

## Authorized Generics: Frequently Asked Questions

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**Q: *What are Authorized Generics?***

**A:** The term Authorized Generics refers to prescription drugs that are produced by brand companies and marketed as generics under private label.

Authorized Generics compete with standard generic products approved by the FDA as substitutable for specific brand products. Authorized Generics are marketed to consumers during and after what is commonly known as “the 180-day exclusivity period.”

**Q: *What is the difference between Authorized Generics and other Generics?***

**A:** An Authorized Generic is a brand-name prescription drug already approved by the FDA, but marketed as a generic under a private label. It has the identical size, shape, color, taste, smell, mouth feel, and active ingredients as the brand. Unlike a standard generic, the Authorized Generic has the identical inactive ingredients as well.

According to the FDA, “A generic drug is a copy that is the same as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use.”<sup>1</sup> Generics are produced and marketed under an Abbreviated New Drug Application (ANDA).

**Q: *What are the similarities between Authorized Generics and other Generics?***

**A:** Authorized Generics and standard generics are marketed and sold as generic alternatives to brand prescription products. Both provide consumer savings, and are approved by the FDA to be marketed to the public. Both are highly regulated and undergo a rigorous approval process resulting in a safe and effective treatment methodology.

**Q: *What are the consumer advantages of Authorized Generics?***

**A:** Simply put, Authorized Generics provide consumers the highest brand quality at lower generic prices. The FDA answers this best, stating: “Marketing of Authorized Generics increases competition, promoting lower prices for pharmaceuticals...”<sup>2</sup> The presence of an Authorized Generic increases competition in the marketplace and provides consumers with greater access to affordable generic options.

The consumer impact of increased competition is detailed by the Federal Trade Commission (FTC), which states “the entry of a second generic drug product generally doubles the price decrease introduced by the first generic product from the branded



drug product's price. Three or more companies offering a generic version of a listed drug can lower the price by at least fifty percent, if not substantially more."<sup>3</sup>

According to a recent GPhA report, 89% of all prescriptions dispensed in the United States in 2015 were filled with generic drugs, yet only accounting for 27% of the total drug spending that year. This resulted in over \$227 billion in health system savings, bringing the total saving over the last ten years to \$1.46 trillion.<sup>4</sup>

Authorized Generics provide consumers brand quality at generic prices. The availability of raw materials and production capacity for Authorized Generics reduces the possibility of marketplace supply interruptions. Consumers also have the identical product experiences with Authorized Generics as they do with brand products in areas such as taste, color, mouth feel and shape. And, by being an additional generic competitor, Authorized Generics reduce the cost of prescription drugs more than the reduction offered by the first generic entrant in the market.

***Q: What is the 180-day exclusivity period?***

**A:** "Section 505(j)(5)(B)(iv) of the Federal Food, Drug and Cosmetic Act (FDCA) establishes a 180-day period following the approval of abbreviated new drug applications ("ANDAs"), during which FDA may not approve other ANDAs for the same drug product. While this is commonly referred to as "180-day exclusivity," in practice this period has never been truly an "exclusive" as the NDA holders and its distributors and licensees have always been authorized to continue to sell the originally approved drug product throughout this 180-day period and beyond. If there are multiple ANDAs submitted on the same day as the first ANDA qualifying for the 180-day exclusivity, they all share the 180-day exclusivity."<sup>7</sup>

***Q: How many Authorized Generics have been launched, and are they still in the marketplace?***

**A:** Since 2006, 689 Authorized Generics have been launched.<sup>8</sup> 505 (73%) of these products are still being marketed today.

***Q: Are Authorized Generics ever on the market all by themselves?***

**A:** Authorized Generics, as an FDA approved product, can enter into the marketplace at any time upon the decision of the NDA holder.

***Q: How are Authorized Generics brought to market?***

**A:** Authorized Generics can be brought to the marketplace a number of ways: three of the most common are identified below:

- Brand companies establish agreements with private label marketing and distribution companies to market and distribute Authorized Generic products. This type of agreement usually results in two generics competing in the marketplace.



- Brand pharmaceutical companies can establish subsidiaries to market Authorized Generics of their own brands. Several companies have launched Authorized Generics this way, but some have abandoned this approach for other options. This usually results in two generics competing in the marketplace.
- Brand companies establish agreements (oftentimes a result of a patent challenge settlement) with a generic drug manufacturer to permit them to offer the Authorized Generic product until the generic company gets its ANDA approval. Once the ANDA is approved, the generic company stops offering the Authorized Generic. This strategy generally results in just one generic drug in the marketplace.

According to industry experts Robert P. Reznick and James B. Kobak, “History suggests there is no shortage of generic manufacturers ready to make a product otherwise likely to be the subject of an Authorized Generic.”<sup>9</sup> The presence of an Authorized Generic in the market provides consumers with a lower priced alternative to an otherwise monopolistic generic price.

