



Generics 2030

**Three strategies to curb
the downward spiral**

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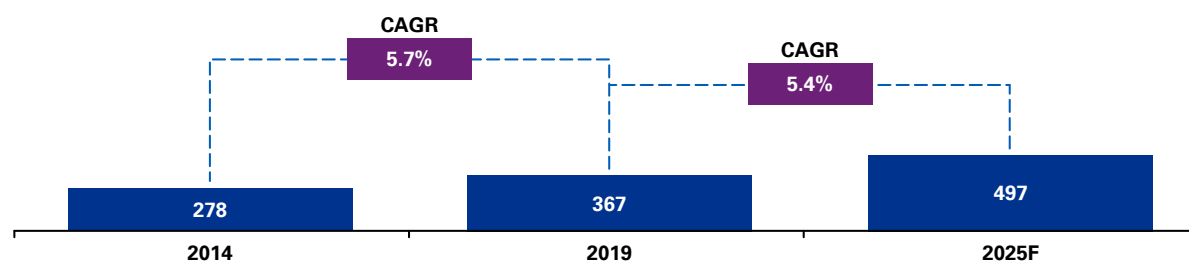
Introduction

In the current environment, the generics industry faces two opposing forces that complicate profitability and growth. On the one hand, demand for generics continues to rise. At the same time, there are increasing barriers: supply constraints and deteriorating economics.

Significant untapped demand:

Worldwide demand for generic drugs continues to grow as payers and consumers seek ways to cut healthcare costs. From 2014 to 2019, blockbuster drug patent expirations helped generics sales grow by 5.7 percent per year (Exhibit 1). In 2019, patent expiries totaling nearly \$8 billion¹ in U.S. annual sales opened up opportunities for creating generic counterparts. A number of additional expirations are expected in the next five years, which could help sustain growth in the range of 5.4 percent CAGR and sales of \$497 billion by 2025² (for more details, see “Quantifying the opportunities”).

Exhibit 1. Generics could hit almost \$500 billion in 2025



Source: Generic Drugs Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2020-2025, imarc Group

Deteriorating economics and product shortages:

Even as demand rises, however, buyers are consolidating and thus creating more leverage when it comes to pricing. This means intensifying profit pressure on suppliers and a growing likelihood that manufacturers will exit unprofitable products. On top of this, offshore supply chains are being disrupted by COVID-19 and other issues. As a result, generic manufacturers are also consolidating, causing product shortages (for more details, see “Dissecting the challenges”).

In this paper, we look at how these trends are shaping the generics market. We provide CEOs, CFOs, and other top leaders in generics with three possible strategies to deal with these conflicting forces and drive healthy growth through 2030.

¹ Eric Sagonowsky, The top 10 drugs losing U.S. exclusivity in 2020, FiercePharma, March 17, 2020.

² Generic Drugs Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2020-2025, imarc Group.

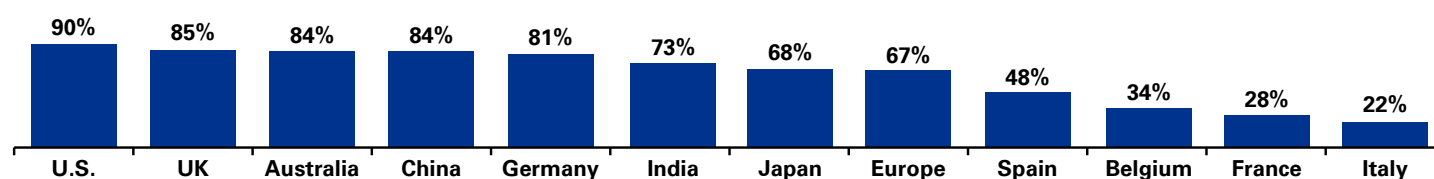
Quantifying the opportunities

We expect demand for generics to remain strong and that the next wave of patent expiries will create additional opportunities.

Generics penetration is increasing:

The U.S. has been the leading market for generics, with volume penetration reaching about 90 percent in 2019 (Exhibit 2). That is 90 percent volume share of a market that is expected to be worth nearly \$415 billion (in invoice spending) by 2023.³ In many other countries, including those with historically low generics utilization, rising healthcare costs are driving increased use of generics, too. For example in Japan, which has had historically low generics usage, penetration rose from 30 percent to 68 percent over the last decade and is expected to reach 80 percent by the end of 2020.⁴

Exhibit 2. The U.S. is leading the market for generics (as of 2019)



Note: Generics utilization rates refer to market share (by volume) of generics within the overall prescription drug market

Sources: The positive impact that generic and biosimilar medicines have on patients and health systems, International Generic and Biosimilar Association, Oct 2019; Improving market efficiencies will promote greater drug affordability, PRI Center for Medical Economics and Innovation, Jan 2020; US Specialty Pharmaceuticals, Barclays, Jun 2019.

More branded drug patents are expiring:

Expirations of total small-molecule drugs will nearly double by 2026 (Exhibit 3). Expiring drugs open up significant opportunities for generics manufacturers (Exhibit 4), with some therapeutics—such as oncology treatments, central nervous system drugs, and systemic anti-infectives, for example—offering more potential opportunity than others (Exhibit 5).

Exhibit 3. Patent expiries open up generics opportunities

# of blockbusters and other small-molecule drugs going off-patent globally							
Year	2020	2021	2022	2023	2024	2025	2026
Blockbuster drugs	1	1	3	5	5	6	7
Total small-molecule drugs	190	219	291	254	255	318	383

