How to compete and win in a world with biosimilars

Commercial launch strategies and defensive positioning for the U.S.

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$25 BILLION

out of $100 billion in biologics will be used for off-patent therapeutics by 2020, analysts say.

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No matter which path companies take, two things are certain: Biosimilars are coming to the U.S., and biopharmaceutical companies will need to evolve their commercial strategies to address them.

Biosimilars Defined

Traditional pharmaceutical products are inorganic, small-molecule compounds created through a series of chemical processes. As final versions of these drug products can be fully characterized with analytical techniques, companies other than the original drug innovator can reliably engineer and produce active-ingredient molecules that are structurally identical – otherwise known as generics. Large-scale clinical trials are not required for regulatory approval of generic small-molecule drugs, as they can rely on previous safety and efficacy findings of innovator drugs and relatively inexpensive phamacokinetic assessments of bioequivalence.

By contrast, biologics, sometimes referred to as biotechnology or large-molecule drugs, are typically proteins and antibodies derived from genetically modified living sources such as bacteria, yeast, or mammalian cells. Since the cell lines in a given source are unique and generate drug products via complex biological systems and production methods, biopharmaceuticals manufactured by companies other than the original drug innovator are not identical molecular copies. Thus the name biosimilars was created for products that are similar, but not identical, to reference biologic agents. Biosimilars require extensive (and expensive) regulatory studies and assessment distinct from those required for generics.

Since biologics are among the highest-cost drug treatments on the market today, biosimilars offer the potential for lower-cost alternatives. As can be seen in emerging markets, biosimilars are already offering more affordable prices, which are not only attractive but indispensable in economies where expensive treatments are not financially feasible. Biosimilars are making treatments available to patients in these countries who might otherwise lack access to advanced drug therapies. In the U.S., the Biologics Price Competition and Innovation Act of 2009 (BPCIA) allows for biosimilar development and thereby contributes to the Affordable Care Act's objective to reduce costs in the U.S. healthcare system.[1]

INTRODUCTION

Biosimilars are entering the U.S. market, and, no matter what role a company plays in the healthcare landscape, biosimilars will be a disrupter. The key challenge companies need to face now is how they will adapt their commercial strategies to be successful.

Biosimilars are on the minds of many leaders in the biopharmaceutical industry, whether they come from biologics innovators, biosimilar sponsors, generics manufacturers, or contract channel partners. Commercial players have already selected their products and markets of focus, thus establishing the playing field for the first phase of biosimilars in the U.S. Companies on all sides must now shift attention to the commercial strategies and tactics that will determine how the expansion of biosimilars will unfold.

Most are looking to Europe's track record for lessons learned, but the United States has unique market and regulatory characteristics that create distinct challenges and opportunities. The most applicable lessons we've learned from Europe are that biosimilar launches are not like generic or branded launches, and product uptake varies widely based on the specific dynamics of the medication, market, and competitive landscape. For example, even with substantial biosimilar discounting, the erythropoietin market in Europe is still dominated by established erythropoiesis-stimulating agent (ESA) brands. On the other hand, the European launch of enoxaparin, a biosimilar anticoagulant to Sanofi's Lovenox, has been more successful, boasting a share differential more like a typical generic pharmaceutical launch.[2]

Although the United States has been behind the rest of the world in providing a clear approval pathway for biosimilars, two developments are now driving a push forward: The first, President Obama incorporated the Biosimilar Price Competition and Innovation Act (BPCIA) into the Affordable Care Act in 2010, thus facilitating the spate of FDA approvals expected in the coming months and years. Second, biologic products with aggregate sales of approximately $60 billion are expected to be off patent in the U.S. by 2016.[3]

By 2020, analysts predict that $25 billion of $100 billion in biologics sales will be for off-patent therapeutics.[4] Beginning July 2014 with Sandoz's filgrastim filing, a first group of biosimilar applications is now under evaluation at the FDA, and approvals and U.S. market entry are expected in 2015. The time for biosimilars is clearly now, and the market is only going to grow.

For biopharmaceutical companies designing commercial strategies for biosimilars, this paper details a range of possible commercial approaches – including proactive, reactive, or a blend of both – and also addresses the issues of partnering, regulatory developments, and go-to-market considerations. Most significantly, there are a host of implications for organizational configurations, processes, cost structures, and even company cultures that need to be evaluated and addressed.

