MARKET ACCESS INSIGHT: COMMERCIAL CONSIDERATIONS

John D. McDermott, Jr., Vice President, Covance Market Access Services, discusses approaches to maximize a product’s commercial value.

Understanding the clinical and technical factors surrounding a product during development is critical for downstream success. But beyond the pillars of safety, efficacy and quality, drug developers must also consider how key stakeholders will react to a product after regulatory approval.

Today’s product pipelines increasingly face barriers within a complex economic landscape. From new financial drivers to varying reimbursement models to detailed regulations, the ever-changing environment can greatly affect a product’s market potential.

Market access aims to identify all-important commercial considerations—early in development—to build confidence that a viable market exists. By understanding the needs and incentives of key stakeholders in the context of the commercial environment, market access can validate the opportunity for potential investors or licensees to maximize commercial success.

Market access can accelerate the coverage process and maximize a product’s market potential.
Critical Features of Market Access

A robust market access strategy can encompass many dimensions to provide a holistic assessment of the product’s potential within the drug development landscape:

- **Identifying access barriers—and opportunities**
  Accumulating market access insights helps develop responses to potential barriers early in development, before it is too late to change the course of action.

- **Assessing the landscape from critical angles**
  It is essential to determine the most important uptake drivers of products for payers, providers and patients. This process evaluates key stakeholders’ unique needs—from all critical perspectives—to support a robust commercial plan.

- **Forming a strategy—earlier**
  Market access strategies are most effective when you have enough time to integrate economic endpoints into a clinical research program. Forming a strategy can start as early as Phase I with additional incremental market access activities at the next developmental phases, all the way through commercialization.

- **Demonstrating market viability**
  Communicating the full benefit of a product to the right decision makers—regulatory agencies, venture capitalists, investors and potential licensing partners—enhances the potential for higher valuations.

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**Market Access In Action**

In a recent example, a company hoped to license a new drug. With a more favorable side effect profile, the product was poised to compare favorably to the market’s current treatment, but the developer had concerns about under-valuing the product’s potential. The developer undertook a market access strategy process to get a better understanding of the product’s valuation.

With Covance’s help, the company realized a better value proposition: utilizing the benefits of a buy-and-bill commercial model over those available through a retail pharmacy model. This shifted the conversation from incremental differences in the clinical profile to major differences in the economic profile.

Market access experts modeled the financial impact and proposed a new valuation—*two times the company’s initial amount*. As a result, the company sought and achieved a higher sales price, based on a broader definition of the product’s value that looked beyond merely the product’s clinical attributes.
An Integrated Approach

Developing the foundation for market access starts with mapping the connection points between the product and its market. Depending on the product’s specific needs, a market access plan may look at these dimensions, among others, as key drivers of value: burden of illness, treatment pathway, health economics, patient-reported outcomes, pricing and reimbursement. Detailed consideration of these dimensions can then be integrated into a comprehensive strategy for developing evidence to support a product’s value proposition to highlight key differentiators important to stakeholders.

Dimensions of Market Access

Partnering Considerations

No two market access strategies are alike, and each must consider a product’s needs, phase of development and desired outcomes. Partner organizations like Covance are often called upon to bridge potential gaps between products and markets, as well as to provide seamless access to networks of global clinical and regulatory experts.

With market access, it is important that a partner can adjust to unique requirements by offering a range of solutions, from limited consulting support to comprehensive product strategies, spanning discovery through commercialization.

Whether your end goal is to sell or license or develop in-house, a market access strategy lays the foundation for accelerated market uptake, whether you or your development partner ultimately brings the product to market. Investing in a market access strategy ultimately increases the value of your product because it reduces the likelihood of a commercial failure after regulatory approval.

Learn more about our market access solutions at www.covance.com/marketaccess