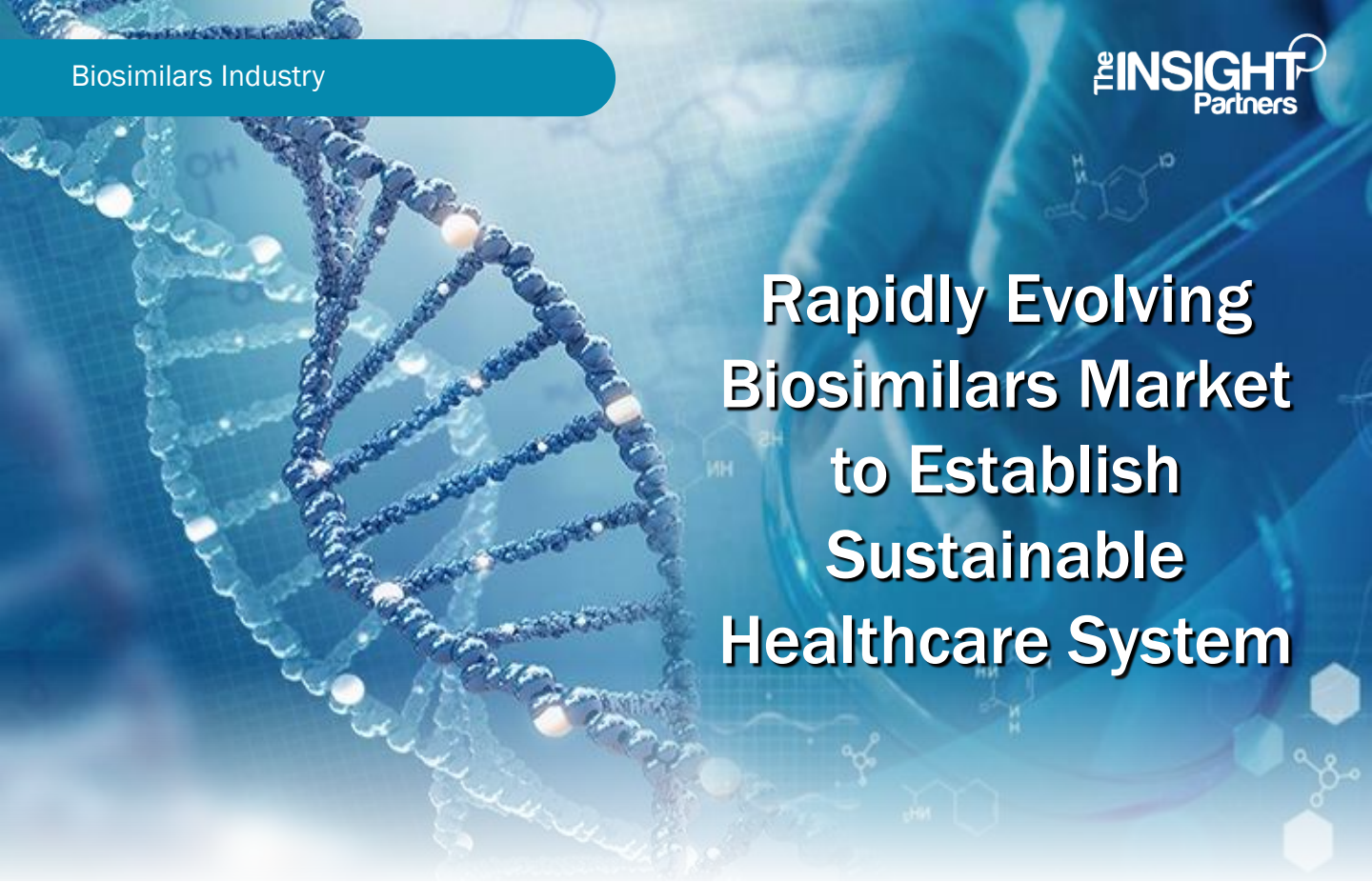
The INSIGHT Partners

Biosimilars Industry



Rapidly Evolving Biosimilars Market to Establish Sustainable Healthcare System

Biologics have developed a strong position in the pharmaceutical industry over the last three decades, encouraging stakeholders to introduce advanced substitute therapies for incurable diseases, including autoimmune diseases and cancer. Biosimilars are an innovative form of biologics similar to reference biologics with no clinically meaningful differences from their existing reference product.

