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US Biosimilars Market: AmerisourceBergen Q&A

Q&A With Sean McGowan, Senior Director Of Biosimilars

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Executive Summary

Incentives for uptake, physician education, legal barriers and patient services are among the issues covered in a wide-ranging question-and-answer session conducted with Sean McGowan, senior director of biosimilars at AmerisourceBergen.

AMERISOURCEBERGEN SAYS IT IS WORKING WITH BOTH MANUFACTURERS AND HEALTHCARE PROVIDERS TO ESTABLISH TO A VIBRANT US BIOSIMILARS MARKET

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Q **GB: As a major wholesaler and healthcare services provider, how is AmerisourceBergen working to realize the potential of biosimilars in the US?**

A SM: As we've seen in Europe, biosimilars have the potential to create more competition in the marketplace, provide more affordable product options, and increase access to therapies. Distribution partners, like AmerisourceBergen, are well positioned within the supply chain to help stakeholders across the value chain seize the opportunity presented by the US biosimilars market and work towards these same results. Every day, we work to expand access, improve quality and increase the affordability of the biosimilars by leveraging insights from our work with both manufacturers and downstream sites of care throughout the commercialization process. While helping manufacturers understand market opportunities, evaluate channel strategies and move from clinical development to commercial settings, we are also working closely with healthcare providers to educate them on the safety and efficacy of biosimilars within their practice and help them realize the potential value and savings of these products. We're committed to helping create healthier futures, and this means supporting access to all therapeutic categories.

Q **GB: Some commentators have claimed it is time to 'throw in the towel' on biosimilars in the US – to what extent can the US biosimilars market to date be seen to be a success or failure?**

A SM: While biosimilar adoption hasn't been as robust as initially expected, we're seeing significant momentum in the US that gives us hope for the future. It has been a historic year for biosimilars – in 2019 alone, we saw 10 biosimilar approvals and seven launches [following Pfizer's 31 December introduction of Zirabev (bevacizumab-bvzr)]. This is also the first time that we had three biosimilars competing in one category [on pegfilgrastim] – which is what's required if we're going to see the cost savings we've been looking for over time. It's also worth noting that Rand Health's recent study projects that with the adoption of biosimilars, the US can decrease direct spending on biologics by $54 billion from 2017 to 2026. That's a great incentive to keep supporting this platform. The European biosimilar market has also given us a glimpse into the impact these products can have on making the entire therapy class more affordable. To achieve the same cost saving potentials that Europe has experienced, we must create a supportive healthcare system for biosimilars and enable a competitive market. This can be accomplished by continuing to remove legal hurdles like patent thickets, establishing a clearer path to interchangeability between biosimilars and originator biologics, and pushing to prevent biosimilars from being blocked or disadvantaged on formularies.

Q **GB: In reviewing AmerisourceBergen's recent 'Biosimilars Check-Up' survey, I noticed there were statistics about ideal costs to foster adoption, reluctance to switch patients to biosimilars and overall confidence concerns of physicians. Could you expand on the findings and what you feel is important to address this?**

A SM: We're seeing that when a biosimilar launches in the US it is on average 15% less expensive than the originator, which certainly helps give patients more affordable treatment options and creates demand for this at the point of care. We're eager to see how the increased competition of biosimilars will increase access and choice for providers and patients and increase the affordability of these traditionally expensive therapies. We believe that, if additional biosimilars become available – specifically, multiple biosimilars for the same indication – it will create more marketplace competition, and that savings percentages could grow significantly. For this to happen, manufacturers must continue to invest in the development and launch of biosimilars, which requires a supportive regulatory and legal environment. Manufacturers must also focus on physician uptake as it is one of the most crucial factors that is sometimes undervalued. Physician adoption begins with education. Some physicians may be reluctant to make the switch from an originator product that has been working for their patients to a biosimilar, which in their minds may be unproven. That is why, beyond the cost of a product, physicians need clinical data and information that demonstrate biosimilar products are efficacious and safe. They need to understand the US Food and Drug Administration approval process, so they can build trust in these relatively new products, and they need counsel on how to use or administer the biosimilar. Manufacturers can support provider education by building out a pre-launch plan that addresses varying concerns and opportunities. As a distribution partner, AmerisourceBergen is constantly working with customers to increase communication between sites of care and biosimilar manufacturers, so both groups can work together to bring these innovative and life-saving products to patients.

