The Importance of Early Key Opinion Leader Outreach in the Biologics and Biosimilars Marketplace

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Concept Paper

Highlights

- In order to fully address the competitive marketplace for biologics and biosimilars, manufacturers of both must commit to early interactions with key opinion leaders (KOLs) who will affect a product's approval, pricing, and market uptake.
- As a manufacturer's product undergoes the rigorous approval process, concurrent needs for effective pre- and post-launch stakeholder engagement and market access strategies are critical. Accurately identifying key stakeholders throughout various phases of product development is essential to successfully achieving this.
- As reflected in this concept paper, acknowledging various stakeholder networks, as well as recognizing variances within the regulatory environment, is essential for companies looking to uncover the right decision-makers in support of biologics or biosimilars.

Introduction

In many markets, the introduction of biosimilar products is viewed as economically beneficial — in other words, the introduction of a biosimilar either will lower the average annual cost of an existing biologic therapy or, because of lower prices, promote increased access for (and use of) biologics — or both. There is often an implicit assumption of bioequivalence, such that the economic savings are achieved at no net loss of clinical benefit or no net safety consequence.

Over the past several years, the pharmaceutical industry has witnessed significant growth in the biologics sector, with biologics representing more than $150 billion in global sales in 2013. By 2020 they are predicted to generate $290 billion in revenue and comprise 27 percent of the pharmaceutical market.[1]

Forty-eight percent of sales come from 11 biologics that face loss of exclusivity between now and 2022.[2] This, along with the increasing worldwide focus on improving healthcare access and the cost of care, presents an undeniable opportunity for biosimilar manufacturers.

In reality though, the impact of biosimilar entry is not purely economic. Due to the myriad forms of intellectual property incorporated into most biologics — proprietary cell lines, formulation processes, and the like — a biosimilar is just that: similar, but not identical, to the branded product it hopes to supplant. The salient question to ask of any potential biosimilar entrant is this: Just how similar is similar?

With changes occurring now, and imminent change due to biologic patent expiration, evolving biologic and biosimilar sectors around the world require much more than just effective research and development. Manufacturers need a precise, thorough understanding of the various areas of expertise and input, knowledge of the multi-criteria decision-making processes by region, and insight into how related stakeholder networks can impact a successful market access strategy.

So, what is the current environment for clinician and market access stakeholder outreach in the biologic and biosimilar space? How does that vary among mature and burgeoning markets around the world? At which juncture(s) in the pipeline does a manufacturer need to reach out to stakeholders?

Clinician Perspective Versus Other Key Stakeholders — Biologics Versus Biosimilars

Clinicians are key stakeholders as decision-makers for patient therapy and can often make prescription decisions on brand versus generic formulations. Early biologics, such as insulin, erythropoietin (EPO), and growth hormones, have been invaluable in the treatment of serious illnesses such as diabetes, anemia, and renal diseases.[3] More complex biologics, such as monoclonal antibodies (mAbs), cytokines, and therapeutic vaccines, are helping to revolutionize treatment of cancer, autoimmune disorders, and other difficult-to-treat diseases.[3] In higher-cost disease arenas, biosimilars offer significant opportunities for expanding access to populations that need these therapies but are not currently able to utilize them. Clinician outreach and pricing policies are therefore inextricably linked.

Still, the primary concerns that drive clinician decisions around using biosimilars are:

- Safety and efficacy of the biosimilar in relation to the original biologic
- Knowledge about the biosimilar versus the original biologic

For example, if a key opinion leader (KOL) has been treating patients with a company's biologic for 20 years and is a strong advocate for that product, how do you get the KOL to migrate in support of the product's biosimilar? If the support has been established for the biologic, how do you convert that support to the biosimilar? Conversely, how do biologic manufacturers defend their market share from emerging biosimilars in a price-sensitive market?

While pricing is one avenue for achieving this migration, a rigorous commercial strategy that closely resembles the launch of a branded, original biologic is critical. Ensuring a company's share of voice within an increasingly crowded playing field for biosimilars presents an added major challenge for manufacturers, even if they receive reimbursement. The need for direct access to stakeholders who can impact decisions and help gain wide acceptance of a company's biologic or biosimilar is therefore essential at the earliest possible stage in product development.

