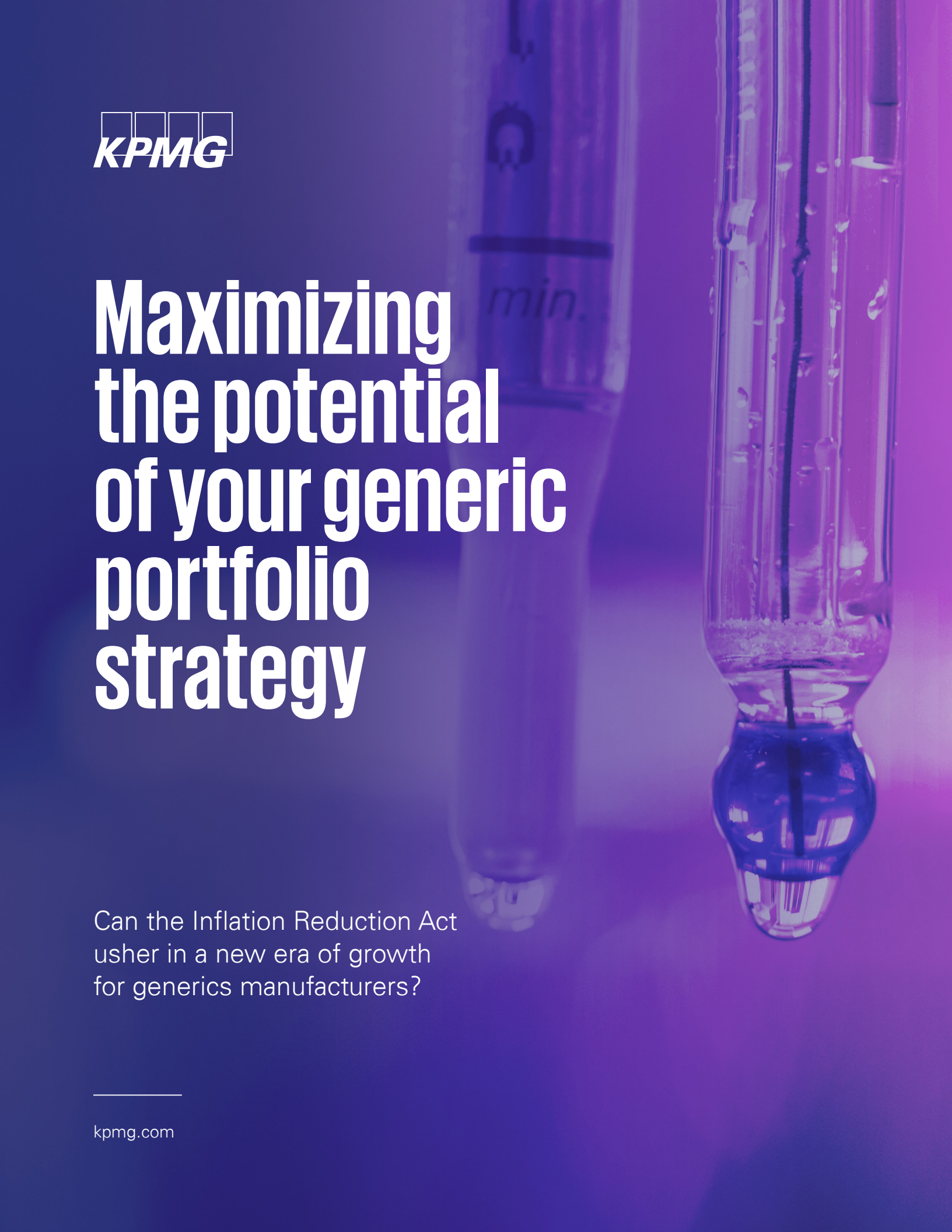

Maximizing the potential of your generic portfolio strategy

Can the Inflation Reduction Act usher in a new era of growth for generics manufacturers?