Biosimilars in Europe

Biosimilars were first introduced in 2006 when the European Medicines Agency (EMA) issued guidance on biosimilar therapeutics, paving the way for the launch of the 19 biosimilar products currently on the European market.[5]

Biosimilars' progress in Europe has been slow but steady, and there is some evidence that the pace is starting to accelerate. Acceptance and demand among payers and the public are increasing. And several challenges have been surmounted, including the introduction of the first monoclonal antibody (mAb) biosimilars -- infliximab marketed by Celltrion as Remsima, and Hospira marketed as Inflectra. These powerful autoimmune drugs were considered good candidates for biosimilars because of their high price, but their development was delayed due to their large molecule size and complexity.[6] Finally, biosimilar versions of more than 40 insulins are currently under development in the European Union.[7]

While slower than expected, Europe's biosimilars uptake is now beginning to show more promise. Global biosimilars sales in 2013 reached only $1.3 billion, but by 2020 biosimilars penetration is expected to have delivered from $11 billion to $33 billion in savings across the EU.[8]

EVOLVING COMMERCIAL STRATEGIES

Depending on a company's objectives in the biopharmaceuticals market, the commercial strategies and associated tactics necessary to execute a biosimilar market plan will vary.

The strategic capabilities a biologics company must develop or expand, independently or through partnerships, are dictated by its position in the biosimilars landscape and the degree to which its product portfolio must be defended against biosimilar competition.

Biologics innovators focused on the development of original biologic medicines must defend their portfolios against biosimilar competition with aggressive intellectual property strategies and lifecycle-extending commercialization strategies.

Biosimilar sponsors seeking market entry for their therapeutics must efficiently manufacture and develop biosimilars, and establish clinical, regulatory, and effective commercial expertise - sometimes from scratch - in a complex marketplace.

Companies pursuing a blended approach of biosimilars development alongside innovative biologics brands need to effectively balance organizational resources and investments across disparate, and often competing, strategies.

Biologics Innovators

Biologics innovators are already under market pressure from biosimilar market entrants in most global markets. Fortunately for innovators, European market uptake, for example, has been slow and mixed, allowing companies time to forge defensive strategies. Also fortunate for innovators is that the discounts for biosimilars have not been nearly as drastic as the 80-90 percent discounts typically associated with generic pharmaceuticals. Hence, even with competition from biosimilars, innovators continue to retain strong positions in the European biologics markets.

Taking a more competitive stance. Many biosimilar entrants in the U.S. will be launched by companies with European market experience, and innovators will need to take steps to protect or extend the value of their brand portfolios. These include developing a robust understanding of the broad competitive threat and clinical positioning of biosimilars, building defensive strategies, and taking substantive action in the marketplace. Historically, biologics innovators have faced limited, largely predictable threats and competition. Therefore, many now find it challenging to quickly establish competitive intelligence capabilities and use them to understand the intricacies of the biosimilar landscape. Further, the need for competitive pricing, margin pressure, and aggressive contracting can be a wake-up call for some innovators not experienced in such hard-hitting commercial tactics. Cultural change will need to occur alongside the expansion of new strategic capabilities in order for innovators to maintain market share.

Repositioning existing products. Innovators' strategic market planning should focus on employing brand teams and targeted messaging to reinforce any degree of differentiation from biosimilar entrants, which will vary from product to product, well in advance of forecasted competitive launches. Particularly with large, complex monoclonal antibodies, it is important to carefully review safety and efficacy data to thoroughly understand product differences. Additionally, innovators should investigate ways to expand their products' applications by repositioning them for new therapeutic areas. Some examples include: devising safer or more patient-friendly delivery mechanisms, simplifying dosing, considering portfolio-based approaches to specific customer segments, or developing next-generation versions of existing biologics, otherwise known as "biobetters."

Innovators will need to take steps to protect or extend the value of their brand portfolios.

Highlighting manufacturing processes as differentiators. Furthermore, most biologics are protected by unique form and formulation process patents. Innovators need to ensure that provider and patient stakeholders are aware of a proven track record in quality and supply reliability, and highlight any weaknesses biosimilar entrants may have in manufacturing capacity and expertise. Additionally, companies need to enforce patents and intellectual property rights related to manufacturing and continue to upgrade their own production capabilities.

Discounting when necessary. Finally, when faced with biosimilar manufacturers that are able to assuage provider concerns about safety and efficacy while successfully differentiating their products, biologics innovators may need to consider discounting and contracting strategies. In such cases, innovators must model high-probability pricing scenarios within purchaser segments and commit to thresholds of action and reaction. It is important that biologics marketers make decisions quickly before market share erodes, as lost share is difficult to regain without further aggressive discounting.

