CRA Insights: Life Sciences

CRA Charles River Associates

November 2014

Economic value myths

Assessments of products in development often focus on clinical and regulatory success—the chances of hitting target endpoints and of the drug being approved for its target indications. This is underscored by the positive press that typically accompanies clinical trials milestones and the expectations they create among investors. The economic value proposition, however, is becoming an issue of equal significance. A failed economic value proposition often underlies approved drugs that have not lived up to expectations.

Setting aside failed launch *execution*, we find that many launch *strategy* mistakes result from unrealistic expectations regarding product value, particularly in a global economic environment characterized by an increasing focus on cost-containment and shared financial accountability. The most damaging economic value myths are variants of the following:

- Stakeholders will perceive value the same way that the pharmaceutical company does;
- A clinically superior product needs a premium price to justify its value; and
- Value today equals value tomorrow.

These myths can cause significant damage to generating and sustaining demand and financial value for a new product.

Myth 1: "Stakeholders will perceive value the same way that the pharmaceutical company does"

Evidence of a sufficiently good risk/benefit profile compared to a placebo may be enough for product approval. Drug companies, however, ultimately need to persuade market stakeholders—most critically, payers, clinicians, and patients—to adopt their products. The evaluation approach and incentives of each of these stakeholders are different and not necessarily aligned. Ultimately, these stakeholders simply may not value certain attributes of new products, even if these products appear to confer clinical or other advantages.

Payers need economic rationale

As payers are forced to consider total budget impact and cost effectiveness in their evaluations, new products will need to demonstrate not only clinical but also economic value. What other stakeholders may see as differentiating attributes of a new product (e.g., modest survival benefit or patient

convenience) may not be valued by payers, especially as comparative effectiveness increases in importance. Even products with strong clinical profiles may face challenges from payers that seek to constrain access due to budget imperatives, thereby relegating potentially new "gold standard" therapies to second line. Thus, the impact of payer decisions can be devastating to the adoption of new products, hindering clinician prescribing and patient affordability.

Clinicians need motivation to switch and an absence of prescribing barriers

In many therapeutic areas clinicians are satisfied and comfortable with current options, aided by incumbent manufacturers who may up the ante on promotional activities and support services in the face of competing entry. These clinicians are often unwilling to switch stable patients even if the new product conveys clinical or convenience advantages; as a result, the new product may be reserved for new patients or otherwise uncontrolled patients, leading to a slower than anticipated launch and a potentially damning lack of broad-based acceptance. Even if clinicians know about and are impressed with a new product, they may see insufficient value in it to work through payer-imposed barriers to access.

Patients need to be engaged

Even products with significant clinical advantages might suffer due to factors that are important to the value perceived by patients, including dosing, administration, convenience, cost, and support services. For example, will the clinical superiority of a new infused product be enough for patients to be willing to go to a clinician's office for an infusion as opposed to taking a once-daily pill? Will a device that accompanies a new product be difficult to use? Will the dosing requirements be onerous compared to existing alternatives? Will reimbursement or patient cost-sharing levels be a barrier? Clinically solid products have struggled when perceived by patients as "hassles" relative to their competition.

To improve the chances of launch success, it is essential to conduct due diligence in the form of primary research, aimed at understanding precisely how stakeholders define and perceive value as it relates to products in the category. This needs to be done early enough in the development cycle in order to make appropriate adjustments, formulate value propositions, and engage in market preparation strategies and tactics tailored to each stakeholder.

Myth 2: "A clinically superior product needs a premium price to justify its value"

Even if a new product is seen as clinically valuable, that value needs to be considered in the context of its price. One of the hardest urges to suppress is assuming that purported clinical advantages automatically "command" a premium price. The fallacy that clinical superiority always supports premium pricing continues to persist and can ruin an otherwise compelling product launch. In many cases, the fallacy is driven by historical analogues. A particular product in the past may have thrived with a premium price. At that time, however, it is likely that the competitive environment was different; the regulatory environment was different; and payer willingness and ability to manage the category were different.

