Authorized Generics

In the U.S., prescription drugs approved by the federal Food and Drug Administration (FDA) are granted a specified period of market exclusivity, which varies by exclusivity classification.[1] After patent and market exclusivity protections expire, generic versions may be launched into the market. Under FDA guidelines, there are two types of generic drugs: *Authorized generics* and *generics.* Authorized generics are manufactured by the innovator company and are the same as the brand-name drug in all aspects, with the exception of not using the brand name on the label. Generics are copies of the branded product manufactured by a company other than the innovator and are similar to the brand-name drug with certain permissible differences. Like generics, authorized generics help expand patient access to more affordable treatments, lowering the cost of, and reducing health care spending on, prescription medications. Authorized generics increase competition in the pharmaceutical market by providing alternatives to both innovator and generic products. In addition, patients taking authorized generics have lower rates of switching back to the brand than generics, and help HCPs and patients maximize continuation of therapy. Pfizer has sold authorized generics in the U.S. for the past 25 years through Greenstone, a wholly-owned subsidiary. Greenstone currently has the broadest portfolio of authorized generics in the U.S.

Background

In the U.S., prescription drugs approved by the federal FDA under a New Drug Application (NDA) are granted a specified period of market exclusivity that varies based on classification (e.g., five years for New Chemical Exclusivity; seven years for Orphan Drug Exclusivity, etc.).[2] After patent and market exclusivity protections expire, generic versions of a drug may be launched into the market. Under FDA guidelines, there are two types of generic drugs: "Authorized generics" and "generic" drugs.[3] An authorized generic is the same as a brand-name drug except the brand name is not used on the label. Because they are the same as the brand-name version, authorized generics can be marketed under the brand-name drug's original NDA, are considered to be therapeutically equivalent and, therefore, are not listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book). The NDA holder may market both the authorized generic and the brand-name product at the same time.

Unlike an authorized generic, a generic drug is a copy of a brand-name drug produced by a company other than the innovator company. Based on federal law, to obtain approval of a generic drug, a company must submit an Abbreviated New Drug Application (ANDA) to the FDA and prove that its version of the product is "bioequivalent" to the brand-name drug, meaning it gets to the part of the body where the drug works at the same time and in the same amount.[4] It needs to be the same as the brand-name drug in active ingredient, conditions of use, dosage form, strength, route of administration, and labeling. A generic must also meet the same standards of quality and manufacturing as the brand-name drug. However, a generic may have certain minor differences from the brand-name product, such as permissible label differences and different inactive ingredients. Additionally, the ANDA process does not require the generic drug maker to repeat animal and clinical research on ingredients or dosage forms, and therefore, is generally less costly and burdensome than approval of an application for the brand-name drug.

Under federal law, the first ANDA applicant(s) to challenge the brand-name product's patents, which with certain exception are listed in its NDA, is granted 180 days of market exclusivity before other ANDAs can be approved by the FDA. During this exclusivity period, the innovator biopharmaceutical company may launch an authorized generic version of the branded product or grant a license to another company to do so under the innovator's NDA, which can help improve patient access to affordable medications and increase competition.

Authorized generics have shown no sign of preventing generics from continuing to expand their place in pharmaceutical markets, and the FDA has supported competition from authorized generics, stating that "[t]he marketing of authorized generics during the 180-day exclusivity period is a long-standing, pro-competitive practice, permissible under the [Federal Food, Drug and Cosmetic] Act."[5] Additionally, the Federal Trade Commission found that in the short term, authorized generics were associated with lower retail and wholesale prices and in the long term, they "appear not to have substantially altered generic firms' willingness to enter [the market]."[6]

Key Facts and Figures

- Generic drugs saved the U.S. health care system an estimated $1.67 trillion in the last decade, generating $253 billion in savings in 2016 alone. Medicare savings amounted to $77 billion ($1,883 per enrollee) and Medicaid savings of $37.9 billion ($512 per enrollee).[7]
- Generics currently account for 89 percent of prescriptions dispensed, accounting for nearly 3.9 billion prescriptions dispensed in 2016.[8]
- There are over 900 active authorized generic molecules in the US market as reported in the current "FDA List of Authorized Generics."[9]
- In an FDA-sponsored study of 210,000 patients, switching from a branded to an authorized generic was associated with lower "switchback" rates compared with switching from branded to generic.[10]

Pfizer's Position

Pfizer has extensive experience with authorized generic medications. Greenstone LLC has been a US-based Pfizer company providing authorized generic versions of Pfizer products for over 25 years. There are currently over 75 Greenstone products available on the market. We believe authorized generics help advance public health and the broader health care system by increasing competition, improving access, and helping patients adhere to high-quality, affordable medicines.

How Patients and Health Care Professionals Benefit

Authorized generics enable consumers to purchase high-quality medications at lower costs. Authorized generics also provide physicians and other health care professionals with more affordable treatment options to address patients' medical needs while maintaining the trust of clinical experience gained from their branded-medicine experiences.

How the Health Care System Benefits

By increasing competition in the generic market, authorized generics can help reduce health care spending on prescription medications. Patient adherence to therapy when switching from a branded to a generic product can also be improved as a result of a consistency of product appearance since authorized generics are typically the same size, shape and color as the brand-name version and have the same ingredients. This can help ensure that the patient knows they are taking the same product that had been originally prescribed for them, which can help maximize continuation of therapy.

What It Means for Pfizer

Pfizer is an active participant in the authorized generics market and welcomes opportunities to expand access to treatment by offering patients lower-cost versions of our products.

[1] 21 U.S.C. 9 – Federal Food, Drug and Cosmetic Act.
[2] *Ibid.*

[3] Food & Drug Administration, "definition of Authorized Generic": updated 12/27/17. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm126389.htm.
[4] Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments"). https://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg1585.pdf.
[5] Food & Drug Administration, Re: Docket Nos. 2004P-0075/CP1 & 2004P-0261/CP1, July 2, 2004, http://www.fda.gov/ohrms/dockets/dailys/04/july04/070704/04p-0075-pdn0001.pdf .
[6] Federal Trade Commission, "Authorized Generic Drugs: Short-term Effects and Long-term Impact," August 2011.
[7] Association of Accessible Medicines, 9th Annual Generic Drug Access and Savings in the U.S. report, 2017. https://accessiblemeds.org/resources/blog/2017-generic-drug-access-and-savings-us-report
[8] Association of Accessible Medicines, 9th Annual Generic Drug Access and Savings in the U.S. report, 2017. https://accessiblemeds.org/resources/blog/2017-generic-drug-access-and-savings-us-report.
[9] Food & Drug Administration, "FDA Listing of Authorized Generics." December 2017. https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm126391.htm.
[10] Desai RJ, et al., "Differences in rates of switchbacks after switching from branded to authorized generic and branded to generic drug products: cohort study." BMJ 2018; 361:k1180.