Creating value through differentiation

How big pharma can think differently about LOE strategy

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The Canadian pharmaceuticals landscape is changing—and so are the business models

For years the pharmaceuticals industry has thrived on a business model built around so-called “blockbuster drugs”—those that exceed $1 billion in annual sales. Companies use revenue streams from these products to cover operating costs, execute strategic imperatives and fund research and development (R&D). After a period of seven to ten years, patents expire (an event known as loss of exclusivity, or LOE), generic competitors flood the market and market share of the innovator product (i.e. the brand) is rapidly eroded.

Companies implement tactics to slow this erosion but ultimately lose the battle to their more cost-effective generic counterparts. This futility is both a cause and effect of the classic blockbuster business model that has dominated the industry. Companies spend strategic resources, by and large, not on battling generic competition but on the next product launch.

Classic LOE management strategies—among them price drops, authorized generics and card programs—differ slightly in their benefits and risks, but share two important characteristics. The goal of all these strategies is to bridge the price gap between the brand and the competitor. They’re also unsustainable in the long run and an artifact of an outdated business model.

Over the past 10 to 15 years, several external factors have started to disrupt this business model and have prompted pharmaceutical companies to rethink the way they manage their LOE events.

Fewer blockbuster drugs

Perhaps the most jarring change to the pharmaceutical landscape is the reduction in the widely targeted, small molecule product launches that characterized the 1980s and 1990s. What we see now are high-priced specialty medications that target only a small subset of patient genotypes.

What this means for innovator pharmaceutical companies is smaller individual revenue streams in their portfolio. So it’s imperative that these companies extend their revenue streams beyond LOE to fund R&D and ensure the replenishment of the pipeline.
Reduced efficiency of R&D

The reduction in return on investment on R&D spend is also influencing change in the industry. The reduction in large, reliable revenue streams previously provided by blockbuster drug launches, combined with the need for companies to invest more in R&D to achieve the same level of output, is putting pressure on cash flows. Innovator pharmaceutical companies must compensate for this reduction in productivity by establishing a sustainable competitive advantage for their brands post-LOE.

Increased austerity from payers

Pharmaceutical companies are also experiencing pressure from increasingly fiscally conscious payer groups. Me-too drugs and those offering only a marginal improvement on the status quo will find themselves fighting an uphill battle to obtain formulary listing. What’s more, we’re entering an age in which the promise of positive outcomes for patients alone will no longer be enough—payers will refuse to reimburse new products unless manufacturers agree to substantiate those promises through real-world evidence.

This attitude shift from payers, combined with reduced R&D efficiency, means fewer new products will make it to reimbursement, and those that do will need support from back-end infrastructure to bolster their outcomes claims.

Classic LOE strategy in pharma

In an age where innovator pharmaceutical companies are pouring strategic resources into seeking their next blockbuster, brand managers have pursued LOE strategies that will bridge the price gap between the brand and the generic competitor. There are many tactics commonly employed to this end, but all seek to deprive the generic competitor of its most compelling value proposition: discounted price.

Dropping the price of the branded product

The most straightforward of these tactics is to drop the price of the branded product to match the generic. At surface level, this tactic seems like a simple way to deprive the generic competitor of its competitive advantage and let the sales team continue their physician conversations unencumbered by the need to justify a price premium.

Authorized generics

A more common tactic is to enter into an agreement with an established generics manufacturer and authorize the launch of a generic version of the product, sometimes prior to the end of the product’s exclusivity period. This tactic lets innovator pharmaceutical companies outsource the key capabilities needed to win at the pharmacy level and preserves a (smaller) degree of revenue on a more sustainable basis.

Card programs

Another common tactic is to establish a minimum-offering patient support program (PSP) in the form of a drug payment card that entitles the patient to a discount on the branded price and potentially the coverage of certain ancillary fees.

This tactic is popular with innovator pharmaceutical companies because the physician interaction is central to the execution, which lets them make the most of their promotional strengths. Importantly, though, it also provides an opportunity to collect valuable patient-level data.

The overarching shortcoming of all price-based LOE management strategies is that they’re unsustainable in the long run. Competitors can easily replicate these strategies, which leaves brands susceptible to price wars and subsequent erosion of revenues.

Indeed, the cost-effectiveness, speed and seamlessness with which companies can deploy these price-based tactics means they will continue to have a place in overarching LOE strategy, even in the new environment pharmaceutical companies find themselves in.

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But in the future, these strategies will become increasingly scarce. Pharmaceutical companies that want to maintain their competitive position and financial health need to establish a clear competitive differentiator unique to their brand. By creating tangible value for the patient, brands can command a higher price than generic competitors and maintain market share.

Unlike price-based strategy, differentiation through value creation for patients is sustainable in the long run, puts the patient first and diversifies the revenue model to be less dependent on blockbuster launches.

Value-added LOE strategy: how to establish a sustainable competitive advantage

To establish a sustainable competitive advantage following LOE, brands need to deliver additional value that goes above and beyond clinical outcomes. This strategy helps organizations maintain market share, demonstrate commitment to the patient and create value beyond the brand for which the company initially created the strategy.

In developing tactics to execute these strategies, the company must answer the critical question: How else can our product improve the overall patient journey? Companies must compel their brand teams to identify unmet patient needs and develop innovative solutions.

The establishment of a robust PSP

PSPs are one of the most effective and defensible ways to create value for the patient. A well-executed PSP can itself become a revenue-generating—and potentially self-sustaining—entity within the organization. For these reasons, PSPs are growing in popularity among the largest and most successful pharmaceutical companies and, in many therapeutic categories, have already become a barrier to entry.

