

GENERIC DRUGS



October 2018

An Overview

Generic drugs are exact copies of brand name drugs that have lost patent protection. They have the same concentration of the chemical substance as the original/branded drug and are administered the same way as the branded drug. Generic drugs are considered essential for affordable healthcare as they lower drug prices and increase access to healthcare. Use of generic drugs in the U.S. has increased from 63% in 2008 to 89% of total prescriptions in 2016 (Figure 1).

The generic drug industry got a big boost from the passage of the Hatch-Waxman Act in 1984. This act allows the generic drug manufacturer to use clinical data for safety and efficacy from the corresponding branded drug New Drug Application (NDA). The generic drug manufacturer needs to only demonstrate bio equivalency, not safety and efficacy, of the generic drug to the branded drug in its Abbreviated New Drug Application (ANDA). As a result, the average cost of an ANDA is approximately \$60,000, whereas the average cost of an equivalent NDA is approximately \$800,000. The Hatch-Waxman Act allows the generic maker to conduct its bio equivalency trials and prepare for its ANDA before expiration of the relevant patent. This is done to ensure generic drug entry coincides with patent expiration. Also, the Hatch-Waxman Act grants the first generic manufacturer to get its ANDA approved a 180-day exclusivity.

Generic drugs, on average, cost less than branded drugs. However, the price discount is dependent on the number of manufacturers. The first generic on the market reduces the price of the drug by about 6%, the second one reduces the price by 48%, the third by 56%. Each additional manufacturer lowers the price with the final reduction of 80% for a drug with 9 or more generic suppliers (Figure 2).

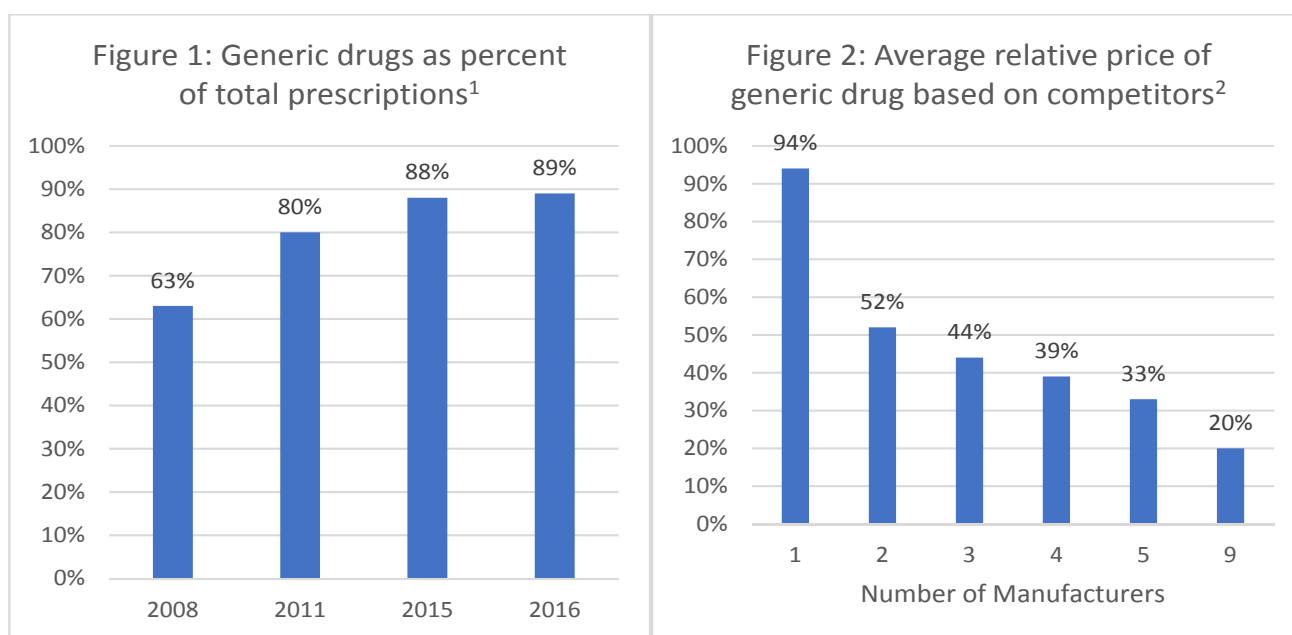


Figure 1: Generic Pharmaceutical Association Annual Savings and Access Report

Figure 2: FDA

The Investment Scenario:

