Commercial Integration Reduces Risk in Bio-Pharma Launch Planning

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The rate of successful product launches in the biopharmaceutical industry is alarmingly low. It is estimated that only 10% percent of drugs which enter clinical trials will eventually receive regulatory approval. Various studies have shown that > 50% of the products that reached the market in recent years have failed to meet commercial expectations.[1] While drug development has always been a risky business, it seems that commercialization success rates have declined over the last five decades. A study published in 2012 found that for every $1 billion spent on R&D, the number of FDA-approved drugs has decreased by approximately 50% each decade since 1950.[2]

Most drug failures can be attributed to either scientific (efficacy or safety) or commercial reasons. The scientific risks are more difficult to control due to the inherent nature of entering new drugs into clinical trials. Drug companies have greater control over commercial planning. However, commercial failure was cited in a recent paper as the reason why approximately 20% of products failed to succeed in clinical development during a 10 year period.[3] More specifically, these drugs failed to demonstrate and effectively communicate substantial value to the market. In other words, their development plans failed to include commercial components that would have either predicted failure or would have better informed the trials to succeed. Another analysis by FiercePharma, which looked at "10 Top Drug Launch Disasters", 8 of the 10 products failed on the market due to poor commercial planning.[4] These products did not adequately address the market needs and expectations at launch because either commercial planning did not start early enough or commercial planning was not integrated and comprehensive. And this is just the tip of the iceberg. Many other products launched in the last 10 years have struggled to reach their full potential. Why is this happening? And why now?

The pharmaceutical industry and the health care market place have changed and continue to change rapidly. Large companies are launching fewer products and many have undergone massive restructuring and workforce reductions. Meanwhile, with talent jumping company to company, it challenges development teams and launch to leverage and align the variability inherent with diversity of backgrounds. Larger companies are challenged with institutional memory loss and departmental and geographical fragmentation. These factors lead to many internal challenges to maintaining company-wide best practices for successful launches. Companies, small or large, often reinvent launch plans and fail to capture learnings.

Small and mid-sized companies are launching a larger number of today's products. These companies also face the challenge of defining their launch processes. Most of their employees come from big-pharma companies. But this can lead to a confusing array of opinions and practices for developing and launching their drugs. How should these companies define their launch process? Which process is right for their company and products?

Today's launches are more complex than ever. They involve hundreds of parallel activities (horizontals), each of which are guided by functions (verticals) and are critical to the ultimate success of the product. What complicates launches is the integration required between the verticals and the horizontals. The clinical plan requires commercial input. The commercial team needs medical guidance to develop communications. Payer feedback is needed to develop the value proposition. The list of critical inputs and exchanges is extremely difficult to compile and manage.

The bottom line is that today's biopharmaceutical companies need to place more emphasis on detailed and integrated planning for all of the key aspects of a pharmaceutical launch. Those in early development cannot ignore the commercial components necessary to design early and late-stage trials. A standardized and coordinated planning system that incorporates the market needs (payer, provider, patient) is critical to manage the inherent risk of developing and launching biopharma products. The planning process must be comprehensive, with the appropriate expertise engaged in developing the launch plan. A company approaching a launch must adopt the appropriate "Launch Culture" early in the development of a product. This doesn't mean that companies in early development need to hire a chief marketing officer, but they should identify those points in their plans where commercial input is needed to inform product development. Ignoring these critical inputs places the product at risk of commercial failure –payers won't pay for it and providers won't use it.

Ultimately, this Launch Culture should feature a dedicated and empowered launch team with a clear vision of customer needs and the value that a new drug represents to the payers. Effective product launch planning and management can ensure a clear vison of the path to the market and establish alignment among the key contributors on the necessary steps and timing to achieve success.

Key Points

- The risk of commercial failure in the launch of bio-pharmaceutical products is more prevalent today due to the scientific challenges, increased pressure on product value and the evolving regulatory environment
- Well planned and integrated commercial input is necessary to reduce or eliminate the risk of commercial failure
- Commercial strategy should be introduced as early as possible in product development but all phases of product development can benefit from a well-designed integrated plan
- Implementing an integrated launch planning process along with the key elements of a Launch Culture will greatly enhance the likelihood that the launch product will reach its full market potential

[1] Helmant Ahlawat, G., & Arkel, i. C. (2014). *The Secret of Successful Drug Launches.* Brussels: McKinsey & Company.

[2] Scannell IW, B. A. (2012). Diagnosing the Decline in Pharmaceutical R&D Efficiency. *Nat Rev Drug Discovery* , 11(3), 191-200.

[3] Tufts University CSDD. (2013). Causes of Clinical Failures. *Tufts CSDD Impact Report*, 15(5).

[4] John Carroll, T. S. (2016). *10 Top Drug Launch Disasters.* Newton, MA: Fierce Pharma.

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