But this value comes at a significant cost to the organization. A company looking to develop PSP infrastructure internally must carefully consider the impact such an undertaking would have on the profit and loss of the organization. If companies conclude that they don’t have the organizational scale to build out these capabilities internally, they should consider partnering with a third-party provider.

Manufacturers have many different elements to choose from when designing their PSP. It’s critical they carefully select those most closely aligned with the needs of the patient, strategic goals of the organization and their internal constraints. Here are several elements (beyond the already discussed card programs) of a PSP that can create significant value for the patient:

- **Direct delivery**: Home delivery of medications is a simple convenience that can be easily overlooked. This service is especially valuable to elderly patients, less able patients, patients living in remote areas and patients with rare diseases requiring specialty medications.

- **Reimbursement/benefits navigation**: Reimbursement pathways can be confusing and difficult to navigate, especially for patients without adequate coverage or taking high-priced medications. In addition, patients with a life-threatening or disabling condition place significant value in a service that lets them focus on their family and health.
• **Nurse support**: Occasional conversations and follow-up calls with a nurse can help ease anxiety, manage side effects and improve adherence for patients.

• **Financial assistance**: For patients without adequate insurance coverage, or who recently lost coverage and have yet to enroll in new coverage, a card program may not sufficiently improve the affordability of their medication. Financial assistance can help build brand equity while maintaining a marginal revenue stream.

Companies can use many of the elements of a PSP across brands. Consolidating PSP activities for multiple brands approaching or experiencing an LOE event can let companies realize cost synergies and lessen the overall financial burden of the program.

What’s more, a program running below capacity can provide an additional source of revenue if it extends these services to companies without the organizational scale needed to support an internal offering.

Companies can also use PSPs to generate real-world evidence for the brand. In an age where contingency-based listing agreements are becoming the norm, the ability to generate and make use of this data will transition from a powerful tool for managing LOE to a necessity for obtaining and maintaining reimbursement.

### Real-world evidence

Real-world evidence can itself be an execution tool for value-added LOE management strategy. Real-world evidence can aid in discussions with payers by equipping the manufacturer with more detailed information about the brand and its users. It can help in the following ways:

• **Personalized medicine**: The collection of demographic (or even genomic) data about the users of the brand can help build a profile for which the product produces outcomes superior to that of the general population. Armed with this intimate understanding of the patient population, manufacturers can demonstrate to payers the ability of their product to achieve exceptional outcomes.

• **Demonstrate the value of a PSP**: Real-world evidence can supplement a PSP by demonstrating its effect on patient outcomes. If manufacturers can demonstrate to payers that the PSP improves patient outcomes along metrics valued by those payers, they have a tangible value proposition over generic alternatives.

• **Demonstrating the shortcomings of a generic alternative**: In some cases, generic products may demonstrate bioequivalence to the reference product but fail to produce the same outcomes. This phenomenon is sometimes found in products with a complex or unique delivery method, release profile or manufacturing process.

Whether through investigator-initiated trials, PSPs, electronic medical records or some other medium, innovator pharmaceutical companies must carefully consider how each option aligns with the endpoints they seek to collect. To capture sufficient longitude and establish a valid baseline, it’s important to begin collecting data at least two years before an LOE event.

### Product reformulation

Though capital-intensive and not suitable for all products, reformulations are among the most powerful ways to create value and manage the life cycle of a product. By leveraging an innovative
delivery device or novel route of administration, companies can fortify the value proposition of the brand, reduce physician burden and/or create new, patentable intellectual property.

Innovator pharmaceutical companies must have an intimate understanding of their patient population to effectively execute this tactic. A misread market can result in damage to the company’s reputation as an innovator (e.g. being seen as a me-too company) and sinking significant costs in product development. Done properly, a reformulated product can create value for the patient and an airtight, lasting competitive advantage for a brand following LOE.

The art and science of effective execution

Once a pharmaceutical company has designed its value-added LOE management strategy, one critical task remains: execution. The poor execution of LOE tactics can result in a loss of market share to generic competitors that’s not easily reclaimed.

Luckily, a company can take steps to make sure it implements these strategies effectively. Above all else, it must tailor the strategy and tactics to the patient’s needs and the brand. There are three core questions PwC Canada has identified to ensure the effective execution of value-added LOE management strategy.

1. What are the patient’s core values?

   What does the patient value most? This question is perhaps the most critical because the answer provides the framework for testing the viability of the strategy. These values can vary between individuals, but common answers include:

2. What benefits can we deliver to cater to these values?

   This question is the medium by which a company creates value for the patient. The question can also be: What about our strategy speaks to the core values of the patient, and does it truly deliver what we designed it to deliver? A company can only answer this question through open communication with the patient.

3. What features can we design to deliver these benefits?

   Lastly, the company must select the correct features that create value for the patient to deliver benefits that speak to their core values. Consider one of the features discussed earlier: direct delivery of medications. This is a feature that benefits patients by removing the need to travel to a retail pharmacy to fill their prescription. The most apparent value catered to would be convenience, but another may be discretion. Without an intimate understanding of the patient population, the company cannot make assumptions about whether these benefits are valued.
Final thoughts

The pharmaceuticals industry is often criticized for being slow to adapt to change. Indeed, long drug development timelines and product life cycles, as well as the perpetual demand that exists for these products, has not cultivated a need to adapt to change quickly. But changes to the environment in which pharmaceutical companies operate are already in place and stand to disrupt the conventional commercial model and challenge pharmaceutical companies to innovate.

To stay competitive, pharmaceutical companies need to demand more from their brands and stop viewing LOE as the end of the useful life of a product. They must be prepared to work cross-functionally and establish open lines of communication with payer groups, physicians and patients to develop a lasting, value-added competitive advantage for their products following LOE.