MM&M
MEDICAL MARKETING & MEDIA

Playing to Win in the Global Biosimilars Environment

BY FAITH GLAZIER AND ROB JACOBY

The recent FDA filing of Sandoz's filgrastim has set the wheels in motion for the United States launch and commercialization of biosimilars, also known as follow-on biologics. Biologics have gained significant traction in the pharmaceutical industry, representing more than $100 billion in global sales in 2013 and predicted to generate $250 billion by 2020[1]. About 40 percent of these sales come from 12 biologics that face loss of exclusivity over the next five years[2]. This, along with the increasing worldwide focus on improving healthcare access and costs, presents an attractive opportunity for biosimilars manufacturers. Indeed, cost savings from switching to biosimilars in the United States alone are projected to be $250 billion over the next 10 years[3].

Although the United States represents almost half of the biologics market in terms of revenue and volume, biosimilars growth will be fueled by focusing on the emerging markets, by addressing non-consumption and patient inability to pay for high-priced biologics.

Biosimilars face competition from bio-betters and non-original biologics. While biosimilars are approved via a dedicated regulatory pathway, bio-betters follow the same regulatory pathway as the innovator drug and are step-wise improvements on innovator molecules (for example, Gazyva and Rituxan from Roche). Non-original biologics are copies of innovator drugs, more common in markets with less stringent intellectual property protection, and do not have a dedicated regulatory pathway for approval (for example, Reditux from Dr. Reddy's).

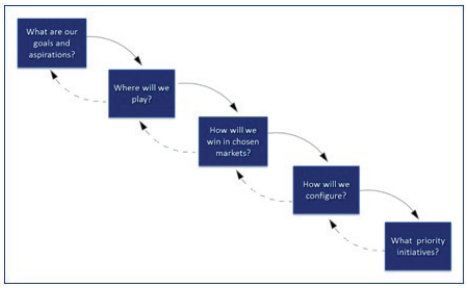
Although biosimilars are expected to emerge as a distinct and rapidly growing segment of the biopharmaceutical industry, their uptake faces several challenges. First, the regulatory policies governing biosimilars are still in flux, with major markets like China and the United States lacking a consistent and clear pathway. Second, the lack of clear guidelines on substitutability and interchangeability with reference biologics will likely cause physicians to exercise more caution in prescribing biosimilars until they gain comfort with the quality and efficacy. Third, unlike generics, complexity in the development and manufacturing of follow-on biologics raise the cost, time required and risk of production - increases which are in turn passed on to the consumer in terms of price. Fourth, biosimilars face brand competition, both in terms of bio-betters from branded companies and brand consciousness from the consumer side. Finally, it will take companies a longer time to convince stakeholders of the risk benefit of more sophisticated and long-term follow-on biologics such as monoclonal antibodies and growth hormones due to the nature of their treatment chronicity.

PLAYING TO WIN: WHERE TO PLAY, HOW TO WIN

In our Monitor Deloitte practice, we advise our clients to think about strategy as an integrated set of choices. Choices about when and where to compete and how to win in the businesses they have chosen. The Choice Cascade™ (Figure 1) expresses this integrated set of choices across five dimensions. The most sustainable strategies are those in which the 'Where to Play' and 'How to Win' reinforce each other and are supported by appropriate and distinct capabilities and initiatives.

Therefore, as companies think about how to win in the biosimilars space, there are a number of important considerations based on the 'Where to Play' – the market and therapeutic area.

Figure 1: The Choice Cascade™



We have conducted extensive secondary research and primary research with Deloitte experts on three market segments: developed markets (United States, EU5 and Japan), BRICS markets (Brazil, Russia, India, China and South Africa) and MIST markets (Mexico, Indonesia, South Korea and Turkey). Figure 2 shows the biosimilars environment across several dimensions in these markets.

The United States, EU5 and Japan are the focus of several biosimilars companies given their market size. This is represented in Figure 3 which shows that the highest numbers of biosimilar molecules in development are in the developed markets.

Figure 2: Biosimilars Environment in Different Markets*

	Biosimilars Presence	Regulatory Environment	Payer Assessment and Access	Prescriber Acceptance	Patient Acceptance	Strength of IP Protection
US						
EU5						
Japan						
Brazil						
Russia						
India						
China						
S. Africa						
Mexico						

Source: Deloitte Analysis

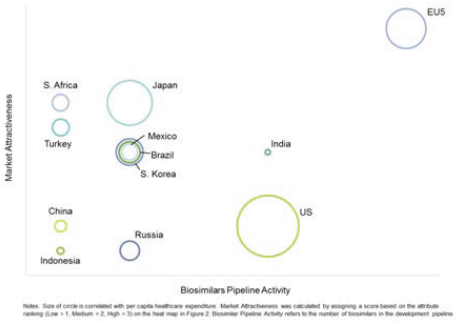
***Please refer to appendix for explanation of scale and attributes**

