

Assessment of Biosimilar Market Landscape

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Introduction to Biosimilars

Basically, a biosimilar is a highly similar version of an approved original biologic drug. They can be associated with increasing patient access and thereby reducing healthcare costs if one never forgets that success is directly related to the ability to navigate a complex regulatory environment.



BIOSIMILAR

Regulatory Landscape and Approval Pathways

Global Regulations

Biosimilars, in different high-profile markets of the world, are strictly regulated to protect safety and efficacy. The approval pathways are different from region to region. The EU, US, and other high-profile markets each have their own regulatory standards.

Analytical Similarity

Critical requirements are that the similarity be analytical similarity to the reference product. Effective demonstration of biosimilarity needs in-depth characterization and comparative studies.

Clinical Trials

While not always required, clinical trials to evaluate immunogenicity and confirm no clinically meaningful differences are often needed for the approval of biosimilars.

Competitive Dynamics and Market Trends

1

Entry of Biosimilars

With biologics patents set to expire, biosimilars are beginning to enter the market and present competition.

2

Pricing Competition

Biosimilar manufacturers are cost-competitive, and at the end of the day, this activity of current market share penetration reduces the price for the patients.

3

Evolving Landscape

Biosimilars is a rapidly evolving market, with new entrants, products, and strategies to sail through this complex space.

Competition in the Pharmaceutical Industry

- Reps quadrupled to 120K last 10-15 years
- 12B on sales force, 2.76B on ads
- Managed care bet – Pfizer from 14th to 1st
- 529 visits yearly, average length – 2.5 min
 - 8% remember
- Glaxo can reach 80% of the Drs in a week
- “Is this necessary. No, but if my competitors do it and I can’t, then I’m at a disadvantage. This has been an arms race in the worst possible manner.”

Tumors	(GIP-R)	3B-402		
CAIX Expressing Tumors	Carbonic Anhydrase IX (CAIX)	Debio 0228		
Solid Tumors	Undisclosed	NTA		
Solid Tumors	Undisclosed	NTB		

Product Pipeline and Upcoming Launches

Robust Pipeline

There is a robust pipeline of biosimilars in development, spanning various therapeutic areas and targeting some of the world's best-selling biologics.

Upcoming Launches

In the coming years, many new biosimilar products are expected to launch, further expanding patient access and driving competition.

Therapeutic Areas

Biosimilars are being developed for a wide range of therapeutic areas, including oncology, immunology, and endocrinology, among others.

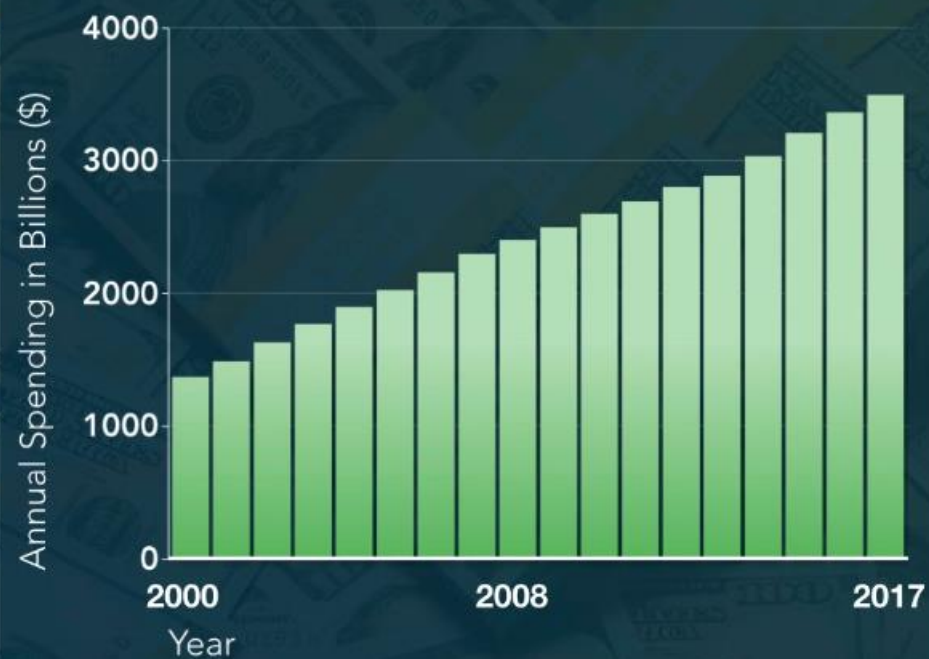
Innovation

Biosimilar manufacturers are also exploring innovative approaches, such as combining biosimilars with other therapies or developing next-generation products.

Total Healthcare Costs in the US

Total US Healthcare spending continues to grow with population growth and cost growth.

Total US Healthcare Spending



Clearvue Health

CMS: NHEA

Pricing and Reimbursement Considerations

1

Pricing Strategies

Biosimilar manufacturers must carefully consider pricing strategies to balance market access, affordability, and profitability.

2

Reimbursement Policies

Reimbursement policies vary across markets and can significantly impact the uptake and adoption of biosimilars.

3

Payer Negotiations

Effective payer negotiations are critical to secure favorable reimbursement and ensure patients have access to affordable biosimilars.

4

Cost Savings

The introduction of biosimilars can generate substantial cost savings for healthcare systems, leading to increased patient access.