One potential reason why clinical advantages may not always translate into pricing advantages is that payers may have a different *economic* comparator in mind. Payers may consider pricing reference points beyond the *clinical* comparator. Further, different geographic markets may focus on different clinical or economic comparators, and the clinical trial protocols and results may not resonate equally well in different markets with different prevailing patterns of care. Accordingly, manufacturers need to be mindful of the payers' frames of reference to evaluate a new product in the context of budget impact, including contractual relationships for competing products.

In today's environment, a manufacturer is unlikely to be able to attach a premium price to a marginally superior therapy and rely on marketing muscle alone. Payers and financial risk-bearing clinicians are becoming more aggressive in managing new therapies that do not demonstrate clear clinical and economic advantages. If coverage is impaired, it will be difficult for sales and marketing investments to overcome disadvantaged access and reimbursement.

Crafting a well thought-out and robust pricing strategy is critical to a new product launch and ongoing lifecycle management. Using analogues to formulate pricing strategy may be an incomplete and flawed approach, framed in an outdated stakeholder environment. Pricing research and analysis need to capture stakeholder perceptions regarding value and quantify willingness-to-pay in the current environment, cognizant of anticipated changes.

Myth 3: "Value today equals value tomorrow"

When a company asks "*why didn't this product launch perform as expected?*" changes in the competitive environment are often part of the answer. The drivers of perceived value during product development may change significantly by the time a product is launched, due to shifts in the healthcare environment and competitive dynamics. These changes, in turn, may be linked to strategic blind spots. It can be too easy to mistakenly base product expectations on an overly narrow and static view of the competition and the environment.

Examples of unforeseen product launch challenges include the following:

- a major competitor locking up key customers or distribution partners;
- an emerging competitor taking an unexpectedly aggressive pricing approach; or
- a modified reimbursement environment shifting customer incentives.

But, none of these challenges should be unexpected; a successful launch needs to be prepared for potentially significant contingencies. Such preparation requires an approach that considers the incentives of stakeholders and competitors. What are the key factors and uncertainties in the marketplace? Are there identifiable trends? Which factors will most affect launch success? How could the objectives and incentives of stakeholders result in actions and circumstances that hinder launch success? What is the likelihood and potential impact of each risk?

A structured scenario planning initiative should highlight unforeseen challenges and produce useful insights regarding the potential behavior of competitors, customers, and other stakeholders. The first phase of this effort often involves identifying and mapping critical uncertainties and their potential outcomes; the second phase involves formulating and simulating scenarios; the third phase focuses on launch strategy implications. As appropriate, scenario planning should incorporate competitive simulation—i.e., a realistic, role-playing exercise where well-briefed teams have incentives to develop successful strategies for the product sponsor and key competitors.

Summation: Looking outside and forward

It has always been the case that a key to mitigating launch issues is to rigorously stress test the launch strategy by explicitly considering the evolving perspectives of all market participants: customers, competitors, and influencers. Today, those evolving perspectives are increasingly focused on economic value. Accordingly, the opportunity for launch success will increase as commercialization efforts are approached with a critical eye on the economic value perspectives of key stakeholders.

Contact
Lev Gerlovin
Principal
Boston
+1-617-425-3083
lgerlovin@crai.com

About CRA's Life Sciences Practice

CRA is a leading global consulting firm that offers strategy, financial, and economic consulting services to industry, government, and financial clients. Maximizing product value and corporate performance, CRA consultants combine knowledge and experience with state-of-the-art analytical tools and methodologies tailored to client-specific needs. Founded in 1965, CRA has offices throughout the world.

The Life Sciences Practice works with leading biotech, medical device, and pharmaceutical companies; law firms; regulatory agencies; and national and international industry associations. We provide the analytical expertise and industry experience needed to address the industry's toughest issues. We have a reputation for rigorous and innovative analysis, careful attention to detail, and the ability to work effectively as part of a wider team of advisers. To learn more, visit **www.crai.com/lifesciences**.