Near-Term Biologic Patent Expiries

Drug	Company	U.S. Patent Expiry*	2014 Sales: U.S. / Global†
Lantus	Sanofi SA	February 2015	$4.4B/$7.2B
Humira	AbbVie	December 2016	$6.5B/$12.5B
Rituxan/MabThera	Genentech/Biogen	September 2016	$3.4B/$7.1B
Remicade	Janssen/Merck	September 2018	$3.9B/$9.2B
Avastin	Genentech	July 2019	$2.8B/$6.6B
Enbrel	Amgen/Pfizer	April 2029	$4.4/$8.5B
Herceptin	Genentech	June 2019	$2.0B/$6.5B
Lucentis	Genentech	June 2020	$1.8B/na

*Source: GaBI, dates subject to change

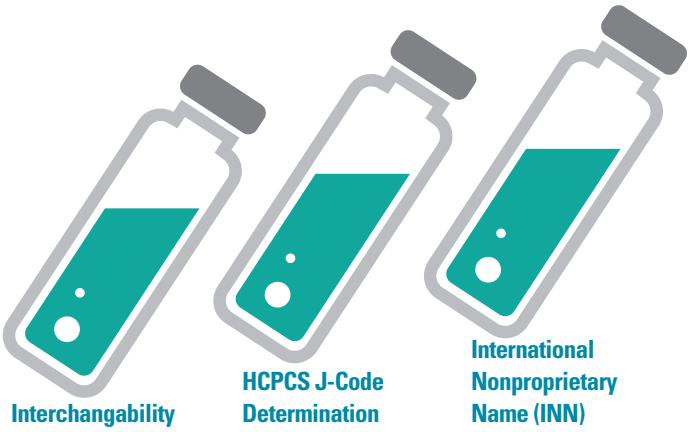
†Source: company reports

Developers must actively focus on their commercialization capabilities and be able to ensure maximum market access.

Biosimilars Sponsors

Whether working independently or with partners, developers pursuing biosimilars must integrate capabilities in clinical development, regulatory compliance, advanced and safe manufacturing, and commercialization. As regulatory requirements for biosimilar approval are still evolving, clinical development strategies must entail early engagement with regulators to identify appropriate clinical endpoints and manage clinical trial aspects, such as patient recruitment, costs and time. In the event that a regulatory pathway seems clear and biosimilars sponsors are able to reference analytical and clinical data demonstrating similarity and addressing any uncertainty, there may be a strong case for pursuing a biosimilars program.

Regulatory Challenges



Fostering product acceptance. Developers must actively focus on their commercialization capabilities for broadest market access following launch. Although providers and some patients are familiar with the lower cost potential of biosimilars, educating these stakeholders about their safety and efficacy will likely require cultivating knowledgeable market and opinion leaders. Further, securing third-party support from providers, media, and analysts will assist in product market acceptance.

Several key regulatory issues will strongly impact products' commercial strategies, including interchangeability, HCPCS J-Code determination, and the International Nonproprietary Name (INN) (**see sidebar on page 7**). Each of these developments will have implications for communications campaigns, messaging, discounting, and contracting strategies.

Segmenting market outreach. Executing a commercial strategy for biosimilars comes down to having the capabilities to compete. Whether by building focused marketing and medical communications organizations, or developing such capabilities through partnering, it is vital for biosimilar sponsors to understand capability gaps and develop plans to fill them. Knowledge of specific market segments within therapeutic areas is essential because each segment will assess the value of biosimilars differently and be influenced by varying factors. By contrast, launching with a broad-based commercial strategy that views the whole market as homogenous will likely result in slower uptake and/or a need to more heavily discount to gain desired market share. While establishing commercial expertise, reliable market intelligence, and stakeholder relationships in a new therapeutic area requires a large commitment of expense, effort, and time, the cost of neglecting to do so could be much greater.

Tempering short-term expectations. Biosimilars sponsors must also recognize the market power that biologic brand innovators will likely continue to hold. Innovators have made substantial investments in product development and, in most cases, have established well-known brands with demonstrated clinical value and relationships with key opinion leaders. Thus, the ongoing investment required of the biologic brand innovators to maintain share will likely be less than that required by biosimilar sponsors. Additionally, as we have seen in Europe, innovators have been willing to discount branded products to maintain market share, and we expect this to be the case in the U.S. as well. As such, biosimilar sponsors are well advised to set conservative expectations about share and price in the early stages of their launches. *(continued on page 8)*

REGULATORY UNCERTAINTIES AND THEIR IMPACT ON COMMERCIAL STRATEGIES

Interchangeability One of the most complicated regulatory issues has been automatic substitution, or the ability for a pharmacist to substitute a biosimilar drug for the biologic specified on a provider's prescription. In Europe, the EMA has made it clear that it will not make decisions about interchangeability but will leave it to member states to decide whether switching between biologics and biosimilars can occur at the pharmacy level. While a number of member states have gone as far as banning the practice, France has passed legislation allowing automatic substitution in treatment-naiive patients, and other countries may follow similarly.[9] *

In the U.S., the FDA was given the authority by the BPCIA to designate a biosimilar as substitutable, and decisions about interchangeability are also being made at the state level. Eight states have thus far enacted legislation allowing it,[10] and in these cases the pharmacist is required to notify the prescribing physician of substitution decisions. Arguably, there is potential to come up with additional innovative protocols for dealing with this issue in the U.S. In the midst of these legislative decisions, companies should put particular emphasis on commercial messaging that stresses similarity in safety and efficacy. Additionally, it is important to note that particular health plans may limit whether a pharmacist can substitute. These issues must be addressed by the industry at large since, without interchangeability, expected uptake of biosimilars will likely be lower and the required commercial investment will be higher.

