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Asset Smarter

SMARTER PERSPECTIVE: PHARMACEUTICAL

A Generic Pharmaceuticals Primer for Asset Based Lenders

By Gary Dressler

In this article we provide an overview of the generic pharmaceutical market and offer guidance for asset based lenders with related portfolio exposure.

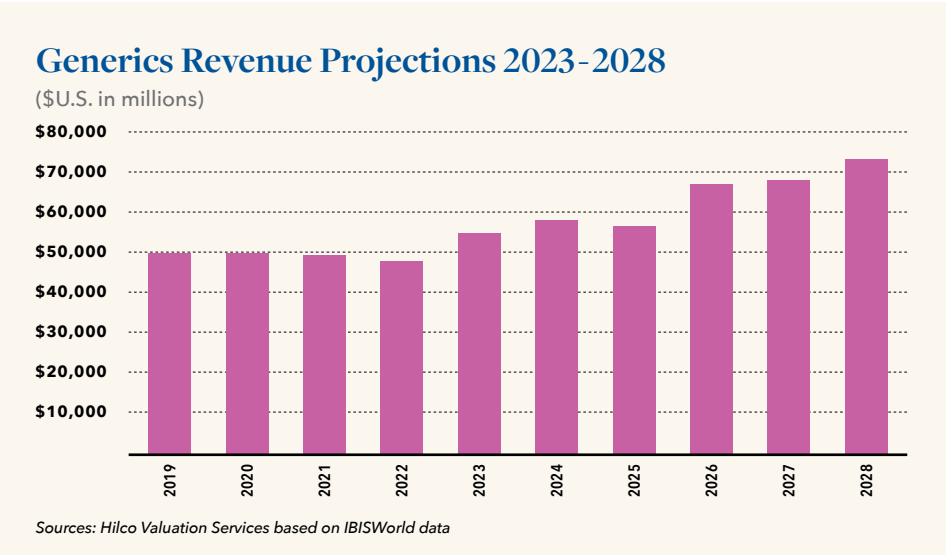
GENERIC MEDICATIONS OVERVIEW

A generic medication is designed to replicate a brand-name drug that is already available on the market, matching it in terms of dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. This similarity is crucial to establish bio-equivalence, meaning that a generic medicine functions in the same manner and offers the same clinical advantages as its brand-name counterpart. In simpler terms, you can consider a generic medicine as a suitable substitute for the brand-name version.

For any generic medication to be approved, it must exhibit identical performance in the body as the brand-name drug. This entails mirroring the brand-name medication in terms of dosage, form, route of administration, safety, effectiveness, strength, and labeling, with a few limited exceptions. Moreover, it must adhere to the same stringent quality and manufacturing standards as the brand-name product, as well as being used in the same manner. These criteria apply universally to all generic medicines.

Generic medicines contain the same active ingredients as brand-name drugs and operate in the same way, resulting in similar risks and benefits. The FDA Generic Drugs Program conducts a thorough evaluation to ensure generic medicines meet these standards, which includes inspections of manufacturing facilities and ongoing monitoring of drug safety after the generic medicine receives approval and enters the market.

Generic drugs are granted approval only after undergoing a rigorous evaluation by the FDA and following a specific time-frame during which the brand-name product is exclusively available on the market. This is because new drugs, like other novel products, are usually protected by patents that prevent others



While generic pharmaceutical market revenues have declined in recent years, they are expected to grow to a level of more than $70 billion over the next five years.

from producing and selling identical copies of the same drug.

The lower cost of generic drugs can be attributed to the fact that generic drug applicants are not required to repeat animal and clinical (human) studies, which were mandatory for brand-name medicines to demonstrate safety and effectiveness. This expedited process is referred to as an "abbreviated new drug application."

The decrease in initial research expenses means that, despite having the same therapeutic effects as their brand-name counterparts, generic medicines are typically offered at substantial discounts, often estimated to be 80 to 85% less expensive than the price of the brand-name drug. According to the IMS Health Institute, generic drugs contributed to nearly $2.2 trillion in savings for the U.S. healthcare system between 2009 and 2019.

When multiple generic companies receive approval to market a single product, increased competition within the marketplace usually results in lower prices for patients.

Promoting more competition in the drug market and addressing the high cost of medications is a top priority for the FDA. In 2017, the FDA introduced the Drug Competition Action Plan (DCAP) to further encourage robust and timely market competition for generic drugs, while also enhancing efficiency and transparency in the generic drug review process, all without compromising the scientific rigor underlying their generic drug program.

CURRENT TRENDS IN THE U.S.

Intensified Price Competition

Market Dynamics The industry has experienced a significant escalation in price competition. With the expiration of patents on various brand-name drugs, multiple generic manufacturers often enter the market simultaneously, leading to aggressive pricing strategies.