These economic realities are underscored by Jonathan Siegel, vice president of pharmaceuticals equity research at Bear Stearns. In a presentation at a Food and Drug Law Institute generic drug conference he said that, “even with an Authorized Generic on the market, the 180-day exclusivity period still provides a significant return on investment,”<sup>10</sup> which he estimated to be approximately 470% for the generic drug firm operating under such exclusivity.

***Q: Are Authorized Generics an effort by large pharmaceutical companies and their partners to circumvent the intent of the Hatch-Waxman Act which created the 180-day exclusivity period for the first generic drug approvals?***

**A:** No. The intent of Hatch-Waxman was to promote competition and allow low cost generic drugs to reach the marketplace. There is nothing in Hatch-Waxman to suggest that Authorized Generics are against public policy, in fact AG’s accomplish its goal by increasing competition and the number generics available to consumers.

In addition, Hatch-Waxman always contemplated more than one generic company during the exclusivity period. The original statute gave preference to the first to file, but Congress, in 2003, specifically provided for multiple ANDA filers on the same day to share the 180-day exclusivity. The presence of a second generic competitor in the 180-day exclusivity period is good for consumers and was clearly contemplated by Congress.

**Q: What are other interested parties saying about this?**

**A:**

**FDA**

“Marketing of Authorized Generics increases competition, promoting lower prices for pharmaceuticals particularly during the 180-day exclusivity period in which the prices for generic drugs are often substantially higher than after other generic products are able to enter the market.”<sup>2</sup>

“FDA considers Authorized Generics legal and pro-competitive. Appears to promote competition in the pharmaceutical marketplace, in furtherance of a fundamental objective of the Hatch-Waxman amendments.”<sup>11</sup>

**FTC**

“FTC’s position historically has been that Authorized Generic arrangements are pro-consumer because they allow multiple generic entrants sooner.”<sup>12</sup>

**Federal Courts**

“Nothing in the statute provides support for the argument that the FDA can prohibit NDA holders from entering the market with a brand generic drug during the exclusivity period.”<sup>13</sup>

“The Court can not fathom any reason to apply section 355(j)(5)(B)(iv), a provision clearly addressing only ANDAs, to limit the introduction into the market of a generic drug of a NDA holder.”<sup>14</sup>

**The National Center for Public Policy Research**

“An ‘Authorized Generic’ can come into the market very quickly to provide consumers with lower prices because the know-how of the medicine’s original developers can be quickly and efficiently transferred.” “...the competition should be welcome because it serves the needs of consumers. The original brand-name medicine now faces two competitors – the ‘Authorized Generic’ and the copy made by the first traditional generic drug maker who enters the market. Because consumers now have more choices, all of the drug companies are forced to price their products lower to stay competitive. This can only benefit consumers.”<sup>15</sup>

**Industry Financial Analyst**

“Even with an Authorized Generic on the market, the 180-day exclusivity period... still provides a significant return on investment... Without an Authorized Generic, a generic firm with 180-day exclusivity could reap 1,000 percent [return on investment] ROI. With an Authorized Generic product on the market, the ROI declines by about one-half to approximately 470 percent.”<sup>10</sup>

**National Economists**

“...The practice of Authorized Generics provides no meaningful disincentive for generic pharmaceutical companies to challenge questionable patents...competition from Authorized Generics reduces prices and increases the availability of safe and lower priced generic medicines, which benefits American consumers.”<sup>16</sup>



### ***Industry Trade***

“In addition to lowering costs for consumers and payers, the entry of an Authorized Generic product at patent expiration often helps with the market transition from brand to generic, reducing risks associated with some generic launches, including inventory supplies.”<sup>17</sup>

### ***Bear Stearns***

“without an Authorized Generic, a generic firm with 180-day exclusivity could reap a 1,000% [return on investment] ROI. With an Authorized Generic on the market, the ROI declines by about one-half.”<sup>10</sup>

### ***Investor’s Business Daily***

“...Authorized Generics are pro-competition...They bring another generic drug to market sooner. It’s beneficial for the consumer.”<sup>18</sup>

***Q: Will competition from Authorized Generics further drive down the price of off-patent pharmaceuticals, ultimately benefiting consumers through greater access to more affordable prescription drugs?***

**A:** Yes. Authorized Generics add to competition and competition lowers prices. Supply, demand, and pricing are by-products of market conditions.

***Q: Opponents of Authorized Generics contend that such products violate anti-trust laws. Is this so?***

**A:** No. The appropriate agencies of the federal government, the FDA and FTC, have both examined the consumer impact, the anti-trust implications, and other relevant federal statutes and regulations, and have subsequently allowed the marketing of Authorized Generics.