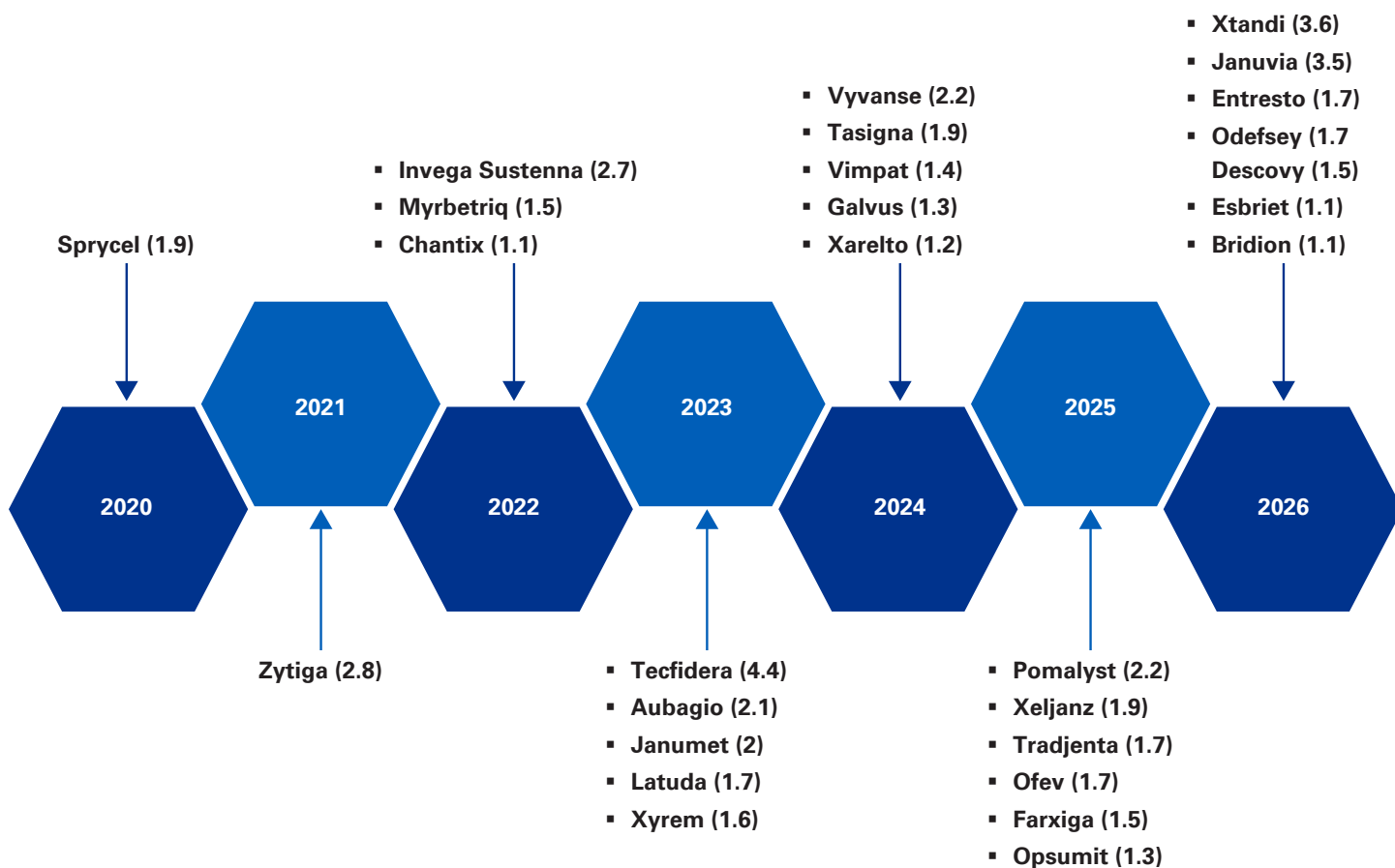
Notes: “Blockbuster” refers to drugs with annual gross sales greater than \$1 billion. Year of patent expiration for the last patent-protected variant of a drug has been considered for analysis. For example, if a drug is going off patent in the U.S. in 2022 and in Europe in 2023, it has been included in the patent expirations for 2023.

Source: KPMG analysis based on Evaluate Pharma data.

³The Global Use of Medicine in 2019 and Outlook to 2023 IQVIA, Jan 2019.

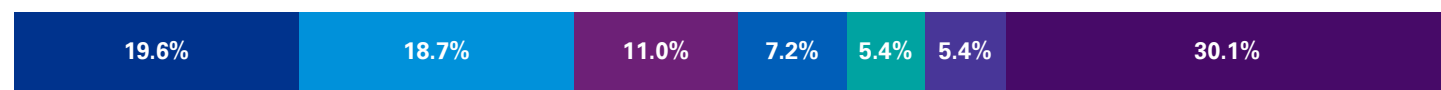
⁴Japan pharma market review, thepharmaletter, Jun 2019.

Exhibit 4. Specific drugs going off-patent in the next six years (value of 2019 sales in \$ billions)

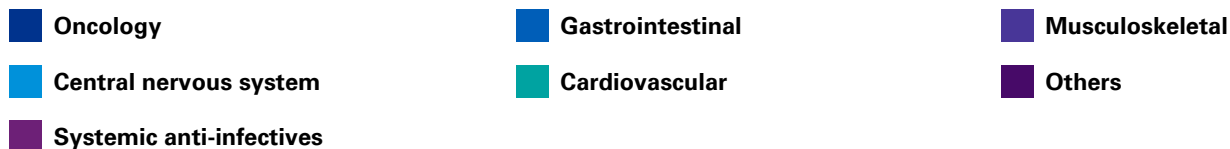


Source: KPMG analysis based on Evaluate Pharma data

Exhibit 5. Generics opportunities by therapeutic area



Based on percentage of patent expirations between 2020 and 2026



Source: KPMG analysis based on Evaluate Pharma data (100% = 1,910 drugs)

Dissecting the challenges

Despite growth potential, manufacturers face a confluence of depressed prices and supply chain issues that cause and exacerbate drug shortages.

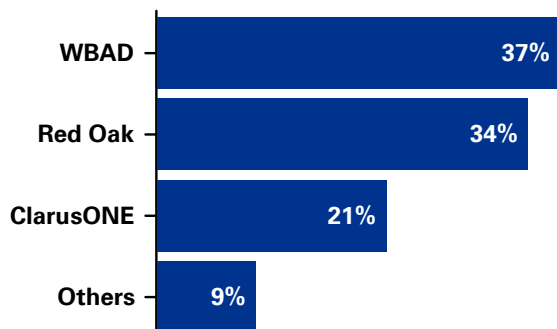
Power buyers can erode generics prices:

A number of U.S. buyers—including wholesale buying consortia, pharmacy benefit managers (PBMs), and group purchasing organizations (GPOs)—have consolidated, either through acquisitions or joint ventures. The three largest wholesale buying consortia together represent about 90 percent of all generics purchases by volume, allowing them to exert significant downward pressure on drug prices. PBMs, which constitute nearly 72 percent of prescription drug spend in the U.S.,⁵ have also gained greater bargaining power through increased scale, helping them to better negotiate terms with drug manufacturers (Exhibit 6).

