
How Diagnostics are Changing Pharma Launches

Through a New Approach & Structure for Diagnostics Strategy



Diaceutics Group

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How Pharma Launches Looked Prior to Personalized Medicine



Pharma is moving away from launching with the one-size-fits-all model of drug launches towards multiple, smaller launches in personalized medicine. The reason for this shift? The dismal return of investment (ROI) that was seen with nearly all pharma launches is a key here. With more pipelines thinning out and blockbuster releases becoming less frequent, pharma companies are also facing other challenges when it comes to crafting a new launch. When coupled with an increase in medical costs and restrictive budgets, companies are re-examining their previous launch strategies.

Previously, launches hinged on estimates formulated by managers. Resource allocation, manufacturing plans and investment levels were developed using these figures. Promoting a product's launch to physicians by highlighting its safety and efficacy was a natural extension of this launch plan. Clearly, this broad and largely unfocused method of product launch has not been working, as the statistics show. For example, of the drugs released in 2008, just 33 per cent were projected to see their sales top the \$1 billion mark. (1)

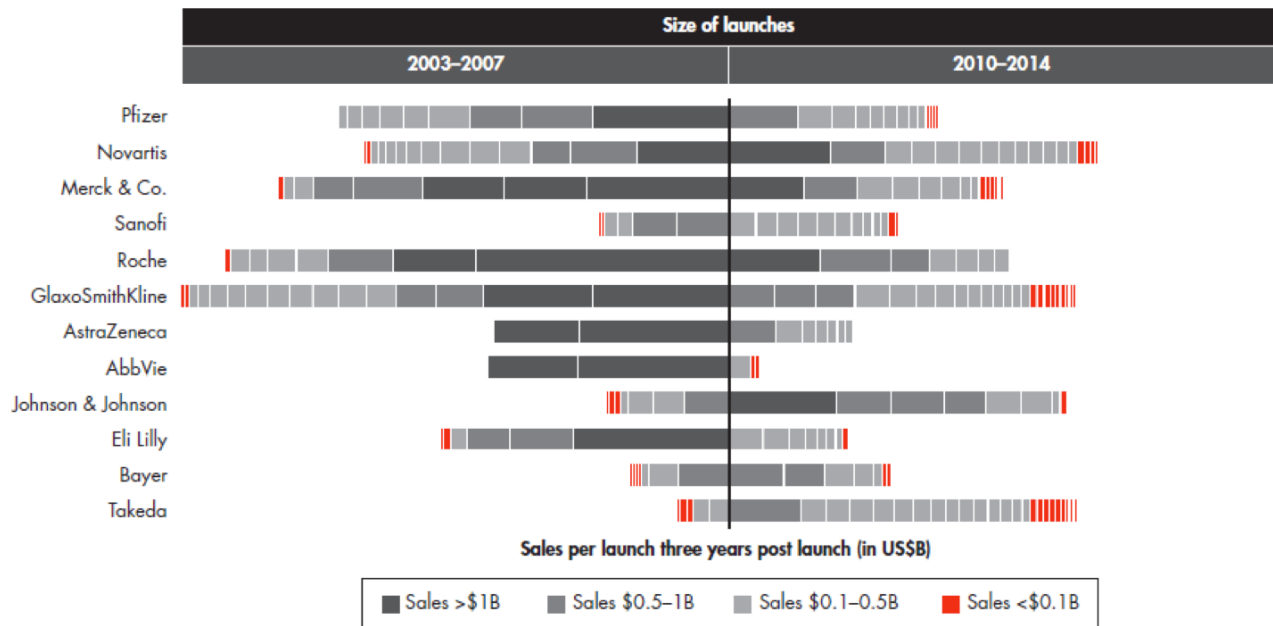


This one-size-fits-all method resulted in large numbers of pharma products being released with the intent of addressing a general medical condition. This approach meant that while one particular group of patients might see promising relief, another could be subjected to debilitating side effects that make them hesitant to continue treatment, or even lead to permanent, long-term damage or death. As an example, research has shown that beta-2 agonists are unsuccessful in treating between 40 and 70 per cent of those patients who are prescribed them, while statins are not effective at treating 30 to 70 per cent of patients. (2)

Diagnosics and Pharma Launches: What Has Changed?

A successful diagnostic strategy can help achieve optimal market adoption for a diagnostic test. Broadening the focus of testing, rather than only looking at a single protein or gene, for example, as well as next generation sequencing and multiplex testing, hold the promise of a more comprehensive analysis and a more thorough correlation.

Changing the focus of testing materials from tissue, for example - which is often difficult to obtain - to serum, blood or other forms of testing, opens up other possibilities that can be tapped for promotional purposes. Utilizing laboratory developed tests has proven beneficial to pharma companies in the past but new FDA regulations may make marrying their results and diagnostics difficult. Of course, the diagnostics backdrop will continue to change and evolve in terms of regulatory pathways, consistency in test scoring, developing standardized test protocols and coding. Those companies that take these into consideration when developing a marketing plan will be better positioned to develop an appropriate diagnostic strategy. (3)



Note: Only launches with reported sales (06-10)/sales estimates (13-17) included
 Sources: EvaluatePharma; Bain analysis

Source: <http://www.bain.com/publications/articles/a-new-pharma-launch-paradigm.aspx>