Adoption and Uptake Challenges



Brand Loyalty

Physicians and patients may be hesitant to switch from the original biologic to a biosimilar due to brand loyalty.



Interchangeability

Regulatory decisions on interchangeability can impact the ease of substitution and drive biosimilar uptake.



Education and Awareness

Continuous education of healthcare providers and patients is crucial to address misconceptions and increase biosimilar acceptance.



Supply Chain Dynamics

Effective supply chain management is essential to ensure reliable and consistent biosimilar availability.

Opportunities for Biosimilar Manufacturers

1

Expanding Markets

Biosimilars provide huge chances to increase access and to help address unmet medical needs across a number of therapeutic areas.

2

Innovation and Differentiation

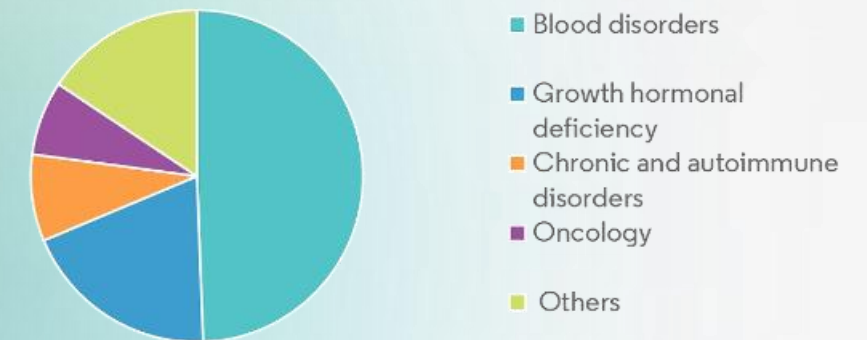
Biosimilar manufacturers can differentiate their products through innovative formulations, delivery devices, or combination therapies.

3

Global Expansion

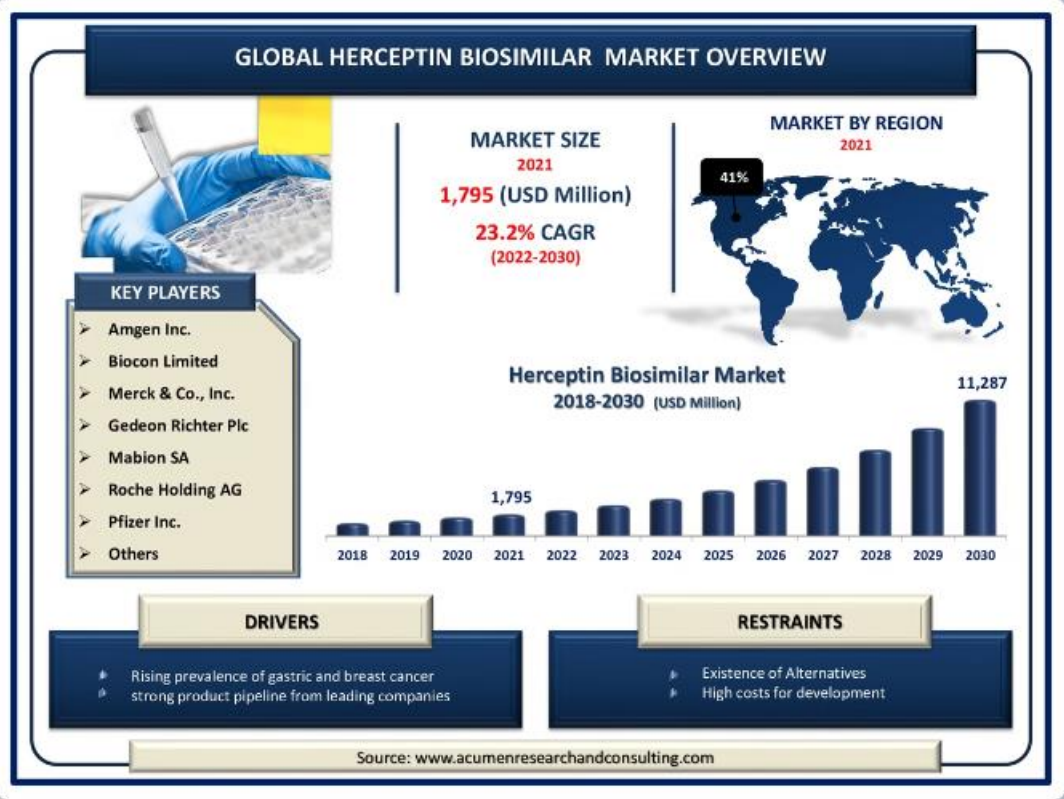
Those successful biosimilar manufacturers build a strong foundation of experience and competence that enables them to move into the newer markets around the world.

Bio Similar Market : Revenue Share (%), by Application , Global, 2018



Source: Mordor Intelligence





Conclusion and Key Takeaways

Increased Access	Biosimilars can improve patient access to essential biologic treatments by increasing competition and driving down costs.
Navigating Complexity	Understanding and successfully navigating the regulatory landscape is crucial for biosimilar manufacturers to achieve approval and commercial success.
Competitive Dynamics	The biosimilar market is rapidly evolving, with new players, products, and strategies emerging to gain a competitive edge.
Adoption Challenges	Overcoming barriers to adoption, such as brand loyalty and education, is essential for driving increased uptake of biosimilars.

