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# The State of Patient Access: Maximizing Access Strategies in the Era of Biosimilars

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## For a drug launch to be successful, its developer must have a winning market access strategy.

This is especially true today, as therapeutics become ever more complex and costly to bring to market. External pressures — including regulatory shifts, vertical integration, and the rapid evolution of biosimilars — are also intensifying access challenges.

At a recent MMIT-sponsored BioPharma Dive webcast, Steve Callahan, senior director of Advisory & Insights at MMIT, and Hannah Baxter, partner at The Dedham Group, presented "*The State of Patient Access: Maximizing Access Strategies in the Era of Biosimilars.*" They shared insights from an independent survey of 250 high-level pharma stakeholders and discussed how brands are rethinking their access strategies in response to these pressures.

## Pharma faces many challenges impacting patient access

Pharma executives report several pain points impeding their strategic planning for both medical and pharmacy benefit products.

- **New-to-market blocks** delay drug coverage between FDA approval and formulary review, limiting patient access and hindering early market uptake. These reviews typically take between four to six months but can extend to one year.
- **Clinically restrictive management** has increased, with payers managing more products beyond their labels with prior authorizations and step edits. Payers are also failing to cover more therapies. Pharma is under pressure to increase rebating in order to avoid excessive restrictions.
- The **Inflation Reduction Act** introduced multiple pricing reforms, including the Medicare Drug Price Negotiation Program and caps on out-of-pocket Medicare costs.
    - The act also introduced penalties for drug price increases that exceed the rate of inflation. These **CPI penalties** inhibit manufacturers' ability to raise prices over time, which may prompt developers to front-load those costs at launch, increasing cost pressures on patients.
- Payer pricing strategies have shifted more of the cost burden onto patients with higher co-insurance rates, making some patients unable or unwilling to pursue treatment due to **high out-of-pocket costs**.
- Increased payer control over **distribution and dispensing** presents access barriers for patients. Factors like white bragging provisions and site-of-care limitations complicate patients' access to treatment.

## A robust pipeline of biosimilars is likely to reshape the market

Biosimilars remain a fairly new sector within the industry, as the first biosimilar (Filgrastim-sndz, a biosimilar for Neupogen) was approved just 10 years ago. Since then, there have been 73 FDA-approved biosimilars for only 20 biologic reference products. As Baxter reported, biosimilars have had a transformative impact on the biologic market in that relatively short time period.

**Key insight**

In 2024, originator biologics with at least one biosimilar on the market retained $11 billion of the post-biosimilar market share. Their biosimilars captured $10 billion.

## Market access is top of mind for biosimilar manufacturers

Market access barriers are four of the top five factors that cause pharma executives not to invest in biosimilar development:

1. Pricing and/or rebating expectations
2. Payer restrictive access concerns
3. HCP prescribing concerns / HCO barriers
4. Development costs / manufacturing challenges or complexity
5. Patient utilization and affordability

Despite these challenges, investment in biosimilars is primed to continue. Even companies that previously started and stopped development of a biosimilar are ready to get back into the game: 86% of that group reports that their company is "likely" or "very likely" to invest in another biosimilar.

"We're seeing executives report they're highly likely to invest in a new biosimilar," Callahan said. "That's driven in part by the IRA, since it includes a few provisions that incentivize the use of biosimilars. But we're also seeing favorable market conditions: Patients are willing to switch to biosimilars, and physicians are willing to prescribe them."