Impact This trend benefits consumers and healthcare systems as it drives down the cost of generic medications. Manufacturers are compelled to adopt cost-effective production techniques, negotiate favorable contracts with purchasers, and enhance supply chain efficiency to maintain profitability.

Increased Import Substitution

Background Import substitution refers to domestic generic manufacturers replacing imported generic drugs, which were often sourced from countries like India and China.

Reasons Concerns over the quality, safety, and reliability of foreign-made generics have led to a resurgence in domestic production. Manufacturers are focusing on ensuring a secure and stable supply of essential medications within the United States.

Exports as a Stable Revenue Source

Focus U.S. generic pharmaceutical companies have continued to rely on exports as a stable source of revenue. They export generic medications to various international markets, benefiting from the global demand for cost-effective healthcare solutions.

Diversification Exporting helps diversify revenue streams and reduce dependence on the domestic market, providing stability even during fluctuations in the U.S. market.

Loss of Exclusivity Rights

Scenario As patents on brand-name drugs expire, generic manufacturers gain opportunities to produce and market generic equivalents. The loss of exclusivity rights by brand-name drugs leads to increased competition in the generic market.

Revenue Growth This increased competition contributes to revenue growth in the generic pharmaceutical manufacturing industry. Manufacturers compete to be the first to launch a generic version, allowing them to command higher prices and capture a substantial market share.

Generic Drug User Fee Amendment (GDUFA)

Efficient Approval Process GDUFA, particularly GDUFA III, aims to streamline the new drug approval process for generic medications. This initiative facilitates faster market entry for generic manufacturers, increasing competition.

Impact on Pricing A more efficient approval process can lead to earlier market availability of generic drugs, further intensifying price competition and potentially lowering drug costs for consumers.

Cost Reduction and Focus on High-Profit Products

Operational Efficiency To remain competitive, generic pharmaceutical companies are actively pursuing cost reduction measures. This includes optimizing manufacturing processes, reducing overhead, and investing in automation.

High-Profit Products Companies are strategically focusing on high-margin products, including complex generics and niche therapeutic areas. This concentration on lucrative segments helps bolster profitability.

Focus on Biosimilar Drugs and Value-Added Generics

Biosimilars The industry has witnessed a growing emphasis on biosimilar drugs, which are highly similar to biologic drugs. Biosimilars offer a potential avenue for cost savings in the biopharmaceutical market.

Value-Added Generics Manufacturers are increasingly developing value-added generics, which may include extended-release formulations, novel delivery systems, or patient-friendly packaging. These innovations can provide differentiation and enhance market competitiveness.

These and other trends are collectively shaping the landscape of generic pharmaceutical manufacturing in the United States, influencing pricing, market dynamics, and the strategies employed by companies in this industry.

WHOLESALE DISTRIBUTORS

Distributors acquire pharmaceuticals from manufacturers, keep these products in inventory, and subsequently market and distribute them to various entities, including chain pharmacies, independent pharmacies, hospitals, clinics, nursing homes, and mail-order pharmacies. According to data from Deloitte and the Healthcare Distribution Alliance, In the United States, approximately 92% of prescription drugs flow through three large wholesalers, which collectively account for over 90 percent of all wholesale distribution of pharmaceuticals in this country.

When it comes to generic drugs, distributors play a more significant role in both distribution and pricing as compared with brand-name drugs. Generic drug manufacturers compete to secure contracts with the three major distributors – McKesson, Cardinal Health and AmerisourceBergen. A generic manufacturer that fails to solidify contracts with one or more of these dominant companies, can find itself largely excluded from competing in the market. This dynamic has provided these big three and other powerful wholesalers with notable bargaining power during negotiations related to generic drug pricing.

NEW AGGREGATION REGULATIONS

Certain requirements in the U.S. FDA regulation Drug Supply Chain Security Act (DSCSA) and the EU Falsified Medicines Directive (FMD) require protocols and systems to ensure that consumers are protected from drugs that may be contaminated, counterfeit, harmful or stolen. Pharmaceutical aggregation enables every company in the pharmaceutical supply chain to assign and track medications by their unique serialized numbers which link them to distinct containers, cases, bundles and pallets. DSCSA will soon require (by the end of November this year) that all authorized pharmaceutical trading partners incorporate the use of serial and aggregation data as part of their business practices, underscoring the industry's commitment to enhancing pharmaceutical supply chain security and ensuring the safety of medications.