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Introduction

The passing of the Inflation Reduction Act (IRA)[1] in August 2022 may create a more attractive market for generics manufacturers to consider innovative portfolio strategy management. Among many aspects of the IRA that will impact the pharmaceutical industry, the most salient may be the Department of Health and Human Services' (HHS) ability to negotiate drug prices for Medicare Parts B and D. Once the legislation is implemented, there will be pricing negotiations for small molecule drugs and biologics that have been in the market for nine and 13 years, respectively, unless they meet exception criteria. These parameters will have a significant impact on the pathways manufacturers choose to commercialize products, invest in R&D, and consider the viability of their portfolios for the future.[2]

As the IRA is implemented and drug manufacturers evaluate the impact, they will need to consider the value to their portfolios of innovative generics, as well as generic alternatives to reference products that are either included on or likely to be added to the list of IRA-impacted drugs. Such efforts can help companies balance their portfolios, open new revenue streams, and better prepare for revenue cycle implications. (For more, click here to read the KPMG paper, "Impact of the Inflation Reduction Act on bio-pharma portfolio strategies.")

[1] Through the Inflation Reduction Act, passed on August 16, 2022, Medicare beneficiaries (and potentially some holders of commercial insurance) are poised to realize upwards of $265 billion in savings on their prescriptions. The four main tenets of the act are: The federal government will be required to negotiate prices for specific high-cost prescription drugs covered under Medicare; drug companies will have to pay a rebate if they increase the price of prescription drugs covered under Medicare by more than the rate of inflation; the cost of insulin for Medicare participants will be limited to $35 per month; and out-of-pocket costs for Medicare Part D participants will be capped at $4,000 in 2024 and $2,000 in 2025.

[2] Inflation Reduction Act

Three key strategies for generic drug makers

As generic drug manufacturers evaluate their portfolios and commercial/R&D investments after the passing of the Inflation Reduction Act, they will need to take a highly individualized approach to growing share and maintaining margins for future viability. While competition in the generics market is greater than ever, scale alone is no longer a sure-fire approach to success. Instead, it is critical that pharmaceutical companies center their generics strategies on meeting the needs of a rapidly changing healthcare system and evolving medical science.

Following are three strategies generic drug manufacturers can consider as they evolve their portfolios to compete in the increasingly complex healthcare economy and provide accessible and affordable prescription drugs:

01 Value creation through portfolio management and differentiation

Demand for generic alternatives has been a consistent theme since the passing of the Hatch-Waxman Act[3] in 1984. The evolution of the generics market over the subsequent decades has been notable: In 1985, the Food and Drug administration (FDA) received more than 1,000 applications intended to realize $1 billion[4] in drug savings. By 1990, nearly 40 percent of prescriptions were filled with generic drugs at an average cost of 35 cents a day.[5] By 2014, applications had grown exponentially, creating an estimated $230 billion in savings.[6] The 2010 Biologics Price Competition and Innovation Act [7] and the 2017 Drug Competition Action Plan[8]—together with a tremendous number of blockbuster patent expirations in the intervening years—helped generics grow in unit share from about 75 percent to more than 90 percent of all prescriptions. *[Exhibit 1]*