## An explosion of biosimilars is just over the horizon

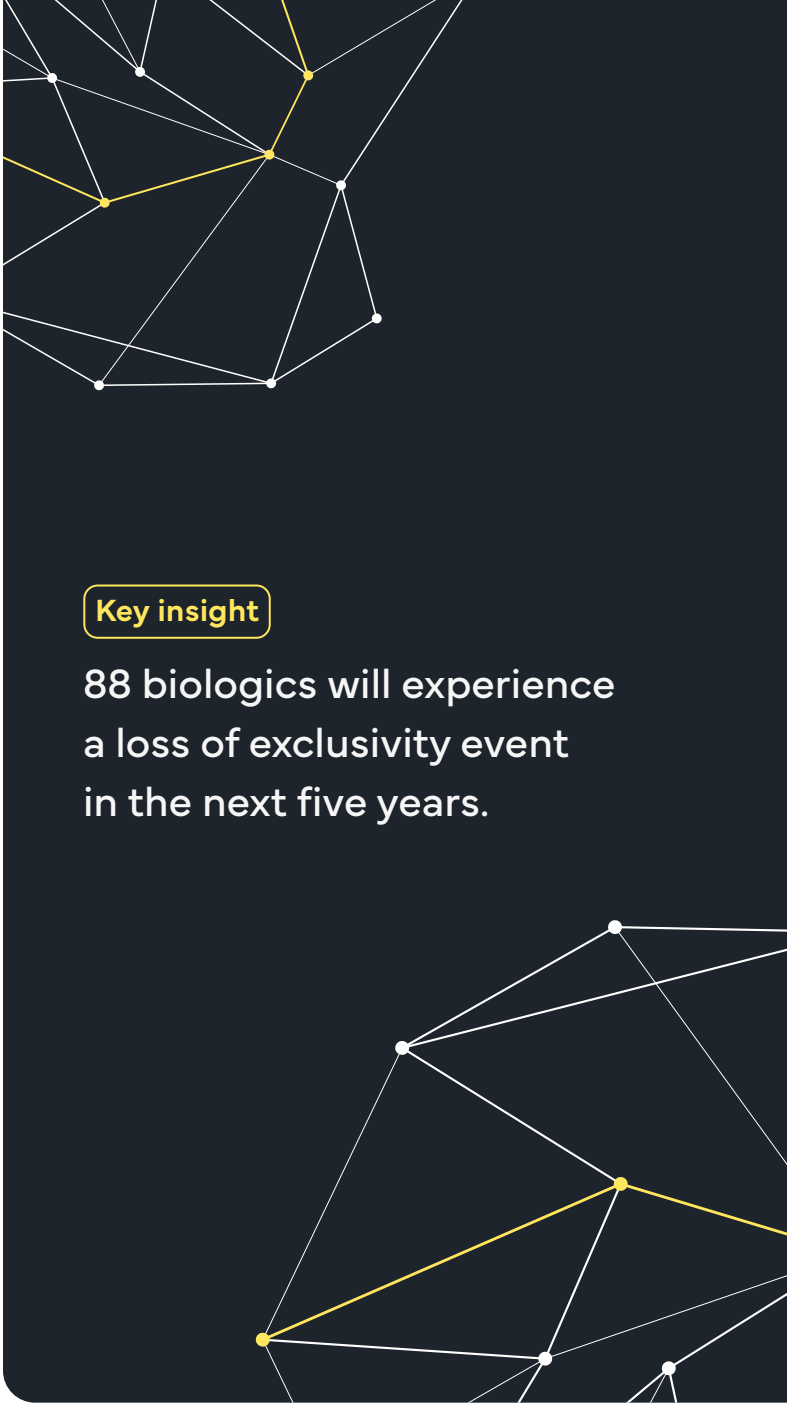
Biosimilars represent an enormous opportunity for manufacturers in the next few years. More and more biosimilars will certainly come to market, including biosimilars of blockbuster originators like Keytruda, Eliquis, Darzalex and Opdivo.

The rapid evolution of biosimilars has contributed to significant shifts in the market, including:

1. Greater access challenges and downward pressure on pricing.
2. Vertical integration across stakeholders (health plans, PBMs, GPOs, etc.) increasing payer control over market access and formulary management.
3. Stronger enforcement tactics like step therapy, tighter formularies, and multi-product preference structures (e.g., 2 out of 4 preferred biosimilars).
4. Rapid adoption of multi-source biosimilars, supported by payer preference and providers' willingness to switch.
5. Emergence of new players and contracting partners, from private label distributors like CVS's Cordavis to contracting organizations focused on medical benefit drugs, like Synergie Collective Medication.

However, Callahan noted that biologic developers can still pull a number of levers to retain market share, including:

- **Portfolio contracting:** Some developers bundle their biologics with other therapeutics to provide payers with greater cumulative savings via portfolio rebates.
    - Humira used this method to retain 77% market share in 2024.
- **Novel pricing strategies:** Some developers lower prices to more readily compete with biosimilars.
- **Extending exclusivity to delay biosimilar launches:** Some developers accumulate secondary patents to prolong exclusivity, expanding indications for new populations or TAs, or creating novel combination therapies.
    - These strategies can delay the release of biosimilars for years. For example, Enbrel lost exclusivity in 2016 — but its biosimilars have yet to come out.




## Market access planning now starts in early development

To adapt, pharma executives are centering market access in their launch strategies, beginning commercialization planning much earlier on. Baxter noted that 29% of pharma companies are now initiating their market access strategy during Phase I clinical trials, while 50% have begun by Phase II or III.

They're also leveraging new technologies — such as AI-powered analytics — to support market access planning. Finally, they're changing how they engage with payers and providers, and reaching out to integrated specialty pharmacies and specialty distributors to support greater access for their patients.

## The bottom line

Amidst rising cost pressures, greater vertical integration, and increased payer stringency, manufacturers must be vigilant to ensure patients have access to their therapies. With the threat of greater biosimilar competition just around the corner, they must also be prepared to navigate new landscape complexities in the coming years.

But these challenges also unearth opportunities, said Baxter. "By adopting forward-thinking strategies and adopting new technologies, developers can optimize their market access strategies — and ensure they can bring their life-saving therapies to patients in need."

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