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Critical Timing for Engagement

When during the product lifecycle do biologic and biosimilar manufacturers need to engage with clinicians and other stakeholders?

Our experience has shown that clients should engage with target stakeholders as early as Phase One. Committing to the identification of, and engagement with, the right KOLs from the outset, therefore, means assessing needs within each clinical phase and identifying the key KOL engagement tactics that a manufacturer will execute during each phase.

Phase One

Engagement Tactic:
Conduct Pipeline Interviews During Phase One

This is the ideal time to reach out to KOLs to understand their experience in a particular therapeutic area. When it comes to examining a particular biosimilar pipeline, a clinician's experience — including research or publishing experience, as well as any competitive activity he or she has participated in — will determine if that KOL's work is more aligned with a biosimilar manufacturer or the original biologic manufacturer.

Value

By engaging early with KOLs, manufacturers of biologics and their biosimilars get perspective on key stakeholders who impact decisions, and their approach to biosimilars. Is the feedback generally positive? Negative? Are there concerns around efficacy? Is there product awareness? Is there a deficiency of knowledge about existing clinical trial results for future competing products? During this early stage in the pipeline, manufacturers may also ask for literature reviews to better understand the competitive landscape (current therapies, products, new products coming on the market, placement in treatment), or for existing economic models about the therapeutic area to help inform interactions with KOLs.

Phase Two

Engagement Tactic:
Identify and Engage With KOLs and Market Access Stakeholders

By creating access to decision-makers early, manufacturers can begin to capture and communicate key information that supports a positive advocacy environment. Manufacturers need to know the top investigators for their biosimilars during this phase, as well as Phase Three. It's at this juncture that biosimilar manufacturers can educate existing KOLs about the upcoming biosimilar and cultivate new advocates. Similarly, early market sizing and the assessment of the commercial potential of a biosimilar can help identify gaps in treatment and other obstacles. This is also the ideal phase in which to conduct pricing studies with KOLs to help inform the pricing strategy of a biologic or biosimilar product.

Value

By ensuring engagement with key stakeholders during Phase Two, companies gain an increased understanding of the market appetite — both in terms of advocacy for treatment and pricing. Through a thorough assessment of the KOL landscape, manufacturers gain a clearer understanding of whether or not safety concerns, or a belief that a biosimilar is not similar enough, are the true obstacles to approval. A combined understanding of both advocacy and potential challenges in the marketplace can also inform the pricing strategy for a product during Phase Two.

Phase Three

Engagement Tactic:
Convene Payer and Physician Panels

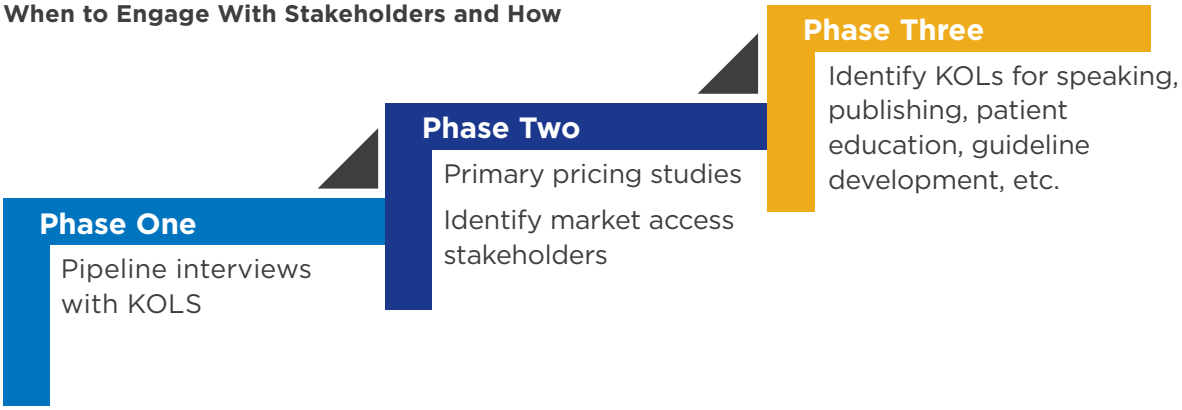
Phase Three of the development process represents the right time to convene payer and physician advisory panels that will help determine differentiation, drivers, and gaps in evidence, to help develop effective value messaging. During this phase, manufacturers can also identify and map KOLs for speaking engagements, publishing, patient education, and guideline development for effective product communication at launch.