This leaves many generics manufacturers with more limited pricing power in their biggest market, which, coupled with substantial competition, has significantly impacted profitability (Exhibit 7). For example, when generic drugs first hit the market, they are usually priced between 30 and 90 percent of the price of their branded counterparts.⁶ When consolidated buyers exert price pressure, however, generics can sell for only 20 percent of branded drug prices or less.⁷

Exhibit 6. Breakdown of generic drug purchases by buyer groups and management by PBMs

*Share of generic drug purchases by various buyer consortiums in the U.S. (by volume, 2018)**

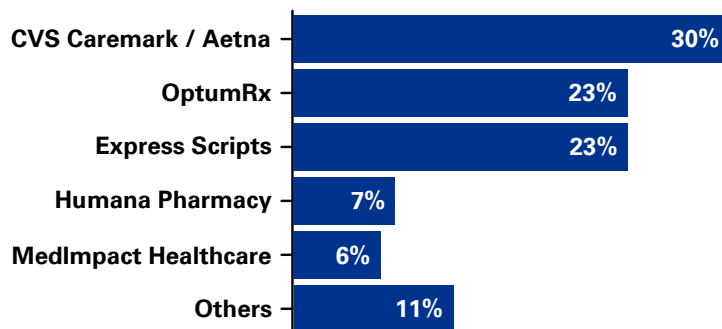


WBAD: Walgreens Boots Alliance Development

*Percentages do not add up to 100% due to rounding error

Sources: US Specialty Pharmaceuticals, Barclays, Jun 2019; Express Scripts + Prime Therapeutics: Our Four Takeaways From This Market Changing Deal, Drug Channels Institute, Jan 2020; Premier Inc: Initiating Convergence, Morningstar, Feb 2018.

Share of total equivalent prescription claims managed by PBMs (by volume, 2018)

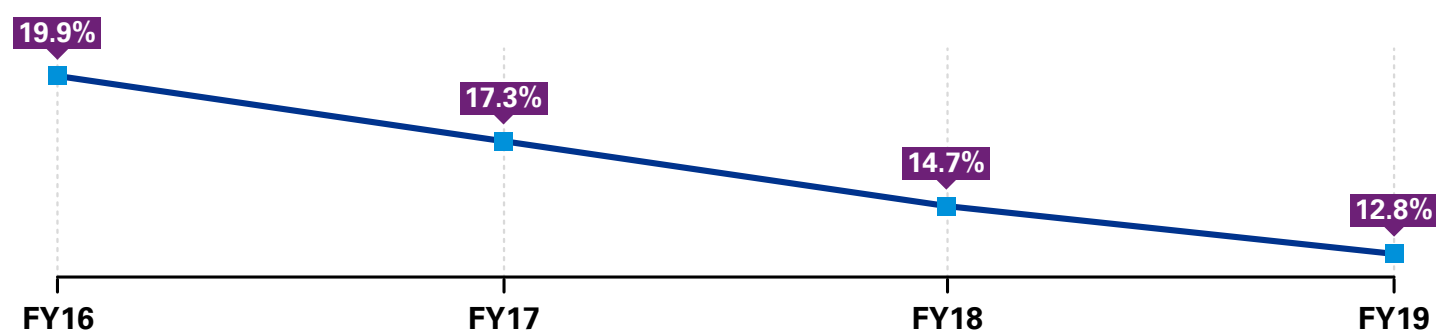


⁵ Understanding how PBMs work, Restoring Medicine, May 2019.

⁶ Big Pharma games the system to make generic drugs more expensive, MarketWatch, Aug 2018.

⁷ Ibid.

Exhibit 7. Generics manufacturers have faced decreasing margins



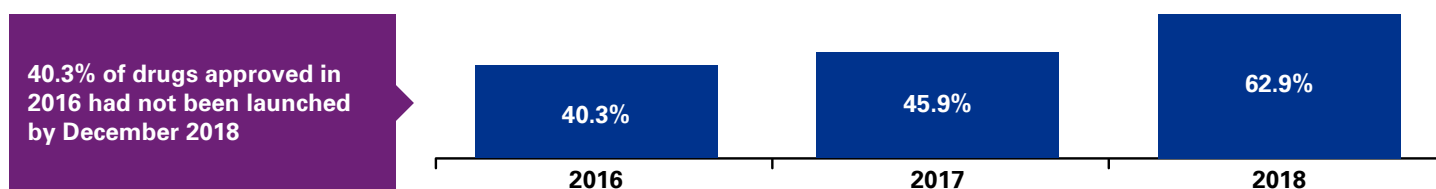
Source: Big Pharma games the system to make generic drugs more expensive, MarketWatch, Aug 2018

Quality issues & competition from India/China are rising:

To remain profitable, most generics players now outsource manufacturing to less expensive markets. But low-cost, offshore manufacturing also raises risks: 49 percent of FDA warning letters and 64 percent of EMA compliance notices between 2018 and 2019 were for facilities in India or China.⁸ Violations can hinder supply to the U.S. and Europe, as manufacturers address quality issues.

At the same time, generics manufacturers increasingly compete with Chinese and Indian drug makers, which further erodes prices. Indian and Chinese generics manufacturers accounted for about 52 percent of all 2019 abbreviated new drug applications (ANDA), with Indian manufacturers accounting for 45 percent of all 2019 ANDA approvals.⁹ The growth of these manufacturers has further eroded generics prices worldwide, reducing incentives to launch new products. In fact, it is increasingly common to see manufacturers postponing and even cancelling plans to bring generic products to market even after they have been approved. (Exhibit 8).

Exhibit 8. Cancelled/postponed launches of approved ANDA (by year of approval)



Source: Global/U.S. Generics and Biosimilars: Trends, Issues and Outlook, IQVIA, Feb 2019.

Some players are exiting generics:

Faced with falling prices over time, some manufacturers have opted to discontinue production of certain generic drugs. This can lead to insufficient supply to meet patient demand. For instance, in July 2019, Teva discontinued production of the pediatric oncology drug Vincristine due to low profitability, which led to a shortage in the U.S.¹⁰ Similarly, the cancer immunotherapy BCG is frequently in short supply because manufacturers have exited the market, leaving Merck as the drug's sole supplier in the U.S. and Europe.¹¹ This shortage has additional implications outside of cancer treatment, since BCG is being tested in COVID-19 patients.

⁸ Analysis finds bulk of warnings delivered to Indian and Chinese drugmakers, Outsourcing-Pharma, Aug 2019.

⁹ ANDA approvals in 2019: Trends for the generics industry, Express Pharma, Jan 2020.