In general, stock performance of the generic drug manufacturers is correlated to drug price inflation. In periods of high inflation, revenue growth begins to accelerate and gross margins expand resulting in higher returns. This was the case in 2013-2014, when drug shortages due to manufacturing issues as well as lower ANDA approvals led to price inflation of about 10% per year (Figures 4,5,6). Since 2015, generic drug prices in the U.S. have fallen by about 8-10% per year. This price deflation is mainly due to the following:

1. *Buying Consortiums:* Consolidation as well as partnerships in the 2015-2017 period has given rise to pharmaceutical buying consortiums. It is estimated that 90% of all generic drug purchasing is done by three mega consortiums. The major consortiums include Red Oak Sourcing (CVS+ Cardinal Health), Walgreens Boots Alliance (Walgreens+ Amerisource Bergen+ Express Script's Econ Disc), McKesson (McKesson+ Walmart's Clarus One) (Figure 3). As a result, they have a greater bargaining power over individual generic manufacturers.
2. *Fragmented Industry:* Teva Pharmaceuticals (TEVA), Mylan N.V. (MYL) and Sandoz, the generic division of Novartis (NVS) are the leading generic suppliers. However, they hold only 33% of market share. This has allowed numerous independent and international companies to enter and gain market share by lowering prices.
3. *Higher Generic Approvals:* After record approvals in 2012, ANDA approvals declined in the 2013-2014 time period. The FDA has been making a push for faster generic approvals as one way to reduce rising drug prices. As a result, ANDA approvals have increased every year from 2015 (Figure 4).

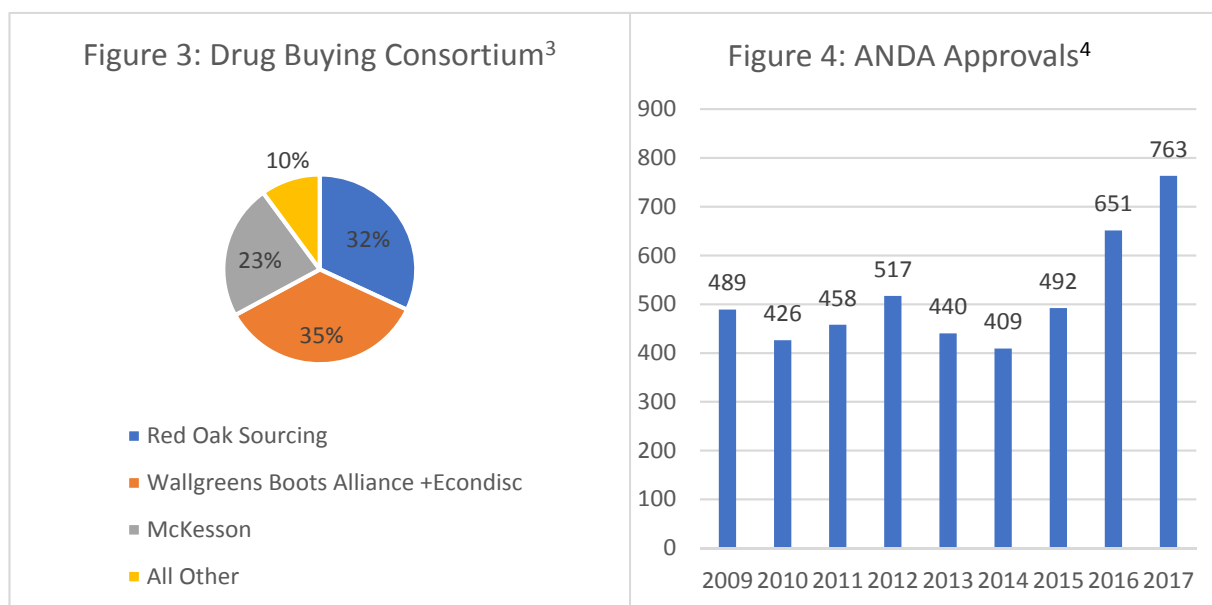


Figure 3: Drug Channel

Figure 4: FDA

Revenue growth has decelerated from a peak of 11% in 2014-2015 period to only 0.3% in 2017. At the same time, gross margin for U.S. generic manufacturers has dropped from 55% in 2013 to about 48% in 2017 (Figure 5). As a result, after outperforming during the 2013-2014 period, this group has underperformed the broad market since 2015. This can be seen using Mylan N.V. as an example (Figure 6).