HCPCS J-Code Determination The Healthcare Common Procedure Coding System (HCPCS) is a set of healthcare procedure codes used to determine reimbursement to the Centers for Medicare and Medicaid Services (CMS) in the medical billing process. Group J under HCPCS is used for "Drugs Administered Other Than Oral Method, Chemotherapy Drugs," and this is where biologic therapeutics are listed. An established branded biologic has an assigned J-Code that determines the reimbursement price. This price fluctuates over time based on all the products sold under a particular J-Code.

If a low-cost biosimilar competitor enters the market with the same J-Code, the reimbursement rate will fall for all products in that J-Code. If the low-cost entrant has a different J-Code, the reimbursement rate of the established products will not be impacted. The implications and detailed nuances of this are significant and amount to more than can be outlined in this paper. Simply put, each stakeholder is impacted by reimbursement rates, particularly given the high rate of CMS funding for biologic products. Whether a biosimilar gets the same J-Code as the branded product or a different J-Code, companies must bear this issue in mind when crafting their commercial strategies and pricing over the near- and long-term.

The Name Game While more European industry leaders favor giving biosimilars unique names from their corresponding biologics, there is a movement in the U.S., spearheaded by the Generic Pharmaceutical Association and supported by Novartis, to have biosimilars share the same International Nonproprietary Name (INN) as their reference biologics.

Some providers believe that giving biosimilars the same INN as the originator product would be helpful. Dr. Michael Oleksyk, Vice President of Medical Affairs and Chief Medical Officer of Baptist Health Care in Pensacola, Florida, said: "If you give it another brand name, doctors won't remember. We already have to learn two names for every drug. Remembering three is putting another obstacle in the way of biosimilars adoption."

A leading physician from one of the world's largest healthcare systems disagrees: "Giving biologics and biosimilars the same name may be a bigger deal for solo practitioners who only get their education from reps. Doctors in hospitals are used to multiple names." Other industry leaders, including Johnson & Johnson, are also in favor of separate names, arguing that giving both types of drugs the same name could cause confusion and potentially jeopardize patient safety by making it more difficult to track adverse events.

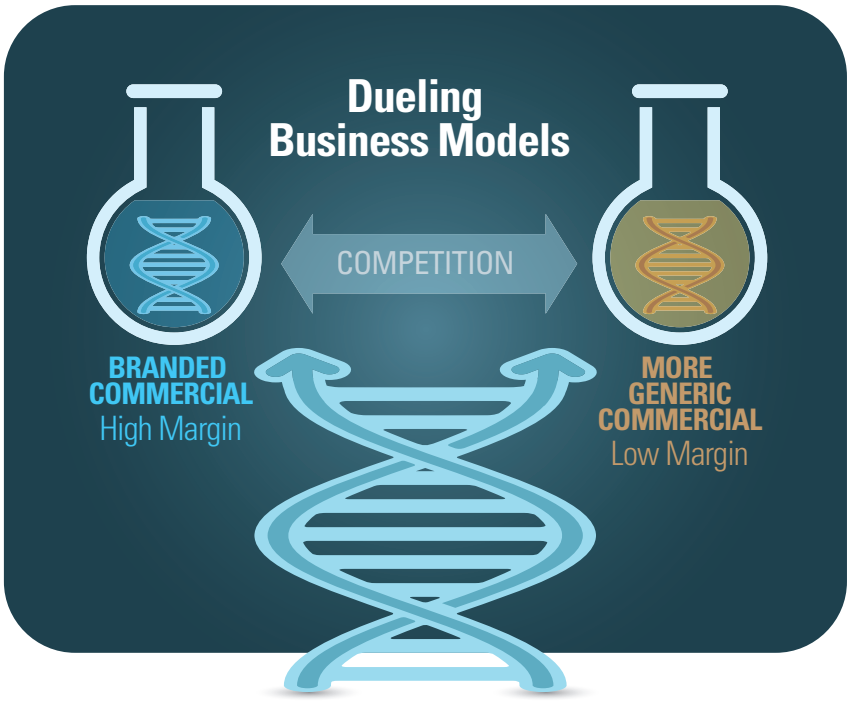
Many experts believe that the FDA is reserving judgment on this issue while it awaits the World Health Organization's (WHO) position.[11] Recently, the WHO suggested a possible compromise solution: Non-glycosylated biosimilars (e.g. insulin and filgrastim) could be given the same INN as their reference drugs. By contrast, glycosylated biosimilars (monoclonal antibodies, erythropoietins) could be appended with a Greek letter suffix to indicate the drugs are similar but distinct.[12]

* Correction: A previous version of this paper stated that Denmark had passed legislation allowing interchangeability. Current guidelines in Denmark do not support automatic substitution.

