How Biosimilars Track a Unique Sales Path:
Three Case Studies to Help Anticipate Biosimilar Entry in Your Market

Judith Kulich and Emily Jin
The promise of biosimilars in the United States is finally materializing—the FDA has established an approval pathway for biosimilars, and global sales could top $24 billion in five years.

Biosimilars are clearly an opportunity for new entrants and a threat to biologic innovators. Less clear is how a biosimilar’s introduction will affect market dynamics. Will a biosimilar quickly gain a large share of the market, as with many small-molecule generics, or will the nature of a biologic and the condition it treats limit market share erosion for the innovator?

This paper examines case studies of biosimilar-like drug introductions in the United States, including Omnitrope (approved as a biosimilar for Genotropin), VPRIV (Cerezyme) and enoxaparin (Lovenox). The case studies offer pointed insight on the specific circumstances and company tactics that affected market share.
After several stops and starts, biosimilars are making inroads in the U.S. biologic market. The FDA has established an approval pathway for biosimilars, while globally, biosimilar sales are expected to reach $24 billion by 2019, compared with $1.2 billion in 2013.¹

So what does biosimilar market entry mean for biologic innovators? Are innovators doomed to major market share loss, like most small-molecule drugs coming off patent?

At first glance, it would appear to be the case. As blockbusters lose exclusivity, including Humira ($7.9 billion in 2011 sales and U.S. patent expiration in 2018), Enbrel ($7.3 billion and 2015 EU patent expiration) and Remicade ($6.9 billion and expiration this year), payers and providers see potential cost-cutting in biosimilars. And there’s a lot of money to be saved: Biologic sales are expected to reach as much as $180 billion worldwide by 2017.²

But biosimilars and generics are not the same thing. Unlike small-molecule generics, which are far easier to produce than biosimilars and can offer a dramatic price discount over branded products, price is less of a factor in determining a biosimilar’s success. In Europe, where biosimilars have been on the market several years, the market cost for biosimilars has been estimated to be 65% to 85% of an innovator’s biologic.³

There’s been little examination of the nascent U.S. biosimilars market, and what these examples mean in terms of forecasting their impact. Because of biosimilars’ complexity and newness, the established market presence of many biologics and an unsettled regulatory environment, it takes close examination of each specific situation to assess the dynamics that will inform forecasting. Although the cases examined in this paper are imperfect—technically, they may not be “biosimilars”—they nonetheless offer valuable insight into how biosimilar introduction will affect market dynamics.

Using a framework that illustrates how payers, physicians, pricing and therapy affect market share [see Figure 1], the examples show that market behavior often depends upon how a branded product reacts to the biosimilar or the promotional efforts for the biosimilar. The framework also gives direction as to how biosimilar makers—and original market innovators—can increase market share or mitigate losses.

Pharma Companies’ Influence on Biosimilar Performance

Less manufacturer influence  
- Brand loyalty  
- Willingness to switch (new or existing patients)

Greater manufacturer influence  
- Market access/contracting  
- Utilization controls

Figure 1. Product differentiation aside, there is clear delineation between which factors manufacturers can and cannot leverage to affect a biosimilar’s performance, or how an innovator protects its biologic franchise.

Source: ZS Associates

The examples reveal a surprising truth about biosimilars: Price alone may not be enough to drive significant biosimilar uptake. We have seen estimates of innovator market share loss of anywhere from 30% to 70%; the framework can help narrow this range to improve marketing plans and strategies.

Genotropin and Omnitrope: When a biosimilar competes on the market’s terms

In the crowded human growth hormone (HGH) treatment market, success is considered a function of market access and safety (patients are primarily children), patient support and delivery devices. It was in this environment that Sandoz’s Omnitrope—considered the first biosimilar in the United States—obtained identical indications to Pfizer biologic Genotropin. Sandoz launched over the course of 2010 and 2011 with a 40% list price (wholesale acquisition cost) discount to Genotropin.

When price alone does not result in switching, biosimilar success depends upon investment in other share drivers, like patient support and aggressive rebating.

In the first two years following its launch, Omnitrope had little effect on competitor sales. HGH products were not a high-cost line item for payers and, with a largely pediatric patient base requiring chronic treatment, payers did not immediately force switches for cost savings.

After Omnitrope started competing through patient support programs, rebating and new indications, Genotropin and others did suffer market losses.\(^5\) Genotropin had a peak market erosion of 16%, while other competitors had erosion between 10% and 33%. Omnitrope reached its peak market share of about 17% in June 2012, five years after launch.\(^6\)

So when price alone does not result in switching, biosimilar success depends upon investment in other share drivers, like patient support and aggressive rebating. Genotropin-Omnitrope also illustrated other lessons (when there is no automatic substitution at the pharmacy):

- The amount of discounting can exceed the amount of market share gained.
- An approved label in all relevant indications may be necessary to build physician trust in the product.
- Multiyear contracts with large payers help maintain preferred access; increased innovator discounting may mitigate impact of the biosimilar.
- In undifferentiated markets, competitors other than the innovator should be prepared for some erosion as well.