¹⁰ Pfizer scrambles to fill void after Teva stops making chemo drug often given to children, FiercePharma, Oct 2019

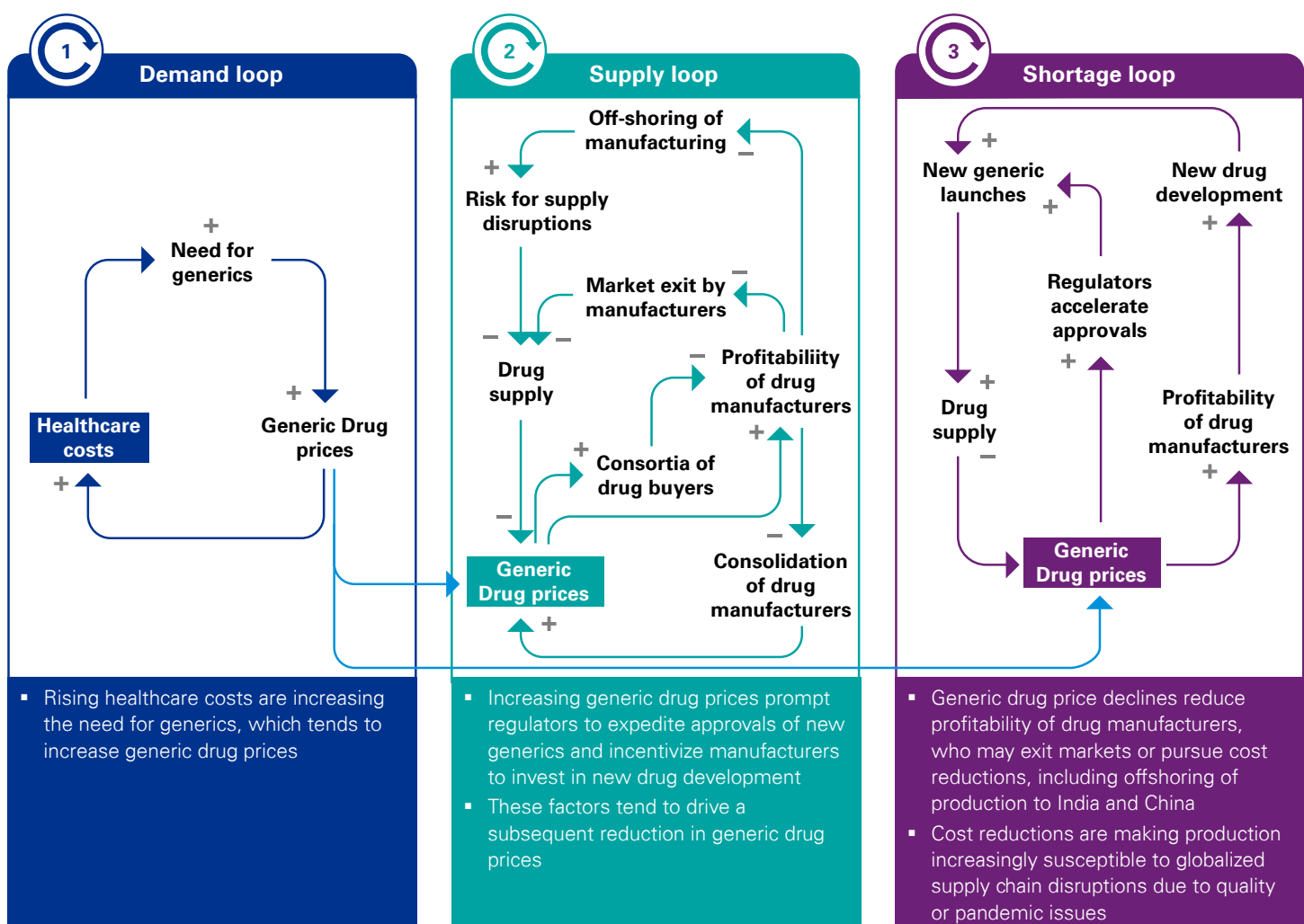
¹¹ Gil Redelman-Sidi Could BCG be used to protect against COVID-19? Nature Reviews Urology, April 27, 2020

The intersection of opportunities and challenges

Rising healthcare costs continue to generate increasing demand for generic drugs, which would lead to increased generic prices under normal market conditions. Increasing numbers of generics manufacturers have simultaneously been willing to invest to increase supply and meet market demand (a process known as “herding”), and an expedited FDA generics approval process has helped accelerate this increased supply. However, when increased supply outstrips demand, prices tend to fall, a challenge exacerbated by consolidated drug buyer consortia wielding further pricing leverage. As prices decline, drug manufacturers see a decrease in profitability, and may choose to exit markets. Other manufacturers may face quality or product challenges as they seek to operate profitably in lower-priced environments.

This dynamic is illustrated in a series of causal loops outlined below. Each loop provides a series of potential market intervention points, with an indication of each step’s correlation to its adjacent points in the loop. For example, in the Demand Loop, an increase in “healthcare costs” correlates positively with the “need for generics,” as indicated by the “+” between the two points. In other words, as healthcare costs go up, the need for generics goes up. The three loops—demand, shortage, and supply—are also interconnected.

Exhibit 9. Three causal loops illustrating generics dynamics



Source: KPMG Analysis

Legend: + Indicates positive correlation - Indicates negative correlation

Three strategies to curb the downward spiral

If the generics industry accepts the status quo, commoditization and erosion of profitability will likely continue for the foreseeable future. Through our industry analyses and on-the-ground work with clients, we have identified the following three scenarios for change, which are all possible and not mutually exclusive:



1. Become bigger and better

Consider mergers and acquisitions that increase scale to allow more effective negotiation with consolidated buyers.



2. Eliminate the middlemen

Redesign the supply chain through forward/backward integration to reduce dependence on distributors and active pharmaceutical ingredient (API) suppliers and help secure the supply chain in times of volatility.



3. Develop higher-value generics

Instead of focusing on identical generic products, invest in innovation to create differentiated, high-value products.

Scenario 1: Become bigger and better

As large buying consortia exert increased bargaining leverage, generics manufacturers can counter with consolidation of their own. To the extent that consolidation takes place, the generics industry will be left with fewer, larger players holding greater market share and improved commercial negotiation positions across geographies. Further, a reduction in the number of generics companies could potentially help re-balance competition and reduce problems of oversupply.

The appeal of large-scale M&A can be seen through activity in the sector: Diversified pharmaceutical companies have struggled to manage fluctuating generics prices and have sold businesses or attempted to divest significant portions of their generics holdings. Still others have merged spun-out generics businesses with those of established generics companies such as the Pfizer/Upjohn merger with Mylan¹² (see “How the Mylan-Upjohn deal affects generics”).

¹² Mylan/Pfizer's Upjohn unit merger on track to close in Q4 2020, Yahoo Finance, September 17, 2020.

How the Mylan-Upjohn deal affects generics

The merger of Mylan and Pfizer's Upjohn division will create a new global pharmaceutical company called Viatris, which will be the largest generics manufacturer in the world.¹³ Viatris will operate 51 production facilities and have access to 165 markets across the globe.

The deal presents clear benefits to both companies:

- **Pfizer:** Separating the Upjohn division from core branded drug operations will allow the company to focus on its higher-margin innovative drug business and could produce surplus capital to invest in branded R&D efforts. Further, Viatris is expected to pay a dividend amounting to about 25 percent of its free cash flow post-merger, which could mitigate some of the financial risks associated with such a large transaction.
- **Mylan:** The merger will reduce Mylan's dependence on U.S. markets and allow distribution in emerging markets like China via Upjohn's strong sales network. Viatris is expected to derive 15 percent of its revenue from the U.S. and about 45 percent of its revenue from the Asia-Pacific region. Annual synergies are estimated to reach nearly \$1 billion by 2023, creating savings to be invested in R&D.