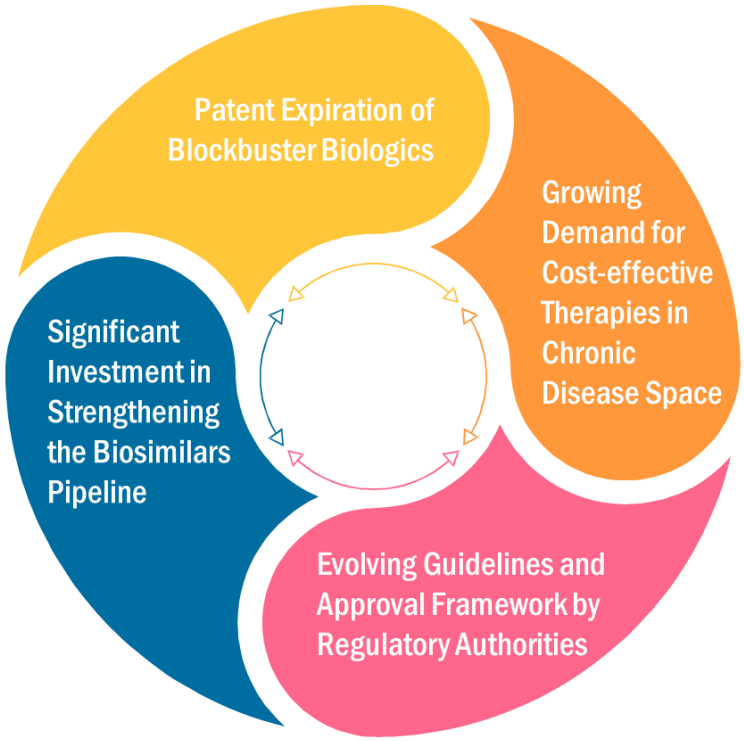
Biosimilars are a relatively lower-cost version of biologics and are approved by regulatory authorities as products for curing certain illnesses. Since the entry of the first biosimilar in the US market in 2015, nearly 40 biosimilars have been approved as of 2022, reflecting remarkable opportunities for the industry's growth amid the growing cost burden in the pharmaceutical space.

The approval of biosimilars is built on existing safety and efficacy data and scientific knowledge of the reference biologic gained during its clinical use. Thus, fewer clinical research data is needed for biosimilars and does not require the execution of the entire clinical development program of the reference medicine.

According to IQVIA, biosimilars achieved 20% market share by the end of 2019, and ~50% of biologic market share is likely to face biosimilar competition in the coming years.

Europe has pioneered the biosimilars industry and constructed appropriate regulations. The region has approved the highest number of biosimilars globally, amassing their considerable safety and use experience. The uptake of biosimilars in the European market has been slow and mixed since the last decade, allowing biopharmaceutical giants time to furnish defensive strategies. Furthermore, the discounts for biosimilars are not as drastic as 70–90%, unlike generic pharmaceuticals, which is a potential influential factor for entering this market space. Despite the COVID-19 pandemic, the volume of biosimilar prescriptions generated significant savings from biosimilar competition in 2020, with the list price savings accounting for over EUR 5.7 billion in savings as compared to the pre-biosimilar cost of their originator biologics. Even though Europe's track record has been proven in the biosimilars market, the US owns unique regulatory characteristics expected to create distinct opportunities in the country.

The US biosimilar marketplace is evolving rapidly as most manufacturers remain focused on the developed markets. Over 22 biosimilars have been introduced in the US market with prices averaging 30–40% less than their reference biologics. Nearly 6–7 biosimilars are expected to enter the market by the end of 2023. A biosimilar of Humira is expected to be a cost-effective alternative to the anti-tumor necrosis factor biologic and is likely to enter the US market in 2023 after pro-competitive patent settlements between the stakeholders. Biologic innovators are under significant pressure from biosimilar market entrants. Therefore, innovators are developing strategies to retain their existing position in biologics markets of the US, even with a cut-throat competition from biosimilars. Since emerging markets account for around 7–8% share in biologics value versus over 48% in the US, the region is anticipated to grow in the biosimilars market with a significant growth rate in the coming years. The country is expecting biosimilars for diverse molecules, including secukinumab, tocilizumab, ustekinumab, and etanercept, along with additional 10 biologics by the end of 2029.



Factors Bringing Disruption in Global Biosimilars Market

Even though the commercial returns on the manufacturers' investments have disappointed certain countries, its impact triggers the importance of building the right strategies among the stakeholders. The uptake of biosimilars is significantly dependent on various micro-economic factors, including product pricing, competitive matrix, and dynamics of the medications.

