Which Novel drug will be next Authorized Generics ?

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RESEARCH DELTA

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Authorized Generics: The Innovator's Playbook to Stay in the Game

Over the past decade, the U.S. pharmaceutical market has quietly witnessed a new trend reshape the way innovator companies fight for survival after patent expiry: **Authorized Generics (AGs)**.

On the surface, AGs look simple—just another version of the same medicine, stripped of its brand name, and sold under a generic label. But the story behind them is far more strategic. Unlike traditional generics, which are manufactured by independent competitors, AGs come directly from the innovator or a licensed partner. In essence, the brand company decides to "compete with itself." And this move is rarely about altruism or expanding patient access. Instead, it's a calculated manoeuvre to capture revenue in the crucial early stages of generic competition—the window where margins are still attractive, and brand loyalty can be redirected under a different label.

The Billion-Dollar Illusion

When we first began studying AGs, our initial hypothesis was straightforward: *blockbuster drugs would be the natural candidates for AG launches.* After all, if a product generates over a billion dollars in sales, wouldn't the innovator want to squeeze every last drop of value before generics flood the market?

There were many top Billion-Dollar product which had Authorized Generics already launched. But further analysis gave us a new view. Taking the example of **Adderall XR**, the ADHD drug with sales of $1.3 billion. Generics entered in 2012, and approvals trickled in slowly over time. Yet, Takeda had already anticipated the battle and partnered with Sandoz to launch an AG as early as 2009. To this day, that AG continues to hold its ground.

Then there's **Lovenox**, a $1.2 billion anticoagulant. Sandoz broke through first in 2010 with a generic. Sanofi, the innovator, wasted no time. Within just eight months, it launched its own AG in March 2011. FDA approvals for other generics didn't come until later—one in September 2011 and another not until 2015. In that window, Sanofi's AG became the shield protecting its revenue stream.

It seemed obvious: billion-dollar drugs meant fertile ground for AGs. But the deeper we looked, the more the story shifted. **High sales alone don't guarantee an AG launch.** The real determinant was the *pattern of generic entry*. When approvals came in a staggered fashion, AGs gave innovators a way to stretch out their earnings. When approvals came all at once, the AG strategy often collapsed before it could even begin.

The Rise and Fall of Short-Term AGs

Another chapter in the AG story involves innovators who played the strategy only briefly. They launched AGs during or around the 180-day exclusivity period—the most profitable moment—and then quietly withdrew once the floodgates of competition opened.

This was the case for drugs like Eloxatin, Advair Diskus, and Allegra. Each saw AG launches timed with exclusivity, giving the brand company a slice of the early profits. But once multiple generics crowded the market and price erosion became severe, maintaining AGs no longer made sense. These short-lived AGs highlight that timing is not just important—it is everything.

Small Innovators, Big Dependence

While large companies weigh AGs as just one tool among many, smaller innovators often depend on them for survival. Consider Collegium Pharma, whose annual revenue is just $631 million—tiny compared to pharma giants. Its flagship drugs, Nucynta and Nucynta ER, are set to lose exclusivity in December 2025. Multiple generics are poised to enter simultaneously, threatening Collegium's lifeline.

The company's response? A settlement with Hikma Pharmaceuticals. Under the deal, Hikma gets the rights to sell AGs one month before full generic entry. For Collegium, this ensures it retains at least part of the market during the initial shockwave of genericization. For Hikma, it's an early-mover advantage. For patients, it's just another generic label on the shelf—but behind the scenes, it's a finely negotiated survival tactic.

Complex Drugs and Staggered Battles

The AG story becomes even more interesting with GDUFA III guided complex drugs—products that are difficult to replicate due to intricate formulations or delivery mechanisms. Complexity often means staggered approvals for generics, and staggered approvals create opportunity.