“Marketing of Authorized Generics increases competition, promoting lower prices for pharmaceuticals, particularly during the 180-day exclusivity period in which the prices for generic drugs are...substantially higher than after other generic products are able to enter the market.”<sup>2</sup>

Nearly all of the largest generic companies offer both ANDA generics and Authorized Generics. There have been over 100 AG launches from these generic companies since 2006.



***Q: Is it anticompetitive to allow a brand company to compete with generic versions of its own brand product?***

**A:** No. The FTC, which governs conduct that restricts competition, has reviewed Authorized Generics and concluded that they are in fact pro-competitive in the short term and is currently doing a study to ensure they are good for the consuming marketplace for the long term.

***Q: Does the marketing of Authorized Generics offer consumers benefits during the 180-day exclusivity period while preserving the value of patent challenges?***

**A:** Yes. The introduction of Authorized Generics in the marketplace lowers prices during the 180-day exclusivity period, and the presence of Authorized Generics does not eliminate the economic incentive for challenging patents.

As stated before, if an Authorized Generic is available during the 180-day period, the patent-challenging generic still has a potential return on investment of approximately 470%.<sup>10</sup> There is no evidence that patent challenges are discouraged. In fact, Tim Catlett, Barr's Senior Vice President of Sales and Marketing, said, "This is a very large marketplace. There is room for two competitors."<sup>19</sup>

***Q: Is the 180-day exclusivity period a way for generic companies to recoup their development and legal costs?***

**A:** Sure. Generic companies have a substantial return on their investment and that is true even if they face competition during the 180-day exclusivity period. Moreover, generic companies do not make their investment decisions solely on their ability to obtain the exclusivity period. In many cases, they are not the first to file, but still find it financially viable to invest resources and come to market.

***Q: Will generic companies stop challenging brand drug patents if Authorized Generics are allowed to continue?***

**A:** No. Generic manufacturers continue to challenge patents, invest in developing their own generics, and enter the market at competitive prices. But with Authorized Generics, the consumer will receive a further break in prices and access to brand quality products.

An Authorized Generic product simply adds one competitor to a generic market. A generic company able to gain 180-day exclusivity through a successful patent challenge currently has no competition absent an Authorized Generic. Without an Authorized Generic on the market, there is no incentive to lower price more than a small margin from the brand product price.

Authorized Generics have been in the market for years and generic companies have continued to invest in patent challenges. Historically, generic companies have invested in patent challenge because the return on investment has been potentially enormous when challenging drugs with blockbuster revenues. In the instances where generic



companies made such investments, they did so with the knowledge that they were seeking access to a market. As discussed above, even when the generic company has one competitor during the exclusivity period, the opportunity for return on investment is considerable and worth the investment. That is why, even with Authorized Generics in the market over the years, and even with the uncertainty of a first to file status, generic companies will very likely continue to invest in patent challenges. With patent challenges, the potential returns far outweigh the costs of patent challenges.

***Q: Are Authorized Generics only offered by brand companies with generic subsidiaries?***

**A:** No, not all brand companies have generic subsidiaries; rather they establish commercial supply/licensing agreements independent pharmaceutical companies that specialize in AGs. Benefits of doing this include expertise in generic sales and marketing, relationships with all major generic classes of trade, and full service supply chain and distribution resources.

***Generic Marketplace Facts***

- Sales of generic medicines increased +7.4% to \$114.1 billion in 2015.<sup>4</sup>
- Generic prescriptions grew from 57% to 89% of total prescriptions dispensed between 2005 and 2015. By 2021, generics are expected to account for 92% of all prescriptions.<sup>4</sup>
- Generic drugs account for nearly 9 out of every 10 prescriptions but only 27% of total drug spending.
- Generics represented \$227 billion in health system savings in 2015, bringing the total savings over the last 10 years to \$1.46 trillion<sup>4</sup>
- Americans filled 3.6 billion generic prescriptions in 2015, up from 1.3 billion 20 years ago.<sup>4</sup>
- Since 2008, the price of generic drugs has been cut roughly in half, while the price of brand drugs has almost doubled.
- 689 Authorized Generics have been launched in the past decade (2006 – 2016), 34 in 2006, 33 in 2007, 44 in 2008, 39 in 2009, 46 in 2009, 60 in 2011, 85 in 2012, 70 in 2013, 104 in 2014, 92 in 2015, and 82 in 2016.<sup>8</sup>

\* The term “Generics and generic market” include both generic and Authorized Generic pharmaceutical products.

In short, the market for generic drugs has grown and will continue to grow because consumers are demanding more, not less, competition among pharmaceutical manufacturers. Authorized Generics are just one more competitor in the marketplace bringing cheaper drugs faster to consumers.





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