Blended Strategies

A handful of companies have chosen to simultaneously develop next-generation innovator biologics and pursue market opportunities with biosimilars. These firms have the opportunity to leverage capabilities established in biologics manufacturing and commercial efforts, but must also execute a challenging dual-business model comprising a high-margin and a low-margin business simultaneously. The goal is to increase leverage without burdening the lean, operationally efficient business of a biosimilars division with the overhead of a high-margin biologics business. This requires managing the differences between the corporate mindset inherent in a high-margin, well-resourced, branded commercial organization and the mindset of a low-margin, minimally resourced, more "generic" commercial approach. These adjacent business models can become dueling business models if not managed effectively, and a company needs to assess its commercial capabilities and determine which should be shared and which should be kept separate. Some biopharmaceutical companies have successfully managed this internal competition by establishing separate divisions and allowing them to operate largely independently, as is the case with Novartis and Sandoz.[13]

Another nuance of a blended strategy is when, in certain markets, two competitive products are promoted by the same company. In these cases, messaging needs to be thoughtful and clear to avoid potential confusion amongst providers about which product to choose for a particular patient. Although difficult, promoting both biologics and biosimilars is not impossible and may be a winning strategy if companies employ unique contracting tactics as discussed below.



Biopharmaceutical companies have successfully managed internal competition for resources by establishing separate divisions and allowing them to operate independently.

Partnering Organizations

Recognizing the challenges of establishing the necessary capabilities to launch a biosimilars business, many firms are partnering to augment capabilities that they had either deemed strategically unnecessary or have not yet developed. Since investment in biologics is a long-term, complex proposition, these are, in turn, lengthy relationships. As such, careful selection and management of value-chain partners are critical.

Value-chain partnerships can help companies expand expertise, blend core competencies, and mitigate investment risks. These partnerships are, to-date, encompassing a range of manufacturing and commercialization arrangements, co-development licensing, and international agreements.

A sampling follows:

- **Large pharmaceutical leader partnering with an experienced developer of complex biologics:** Baxter International and Momenta Pharmaceuticals have been jointly developing interchangeable biosimilars since December 2011.[14] Baxter provides manufacturing, clinical development, and commercial expertise. Momenta contributes product development capabilities.
- **Biotechnology leader partnering with specialty drug and large generics company:** Amgen and the Watson division of Actavis are collaborating on the development and commercialization of biosimilars, with Amgen contributing development and manufacturing and Watson providing marketing expertise.[15] Additionally, Amgen develops its own biosimilars outside of this agreement.
- **Generics injectable leader and experienced biologics manufacturer:** Hospira and South Korean firm Celltrion are jointly developing and manufacturing such drugs as Remsima and Inflectra, both biosimilar versions of Jannsen's Remicade (infliximab) for rheumatoid arthritis.[16] This was the second filing for a biosimilar product in the U.S. and the first for a monoclonal antibody (mAb). Additionally, Hospira develops its own biosimilars outside of this agreement.
- **Biologics innovation division of major pharmaceutical company and large international generics manufacturer:** Merck Serono is in a partnership with Indian generics firm Dr. Reddy's Laboratories to work on better ways to meet biosimilar regulatory requirements in the U.S. and Europe.[17]
- **Specialty bio-technology firm, biopharmaceutical manufacturer, and large diversified healthcare firm:** Samsung and Biogen created the joint venture Samsung Bioepis to develop, manufacture, and market biosimilars.[18] Biogen is contributing expertise in protein engineering and biologics manufacturing and commercialization partner Merck is handling preclinical and clinical development, manufacturing, and clinical trials.[19]

In the long term, there will be partnership opportunities representing various points in the value chain. However, at this early stage in the biosimilar cycle, effective partnerships driving speed-to-market, launch excellence, and cost strategies will be much more important for most companies than owning a broader spectrum of the value chain. Further, protecting trade secret assets in partnerships will be critical as manufacturing processes are often the core intellectual property.

GO-TO-MARKET CONSIDERATIONS

PRICING STRATEGIES: Like generics, the attraction of biosimilars is the potential of lower prices for high-cost therapeutics. Biosimilars mimic their reference biologics in use, safety, and efficacy.