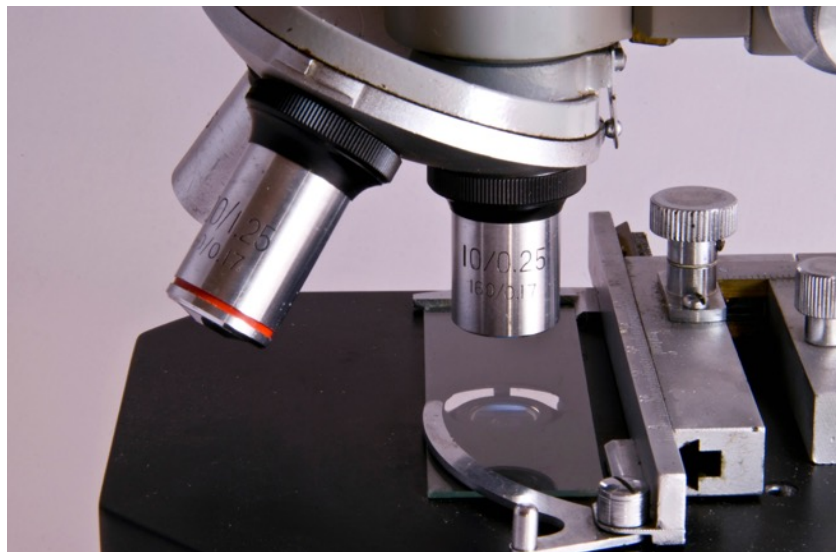
Approach and Structure for Diagnostic Strategy

With the emphasis on personalized medicine, pharma companies are changing the way they handle launches. Instead of releasing one drug that is designed for multiple patients, there is a more personalized approach. This involves a more focused release wherein pharma companies marry diagnostics with their drug releases. (4)

The analysis of this information is designed to ensure that drug launches are ultimately successful by increasing the chances of the regime's success. This, in turn, lowers costs for everyone -- including pharma companies. Using diagnostics helps pharma companies to classify pools of patients prior to the clinical phase that are likely to best benefit from their new launches.

Since only ten percent of current pharma launches are making it to the regulatory approval stage after clinical trials, implementing diagnostics will reduce the timelines needed for developing these drugs from start to launch. Additionally, efficacy in clinical trials can be demonstrated with a reduced number of patients since these individuals have all been prescreened as those who are most likely to benefit -- rather than be potentially harmed -- by those treatments. Thus, diagnostics answers the concerns raised by the FDA in regards to safer treatments that are also more effective.

Additionally, it has the potential to curb skyrocketing healthcare costs by ensuring that payers are able to obtain better value since they are reimbursing patients for those medications that are targeted to their particular medical conditions. (5)



Changing Diagnostic Launches for Pharma Success

Launches for diagnostics have to be in alignment with the targeted therapy launch and planned well in advance in order to be successful. While some pharma companies have their own diagnostic departments with which they can partner internally, others are partnering with independent diagnostic companies in an effort to ensure that they pinpoint the diagnostic connection with its medication very early in the process.

Determining this relationship as early as possible helps ensure that diagnostic launches are successful more often. Though this is a still-developing sector, it is one the the FDA is encouraging. As of 2009, diagnostic and pharma companies were collaborating on about 28 projects. About 60 percent of those focused on oncology while autoimmune diseases, infectious diseases and others made up the remaining 30 percent. (6)



Here's How to Understand and Master Diagnostic Launches

Personalized medicine with diagnostics enabling therapies are here to stay. Pharma companies need to develop a new approach to their launches in order to address these changes while also ensuring success. We at the Diaceutics Group have identified 11 frameworks that pharma companies can focus their targeted therapy launches within in order to help align the timelines for near-simultaneous release of diagnostic testing and the drugs that are designed to address the condition. These frameworks form crucial supports for seamless program development.



By fully aligning all 11 frameworks, pharma companies can synchronize a launch for both therapy and testing in a methodical and logical method. The 11 frameworks identified are as followed:



Within each of these 11 frameworks are 250 workstreams. These workstreams are designed to be specific to each asset and its development program. A timeline influenced upon the status of both the drug and the diagnostic indicates the ideal starting point, as well as the duration, of each workstream. Key business questions underpin each workstream. What is the purpose of these business questions? Each of these key business questions facilitates the success of the diagnostic launch by ensuring that important concepts are addressed at the appropriate stage before it is allowed to move further along in the process. This focused approach saves valuable resources while also opening up the possibility of new and exciting developments that have not yet been tapped.

Some examples of key business questions that are appropriate within the Strategy framework include:

- What is a Dx strategy and its key components?
- Why and when do we need a Dx strategy?
- What are the timelines involved in Dx strategy planning and execution?
- How are other pharma companies addressing their Dx strategy?
- How is the Dx business model different?
- How should we prioritize Dx strategy planning if we have missed the ideal starting point?
- How do we need to organize our Dx strategy planning?
- How does a biomarker improve the commercial feasibility of the therapy?
- What is the importance of a diagnostic's position and how might a Dx strategy impact the therapy positioning?

Diagnostics in alignment with targeted therapies is the wave of the future for pharma company launches. With careful and methodical introspection at each stage of the process -- made more precise by following the 11 frameworks -- pharma companies help ensure that their resources are used most effectively for the greatest return of investment.



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