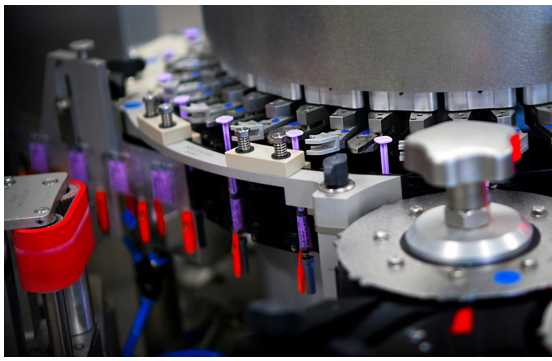
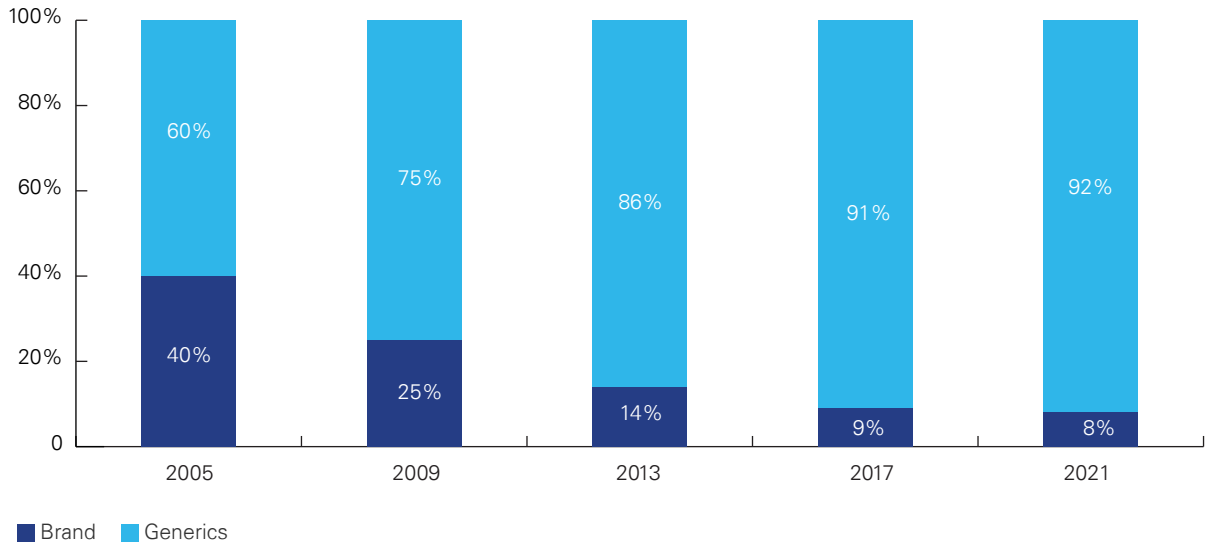


Exhibit 1. Generics continue to outpace branded drugs



Source: IQVIA, April 2022

[3] The Hatch-Waxman Act, otherwise known as the Drug Price Competition and Patent Term Restoration Act (Public Law 98-417), was passed in 1984 in the first effort to modernize the generic drug industry.

[4] Timeline: Generic medicines in the US, USP.org

[5] Alfred Engleberg, "Unaffordable prescription drugs: the real legacy of the Hatch-Waxman Act," StatNews, December 16, 2020.

[6] Ibid

[7] The Biologics Price Competition and Innovation Act (BPCIA), enacted as part of the Affordable Care Act in 2010, established a pathway for approving generic biologic (biosimilar) drugs while giving branded manufacturers 12 years of guaranteed market exclusivity, which allowed patent owners to delay competition.

