Coming to America: How Ex-US Drug Companies May Best Prepare for the Complexities of a US Market Product Launch

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Introduction

The US pharmaceutical market is one of the most promising markets in the global pharmaceutical market, accounting for nearly 50% of the global pharmaceutical sales revenue.[1] Many of the top pharmaceutical companies are based in the US, including Pfizer, Merck & Co., Bristol Myers Squibb, and Johnson & Johnson. Pharmaceutical innovation, however, does not merely come from these big pharma companies. Ex-US biotech companies or startups play an increasing role in R&D activities in recent years. Winning the US pharmaceutical market can often be essential for those companies to successfully commercialize their products globally. Establishing an international presence with a first launch is a challenge, but learning from others' experiences can help ex-US biotech companies avoid missteps and maximize their chances of success.

Objectives

The objective is to determine the unique US policy and market access nuances which must be addressed for ex-US biotech companies or startups to enter the US market. Given the differences between other global landscapes, this study aims to identify areas ex-US biotech startups must understand and focus on within the US market access space to best position for new drug launches. Additionally, this work provides a framework of issues to explore during the early decision-making process of a pre-launch setting.

Methods

Through secondary research and primary research with key stakeholders, Clarivate looked at the new policy changes as well as interpreted the evolving market access landscape and the implications of pricing and reimbursement in the US. Qualitative research with key opinion leaders (KOLs) and subject matter experts in the US was performed to understand the unique challenges and key lessons learned. Interviewed experts had experience working with product launches at ex-US companies.

Results

Our research identified specific nuances and differences in the US market access landscape as well as the early phase of new product planning that could be easily overlooked. Addressing these differences can be used to formulate a successful launch strategy for bringing pharmaceutical innovation from other geographies into the US market. Additionally, Clarivate provided specific recommendations for ex-US biotech startups that pull best practices from other experiences to avoid critical blind-spots, inefficiencies, and missteps within the US market access environment.

Develop strong value proposition in the new product planning phase

To effectively introduce a new treatment, it is crucial to have a realistic understanding of the current treatment options available to patients and the potential role a new treatment could play in their treatment journey. To gain support from key stakeholders such as payers, physicians, and patients, companies looking to enter the market must demonstrate a clear and meaningful value proposition that addresses unmet needs within the indication. Conducting a competitive landscape and treatment journey analysis can help identify potential issues patients may face before receiving the new treatment.

Developing a clinical trial design plan must incorporate input from key stakeholders and focus on demonstrating how the new treatment adds value compared to standard care. Any claims made regarding the value of the new treatment must have strong clinical evidence to support them. Communication with stakeholders should be a dedicated effort to ensure that the clinical development strategy aligns with their expectations. Additionally, the ex-US company must understand the United States Federal Drug Administration (USFDA) regulatory requirements. Obtaining regulatory approval requires a commitment from all involved parties to the transparency and impartiality of the review process.

Design evidence-based market access strategy before product launch

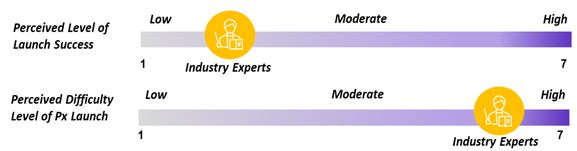
Unlike other major global pharmaceutical markets, the US market has a significant portion of private, commercial insurance. As a result, coverage, reimbursement, and access are more complicated in the US compared with other single-payer markets. There are constantly evolving legislative changes on Medicare, Medicaid, and commercial plans at the state and federal levels; healthcare is one of the key political agenda items for both major political parties. Specifically, the intended and unintended ramifications of the Inflation Reduction Act of 2022 on the pharmaceutical industry require a detailed study to understand its impact on future product launches and R&D strategy.

