

# Biosimilars Redefining Therapeutic Access: US & EU Markets on the Brink of \$171 Billion Revolution | DataM Intelligence

*Biosimilars surge with interchangeable approvals, cost savings, and broad pipeline growth, set to hit \$171B by 2033. The next wave of drug affordability is here*

AUSTIN, TX, UNITED STATES, June 19, 2025 /EINPresswire.com/ -- [Biosimilars](https://www.datamintelligence.com/strategic-insights/ci/biosimilars-us-and-eu) Are Taking Center Stage in Pharma: Competitive Intelligence Across the US & EU

Biosimilars, once considered the low-cost alternative to biologics, have now cemented their place as a cornerstone of affordable, high-impact healthcare. A biosimilar is a biologic product that is highly similar to, and has no clinically meaningful differences from, an already FDA-approved reference biologic. With the rise of interchangeable biosimilars that can be substituted at the pharmacy level without prescriber intervention, the biosimilar revolution is no longer on the horizon—it's here.

“

Biosimilars aren't just cheaper copies—they're the future of equitable, sustainable healthcare. With pipeline growth and policy shifts, true therapeutic equality is finally within reach.”

*DataM Intelligence*



Download CI Sample Report:

<https://www.datamintelligence.com/strategic-insights/ci/biosimilars-us-and-eu>

As of March 2025, the U.S. FDA has approved 71 biosimilars, with at least 15 carrying interchangeable designations. Europe, a pioneer in biosimilar adoption, continues to see wide penetration across oncology, autoimmune conditions, endocrinology, and more. Together, the US and EU biosimilars markets are

forecasted to skyrocket from \$22.58 billion in 2024 to a projected \$171.79 billion by 2033, at an impressive CAGR of 25.5%.

## What's Driving the Biosimilar Surge?

Several interconnected trends are propelling biosimilar development and adoption:

- Expanding Therapeutic Applications: Initially limited to oncology and rheumatology, biosimilars are now entering ophthalmology (e.g., Eylea biosimilars), endocrinology (e.g., insulin biosimilars), and even rare diseases and neurology (e.g., Tysabri biosimilars).
- Regulatory Acceleration: Agencies like the FDA and EMA are streamlining approval processes for biosimilars, especially those targeting blockbuster drugs with upcoming patent expirations.
- Pharmacy-Level Substitution: With an increasing number of biosimilars gaining FDA interchangeability designation, automatic substitution at the pharmacy is becoming more commonplace—mirroring generic drug models.
- Cost Competitiveness: Biosimilars are generally priced 40–86% lower than reference biologics, offering substantial savings for payers and patients alike.
- Global Expansion: Patent cliffs in the next 5–8 years are opening up global biosimilar opportunities, particularly in emerging markets where affordability is key.

## Approved Biosimilars: A Rapid Rise in Numbers

- The U.S. FDA has approved 71 biosimilars to date. Notably, 15 of these are interchangeable—a designation that significantly enhances market uptake due to easier substitution pathways.
- Europe continues to lead in clinical use and volume of biosimilars, benefiting from a more biosimilar-friendly regulatory and pricing environment.
- Biologics like Humira, Herceptin, Avastin, Enbrel, Remicade, and Eylea are among the top targets for biosimilar competition, each with multiple approved or pipeline biosimilar challengers.

## Biosimilar Pipeline: What's Coming Next

The biosimilar pipeline is rich and diverse, targeting high-revenue biologics across several therapeutic categories. Highlights include:

- Ophthalmology: Biosimilars for Eylea (aflibercept) and Lucentis (ranibizumab) are approaching final approval stages.
- Neurology: Tysabri (natalizumab) biosimilars are entering late-stage trials with limited existing competition, presenting a lucrative opportunity for early market entry.
- Immunology: Biosimilars for Stelara, Cosentyx, and Dupixent are in the pipeline, targeting conditions like psoriasis, Crohn's disease, and atopic dermatitis.
- Endocrinology: Insulin biosimilars like SEMGLEE are gaining FDA approval and interchangeability status, helping to address rising diabetes-related costs.