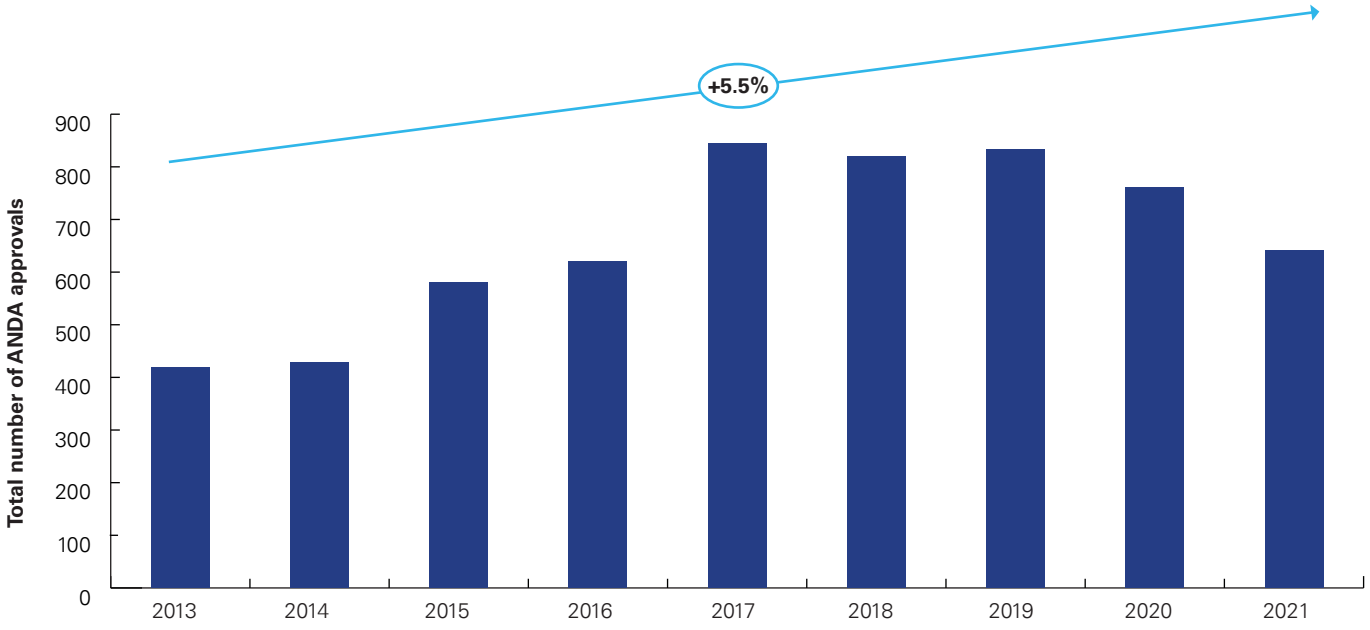
[8] The Drug Competition Action Plan was introduced by the FDA in 2017 to improve patient access, while also preventing pharmaceutical companies from extending brand monopolies beyond the guidelines introduced in amendments to the Hatch-Waxman Act of 1984; FDA Drug Competition Action Plan, FDA

From the inception of the generics industry to the present, economic success has been dependent on achieving massive scale for these low-cost/low-margin products.

In contrast, as fewer small molecule blockbuster drugs face patent expiration today, the opportunity is waning to base the economics of generic drug development solely on volume. Achievable margins have been reduced by downward pressure from buying consortia. Competition among manufacturers at launch has also grown, driven in part by a softer generic pipeline, exacerbated by five or more players often coming to market at generic launch.

Nevertheless, the generics pie continues to grow as a record number of abbreviated new drug applications (ANDA) have been approved annually since the 2012 introduction of Generic Drug User Fee Amendments.[9] [Exhibit 2] In addition, the FDA has issued thousands of supplements to already-approved drugs. In this environment, generic drug manufacturers that find new ways to provide value to customers and patients can create opportunities to reset pricing strategies based on differentiation and value as opposed to the lowest cost.

Exhibit 2. ANDA approvals supplant patent expirations as main drivers of generic drug opportunities