Potential opportunities for other generics companies

Both Mylan and Upjohn are expected to divest parts of their portfolios in order to get anti-trust approvals for their merger. For instance, the European Commission has asked Mylan to sell nearly a dozen drugs across 20 countries as part of the approval process. These divestitures could provide opportunities for other generics manufacturers to strengthen their portfolios through acquisitions.

There are significant opportunities for smaller generics manufacturers to acquire or merge with both generic and non-generic businesses being spun or carved out of larger pharmaceutical companies. For example, Indian generics manufacturer Aurobindo Pharma made a recent attempt to acquire the U.S.-based oral solids and dermatology businesses of Sandoz.¹⁴ Although the acquisition ultimately did not come to fruition, this model could prompt other smaller manufacturers to pursue similar bolt-on acquisitions with divisions of large manufacturers to enhance their presence in lucrative generics markets.

In sum, consolidation may make the most sense for small- and mid-sized companies, as it affords them the bargaining power and scale that will allow them to sustain their businesses over time. Larger companies may need to assess whether the complexities and costs of managing a large portfolio negate economies of scale.

Scenario 2: Eliminate the middlemen

Companies can improve efficiency and build profitability by moving into other segments of the value chain. They can move up into distribution, take control of critical supplies such as APIs, or invest in innovative manufacturing and distribution models.

Forward integration:

Generics manufacturers can capture additional revenue along the value chain by acquiring a distributor or building in-house distribution capabilities. This would give manufacturers access to end customers that can (1) yield customer demand data and insights to be used in shaping portfolio decisions, (2) create barriers to entry for competitors, and (3) improve their positions when negotiating with consolidated distributors. (See "Buying distribution dominance")

¹³ Mylan/Pfizer's Upjohn unit merger on track to close in Q4, Yahoo Finance, September 17, 2020.

¹⁴ Angus Liu, Novartis, Aurobindo admit defeat by FTC in aborting their \$1B generics deal, FiercePharma, Apr 2, 2020

Buying distribution dominance

In 2019, Amneal Pharmaceuticals, a U.S.-based manufacturer of generic and specialty drugs, acquired a 65 percent stake in AvKARE, a distributor of private-label generics. AvKARE is the second largest distributor of generics to U.S. federal agencies, including the Department of Defense, Department of Veterans Affairs, and Department of Health and Human Services. These contracts accounted for 83 percent of AvKARE's revenue.¹⁵ Since Amneal derived less than 1 percent of its sales from government agencies,¹⁶ the deal was "a unique opportunity" to diversify and get into a large and complex market, noted Amneal co-CEOs Chirag and Chintu Patel.¹⁷

Backward integration:

By acquiring or developing API manufacturing capabilities, generics companies can secure their supply of raw materials and reduce dependence on third-party suppliers. COVID-19 supply-chain disruptions have highlighted the risk associated with over-dependence on foreign suppliers. India, for example, controls close to 40 percent of the U.S.'s APIs for generics and 26 percent of Europe's.¹⁸ Of particular concern during the events related to COVID-19 were India's restrictions on the export of 26 APIs and finished pharmaceutical products (including acetaminophen/paracetamol and tinidazole). Together, these products represent nearly 10 percent of India's export capacity and their restriction created a significant risk of shortages for a number of global generics manufacturers.¹⁹

Security of supply and supply visibility can be improved with backward integration, particularly when it comes to API manufacturing. To this end, there are a number of recently expanded government incentives devised both before and during COVID-19 that can help mitigate the risks associated with dependence on foreign API suppliers. In the U.S. for example, Phlow Corporation was awarded a four-year, \$354-million contract in May 2020, under the Biomedical Advanced Research and Development Authority (BARDA), to manufacture APIs and generic drugs that could be in short supply due to COVID-19.²⁰ The "Securing America's Medicine Cabinet Act" (SAM-C), introduced in March 2020, seeks to increase U.S. API and finished-dosage-form (FDF) production.²¹ Similarly, the European Commission is expected to introduce measures to increase domestic production of APIs and FDF drug products in its Q4 2020 pharmaceutical strategy document.

Direct-to-market:

Generic drug manufacturers can also pursue more disruptive avenues and fundamentally alter the supply chain through, for example, continuous manufacturing, mobile manufacturing models like factory in a box, and eventually 3D printing. This approach will allow manufacturers to be less reliant on distributors and go directly to consumers or reach patients via specialty pharmacies. This shortened value chain would allow for more agility to meet patient needs and respond to disruptive events like COVID-19 and unexpected geopolitical tensions, and would also likely lower the cost of technologies as they mature over time.

A number of examples of continuous manufacturing are already in flight:

- Continuous Pharmaceuticals is introducing a miniaturised plant the size of a squash court to manufacture FDFs in less than two days.²²
- On Demand Pharmaceuticals has introduced the Pharmacy on Demand (POD), a refrigerator-sized device to manufacture pill and liquid drugs near the point of care.²³
- Several large pharmaceutical manufacturers have been exploring continuous manufacturing, including Eli Lilly for the investigational cancer drug prexasertib, Vertex for its cystic fibrosis combination drug Orkambi, and Janssen for its HIV drug Prezista.²⁴

¹⁵ New Mgmt overhauling AMRX operationally & strategically; AvKARE deal geared towards stabilization, Barclays, Dec 2019

¹⁶ Ibid

¹⁷ Amneal to Acquire Majority Interest in AvKARE, Enhancing Access to Growing Federal Healthcare Market, December 10, 2019.

¹⁸ Eric Palmer, India's restrictions on API exports only temporary, official says: Report, FiercePharma, March 5, 2020.

¹⁹ Ibid

²⁰ Leah Rosenbaum, New pharma company lands \$354 million government contract to produce coronavirus drugs in the U.S., Forbes, May 19, 2020

²¹ Maia Anderson, \$100M Senate bill seeks to wean U.S. from reliance on foreign pharmaceutical ingredients, Becker's Hospital Review, March 12, 2020

²² Shawn Conway and Daniel Bowles, Continuous Pharmaceutical Manufacturing, Contract Pharma, September 11, 2018.

²³ Creating the world's first distributed pharmaceutical manufacturing network, OnDemand Pharmaceuticals

²⁴ Edward Gardner, Compact pharmaceutical factory manufactures drugs on demand, Chemistry World, January 7, 2020.