THE RISING PRICES AND SUPPLY CHALLENGES OF APIS

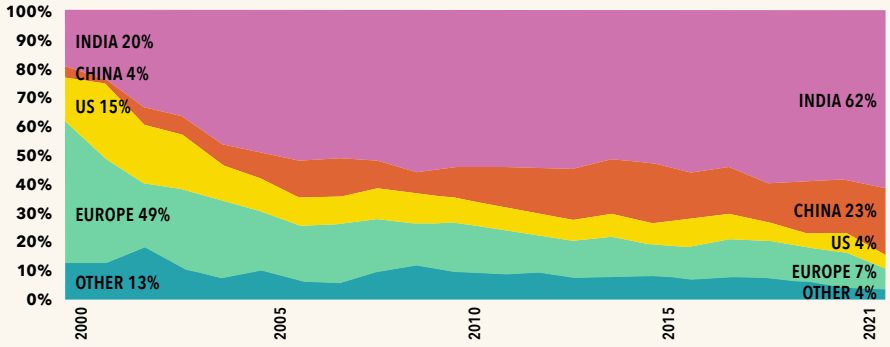
The pharmaceutical industry has been grappling with a significant and concerning issue over the last few years – the escalating prices of active pharmaceutical ingredients (APIs). Several factors have contributed to this surge, including the exponential increase in transportation costs, disruptions in API production lines, and the uptick in energy prices. The COVID-19 pandemic, in particular, has shed light on structural supply challenges, predominantly stemming from the fragmented and vulnerable nature of API manufacturing.

It's worth noting that the United States, a major player in the pharmaceutical sector, relies heavily on imports for approximately 70% of its APIs.

While generic pharmaceutical supply chains have improved since the pandemic, they continue to be a concern for the industry. Disruptions have resulted in delays in obtaining raw materials and, at times, shortages across the pharmaceutical industry. The pandemic exacerbated the hurdles faced by pharmaceutical companies, particularly their heavy dependence on foreign contract manufacturing organizations (CMOs). Although supply chains have shown signs of improvement since the pandemic's onset, concerns linger within the industry.

Furthermore, the U.S. government's emphasis on bolstering domestic manufacturing has prompted pharmaceutical companies to consider re-shoring their production. This movement could potentially reshape the API manufacturing landscape in the coming decade, with an increased focus on production returning to the United States or Europe. This shift underscores the industry's commitment to enhancing supply chain resilience and ensuring a reliable and secure source of APIs.

Global Medicine Supply



Source: US Pharmacopeia Medicine Supply Map

API source dominance has migrated dramatically over the last two decades but U.S. reliance remains high with drug master files (DMF) filings in this country dropping from 15% to 4% over that same period.

SUGGESTED LENDER MONITORING

Hilco recommends a lender to monitor:

- **Margins and Profitability**
  Prices of generic drugs tend to decline significantly once additional pharmaceutical companies, including those from China and India, get approvals and enter the market. Generic drug manufacturers' ability to sustain sales and profitability for specific products declines over time. The programs established under the Generic Drug User Fee Act and increased funding of the FDA's Office of Generic Drugs have led to more and faster generic approvals, increasing competition.

- **Pipeline of New Generics**
  With the above-mentioned prices of generics declining as competition increases, it is important that a manufacturer has a pipeline of new generics it will be able to produce and sell. Margins of newly introduced generics tend to be higher.

- **Expired and Short-Dated Inventory**
  Expired should be deemed as ineligible for lending advancement purposes as it is not salable. Most generic manufacturing customers (e.g. wholesalers, drug stores, group purchasing organizations) require at least one year remaining to expiration when receiving the pharmaceuticals. Some customers will take short-dated inventory to expiration (e.g. less than one year to expiration) with significant discounting. As such, if short-dated is deemed eligible in the borrowing base, an inventory appraisal would take this into consideration in its projected liquidation value. A lender should monitor expired and short-dated inventory, as it provides an indication of how well inventory is being managed.

- **Recalls**
  A lender should be aware of any recall events, as recalled inventory would have no value in a liquidation Sale.

- **Charge-backs/Rebates/ Returns Allowances**
  It is important that the lender is aware in this industry there are significant allowances provided by the manufacturer to customers, such as for charge-backs, discounts, returns, rebates, and other adjustments. For charge-backs, the manufacturer agrees to reimburse wholesalers for the difference between the gross sales price at which the manufacturer sells to wholesalers and the actual prices of the products at the time of resale. Frequently, manufacturers permit customer returns for expired inventory and short-dated inventory (e.g. less than six months remaining to expiration). In an event of a liquidation Sale, it is assumed no inventory would be permitted to be returned to the company.

- **Change in Regulations**
  A generic manufacturer would be regulated by the FDA and other agencies, and depending on the generics being produced may include the U.S. Drug Enforcement Administration (DEA). A manufacturer undergoes periodic audits. A lender is advised to monitor for changes in the federal and state regulatory environments, which affect the salability of the company's products. The previously-mentioned new aggregation regulation is an example.

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