Value

By convening panels with the key clinicians and payers who have, and can, speak knowledgeably about a biologic and/or its biosimilar, manufacturers can effectively craft messaging that will resonate with various stakeholder groups: clinicians, patient advocates, payers and their networks, as well as patients.

Figure 1 below illustrates the distinct opportunities for stakeholder engagement during the clinical development process.

Figure 1: Clinical Development Phases and Stakeholder Outreach



Source:Truven Health Analytics

Case Study: Client Leverages the Truven Health Virtual Advisory Board to Gain Valuable Insight Into the Climate for Insulin Biosimilars

Although face-to-face meetings with stakeholders are ideal, logistically they can be a nightmare. Through the use of the virtual advisory board (VAB) platform from Truven Health Analytics,™ an IBM® Company, clients can reach out to multiple stakeholders simultaneously and engage with them at times and locations most convenient to them. Web discussions, online surveys, and a digital boardroom provide avenues for engagement — either in tandem or individually. All work well within a VAB format.

The following is an example of how one client employed a VAB to garner new insight into biologic and biosimilar treatment for diabetes.

The Challenge

For a new diabetes treatment, a pharmaceutical client needed to ensure stakeholders (including primary care physicians, specialists, pathologists, policymakers, and payers) within a particular region understood points of differentiation, the value proposition, logistics, nuances of therapy, and the value and promise of its therapy for diabetes patients. The client wanted an in-depth view of the perceptions of leading physicians, and to develop a community of stakeholders who could provide: a regional perspective and knowledge of biosimilars in general, the existing climate for an insulin biosimilar, and the regulatory landscape at large.

The Approach

Truven Health conducted a VAB — a cost-effective alternative to traditional advisory boards, comprised of a series of web conferences and accompanying discussion modules — and delivered to the client valuable feedback regarding KOL perspectives on its presence in the biologic and biosimilar market.

The VAB was structured as a series of web conferences for regional clinicians who specialized in the treatment of diabetes. The series was structured to assess the clinicians' knowledge of biosimilars at large and with respect to the treatment of diabetes. It revealed that:

- Two-thirds of the clinicians who participated had some experience with biosimilars, although only one of nine advisors had extensive experience
- VAB participants had positive feedback on their own interactions with the client, on the client's commitment to diabetes, and on their perception of the client in terms of scientific excellence and product innovation