## Market Forecast: The \$171 Billion Biosimilar Future

In 2024, the global biosimilar market was valued at \$22.58 billion. By 2033, that figure is expected to grow nearly eightfold to \$171.79 billion, driven by:

- Patent expirations of major biologics
- Increasing payer demand for cost-effective options
- Expanding pipelines across multiple therapy areas
- Growing public and physician trust in biosimilar efficacy and safety

Ask for Customized CI Consultation as per Your Business Requirement:

<https://www.datamintelligence.com/strategic-insights/ci/biosimilars-us-and-eu>

### Persistent Gaps and Unmet Needs

Despite this explosive growth, several barriers continue to limit biosimilar adoption and access:

- Regulatory Variability: Approval standards vary between the US, EU, and other regions, leading to delays in global product launches.
- Physician & Patient Education: A lack of understanding or lingering skepticism about biosimilar safety and efficacy can hinder adoption.
- Reimbursement Complexities: Biosimilar access often depends on payer policies and formulary placement, which can be inconsistent or restrictive.
- Limited Interchangeables: While the number is growing, most biosimilars still lack interchangeability status, reducing ease of pharmacy substitution.
- High Development Costs: Biosimilars are complex to develop and manufacture, which can eat into pricing flexibility and margins.
- Therapeutic Gaps: There is still a need for biosimilars in rare diseases, neurology, and pediatric conditions, where reference biologics dominate with minimal biosimilar alternatives.

### The Competitive Landscape: Who's Leading the Biosimilar Charge?

The biosimilar ecosystem is dominated by several global powerhouses, with strategies ranging from aggressive pricing to innovation in drug delivery:

- Amgen, Pfizer, Sandoz, Samsung Bioepis, Biocon Biologics, Celltrion, and Coherus BioSciences are among the top players shaping the market.
- Companies like Organon, Mylan-Viatris, and Alvotech are also rapidly expanding their biosimilar portfolios, particularly in the autoimmune and insulin segments.

Strategic moves include:

- Securing interchangeability status to accelerate pharmacy-level substitution
- Launching auto-injectors and prefilled syringe formats for ease of use
- Partnering with PBMs and insurers to ensure favorable formulary placement
- Competing aggressively on pricing and volume-based contracts

Book Free CI Consultation Call: <https://www.datamintelligence.com/strategic-insights/ci/biosimilars-us-and-eu>

### What Makes a Biosimilar Stand Out? (Descriptive Benchmarking)

For a biosimilar to succeed in the competitive US and EU markets, several factors are critical:

- Reference Product: Targeting high-volume reference biologics like Humira, Avastin, and Herceptin maximizes market opportunity.
- Therapeutic Area Focus: Biosimilars in oncology, rheumatology, and endocrinology tend to achieve faster uptake due to high clinical familiarity.
- Patent Expiry Timing: Early entry immediately after loss of exclusivity offers first-mover

advantages.

- Interchangeability Designation: Gaining FDA's interchangeable status, as seen with HADLIMA and CIMERLI, boosts pharmacy-level substitution.
- Competitive Pricing: Biosimilars priced 50–80% lower than reference drugs see better payer support and patient access.
- Manufacturing Scalability: Companies with efficient biologics manufacturing capabilities can better manage margins and pricing pressures.
- Market Access & Reimbursement: Strong relationships with insurers and PBMs improve formulary inclusion and coverage.
- Low Competition Niches: Targeting underserved therapeutic areas like neurology or rare conditions reduces direct competition and price erosion.

### Strategic Outlook: What Lies Ahead

The biosimilars revolution is unfolding rapidly, with key implications for the pharmaceutical ecosystem:

- Wider interchangeability designations will accelerate substitution and reshape prescribing habits.
- New therapeutic areas, especially neurology and rare diseases, offer untapped potential for first movers.
- Greater public and provider education, backed by real-world evidence, will close perception gaps and build trust.
- Payer-driven incentives and national procurement programs will increasingly favor biosimilars for cost savings.
- Manufacturing innovation, including AI-driven biologics process optimization, will lower production costs and enable pricing flexibility.

### Conclusion: Biosimilars—No Longer Optional, But Essential

The biosimilars market is no longer a secondary channel; it is a driving force in global health economics. With rapidly growing pipelines, expanding indications, and strong regulatory tailwinds, biosimilars are positioned to offer sustainable, high-quality treatment options to millions worldwide.

From oncology to endocrinology, and from autoimmune diseases to rare disorders, biosimilars are not just leveling the playing field—they're redrawing it entirely.

Read Related CI Reports:

1. [Uveal Melanoma | Competitive Intelligence](#)
2. [IgG4-Related Disease | Competitive Intelligence](#)

Sai Kumar

DataM Intelligence 4market Research LLP

+1 877-441-4866

sai.k@datamintelligence.com

Visit us on social media:

[LinkedIn](#)

[X](#)

---

This press release can be viewed online at: <https://www.einpresswire.com/article/823791828>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2025 Newsmatics Inc. All Right Reserved.