However, because they are not identical products (only "highly similar"), the approval and appropriate clinical role of biosimilars is not as straight-forward as for generics. This has driven much debate in the industry, with one side arguing for high disclosures including labeling, naming, and prescribing, and the other side arguing to minimize the number of differentiation disclosures based on the logic that the product has the same clinical efficacy and, therefore, no practical therapeutic differences.

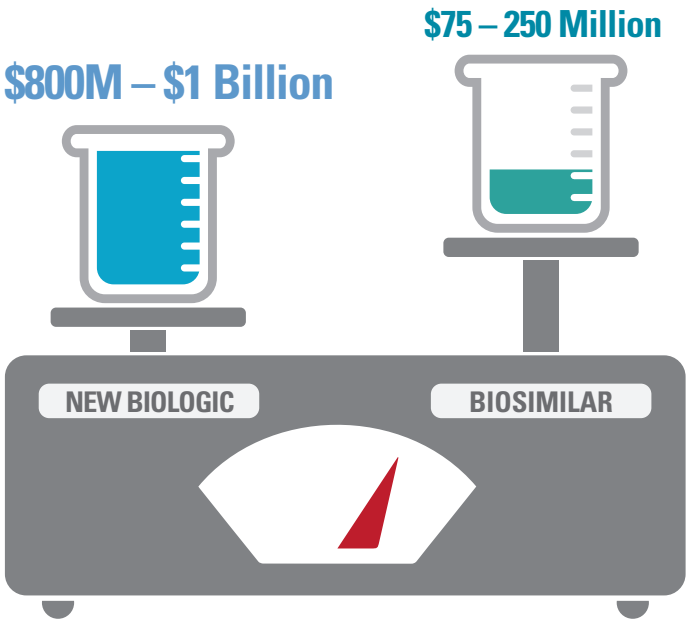
These issues have been debated across the globe and are now in the final stages of being settled in the U.S. The factors being weighed are risk vs. cost savings. The risk comes from abandoning a product known to work well and substituting a highly similar, but not identical, product. The cost savings become possible because biosimilars sponsors have not incurred the cost of funding innovation or of full clinical trials, and can leverage reference biologics' established data. Specifically, it is estimated to cost between $75 and 250 million to develop a biosimilar. By comparison, it is estimated to cost between $800 million and $1 billion to develop a new biologic, according to a 2013 BioWorld report.[20]

The health plan community will also influence pricing and uptake significantly, particularly in situations where interchangeability is established. Both innovators and biosimilars sponsors should assess portfolio-based approaches to health plans geared to specific segments. In-depth understanding of customer segments is of the utmost importance as each segment may be more or less receptive to different incentives.

How price levels will eventually be set will continue to be a matter of some discussion. "When the supply curve crosses the demand curve, that should help companies find the most appropriate price," observed Dr. Oleksyk of Baptist Health Care. Generally, market forecasters, including the Congressional Budget Office, estimate that discounts will fall in the range of 20-30% off the price of the reference product because of fewer testing requirements before approval.[21] However, these forecasts refer to all biosimilar products in all segments, and, in reality, discounts will vary by type of product, customer segment, and competitive mix.

Further, some established biologics brands may be willing to maintain price at the expense of lost market share, while others may lean more toward aggressive discounting to maintain share. The danger is that competition between certain biosimilars and innovator products could amount to a zero-sum game in which total market profits are partitioned between two or more players, and prices spiral to only a fraction above the cost of production. Obviously, this would negate the benefits of any biosimilar introduction, especially with complex, higher-cost products. Before market entry, biosimilar sponsors must carefully model different pricing strategies and the outcomes of assumed reactions of incumbent brands and competitors, while envisioning a market stabilization point where pricing may settle.

Ultimately the market and pricing will have to play out. Winning firms will build agile frameworks that allow them to quickly incorporate new market data; translate data into insights and real intelligence; and enable decisive, management-level responses to the changing market.



Estimated Drug Development Costs

Winning firms will build agile frameworks that allow them to quickly incorporate new market data and take decisive action in the changing market.

As the market awaits a price shakeout, a principal element of biosimilar sponsors' commercial strategies should be education. Providers, patients, and health plans are becoming familiar with biosimilars and how they compare to biologics, but there is still a great deal of anecdotal information being disseminated in the physician community.