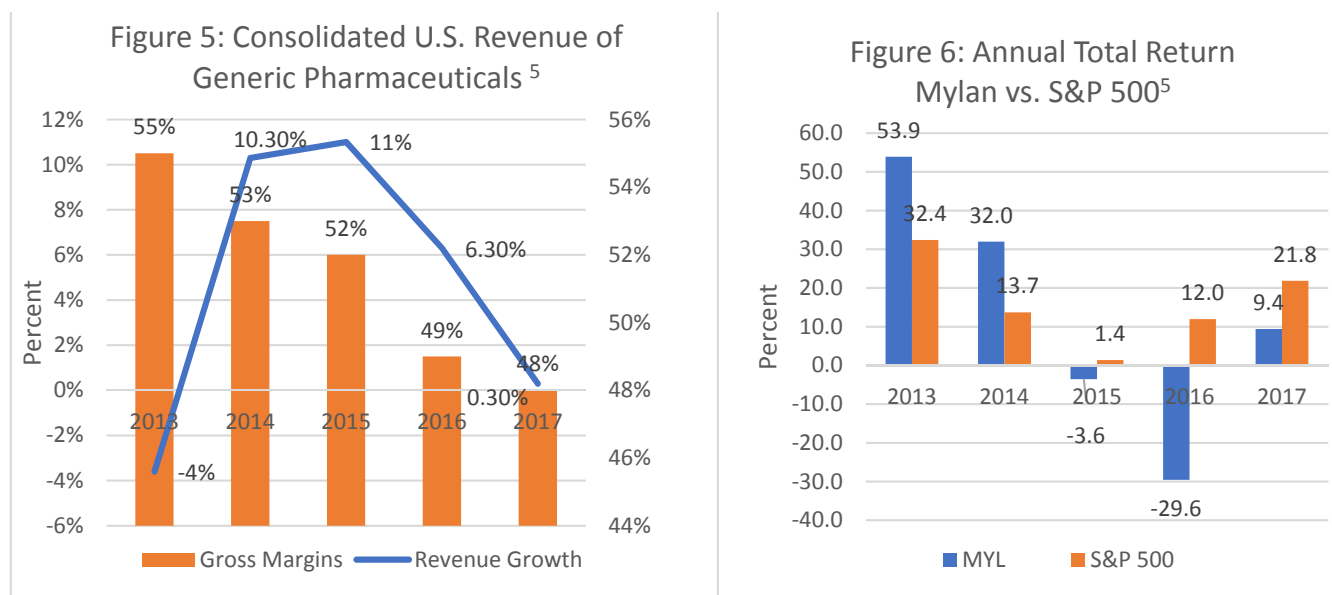


Figure 5 & 6: FactSet

In an effort to increase competition, in June 2017, FDA announced a Drug Competition Action Plan (DCAP). Under this plan, the FDA will publish a list of drugs that are currently off-patent and have no generic competition. It will update this list every six months. Since generic drug prices depend on the number of manufacturers, the DCAP will also prioritize ANDA approvals for drugs that have less than three approved generics. FDA hopes to have these approvals to coincide with the expiration of the 180-day exclusivity period of the first generic of a given drug. These actions should lead to higher ANDA approvals. As there is a significant correlation between generic drug price deflation and number of ANDA approvals, we expect generic drug price deflation to extend over the next 6-12 months.

Summary

Generic drugs, on average, cost less than branded drugs and are considered essential for affordable healthcare. In 2017, in the U.S. generic drugs were used for 89% of total prescriptions. Emergence of generic drug buying consortiums, faster approval of generic drugs as well as a fragmented generic manufacturing industry has resulted in approximately 8-10% generic price deflation over past couple of years. While price deflation has benefitted patients, it has lowered gross margins for generic manufacturers. This has resulted in the underperformance of this group. The FDA's Drug Competition Action Plan will likely maintain this highly competitive generic drug marketplace and could result in continued generic price deflation and the related underperformance over the next 6-12 months.

About \$100B biologics are expected to lose patents by 2025. Biosimilars, which are equivalent to generic biologics, currently have low market penetration of about 30% in the U.S. and 40-50% in the EU and are priced at only a 30-40% discount to the branded biologic. Biosimilars are expected to grow to over \$20B by 2025 and could be the next growth area for generic drug manufacturers.

References:

¹Generic Pharmaceutical Association annual savings and access report.

²<https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm>, FDA.

³Meet the Power Buyers driving generic drug deflation, Drug Channels, Feb 1, 2018.

⁴Meeting the GDUFA commitments, going for the gold, FDA, October 24, 2016.

⁵FACTSET

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