Additionally, the US market access language is distinctive and unique. The pricing structure is complicated, and prices are opaque. Reimbursement ties in with different drug pricing including Average Sales Price (ASP), Average Wholesale Price (AWP), and Wholesale Acquisition Cost (WAC). Different drug formulation has various distribution processes; for example, buy-and-bill for medical benefit products and specialty pharmacy.

Among all the US market access jargon, the concept of contracting is challenging for ex-US companies to understand because formulary management and expenditure containment via rebates in distribution channels are unique in the US market (see Figure 1).

For a pharmacy benefit product, companies, in fact, need to be prepared for multiple contracting relationships including Medicaid, vertical integrations, pharmacy benefit managers (PBMs) and managed care organizations (MCOs). The key to an effective market access strategy is a strong product value proposition that is positioned to address patients' unmet needs in a way that is convincing to US payers. Thus, secondary and primary research with key stakeholders to develop evidence-based pricing and access strategy is a key step before product launch.

Figure 1: Respondent Insights on Launching the First Product X (Px) in the US from Working at an Ex-US Company (N=6)



#1 Strong value proposition to differentiate in competition

"The leadership team felt that the product has a very different formulation, which would be an efficacy improvement even though that was not clinically relevant. They met the hurdle for noninferiority. ***It's innovative to the manufacturer and the patient community but not to a payer****."*

#2 Strong and experienced executive decision making

"The US market is ***unlike any other market in the world****. It's* ***constantly changing****. There are so many changes every week, unlike what they have seen in other markets. So, they don't understand all the weak points, potential issues, and what it actually costs to get in. I think* ***not understanding the US market is a huge liability****."*

"There were a lot of missed opportunities and a lack of understanding of what the marketplace was. ***The idea of a small commercial organization coming on the market that is essentially for all intent and purposes as a commodity market was probably not the best decision****.."*

#3 Deep understanding of US market access and reimbursement

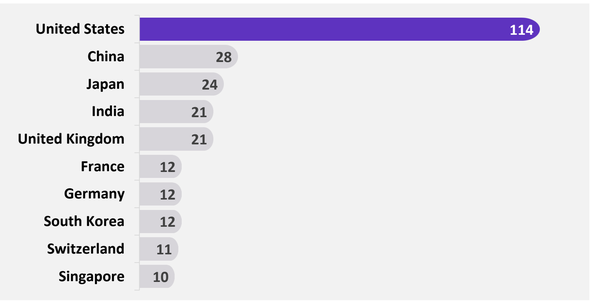
"The problem was that ***the management of the organization*** *refused up front to provide discounts or rebates. There was a* ***real disconnect between the brand team and the executive management****."*

Conclusion and Recommendation

Often, smaller ex-US companies are at great risk for assuming that the US market is simply a larger and more profitable market than their country of origin. However, this is not known to be the case and has led to poor launch performance for products marketed by ex-US companies that are not well-established or familiar with the US market access landscape. Even before developing products, ex-US companies must be informed about the US market demands and unmet needs when conducting portfolio assessments to pre-emptively set themselves up for success. An ex-US company will be better equipped to make successful strategic decisions only after evaluating all options to determine how to be a differentiated competitor within the highly competitive US market.

In addition to developing strong value propositions and designing evidence-based market access strategies, ex-US companies must understand the US market landscape or engage with a partner (e.g., HUB vendors for patient support programs, licensing partners) who understands the landscape thoroughly. A partner who understands the US market dynamics and can advise the ex-US company to help position product favorably within the market. Unless the ex-US company is an established organization with a US presence, they will need to ensure their launch strategy addresses all aspects of the competitive US market, either through partnerships or extensive pre-launch activities, to succeed.

Figure 2: Number of Deals Taking Place in the Pharmaceutical Industry



References

1.PHARMA NEWS INTELLIGENCE. Comparing Global Pharmaceutical Markets: US, UK, and China. Link here. 2.Pharmaceutical Technology. There were the biggest pharmaceutical deals in early 2022. Link here. 3.Clarivate analysis. Data on file 2022.