EDUCATING STAKEHOLDERS

Providers

Based on a 2015 KPMG physician survey, providers' stances toward biosimilars range from highly accepting to "wait-and-see," and, by and large, our survey found that only a few physicians were steadfastly against acceptance. Primarily, physicians have concerns about safety and efficacy and were eager to review products' clinical data. Biosimilar marketers should convey messages centered on clinical pharmacology data, tout their expertise in specific therapeutic areas, and make known their advanced research and development capabilities, so that physicians will feel more confident about taking their counsel on clinical use.[22]

Some early adopters in the provider community do not see substitution as much of a problem. Dr. Oleksyk of Baptist Health Care states: "I would have less concern about switching from a brand name to a biosimilar than I have about switching from one brand name to another brand name." He went on to say: "Most biologics have track records because they have been on the market for 10 years. This makes me feel more confident about prescribing FDA-approved biosimilars."

Dr. David Weitzman, Medical Affairs and Pharmacovigilance Executive Director and CMO of Raleigh-Durham-based DDC, Corp., has some advice for biosimilar sponsors and innovators when it comes to educating physicians about safety and efficacy issues: "In my experience with fellow physicians, it's best to plant a seed and let it gestate." One way to do this is to get in front of medical students and residents, as well as the professors who teach them, with messaging about biosimilars' safety and efficacy, continues Dr. Weitzman, who is also the former chair of the Committee on Graduate Medical Education. "If you can get them comfortable with biosimilars early, they will prescribe them. In this way, biosimilars could follow the same path as generics."

Dr. Oleksyk agrees: "The explosion in the generics market has softened the opposition and paved the way for biosimilars. Over the last 30 years, the vast majority of generics have shown themselves to be equivalent to brand names. If the FDA blesses biosimilars as they have generics, the industry will come to accept them."

Patients

When it comes to infused biologics administered in a hospital, which represent a large portion of biologics, direct-to-consumer marketing may not be useful. However, marketing campaigns geared toward patients can be very powerful. For example, television advertisements for the rheumatoid arthritis medications Enbrel, Humira and Remicade are widely viewed to be very effective at educating and influencing consumers. The marketing muscle pharmaceutical companies put behind particular biosimilars and the currency of their marketing messages will both be crucial factors in influencing patients with brand loyalty to particular biologics. At the same time, biosimilar launches will likely not be able to support the same large-scale commercial budgets as high-profile innovator brands. Therefore, biosimilar firms must invest judiciously in research and thoroughly understand market segments that are likely to be receptive to the value of biosimilars.

Patients may well be reluctant to switch to a biosimilar if they are already achieving stable, satisfactory clinical results with a branded biologic, and their current medication is covered by their health plan. Clearly, patients should not be pressured into switching decisions, and pros and cons should be weighed jointly with their doctors. Dr. Oleksyk feels that attitudes may vary depending on the therapeutic area. He cites rheumatology drugs, insulin, and medications for autoimmune diseases as viable areas for biosimilar development. Dr. Brian Liang, senior advisor at the Global Health Policy Institute and a regularly cited expert on biosimilars, agrees that the focus should not be on high-level drugs until more research is done. He asserts that companies might want to start by educating people about the similarities of more straightforward treatments with less complex molecular structures, such as insulin and human growth hormone, followed by drugs "in the middle" of complexity such as erythropoietins and granulocyte-colony

stimulating factors (G-CSFs). As the former director of patient safety at the University of California, San Diego School of Medicine, Dr. Liang has a long track record of risk versus benefit analysis related to a range of medications and biologics.

Both physicians said they would be more careful when it comes to cancer treatments, however. "If a patient had Stage 2 lung cancer, a small difference in survival rate might become a deciding factor in whether or not to prescribe a biosimilar," said Dr. Oleksyk. "If a biosimilar took the survival rate from 95 to 93 percent, even at a lower price that would be a deal breaker. However, if it went the other direction and took the survival rate from 95 to 97 percent, I would definitely prescribe it."

Willingness to switch may vary based on the severity of an illness or the relative difficulty of managing symptoms. For example, in a recent peer-reviewed article in *Diabetes, Obesity and Metabolism* magazine, researchers from Oxford University (and others) state that, among Type 1 and 2 diabetics, the majority of patients indicate that they would be willing to switch to biosimilar insulin if they were reassured that effectiveness, side effects, and delivery devices would be comparable.[23]

DIFFERENTIATION vs. SIMILARITY

One of the greatest challenges of marketing biosimilars is the conundrum of messaging around differentiation and similarity at the same time. On the one hand, biosimilar sponsors need to try to differentiate their products by something other than price. On the other hand, they do not want to raise concerns about the safety and efficacy of the product because it is similar and not identical. Balancing these two seemingly opposing points of view in their messaging will impact their success versus branded agents and other biosimilar entrants in the marketplace.