Scenario 3: Develop higher-value generics

Not all generic drugs expose manufacturers to race-to-the-bottom economics. Specialty generics, value-added generics, and biosimilars offer better profit potential, although all come with challenges.

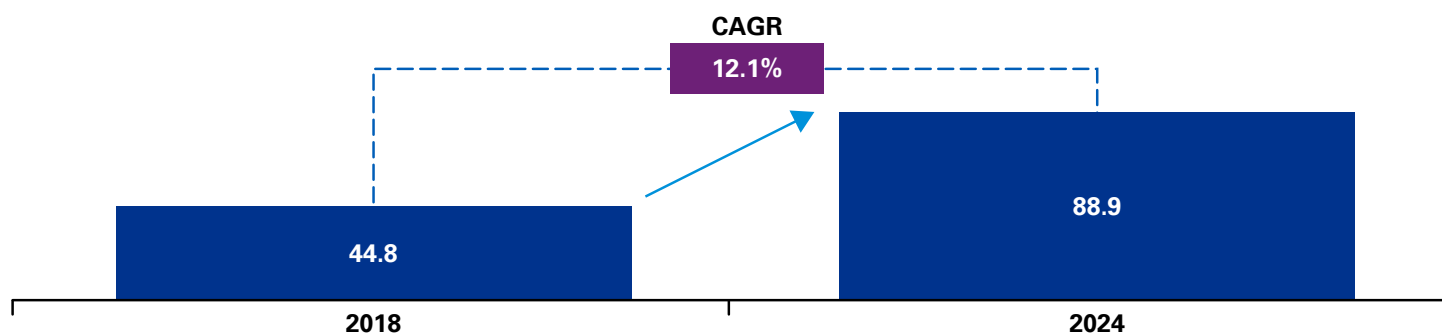
Specialty generics—a limited but lucrative opportunity:

The definition of a specialty generic is evolving, but today includes any generic drug that:

- Contains complex active ingredients like peptides and polymeric compounds
- Has complex formulations like liposomes and colloids
- Requires a complex route of delivery, e.g., dermatological and ophthalmological products
- Comes in a complex dosage form like transdermal drugs and extended-release injectables

The specialty generics segment is expected to grow at about 12.1 percent CAGR through 2024 and reach \$88.9 billion (Exhibit 10).²⁵ Specialty drugs are used to treat rare and chronic diseases like cancer, multiple sclerosis, and HIV, and represent a growing percentage of prescription-drug spending globally. This is driving demand for lower-cost generic versions of these drugs.

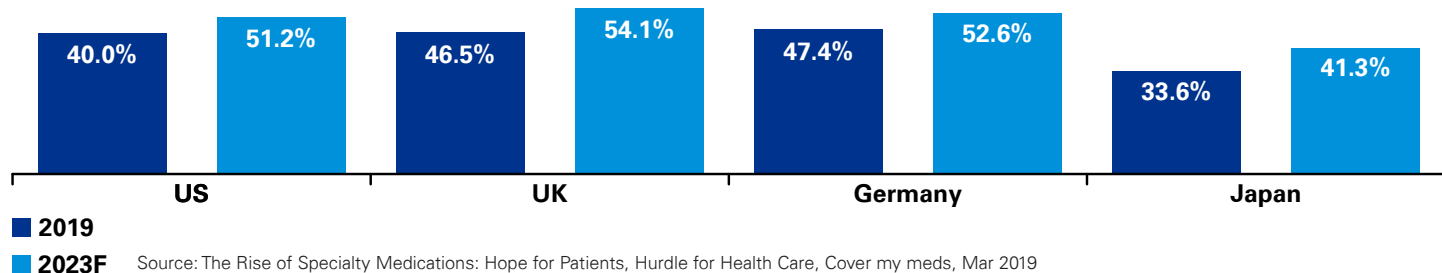
Exhibit 10. Growth of the global specialty generics market (in \$ billions)



Source: Specialty Generics Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2019-2024, ResearchandMarkets, Apr 2019

There is already significant specialty drug penetration in many markets across the globe, which will limit opportunities for new entrants in competitive markets (Exhibit 11).²⁶ Nevertheless, the higher level of expertise required creates a significant entry barrier and can help specialty generics manufacturers differentiate their portfolios and improve profitability. Small biopharma companies that want to play in this market and excel in developing complex molecules may want to partner with large generic drug makers to cut manufacturing costs, shorten time to market, and connect to global sales and distribution networks.

Exhibit 11. Many markets already have significant specialty drug penetration



²⁵ Specialty Generics Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2019-2024, ResearchandMarkets, Apr 2019

²⁶ The Rise of Specialty Medications: Hope for Patients, Hurdle for Health Care, Cover my meds, Mar 2019

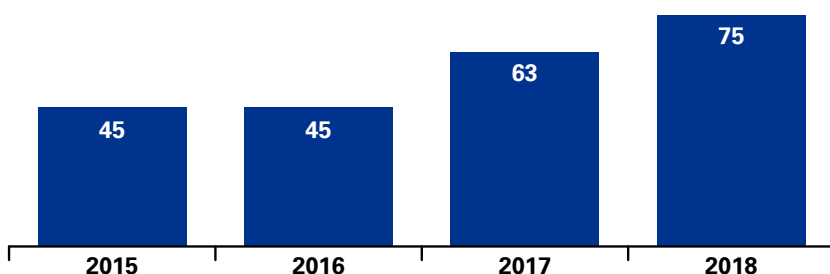
Value-added generics—incremental innovation:

Value-added generic drugs are developed by modifying the strength, indication, or route of administration of an off-patent drug. These variations require a relatively light R&D investment and can be brought to market faster than specialty generics, making them an attractive option—and potentially more profitable—for smaller players.

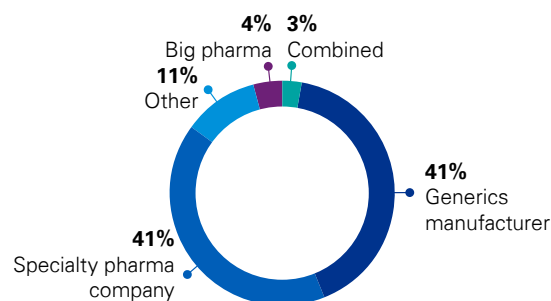
Several European countries are introducing measures to increase the use of value-added generics. For example, the UK has proposed a tax exemption for value-added medicine (VAM) R&D costs and is considering a separate pathway for expedited approvals. In the U.S., there has been an uptick in 505(b)(2) approvals over the last few years (Exhibit 12).²⁷ These products can qualify for up to seven years of market exclusivity under certain conditions, creating a more profitable revenue stream—at least for a time.