The Results

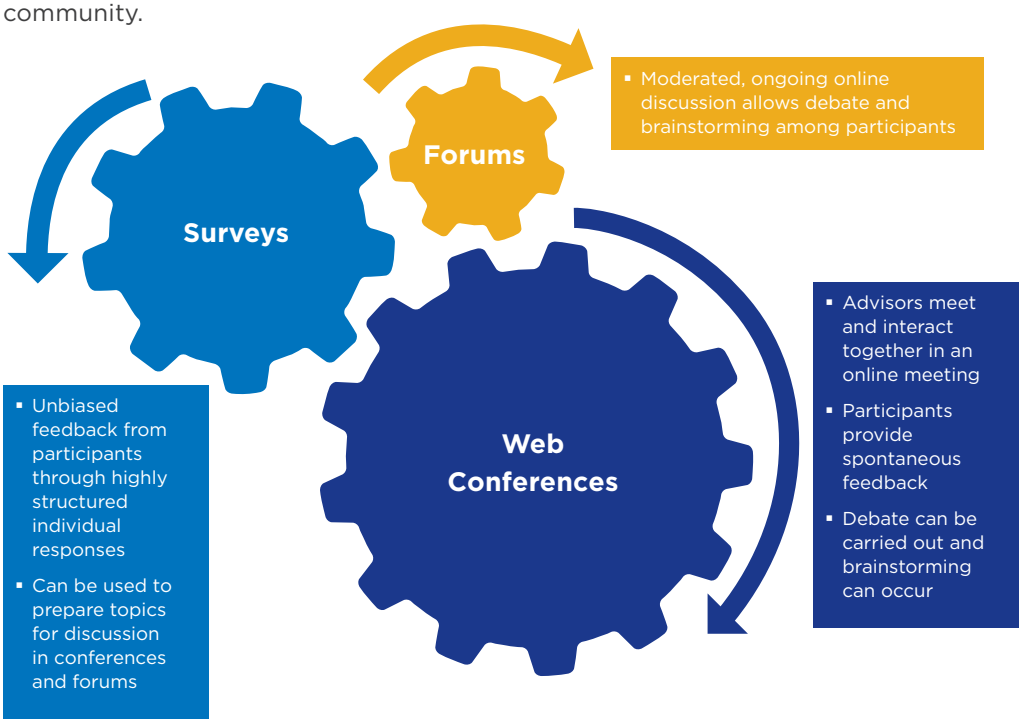
The VAB offered a convenient, cost-effective way for busy stakeholders from multiple countries to participate, express and exchange opinions, and deliver valuable stakeholder input to the client.

As illustrated in Figure 2 below, Truven Health provided a complete analysis and new strategic insights to help inform the client's commercialization strategy. Because the client wanted a better understanding within the region about the biologic and biosimilar landscape, feedback from the participating advisors provided valuable insight into which stakeholders the client would need to further engage. Similarly, because of the varied regulatory environment within the region, we provided the client with a better understanding of how clinician and patient education needs to be enhanced. Feedback from both the client and advisors who participated in the VAB was very positive and highlighted the convenience of the communication platform.

Figure 2: Stakeholder Engagement Through VABs

Phase Four: In-Market Engagement Through VABs

The mix of activities (each short, but flexible for advisors) ensures a more engaged community.



Conclusion

Pharmaceutical companies need to engage with the right KOLs and market access stakeholders throughout the lifecycle of a biologic or biosimilar in every geographic market worldwide. They need to continually receive feedback from and provide education to clinicians, payers, and other stakeholders who may impact the commercialization of their product. To educate the market fully about their products, respond quickly to market changes, and manage costs, VABs offer a viable solution. Similarly, because advisors and stakeholders seek convenient access to the latest information and thought leadership, recognition among their peer groups, and scheduling flexibility with minimal disruption, mutual needs of clients and stakeholders can be met through the creation of a virtual community.

Truven Health platforms for stakeholder management offer convenient, near real-time answers for life science companies seeking to address the multiple enduring challenges that populate the evolving biologic and biosimilar landscape.

About Truven Health Analytics

Truven Health Analytics, an IBM Company, is a full service health economics and outcomes research (HEOR), market access, and stakeholder management consultancy working with biopharmaceutical and medical technology companies across the globe. We help clients develop the rigorous scientific evidence needed to demonstrate value and check alignment with stakeholders' opinions. We understand client challenges because we've lived them in our own careers in this industry.

The Truven Health MarketScan® Research Databases are large, proprietary, de-identified U.S. administrative claims databases linked to data such as electronic medical records and hospital, lab, and indirect cost data, enhancing their richness and enabling these data to be used in economic model development. The Truven Health Heartbeat Profiler Stakeholder Database, a large global database, contains profiles on 2.5 million KOLs and market access stakeholders. Combined with Heartbeat Advisor, our VAB platform, we are able to identify, profile, map, and engage key stakeholders in discussions about product value.

We can help you put the right scientific information into the right hands — typically anywhere in the world.

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For More Information

To learn more about our stakeholder management solutions for KOL and market access stakeholder identification, please contact us at **lifesciences@truvenhealth.com** or visit our website at **truvenhealth.com/life-sciences/sms**.

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