was of critical importance to the smaller company. Adding to the stress, the biotech did not have confidence that the two firms with different corporate cultures could find a happy medium to coordinate a launch.

The winning approach An objective project manager was brought in to oversee the plan and serve as a bridge between the companies. Although the manager was contracted by the biotech, his focus was only on the success of the launch—he was not going to play mediator. It was crucial for the project manager to gain the trust of both parties, especially since he was stationed at the larger pharma company's facility.

By having an unbiased supervisor, both firms were able to create a roadmap that defined exactly what part of the launch each team would handle. Because he created an open line of communication, the project manager helped eliminate disagreements and hard decision-making. The company is well on its way to a smooth launch.

A Good Plan Is Just the Beginning

Even with the best launch plans, there are bumps along the way. There will be issues that are bigger than others, but many problems companies face before launch can be avoided with early planning. Companies uncertain of when or if they'll get an approval letter should consider a contract sales organization instead of immediately expanding its sales force, to prevent using salary and benefits on an idling team. Manufacturing teams also should stay in close contact with regulatory departments so inventory won't be sitting around.

With a detailed project plan and the ability to identify risk, firms can exert far greater control over how quickly a new product reaches the market. But what's most important is how a company responds to the bumps. With skillful risk planning, you can be the early bird every time.

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What Can Throw a Wrench in a Drug's Launch Plans?

Many delays are unintentional and can be prevented with foresight and careful planning. Here are some of the most common obstacles companies encounter. Don't let these hurdles cause a problem for your company.

- Receiving a regulatory approval letter later/earlier than expected
- Poor collaboration between alliance partners
- Inadequate coordination of logistics pertaining to:
  - Raw material procurement
  - Distribution
  - Special shipping requirements
- Inadequate supply of product due to:
  - Poor production planning
  - Third-party manufacturing constraints
  - Unreliable manufacturing processes
  - Quality failures
  - Inefficient quality-release procedures
- Delays in securing payer coverage
- Unprepared sales and marketing teams