**Cerezyme and VPRIV: When marketing falls short**

For many years, Genzyme’s Cerezyme (imiglucerase), a biologic enzyme replacement therapy, was the only option for Type 1 Gaucher disease. Cerezyme cost $200,000 a year, and annual sales topped $1 billion.\(^7\)

In February of 2010, the FDA approved Shire’s VPRIV (velaglucerase alfa) to treat Gaucher disease (although a Cerezyme supply shortage had resulted in early compassionate use of VPRIV in June of 2009).

Technically not a biosimilar, VPRIV replaced the same enzyme and had the same efficacy and side effects, as well as the same administration and dosing, as Cerezyme. VPRIV launched with a 15% discount on list price.

However, Cerezyme had strong loyalty due to its support programs, which provided services such as negotiating with payers on behalf of patients, and had long standing as the only treatment option for this rare condition. Despite the supply shortage, its share erosion was modest—18% at its peak, which happened almost instantaneously.

\(^5\) New indications included for treatment of Prader-Willi syndrome (April 2010), idiopathic short stature (August 2010) and Turner’s syndrome (September 2011).
\(^6\) Source: Bloomberg.
\(^7\) Source: Press reports.
VPRIV’s launch showed that physician and patient loyalty to Cerezyme overcame a 15% price discount even in a cost-sensitive market and despite early physician acceptance of VPRIV due to the Cerezyme supply shortage. In addition, in an orphan or narrow market with long-term customer loyalty to a single dominant product, interchangeability alone cannot sustain uptake.

**Lovenox and enoxaparin: When the setting and price trump a lack of data**

Sanofi-Aventis’ Lovenox, an anticoagulant used in hospitals, had 2009 sales of approximately $2.7 billion. Momenta Pharmaceuticals and Sandoz’s enoxaparin sodium, rated equivalent to Lovenox, went to market in July 2010 with a 14% list price discount at launch, less than typical generic discounts.

Lovenox’s share erosion peaked at 95% in the two years following launch (small-molecule generics typically lose 90% of their market share within a year). About a year after Momenta-Sandoz launched generic enoxaparin, Sanofi launched its own generic and captured about 40% of the generics market.

While generic enoxaparin was approved through traditional small-molecule new drug application (NDA) and generic pathways, it is a biologically derived product that today would go through biosimilar regulation. Enoxaparin was approved as a generic, and treated accordingly in hospital formularies.

This case illuminated an important fact: Because Sandoz launched through the typical small-molecule generic pathway, it did not have to promote enoxaparin aggressively. Enoxaparin was administered in a hospital setting and, given its generic status, pharmacy and therapeutics (P&T) committees had the power to guide usage directly. Despite being only a 14% price difference, the gap was enough to stimulate demand among this audience.

While its generic status was important, enoxaparin raises different considerations for hospital-based biosimilars: Messaging on manufacturing differences did little to minimize Lovenox’s erosion.

**Case study findings**

Ultimately, we saw three major findings from looking at these case studies, as well as examples from Europe, where biosimilars are more common:

1. **Companies need to identify the most important factors in a given market to generate uptake, and compete in those areas.** Sandoz had a much more aggressive discounting and pricing strategy for Omnitrope than Momenta-Sandoz had for enoxaparin, but market opportunity, payer influence and physicians’ willingness to switch limited Omnitrope’s initial impact.

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2. There are major differences between therapy areas and patient bases. Acute, hospital-based conditions may see more pronounced erosion; Genotropin has a large pediatric patient base for a chronic condition and providers were less willing to switch to Omnitrope.

3. When there’s one dominant market leader with established loyalty, such as with Cerezyme, there may be less market share erosion than in a crowded market where physicians are used to selecting from many alternatives.

Figure 2 captures these dynamics against criteria that include company, payers, customers, market decisions and dynamics.

Biosimilar Impact on Biologics

**Impact of specific factors on biosimilar uptake**

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**Biosimilar impact on market share**

Low: VPRIV 18%, Omnitrope 47%, Enoxaparin >95%

Source: ZS Associates

The future will be different

Market conditions for biosimilars are bound to change. Physicians’ comfort with biosimilars will increase and regulatory guidelines will be codified. Different levels of biosimilar status may affect the likelihood of automatic substitution at the pharmacy. Pharmaceutical companies won’t make the same mistakes, and uptake for biosimilars will be faster.

But innovators will work hard to protect their market share, and it may be harder to switch physicians and payers to complex biosimilars. New entrants will struggle especially when the originator company introduces a biosimilar of its own. Companies that use a framework to help determine the right promotional levers are much more likely to lead a successful launch or limit market share losses when their innovator drug faces biosimilar competition.
About the Authors

Judith Kulich is a Principal with ZS Associates in San Francisco and is the leader of ZS’s Forecasting practice. She is responsible for the development of ZS’s forecasting capabilities and dedicated client work, focusing on international forecast generation, platform development and capability building in the pharmaceuticals and biotechnology industry.

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