Source: FDA, September 2022

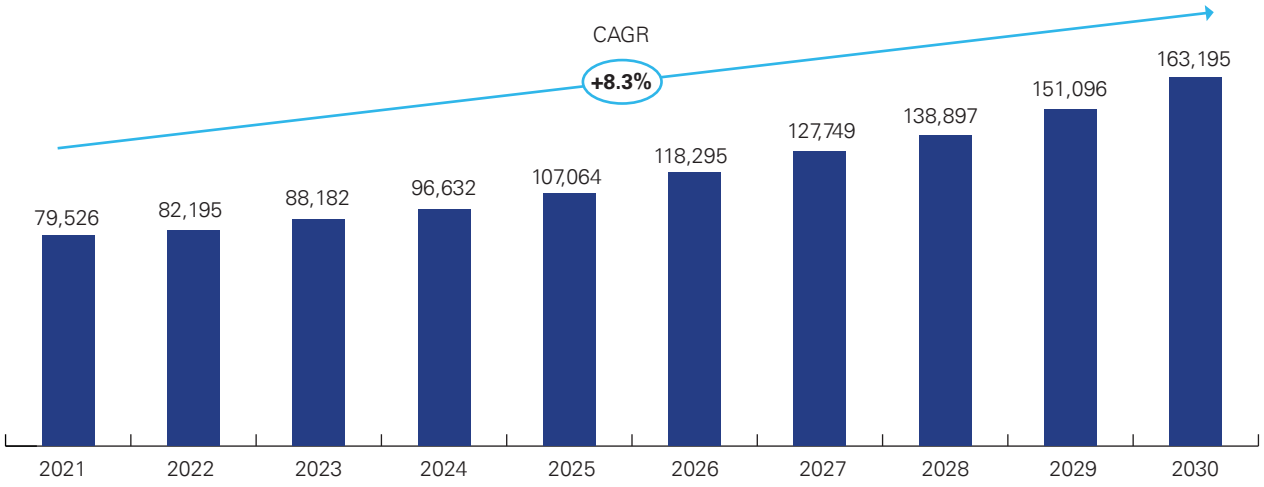
FDA support for generics: The FDA's Office of Generic Drugs and its scientific foundation are supporting investments in innovative generics, including through new complex routes of administration, such as "topical/dermal, ophthalmic, and orally and nasally inhaled products,"[9] as well as through alternative bioequivalence approaches that do not require lengthy comparative clinical endpoint studies.

Route of administration (ROA) innovation can create significant value. For example, in 2020, the FDA approved Valtoco, a drug differentiated with a nasal spray ROA, which can be used as a rescue medicine for patients aged six and older with acute repetitive seizures, often linked to epilepsy. The manufacturer, Neurelis, created a high-value, high-impact product for a defined patient population by using an active generic ingredient originally approved in 1963 (diazepam) combined with a novel delivery mechanism.

The high-impact sterile injectables market continues to grow, which should be considered an opportunity for those who are uniquely positioned to manufacture and commercialize product in the space. In fact, continued investment in this space has a significant upside: the 2021 global generic sterile injectables market was estimated at $79.5 billion and is expected to reach $163.2 billion by 2030, growing at a compound annual growth rate of 8.3 percent during this period. *[Exhibit 3]*

[9] "FDA and Center for Research on Complex Generics Co-Hosted Workshop: Regulatory Utility of Mechanistic Modeling to Support Alternative Bioequivalence Approaches," U.S. FDA, September 30-October 1, 2021

Exhibit 3. Significant growth expected for generic sterile injectables



Source: IQVIA

While demonstrating bioequivalence can be challenging when developing complex generics, the following are drugs that reflect the fact that both economic value for generic drug manufacturers and accessibility for patients can be achieved: In 2021, the FDA's scientific foundation enabled approval of the first complex generic version of the brand-name drug Feraheme—a ferumoxytol injection to treat iron-deficiency anemia in patients with chronic kidney disease. The same year, the FDA approved a generic version of Invega Sustenna, an injectable with long-acting delivery targeting acute treatment of schizophrenia in adults.

IRA provisions may create situations where certain high-quality assets (e.g., biosimilars) become less attractive than they were for asset holders prelegislation, thus creating opportunities for innovation via asset acquisition on the divestiture market. A further incentive for drug makers seeking to focus on higher complexity generics, whether through organic or inorganic strategies, is that the IRA will increase Medicare Part B add-on payments for certain biosimilars from six percent to eight percent of the reference product average sales price, until 2027.[10]

This change in reimbursement levels will likely promote biosimilar uptake in the coming years. In these cases, the assets will likely be more innovative than what manufacturers of small molecule assets currently hold, thus generating targeted portfolio planning and management opportunities for incumbents and new entrants.