The R&D pipeline of biosimilars by emerging and established players, such as Pfizer, Novartis, Amgen, and Biogen, is anticipated to strengthen over the next five years and is expected to fuel the entry of biosimilars across diverse therapeutic areas globally. The limited access of patients to high-cost biologics therapies and efforts taken by healthcare professionals toward lowering the cost of treatment are anticipated to offer significant opportunities for biosimilars in developing countries.

A significant number of biologics are likely to face biosimilar competition in the next 10 years owing to the nearing patent expiration. Cyltezo, the first interchangeable Humira biosimilar by Boehringer Ingelheim, was introduced in the US market in July 2023; it is expected to open floodgate for over five biosimilars in the similar drug class.

There are considerable challenges associated with biosimilars manufacturing and commercialization that are restraining the growth of biosimilars in certain developing countries. The time and cost associated with developing biosimilars is relatively higher than generic pharmaceuticals and thus are passed on to consumers at a higher end price. For instance, generics cost around US$ 1 million to US$ 5 million for their development, while biosimilars cost around US$ 100 million to US$ 200 million.

However, biosimilars are complex to manufacture, attributable to the inherent variability between living cells and the inability to replicate the production or structure of the biologic in a precise manner. Poor guidelines on interchangeability and substitutability with the reference biologic are anticipated to affect the trust factor of healthcare professionals in prescribing biosimilars, as they need to gain comfort with the potency, efficacy, and quality of biosimilars.

Biosimilars can face competition from various components of the ecosystem including biobetters that are produced by branded companies, as bio-betters follow the similar regulatory approval pathway as the biosimilars with step-wise improvements on biologics. Biosimilars are expected to engage in "brand-on-brand" competition with their reference biologics. Moreover, biosimilar discounts can be offset by service agreements for branded biologics and rebates, thereby picturizing biosimilars as less attractive. With long-term and more sophisticated biologic treatments such as monoclonal antibodies and the treatment chronicity associated with such therapeutics, it is anticipated to take longer than expected to demonstrate stakeholders the benefits of switching. Moreover, the biosimilar market is emerging at a slower pace in certain disease areas, including ophthalmology and diabetes, where biosimilars have been approved recently.

Nevertheless, several patents of biologic reference products will be expired by 2025, which is likely to provide immense opportunities for biosimilar manufacturers, and hence, encouraging manufacturers to produce biosimilars.

Players With Strong Biosimilars Pipeline Portfolio

Established biosimilar manufacturers need to address a set of strategic choices, including targeting the geographical focus and the penetration process. To compete strongly with the innovator companies in terms of price, the biosimilar companies need to manage the upstream and downstream manufacturing processes efficiently and aim to reduce the production cost. The pricing strategy for biosimilars should keep patient's out-of-pocket costs as low as possible, which can be achieved by adopting low-cost manufacturing techniques.

Regional companies must shift their attention to furnishing global commercial strategies to unfold the expansion of biosimilars. The companies will need to incorporate an integrated stakeholder approach to support the dynamic landscape in emerging countries and identify the source of revenue. Establishing clinical and regulatory commercial expertise in a complex marketplace can help companies shape the biosimilars industry. Furthermore, the sponsors need to deep-dive into the pricing structure of biosimilars and formulate efficient marketing initiatives for providers. Companies with high-margin biologics and best-in-class manufacturing processes need to leverage their resources efficiently to stay ahead in the competition. Thus, commercial and product development stages should be aligned with each other to gain success in the biosimilars industry.

About Author

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Mrinal has authored an impressive portfolio of 200+ research reports and has spearheaded more than 20+ consulting projects.

As an experienced consultant with a demonstrated history of working in market intelligence industry, Mrinal has developed strong expertise in performing in-depth assessment of companies to construct go-to-market strategies for clients and providing them industry benchmark to cater to their business needs. Her skillsets encompasses corroborating the research inputs and data standpoints to furnish valuable insights & strategic recommendations. Mrinal's clientele features prominent names like Deloitte, Bayer AG, GE Healthcare, Omron, Dr. Reddy's Laboratories, etc.

Mrinal holds a Bachelors in Pharmacy and an MBA in Marketing from Pune University, Maharashtra. In her previous role as a Consultant at Frost & Sullivan in the Pharmaceutical & Life Science sector, she was responsible for driving a variety of research studies pertaining to competitive Intelligence, data triangulation, and development of project proposals.

About us

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Our team for subject matter experts and consultants is dedicated to offering our clients the best possible research and analyses at an affordable cost. Our success depends on a culture of close cooperation and a large, diversified global community that is committed to improving the world and one another every day. Our success depends on a culture of close cooperation with the commitment to improving the decision making for business growth and prosperity.

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