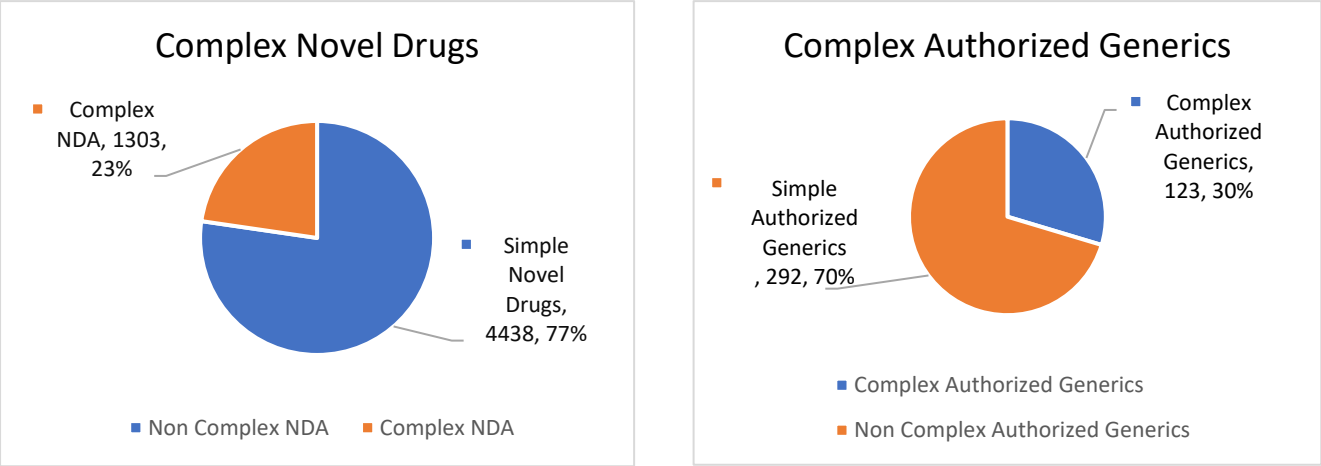

Figure 1 GenUS Database, Research Delta Advisors

The data supports this. Out of 1,303 complex NDAs identified under the GDUFA III framework, 123 already have AGs—roughly 9.5% of the total complex NDA universe. These numbers may look modest, but they underline a consistent trend: wherever competition unfolds in stages, innovators step in with AGs.

When AGs Fail to Appear

Of course, not every blockbuster drug gets an AG. Some of the industry's giants—Entresto, Suboxone, Nexium, Lipitor—never had authorized generics despite enormous sales. Why? The answer lies in the competition landscape. When multiple generics enter simultaneously, the market rapidly fragments. Prices plummet, and even an AG cannot rescue the innovator's share. In such scenarios, innovators often choose to retreat rather than fight.

The Bigger Picture: Lessons from a Decade of AGs

So, what does the story of AGs really teach us? It's not just about sales size. Billion-dollar drugs are tempting, but without staggered competition, AGs rarely succeed. Timing is the heartbeat of the strategy. Launch too late, and the AG is irrelevant. Launch too early, and it may cannibalize the brand unnecessarily. Settlements matter. Deals like Collegium-Hikma show that AGs are as much about negotiation as they are about science or sales. Complexity creates opportunity. The harder a drug is to copy, the more room innovators have to wield AGs as a weapon.

For innovators, AGs are no longer just an experiment—they are part of the playbook of portfolio management, a way to soften the blow of patent expiry and hold ground for just a little longer. For generics, the lesson is equally important: know where AGs are likely to appear and prepare to negotiate rather than simply compete.

Conclusion

The story of authorized generics is not one of altruism, nor is it purely about protecting patients from high drug costs. It is a story of **strategy, timing, and survival.**

In some cases, AGs are long-term fixtures, standing shoulder-to-shoulder with independent generics. In others, they are short-lived tools, designed to extract value during exclusivity before vanishing. And in yet others, they never appear at all—because the competition arrives too fast and too fierce.

In the end, AGs reflect the delicate game between innovators and generics. They are neither fully brand nor fully generic but exist in the grey zone between the two—shaping competition, influencing pricing, and rewriting the rules of the post-patent marketplace.