If companies choose to play in the developed markets, being first to market is critical, as the opportunity will likely

shrink through the lifecycle of the product due to new drug classes and changes in first and second line therapy. Our survey of Deloitte experts indicated that a 20 to 30 percent price discount compared to reference biologics will be satisfactory from a payer and formulary perspective. But in order to convince physicians and patients to switch, significant commercial capabilities along the buying process, key opinion leader and physician engagement and market education programs will be required. Companies can access large health plans and pharmacy benefit managers to compete with branded competitors on favorable pricing, but they should be strategic about contracting and pricing. A downward price spiral may not only reduce the value of the market but can also prevent them from investing in the value-added services and medical community engagement required to penetrate the biosimilars market.

Interchangeability and naming conventions have important implications as well. If there are interchangeability guidelines, as proposed by the FDA, and use of same International Nonproprietary Name, as in the European Union, lower cost companies with a focused approach will have an advantage. But if significant investment in market education and development is required, branded players are better positioned to penetrate the market.

Figure 3: Biosimilars Market Attractiveness and Pipeline Activity



Source: Deloitte Analysis, WHO, Decision Resources Group

The market attractiveness of the emerging markets presents a bigger 'Where to Play' opportunity for biosimilar companies to reach a large, untapped population as governments are engaged in efforts to expand healthcare access in the backdrop of changing epidemiologies.

In the emerging markets, although there is significant potential for volume, the determining factor for success ends up being price because of high out-of-pocket costs and low willingness and ability to pay. In India, for example, a Deloitte survey of physicians showed that they were willing to prescribe a first-line critical therapy provided it was offered at a 60 to 70 percent discount. In China, although getting on the essential drugs list means mandatory usage by many hospitals, it also comes with price cuts of 25 to 50 percent[4]. Manufacturing quality biologics carries a high cost. Lower cost manufacturing techniques through sourcing cheaper API and economies of scale will provide a temporary advantage. But companies need to shift the focus to growing the market through innovative patient access approaches. In some emerging markets like India and China, it is improving physical access (distribution, storage, etc.). In other markets like South Africa and Mexico, it is improving physician and patient awareness of quality and efficacy. The quality aspect is especially important in emerging markets given recent high profile incidents with safety. This is where branded companies can leverage their global standards and reputation for quality to gain the confidence of physicians and patients. Some governments like China, Russia and Brazil are proactively harnessing the horsepower of global brands via policies that compel multinational players to form partnerships with local companies.

Finally, companies have to be strategic about which therapeutic areas to play in. Depending on the chronicity of treatment, the risk-benefit profile of switching from reference products to biosimilars will vary. For more chronic, palliative care there is a lower willingness to pay. For more acute care, our survey of Deloitte experts indicated that physicians rely on the predictability of safety and efficacy that branded biologics offer.

SUMMARY

The biosimilars market currently poses real questions – such as lack of regulatory guidance and strain on the profit model. Although the United States is generally believed to be the next big market for biosimilars, long-term growth will be fueled by the emerging BRICS and MIST markets through addressing the huge volume of non-consumption. Further, the conducive regulatory environment, inability to pay for high priced biologics and extensive experience of lower cost manufacturers should boost the attractiveness of these markets for companies with biosimilars. In order to win in the emerging markets, companies need to develop a distinct set of capabilities and initiatives specific to each market that not only focuses on lowering the price, but also on market expansion.

Faith Glazier is principal, generics practice leader for Deloitte Consulting.

Rob Jacoby is principal for Deloitte Consulting.

APPENDIX

		Ranking			
Variable	Data point	Low	Medium	High	Source
Biosimilars Presence	# biosimilars in market	Low: 0	Medium: 2-10	High: >10	Secondary research
Regulatory and Reform Environment	Presence of an abbreviated or dedicated pathway	No	In development	Yes	Secondary research
Payer Assessment & Access	Degree of engagement and advocacy from payers in favor of biosimilars	Low	Medium	High	Secondary research
Prescriber Acceptance	Willingness to prescribe biosimilar vs. reference molecule	Low	Neutral	High	• Secondary research • SME interviews • Deloitte analysis
Patient / Consumer Acceptance	Patient attitudes towards biosimilars	Strong reluctance	Neutral	In favor	• Secondary research • SME interviews • Deloitte analysis
Strength of IP protection	IPRI Index	Low: 4.8 to 5.8	Medium: 5.8 to 6.8	High: 6.8 to 7.8	Secondary research

Scoring system for biosimilars environment and market attractiveness

[1] IMS Health, 2013
[2] Ibid.
[3] Express Scripts, 2013
[4] The Economist Intelligence Unit Industry Report, 2014