The takeaway

As the IRA is implemented, generic drug manufacturers can consider highly individualized approaches to portfolio optimization. Innovation will not only lead to increased patient value, but also help manufacturers optimize their portfolios in a way that mirrors the evolving complexity of the prescription drug marketplace and allows them to compete for their future. While government-price-negotiated assets will face pressure, some companies will look to divest or out-license. And, for biosimilar assets that will not be subject to price negotiations, there will be pricing tailwinds.

[10] Allison Inserro, "Biosimilar Medicare Part B Payment Boost Begins," The Center for Biosimilars, October 3, 2022

02 Manufacturing investments for a sustainable supply chain

In 2021, up to 76 percent of hospital pharmacies experienced drug shortages on as many as 10 products at a time, according to the Annual Hospital Pharmacy Operations Report.[11] Drug shortages have ravaged patients' access to medicine throughout the pandemic. Part of the impetus for the IRA is that ongoing shortages, prolonged wait times for access, and the potential for unwelcome substitutions demand attention.

Instituting measures to maintain supply chain continuity is critical for all drug manufacturers. Continuing to develop, explore, and expand quality manufacturing capabilities to drive supply chain efficiency —while partnering with suppliers that can demonstrate the level of continuity that the U.S. healthcare system demands—will also provide a a foundation for greater competition. Drug manufacturers should consider making capital investments in existing capabilities, investing in partnerships with select manufacturing collaborators, exploring global geographies outside of those historically leading the category, and other innovative solutions. Ultimately, there is limited value in securing FDA approvals and establishing competitive price points if the supply of products is unreliable.

Historically, outsourcing manufacturing to lower-cost geographies across the globe has been an operational lever for driving down costs. However, in recent years, sourcing raw materials and active pharmaceutical ingredients (APIs) globally has been increasingly challenging. Concerns include manufacturing quality issues in India and China; pandemic-related closures; and increased shipping, oil, and freight costs stemming from geopolitical conflicts. Clearly, efforts to move forward with an aggressive generics market strategy while protecting margins will be hindered by shipping delays, remanufacturing of poorly formulated products, allowing containers to ship below capacity, and juggling multiple shipments to fulfill orders to common geographies. At the same time, if the cost of manufacturing on a global scale continues to rise for many of the reasons we have detailed, it will be particularly difficult for generic drug manufacturers since they operate on razor-thin margins compared to their branded counterparts.

The takeaway

Drug makers seeking to make progress in the generics market may want to invest in manufacturing and supply chain transformation. They can do so by developing more reliable multisourcing programs that allow access to a larger pool of raw materials; establishing partnerships where incentives are closely aligned; and exploring domestic manufacturing options through targeted and collaborative arrangements. The latter is particularly appropriate for high-volume products with established channels. Where possible, some manufacturers may opt to invest in their own compounding and/or commercialization capabilities. Finally, it is critical to conduct more comprehensive assessments of true system costs weighed against considerations of capital investments in manufacturing capabilities. Getting these supply chain imperatives right will create a more enticing generics market for manufacturers and deliver more value to the healthcare ecosystem in the long term.

[11] Hospital Pharmacy Operations Report 2021, Kitcheck.com

03 Strategic scaling to drive share and margin

Over the past three decades of generic drug development, there have been numerous examples of successful scaling achieved by combining complementary assets, filling gaps in companies' portfolios, and making targeted efforts to own a category.