Q **GB: Following Amgen's launches in the US of bevacizumab and trastuzumab, are we likely to see more at-risk launches of biosimilars in future? Will we see an evolution in biologics patent litigation and settlements?**

A SM: We're not anticipating additional at-risk launches of biosimilars in the coming year. However, as competition within the biosimilar market increases, there are bound to be new challenges and changes in biologic patent litigation and settlements. We believe this reinforces the need to create a level playing field for biosimilars and originator biologics. We cannot have a truly competitive marketplace without further alignment on incentives across the supply chain – including addressing any new legal hurdles that arise.

Q **GB: How important for success is the biosimilar sponsor providing patient and caregiver support? Are there best-practice examples currently in the market? How can suppliers square the need to provide such services with demand for deep price discounts? Are there opportunities to share the burden across the biologics supply chain (e.g. manufacturer, distributor, clinic/pharmacy)?**

A SM: Biosimilar manufacturers must provide patient support services to give these products an even playing field. With the increase in biosimilars for oncologic diseases, these types of services are becoming even more important not only as product differentiators but also to encourage patient success and support a practice's operational workflow. Manufacturers should look to partner with hub service providers as they can help deliver patient support services that are critical to bringing the latest therapies to the patients who need them most. Hub service providers can help connect patients and physicians with wrap-around services, inclusive of offering education to ensure patients are taking medications correctly and providing reimbursement support. While we wait to see the potential savings of biosimilars in the US, hub service providers can also play a significant role in coordinating patient assistance programs to support patients financially.

Q **GB: Several bills have been tabled in a bid to spur biosimilar competition. To what extent can Congress act to bring greater competition to the biologics arena? Of the various measures suggested, which do you see as having the greatest potential to be enacted, and which would have the greatest effect?**

A SM: There are many opportunities for legislators to push for greater competition within the biologics area and, as a result, drive potential cost savings. For instance, the Prescription Drug Pricing Reduction Act, slated for Senate review, contains the provision that biosimilars could receive a higher rate of reimbursement than reference products. The act would temporarily increase the reimbursement for biosimilars from 6% of the reference product's average sales price to 8% of the reference product's ASP for a period of five years beginning in 2020. Thus, if this act passes, it would give prescribers more incentive for using biosimilars.

Q **GB: How much of a competitive advantage do you believe it would be for a biosimilar to obtain an interchangeable designation from the FDA?**

A SM: We need to create a system that is supportive of biosimilars, and a part of that is interchangeability. However, gathering efficacy and safety data will be one of the most significant factors in creating a competitive advantage for these products. As the market continues to progress, we will need to gain further clarity around interchangeability and its impact on costs.

Q **GB: Many of the current companies offering biosimilars also market novel biologics. In the medium term, will the same players continue to lead? Is there a 'pain point' on biosimilar prices and margins at which originators will pull out?**

A SM: As I mentioned previously, we are just starting to see more competitive biosimilar markets in the US. Right now, there hasn't been enough downward pressure on pricing that would drive any innovator or biosimilar manufacturers out of the market. However, innovator products continue to own a majority of the market share within most of the US markets where biosimilars have launched. A few of the largest brand, specialty and generic manufacturers have launched biosimilars and continue to invest in their biosimilar platforms. We remain optimistic that the biosimilar market will continue to grow in approvals and launches and that biosimilar manufacturers will continue to invest in the development of new biosimilar products. We also expect that all manufacturers will work to create competitive and sustainable markets where there is patient/provider choice and access to these therapies.

Q **GB: As we go into 2020, how optimistic are you about the future for biosimilars in the US? What landmarks do you foresee for the coming year in the biosimilars space?**

A SM: There are several biosimilar launches slated for 2020 that will increase access, choice and competition for multiple reference products as well as within the oncology drug market. In 2019, the US saw for the first time three biosimilars competing in one category. By the end of 2020, we could see up to five biosimilars competing in the traztuzumab market - targeting certain types of breast and stomach cancer. In 2020, we anticipate that the US will continue to put efforts towards embracing competition. There are several legislative bills slated for review, such as the Prescription Drug Pricing Reduction Act, that hold the potential to increase incentives for biosimilar competition. We anticipate that this movement towards policies that aim to expand the biosimilar platform will encourage more manufacturers to invest in these products and by way, expand accessibility.

References:

Mulcahy AW, Hlavka JP, Case SR. Biosimilar cost savings in the United States: initial experience and future potential. Rand Health Q. 2018;7(4):3.