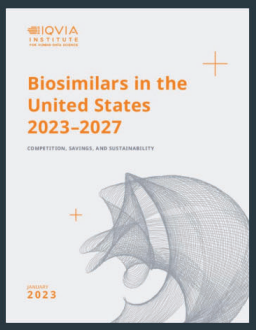
INSTITUTE REPORT

Biosimilars in the United States 2023-2027

Competition, Savings, and Sustainability

Jan 31, 2023



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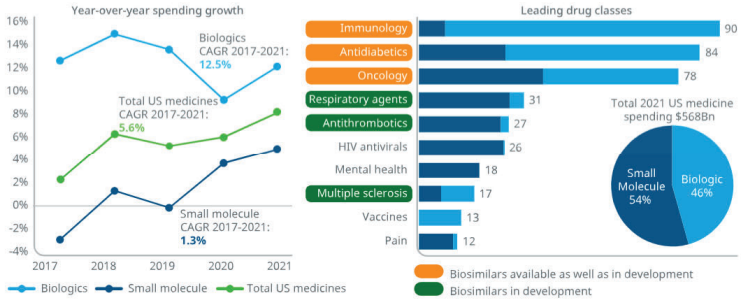
The first biosimilar approved under the abbreviated pathway established by the Biologics Price Competition and Innovation Act launched in the U.S. in 2015, while some non-original biologics have been approved through other pathways both before and since. Despite slower initial uptake, biosimilar launches in the last three years have generally been more successful than earlier, raising important questions for upcoming biosimilars, where savings and patient access could increase substantially.

In this report, the current state of the biologics market in the United States and share of the market facing biosimilar competition are assessed. Factors impacting biosimilar uptake, including reimbursement and provider type, and the impact of biosimilars on molecule volume and price are evaluated. Historic biosimilar trends are utilized to provide potential future biosimilar spending and savings scenarios

Key Findings

- The U.S. biologics market has grown 12.5% annually on average over the last five years on an invoice-price basis, faster than non-biologics, and now comprising 46% of spending.
- Molecules currently facing biosimilar competition total $38Bn of invoice spending, while a further $96Bn is the target of biosimilars in development or approved but not yet launched.
- Recent biosimilars have achieved high volume shares, reaching more than 60% of the molecule's volume within the first three years. Non-340B clinics have seen higher uptake of biosimilars than 340B clinics, likely due to reimbursement dynamics.
- The introduction of biosimilars frequently leads to higher utilization of the molecule as lower costs offer increased access to patients. However, more innovative alternative treatments can lead to volume declines as patients are moved to these successive generation products.
- Expected launches and uptake are likely to increase overall spending on biosimilars significantly to $20–$49Bn in 2027 and cumulative sales of $129Bn over the next five years, with at least 10 molecules facing biosimilar competition over the period.

Other Findings



Source: IQVIA MIDAS, Dec 2021; IQVIA Institute, Nov 2022.
Notes: Oncology includes therapeutic agents as well as supportive care. Invoice prices in this report are ex-manufacturer level, reflecting the prices between manufacturers and their customers (wholesalers or direct purchasers), not including off-invoice discounts and rebates.
Report: Biosimilars in the United States 2023–2027: Competition, Savings, and Sustainability. IQVIA Institute for Human Data Science, January 2023.

Amgen Exhibit 1066
Amgen v. BMS
IPR2025-00602

- In 2021, the United States spent $568Bn on medicines at ex-manufacturer invoice prices, including $260Bn on biologics, which now comprise 46% of total medicine spending.
- Even including the effect of biosimilar competition over the past decade, biologics spending has increased significantly since 2017, at a compound annual growth rate (CAGR) of 12.5%, outpacing the 1.3% CAGR for small molecules and raising the total market CAGR to 5.6%.
- The three classes with the highest spending — immunology, antidiabetics, and oncology — account for 70% of biologics spending, and their biologics growth is at 18.4%, 12.3%, and 14.8% CAGRs, respectively, in the past five years.

- The three molecules with biosimilar launches in 2019 — bevacizumab (82%), trastuzumab (80%), and rituximab (67%) — achieved significant uptake within the first three years. It is unclear if uptake of these recent oncology biosimilars is indicative of future biosimilar uptake, however these have gained higher market share than earlier biosimilars in the U.S. and are similar to or higher than rates of uptake in Europe.2
- Pegfilgrastim and epoetin alfa biosimilars, both launched in 2018, have seen moderate uptake achieving 37% share of molecule volume in the first three years. Pegfilgrastim biosimilar share has continued to rise slowly while epoetin alfa biosimilar share has fallen to 27% as of October 2022.
- Infliximab has seen the lowest adoption of biosimilars, with volume share at 3% after one year and rising slowly to 13% after three years. This has shifted significantly in more recent years as biosimilars now account for 44% of infliximab volume nearly six years after biosimilar entry.

- Introduction of lower cost biosimilars leads to declines in overall molecule costs per unit (i.e., includes originator and biosimilars) at invoice prices over time, typically driving down costs for originators as well.
- Costs are down between 18% and 50% per unit for molecules with biosimilars, with epoetin alfa having the smallest decline at present and infliximab having the largest.
- Bevacizumab and trastuzumab have had the most rapid decline in cost per unit, primarily due to the significant biosimilar uptake driving down molecule level costs

- In the last 10 years, $36Bn of biosimilar spending was associated with savings of $56Bn compared to what spending would have been without biosimilars.
- The next five years are expected to result in an increase in savings to $181Bn, more than four times savings over the past five years ($40Bn), as newly approved biosimilars launch and existing biosimilars see continued uptake and price reductions.
- The most impactful biosimilars in the next five years — those referencing adalimumab — will first appear in early 2023 as a result of negotiated patent litigation settlements. As they reach the market, with eight already approved, patients will undoubtedly benefit from lower costs to receive the world's current top-selling biopharmaceutical.

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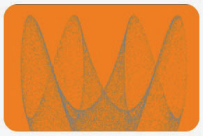
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