BIOSIMILAR DEVELOPMENT

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What Challenges Should Biosimilar Companies Expect In 2018?

By Anna Rose Welch

*Over the past two weeks, I've shared the first two parts of a three-part article series featuring insights from each of the members of Biosimilar Development's inaugural editorial advisory board. The first segment took a closer look at some of the event that occurred in 2017, and how these would continue to evolve in 2018. The second unpacks some of the new trends we should be looking out for as the new year gets underway. Now that we're roughly two weeks into 2018, it's time to share the board's thoughts on which challenges will be in the spotlight for the year ahead. Whether they be IP-,real-world-data-, or ongoing market-access-related challenges, biosimilar companies should expect a busy year ahead.**

What challenges do you expect biosimilar companies to run into in 2018, and what could be done to address these challenges?

A sustainable biosimilar medicines industry implies access to the global market, or at least a multi-region market. In the EU, the European Commission will undertake a debate on pharmaceutical incentives, which is a cornerstone to competition in the pharmaceutical and biologics market. One of the measures at stake, the supplementary patent protection manufacturing waiver, is of fundamental importance for biosimilar manufacturers established in the EU. The change would leave the EU IP landscape unaffected while, at the same time, enabling manufacturers to compete globally for markets where IP protection no longer exists, removing an unintentional adverse effect of the current legislation. This is particularly important in light of the key biologic product monopolies for which expiry is coming. The biggest of all challenges, in my opinion, will be for EU governments and policy makers to put their ambitions in motion, be it for competition in the biologics market or for EU industrial policy. Rather than grand plans and national policies, it may be important to start with small and tailored, yet concrete, policies so the benefits are tangible in a shorter time frame.

— Julie Maréchal-Jamil, director biosimilars policy & science, Medicines for Europe

An ongoing challenge for companies will be considering commercialization challenges and solutions as well as policy and reimbursement trends and scenarios from the moment of product selection. Too many companies have focused entirely on selecting, developing, and investing in products alone, but this is not enough. Companies also have to build a strategy around a true path for differentiation and be clear as to what parts of the value chain will be owned by whom. Hence, you have to engage business development much earlier in the process. Waiting too long to do so greatly lowers options and returns while increasing risks and the possibility of early mistakes, even as far back as portfolio selection itself. In short, development and regulatory success are necessary but certainly not sufficient. One must engage more fully and proactively in policy and commercialization challenges and solutions — not just alone, but with partners and trade associations.

— Edric Engert, managing director, Abraxeolus Consulting

Biosimilars will enable patients with active rheumatoid arthritis and inflammatory bowel disease to get the treatment in its early stages and benefit from aggressive therapy using a TNF-α inhibitor-based combination regimen. However, the increasing number of biosimilars in development raises the possibility that patients may be switched not once, but several times, so healthcare systems maximize cost savings. Physicians and patients continue to emphasize concerns about multiple and cross-switching among biologics and biosimilars. Therefore, biosimilar companies must have robust evidence to reassure the patient community about the safety and efficacy of multiple switching. For instance, studies like the NOR-SWITCH study or the pivotal randomized controlled trial of CT-P13 in Crohn's disease have made a significant contribution to the evidence base for switching.

—HoUng Kim, head of strategy and operations, Celltrion

Market access remains a challenge for biosimilar companies, with patients, pharmacists, and physicians still unsure about biosimilars. Knowledge about and understanding of biosimilars and their development pathway are still lacking, and more education is required at a broader and deeper level. Stakeholders such as payers, regulatory agencies, and others in the healthcare sector should actively promote the use of biosimilars, explaining how they can promote sustainability of the healthcare system. In the EU, gainsharing has certainly helped the uptake of biosimilars, whereby the savings generated by patients taking biosimilars are shared between providers and payers. This acknowledges the efforts by providers in either initiating or switching patients to a biosimilar.

— Sue Naeyaert, global head of pricing, market access, government affairs and policy, biosimilars, Fresenius Kabi SwissBioSim

One main challenge I expect biosimilar companies to run into in 2018 will be effectively balancing pricing that will enable profits and gain commercial payer reimbursement and management support. Biosimilar companies may face challenges to provide lower net-cost pricing relative to competing reference biologics in order to gain support from some commercial health plans. It is important to note this challenge does not apply to Medicare, because Medicare Advantage plans are restricted from providing utilization management support (though this actually could help increase market share for Part B biosimilars).

—Brian Lehman, strategic consultant, Humana Pharmacy Professional Affairs

One of the big challenges at the moment is finding enough patients to accommodate the requirements for clinical trials, seeing as more companies are bringing mainstream biosimilar drugs, such as anti-inflammatory drugs, into Phase 3 clinical trials. One way to address the challenge is by accessing patients in other geographic locations who haven't been treated with these drugs, such as Eastern European countries, where the quality of medicine is high and standardized laboratory tests can be run at another site, such as in Western Europe. In the U.S., administrative burdens, such as documentation requirements and physician sign-off, can interfere with supporting patients in a clinical trial. This challenge could be addressed by streamlining the documentation required and presenting a harmonized approach to data collection and reporting, with support from regulatory agencies and industry associations.

— Don Stewart, CEO, PlantForm

Patent litigation will continue to dampen the growth of the biosimilar market in the U.S. I'd argue public interest litigation and political pressure would help the situation. In general, a stronger biosimilar lobby would help significantly.

— Pankaj Mohan, CEO, Oncobiologics

In my opinion, the greatest challenges biosimilar companies will face in 2018 are acceptance, patent challenges, and developing a successful marketing plan. A critical challenge facing biosimilar companies will be to educate the broader healthcare professional community and then patients about the basics of biosimilars. By necessity, education has until now focused on some professional societies and patient groups. While it is heartening to see an increase in their knowledge and acceptance, it will be more challenging to broaden this knowledge to the rank and file of healthcare professionals and to the ordinary patient so that biosimilars will be broadly accepted.

It has also become apparent that the thicket of patents surrounding reference products will delay the entry of many biosimilars. I am not an expert on patents, but still I recognize that negotiating a path forward in this area will be critical. Adoption of biosimilars in the U.S. once they are launched will also be a challenge. Zarxio has a very respectable market share two years after product launch, but it seems other biosimilars are facing challenges in adoption.

—Hillel Cohen, executive director, scientific affairs, Sandoz

**These statements represent the viewpoints of the individuals, not those of their employers.*