From rapid consolidation in the mid 1990's to mega-deal activity in the 2010s, merger and acquisition (M&A) transactions have been widespread in the generics market, helping to offset declining revenues, stabilize businesses, and, in the best-case scenarios, allow drug manufacturers to ride the wave of high-value generic versions of blockbuster drugs. Notable deal activity has included:[12]

01 22 M&A transactions of generic drug companies totaling $1.86 billion in 2014

02 34 generics deals valued at $33.6 billion in 2015

03 42 deals valued at $44 billion, capped by Teva's mega-acquisition of Allergan, in 2016.

The introduction of generic drug-buying consortia was a strategic reaction to the downward pricing pressure felt by retail pharmacies, distributors, and other buy-side entities during these waves of generic manufacturer consolidation. Today, it is estimated that some 90 percent of all generic drug purchasing in the U.S. flows through the big three buying consortia: Red Oak Sourcing, ClarusOne, and Walgreens Boots Alliance.[13]

When generics manufacturers were operating in a marketplace driven by growing volumes, the combination of manufacturer consolidation and the formation of buying consortia underscored the importance of scale. This was an unprecedented period of blockbuster generic drug launches, with retailers and distributors (among many other stakeholders) reeling to maintain low-cost product.

Today, the approach to achieving scale has shifted for a variety of reasons, including the decreasing number of blockbuster drug patent expirations. Nevertheless, capturing scale continues to be central to whether generic products remain viable. Companies need to approach scale strategically, e.g., by embarking on targeted M&A campaigns, aligning assets in their portfolio through acquisition or divestiture, and/or maintaining tighter control of how and when products are ramped up or down in market via investments in agile manufacturing.

Pfizer's strategic approach to scale:

Viatris, the entity created when Pfizer merged its Upjohn portfolio with the Mylan business, is an example of a strategic approach to scale. Viatris captured scale not only through a blockbuster portfolio of mature generics products, but also through investment in focused, complementary therapeutic areas. By making massive bets on certain therapeutic areas and a margin-driven portfolio, Viatris has been able to invest in ways that promise to maximize value across multiple assets.

The takeaway

While scale has always been critical in the generics market, today's most successful generics manufacturers will take a strategic approach to where and how they achieve scale. Examples include focusing on complementary therapeutic areas, pursuing strategic transactions for assets that align to a portfolio in its entirety, divesting assets that do not fit the bigger picture, and investing in areas where differentiation can drive margins.

[12] Marc-Andre Gagnon and Karena D. Volesky, "Merger mania: mergers and acquisitions in the generic drug sector from 1995 to 2016," Global Health, 2017

[13] "The Big Three Generic Drug Mega-Buyers Drove Double-Digit Deflation in 2018. Stability ahead?," drugchannels.net, Jan. 8, 2019

The Path Forward

Historically, volume has driven the growth of the generic drug industry. The loss of exclusivity for major brands and the availability of safe and effective low-cost generics drove a steady wave of adoption over the last 15 years. These efforts have delivered tremendous value in access and affordability through savings for patients in out-of-pocket costs, and for commercial and government payers as well.

While patent expirations for blockbuster drugs are on the decline, the passage of the IRA highlights a need for low-cost prescription drugs that is more acute than ever. Generics manufacturers can take advantage of this moment by considering how they can advance their portfolios through thoughtful investments in innovative generic assets. Those that build supply and manufacturing capabilities that drive toward availability and efficiency and align their portfolios for growth will be best positioned to win in an ever-changing market.

KPMG Deal Advisory & Strategy (DAS) has helped global generic drug manufacturers navigate changes in the industry. KPMG Strategy provides support to generic drug manufacturers in exploring different value optimization and life cycle growth strategies across areas such as portfolio management and supply chain. In addition, KPMG DAS provides clients with a full suite of due diligence services (commercial, operational, financial) and advises on investments, divestitures, acquisitions, and carve-outs. Connect with a KPMG DAS leader to explore options for your company.

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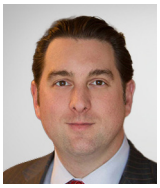

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DASD-2022-11094