Exhibit 12. 505(b)(2) approvals in the U.S.

of 505(b)(2) approvals in the U.S. overall



505(b)(2) approvals by company type (2018)



Source: The Opportunity for Generics Companies and Value Added Medicines in the US and Europe, Camargo Pharma, Oct 2019

Biosimilars—a challenging but attractive long-term strategy:

Biosimilars are biological products that are highly similar to existing biologics approved by drug regulators—the “generic” equivalent of biologics. Since they have no clinically meaningful differences in terms of safety, purity, and effectiveness, they can be used as lower-cost substitutes for off-patent reference products (see “Teva’s bet on biosimilars”).

Historically, the U.S. has had slower uptake of biosimilars than other mature markets like Europe and Japan due to approval delays and low adoption by PBMs and payers (Exhibit 13). Payers and PBMs are not always incentivised to cover biosimilars, as originator biologics manufacturers provide them with substantial rebates in exchange for exclusive formulary placements.

Further, there are several inherent challenges in biosimilar manufacturing:

- **A complex and costly manufacturing process:** Since they are large complex molecules derived from biological products like cells and tissues, biosimilars are harder to manufacture than small-molecule generics.
- **Patent uncertainty:** There is a higher risk of patent litigation from reference drug manufacturers, since not only the product but also the formulations, devices, and manufacturing processes are patented.
- **Competition from large biopharma companies:** Most large pharmaceutical and biotechnology companies have expertise in novel biologics’ development, which gives them an advantage in biosimilars manufacturing.
- **Competing technologies:** Rapid advancements in alternative treatments, such as next-generation gene therapy and messenger RNA, can be headwinds to biosimilars growth.

²⁷The Opportunity for Generics Companies and Value Added Medicines in the U.S. and Europe, Camargo Pharma, Oct 2019

Twenty-eight biologics with annual U.S. sales of more than \$1 billion per year are due to lose their exclusivity in the U.S. between 2020 and 2029. This includes blockbuster drugs such as Humira (U.S. sales of \$14.9 billion), Lucentis (U.S. sales of \$1.8 billion), and others. Therefore, we anticipate significant future growth opportunities for generics (Exhibits 14 and 15).

New FDA interchangeability guidelines introduced in May 2019 also make the biosimilars market more attractive. Under the new rules, some biosimilars can be substituted automatically for their reference biologics at the pharmacy, potentially enabling more favorable formulary placements. The European Medicine Agency (EMA) has not yet introduced common guidelines, but individual EU member states have interchangeability rules for biosimilars that mirror U.S. guidelines.

Exhibit 13. Uptake of biosimilars in the U.S. has lagged (as of Oct 2018)

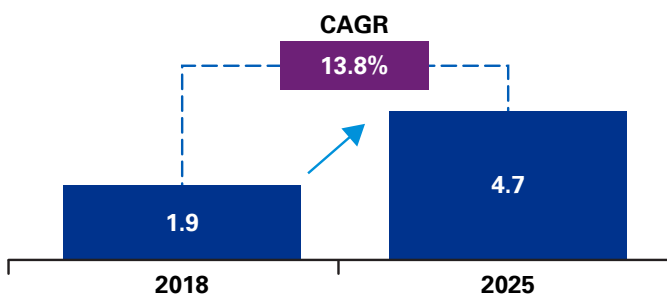
Country	Infliximab	Etanercept	Trastuzumab
UK	92.2%	82.0%	60.7%
Denmark	98.5%	90.6%	99.3%
Netherlands	76.1%	24.1%	95.0%
Canada	9.8%	11.0%	0.2%
Japan	9.0%	6.8%	30.6%
US	6.2%	-	-

■ High penetration
■ Medium penetration
■ Low penetration

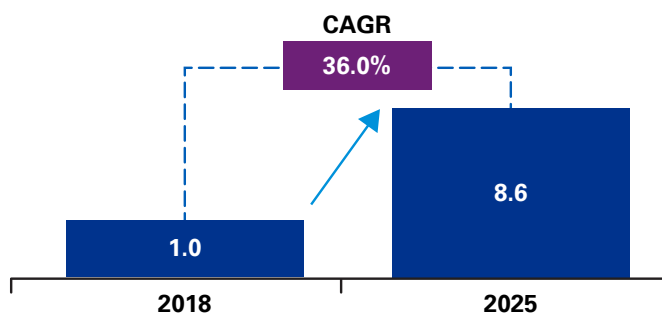
Source: Global/US Generics and Biosimilars: Trends, Issues and Outlook, IQVIA, Feb 2019

Exhibit 14. U.S. biosimilars market now poised to surpass Europe

European biosimilar market (US\$ Billion)



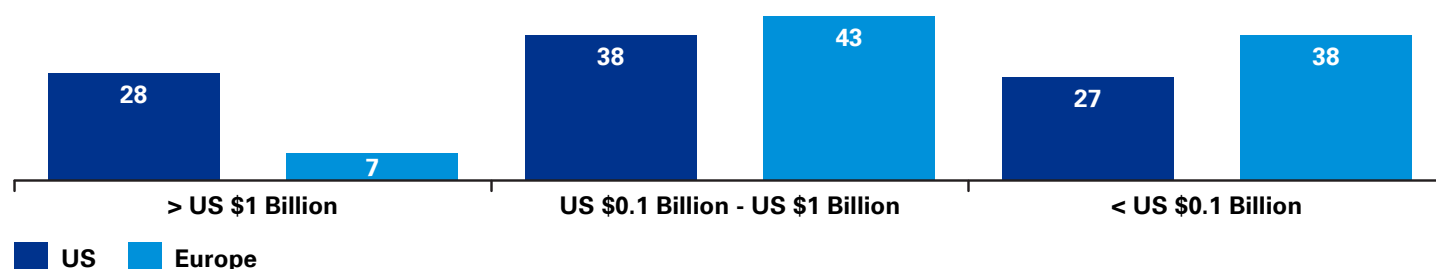
US biosimilar market (US\$ Billion)



Source: Biosimilars: Infancy to Youth—Outlook Through 2025, Morgan Stanley, Mar 2019

Exhibit 15. Expiring biologics patents open up biosimilars opportunities in the U.S. and Europe

Number of biologics facing loss of exclusivity (LOE) over 2020-29 (by forecasted sales)



Source: Future Biosimilar Opportunities, IQVIA, Dec 2019

Teva's bet on biosimilars

Teva has cut its research pipeline in half to focus more on novel biologics, and biosimilars. In partnership with the Korean biotechnology company Celltrion, Teva has launched biosimilars for the reference drugs Rituxan and Herceptin (both manufactured by Roche) in U.S. and Canadian markets.²⁸

As a result of this activity, the company's biologics pipeline is expected to contribute about \$1.2 billion to its top line in 2023.²⁹ "Our total generic business will be growing...because more and more of the products every year that come up for generic competition are biologics or biopharmaceuticals," said Teva CEO Kåre Schultz.³⁰