Dr. Liang, for one, acknowledges this challenge for biosimilars companies. In his opinion, "It may be better to stress what's different than what's the same. The selling point can't just be that a biosimilar is the same product only cheaper." Instead, biosimilars companies should communicate their clinical pharmacology and/or manufacturing quality data to health plans and prescribers, and emphasize any superiority over other biosimilar agents.

CONCLUSION

The biosimilars market will continue to evolve rapidly and with uncertainty. No matter their strategic objectives, all biopharmaceutical companies in the ecosystem need to be ever-present and in tune with the pulse of this disruptive and rapidly evolving market. Leading companies will outline detailed scenario-based plans for various possibilities, have a clear understanding of what they can and cannot control, and build focused tactics managing those areas within their control. Biosimilars sponsors will need to conduct in-depth pricing analyses; formulate provider/patient education campaigns and multi-pronged sales and marketing initiatives; and take positions on fundamental regulatory issues both current and future. Companies with portfolios of high-margin branded biologics, pipeline biobetters, and/or best-in-class manufacturing and large development structures must leverage these assets to defend against competition from biosimilars. Those taking a blended approach must juxtapose strategies and investment for two business units striving for dissimilar objectives under one corporate brand. In all of these positions, success will be driven by execution of aligned commercial and product development strategies for biosimilars.

How KPMG can help

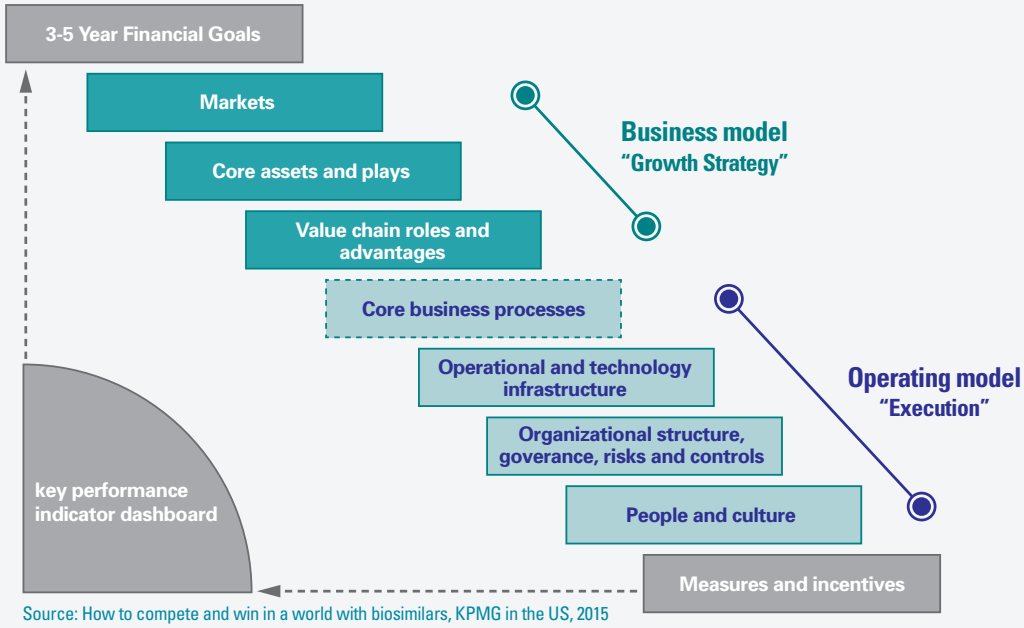
KPMG's member firms provide strategic counsel to brand-name and biosimilars companies across Europe and now in the U.S. Our focus is on helping biopharmaceutical companies make effective product choices, optimize their product launches, and balance their product mixes. To remain competitive in a world with biosimilars, innovators and biosimilar sponsors must clearly define their financial ambitions, establish a feasible market and product strategy, and align their operating model and applicable capabilities to deliver on that strategy efficiently and effectively. The nuances of the operational implications cannot be underestimated and need to be factored in when developing the strategy to ensure it is sound and implementable.

Finally, the KPMG network provides an integrated strategy-through-execution approach (as illustrated below), which helps guide the strategic planning process and accelerate deployment of companies' growth strategies.

KPMG continues to closely monitor biosimilars market developments and regulatory changes. What we have outlined in this paper only scratches the surface on an array of topics that need careful consideration. Our seasoned strategy advisory team can engage with companies to help them develop deep insights into the evolution of this market, lay out scenario-based planning concepts, and determine how to compete and win in a world with biosimilars.

Strategy through execution approach

A well-designed strategy links the implications of the business model to downstream operating-model decisions. Thinking about the interrelationships within the business in the early stages of strategy formation helps companies lay the groundwork for effective strategies and—especially important in the biosimilars market—allows companies to adapt to a rapidly changing marketplace.



Source: How to compete and win in a world with biosimilars, KPMG in the US, 2015

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