Exhibit 16. Biologics under development by Teva Pharmaceuticals (March 2020)

(15 out of 19 drugs under development by Teva are biologics)

Type	Pre-clinical	Phase I	Phase II	Phase III	Total
Novel biologics	3	0	5	1	9
Biosimilars	5	1	0	0	6
Small molecules	1	1	0	2	4

Source: Teva specialty product pipeline by development stage, www.tevapharm.com, July 2020

As the above strategies take hold, the generics market may start to split into two main categories of players:

- **Innovation players:** Operating in markets with relatively high drug prices, these players would focus on innovative drug development and, therefore, participate in both branded and generics markets. Their generics portfolios would comprise specialty generics, value-added generics, and/or biosimilars, shielding them from the competitive pressures of traditional generics.
- **Efficiency players:** Operating in markets with relatively low drug prices, these players' portfolios would focus on traditional generics. Minimizing costs will be of primary importance to offset pricing pressure on their traditional generics portfolios.

As innovation players increase their focus on higher-value generics, white space could open up in the traditional or commodity generics market. Efficiency players that are able to up their game on quality will be better placed to capitalize on this white space.

²⁸ Teva Pharmaceutical, BMO Capital Markets, Aug 2019

²⁹ Ibid

³⁰ Teva Pharmaceutical Industries Limited (TEVA) Q1 2020 Earnings Call Transcript, The Motley Fool, May 9 2020.

Strategy comparison

While each of the three scenarios outlined in this paper could alter the current dynamics in the generics market, they are very different in terms of investment needs, risk, and growth potential (Exhibit 16).

Exhibit 16. Key trade-offs for the three scenarios

	Scenario 1: Become bigger and better	Scenario 2: Eliminate the middlemen	Scenario 3: Develop higher-value generics
Strategic intervention	Horizontal integration	Vertical integration	Focus on innovation
Required investment	 Large-scale M&A activity requires significant investment	 Forward/backward integration requires small- and medium-scale acquisitions and/or investment	 Developing high-value products requires substantial investments in R&D
Level of risk	 Risk of lower-than-expected gains due to integration challenges and regulatory approval delays	 Relatively low risk of regulatory scrutiny and approval delays due to minimal overlap in both businesses	 Risk of significant sunk costs if products do not achieve anticipated uptake
Growth potential	 Large-scale deals can help fast track investments and facilitate overall generics growth potential	 Entry into API production and/or drug distribution would create new revenue streams	 R&D investments in high-growth areas can lead to creation of blockbuster drugs

Legend:  High  Medium  Low

Source: KPMG analysis

Conclusion: Targeted interventions

Despite the increasing demand for generics to lower overall healthcare cost, the future of the generics market is not straight-forward. The dynamic generics manufacturers are currently finding themselves in a complex with many interconnected challenges. There is no silver bullet for escaping what can be felt as a downward spiral nor will incremental steps suffice to curb the trend. Each company will have to assess its position, i.e., its financial means and capabilities, and develop a customized strategic response. It's likely to ultimately include one of the strategies outlined above or a unique combination of these. We recommend the use of dynamic scenario simulations to understand required trade-offs and risks as the generics landscape is not likely to develop in a linear fashion going forward.

As companies weigh these trade-offs, they should keep an unrestricted view and take the following preliminary steps before making a final decision:

-  Analyze the landscape of potential acquisition targets and whether they allow entry into new disease states or geographic areas
-  Put programs in place to stay abreast of government incentives associated with backward integration into API manufacturing
-  Determine whether the organization is better suited to be an "innovation player" or an "efficiency player" and create an applicable road map to guide R&D priorities over the next 10 years

Finally, generics manufacturers should keep in mind that geo-political developments, exacerbated by COVID-19, may present a window of opportunity for first movers around the globe, whether aiming for consolidation, vertical integration, or enhanced innovation, to curb the downward spiral, capitalize on anticipated growth, and emerge as winners.



How KPMG can help

The KPMG Global Strategy Group (GSG) has deep sector experience that can help generics manufacturers strategize and right-align their businesses. Our work with clients encompasses:



Product portfolio mix / prioritizing innovation

- Determining the degree to which a manufacturer's products are differentiated or commoditized
- Assessing what an organization's differentiation implies for its ability to survive competitive pressures and price erosion
- Introducing measures to reduce time to market
- Uncovering growing niches within the market that could result in significant near-term and long-term growth
- Developing strategies to anticipate and compete with potential market entrants
- Quantifying the ROI of past and potential R&D spend
- Identifying underperforming products in a manufacturer's portfolio
- Determining the optimal product mix to drive sales and profitability (e.g., oral solids vs complex)
- Choosing novel technologies that can boost an organization's competitive position



Supply chain optimization

- Determining whether an organization's supplier base is large and varied enough to mitigate concentration risks and ensure best input prices
- Assessing the implications of shifting a portion of a manufacturer's supply chain to high-cost countries
- Understanding and mitigating geopolitical risks
- Comparing just-in-time and just-in-case supply strategies to improve supply chain flexibility
- Ensuring continuous quality improvements



Regulatory consulting

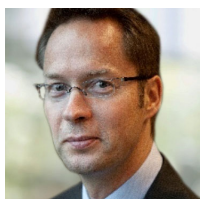
- Staying abreast of how the regulatory landscape around generics is evolving
- Developing mitigation plans to reduce an organization's risk from unfavorable regulatory movements



Deal advisory

- Homing in on ideal criteria / capabilities among potential acquisition targets
- Determining financial health targets to aim for when pursuing an acquisition
- Highlighting private equity (PE) investment patterns and trends in the generics space
- Identifying the pockets within the generics space that are attractive to PE, given their potential to outperform the broader market

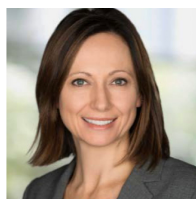
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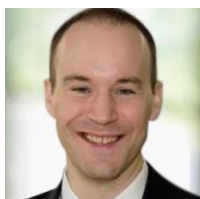
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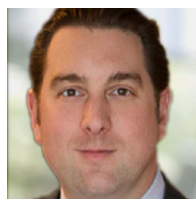
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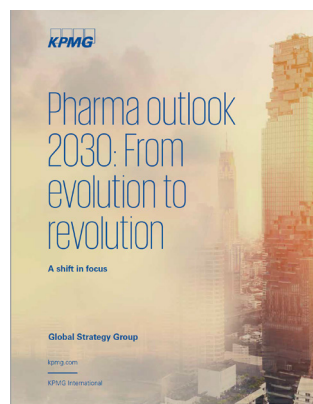
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