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JANUARY 2019

The Global Use of Medicine in 2019 and Outlook to 2023

Forecasts and Areas to Watch

Introduction

Medicines represent an unparalleled contribution to global health, but their value is keenly negotiated by stakeholders across the developed and developing world. The global outlook for medicine use and spending is a much-watched barometer for the results of these 'negotiations' and provides insights into the prospects of life sciences companies, insurers, and the health of populations around the world.

This report includes the latest predictions for the global pharmaceutical market, including areas of growth from a geographic, therapy area and channel perspective. The impact of new drug launches and biosimilars are assessed, as well as growth in the use of specialty medicines and its drivers. In addition to market forecasts, the report highlights ten areas to watch over the next several years for their impact on the use of and cost of medicines. These areas include the use of digital health tools, artificial intelligence and machine learning, Next-Generation Biotherapeutics and incorporation of real-world evidence in clinical development.

The study was produced independently by the IQVIA Institute for Human Data Science as a public service, without industry or government funding.

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Executive summary

The global pharmaceutical market will exceed $1.5 trillion by 2023 growing at a 3–6% compound annual growth rates over the next five years – a notable slowdown from the 6.3% seen over the past five years. The key drivers of growth will continue to be the United States and pharmerging markets with 4–7% and 5–8% compound annual growth, respectively. In the developed markets, the top-five European markets will slow to 1–4%, compared to 3.8% in the past five years, while Japan's topline growth of -3 to 0% is partly due to forecast exchange rate dynamics and masks a more favorable dynamic for branded products. China is the largest pharmerging market, reaching $140–170 billion by 2023, but its growth is expected to slow to 3–6%. All pharmerging markets will see slower growth in the next five years than in the past five as the economic growth and healthcare access expansions of the past contribute less to growth.

In the United States, while invoice spending is expected to increase at a 4–7% compound annual growth rate over the next five years, net manufacturer revenue growth is expected to be slower at 3–6%. Overall spending growth is driven by a range of factors including new product uptake and brand pricing, while it is offset by patent expiries and generics. Brand prices are expected to increase at a historically low 4–7% on an invoice basis for protected branded products over the next five years, but 0–3% on a net manufacturer revenue basis.

Pharmaceutical spending in China reached $137 billion in 2018 driven in part by central government reforms to expand insurance access to both rural and urban residents, as well as expansions and modernizations of the hospital system and primary care services. Spending growth has slowed over the past ten years from double-digit growth rates in 2014 and earlier, to 4.5% in 2018 and is further expected at 3-6% over the next five years.

Medicine spending in Japan totaled $86 billion in 2018, however spending on medicines is expected to decline by -3 to 0% through 2023, largely due to the effect of exchange rates and the continued uptake of generics. The uptake of newer brands will remain strong and price cuts will impact brands less than other products due to a shift in priorities of the biennial price cut system. Generic usage in the unprotected market is expected to exceed the health ministry (MHLW) target of 80% a year early in 2020.

New products and losses of exclusivity will continue to drive similar dynamics across developed markets, while product mix will continue to shift to specialty and orphan products.

Research and development pipelines are growing while success rates are continuing at historic levels, resulting in more new products launching in the next five years. An average of 54 new active substance (NAS) launches per year are expected over the next five years up from 46 in the past five years. New products will also contribute a larger average annual spending on an absolute dollar basis but will account for a lower percentage of brand spending, as the market for brands will grow overall. Nearly two-thirds of launches over the next five years will be specialty products, up from 61% in the past five years, lifting specialty share of spending to near 50% by 2023 in most developed markets. The largest individual therapy area by spending and number of launches will continue to be oncology.

The impact of losses of exclusivity in developed markets is expected to be $121 billion between 2019 and 2023, with 80% of this impact, or $95 billion, in the United States. By 2023, 18 of the current top-20 branded drugs will be facing generic or biosimilar competition. By 2023, biosimilar competition in the biologics market will be nearly three-times larger than it is today. This will result in approximately $160 billion in lower spending over the next five years than it would have if biosimilars

did not enter the market. European markets, where biosimilar markets are more mature, will see earlier and greater biosimilar impact, but remain smaller opportunities for biosimilar companies as spending on biologics is lower on an absolute basis than in the United States. The later introduction of a regulatory framework and differences in intellectual property protection and patent litigation have resulted in slower biosimilar introduction in the United States, but this will begin to be addressed, particularly later in the forecast period. The biggest single event in the biosimilars market in the next five years will be the introduction of adalimumab (Humira) biosimilars in the United States in 2023.

In addition to these market forecasts, there are several areas to watch where the impact of changes are less certain. While a limited number of Next-Generation Biotherapeutics are expected to launch, costs per patient for these therapies are challenging current payment models. Specialty, niche and orphan drugs, in increasing numbers, are reshaping the pricing environment as some have significant costs. Cost-sharing with patients is another factor influencing policy shifts in the United States and the administration has continued to roll out policy proposals associated with its *American Patients First* roadmap. The proposals will impact drug pricing for all stakeholders. While some aspects were expected in the commercially-insured markets for several years, the new policy proposals are expected to have effects across public and privately insured markets, with potential unintended consequences.

The uncertainties around market access and pricing are driving manufacturers to optimize their operating models and drive continuous improvement in margins. Technology investments, such as cloud-computing, artificial intelligence and machine-learning, are among the tools being explored to improve productivity. New technologies are enabling providers and health systems to innovate around care, and manufacturers to refine approaches to customer and stakeholder engagement through multi-channel marketing. Finally, technological innovation in the digital space is leading to the emergence of mobile apps to treat illness, in the form of FDA-approved prescription digital therapeutics (DTx). This new treatment modality offers to help treat a range of conditions, many of which are tied to cognition or behavior, including post-traumatic stress disorder (PTSD), attention deficit disorder (ADHD) and various forms of mental illness, and additionally offer new partnering and marketing opportunities to pharma companies.

Technology is also a democratizing force, enabling emerging biopharma companies to market their developments themselves without a partner, avoiding the sale of their assets to more established companies. Companies are increasingly including patient-centric approaches in their go-to-market strategies, particularly to differentiate from each other, and a growing number are creating C-suite 'patient officer' positions to drive organizational changes and build ties to patient advocacy organizations.

The rising volumes and quality of data and analytics are driving the adoption of real-world data to speed drug approvals and grant new indications, as the FDA has accommodated new approaches in the approval process.[1] The FDA is also expected to make greater use of fast-track and breakthrough designations as well.[2] Perhaps the most impactful area to watch, as measured by the number of patients affected globally, will be whether the past decade of expanded philanthropy will continue to deliver new drugs for neglected diseases of the developing world. By contrast, efforts to address the opioid epidemic in the United States are more focused on the optimal use of resources to address complex social, economic, pain and addiction-related issues in a complex multi-stakeholder environment. Usage of prescription opioids will continue to decline across the country but the rate of decline and the outcomes remain highly uncertain.

Global predictions

- Global spending on medicines reached $1.2 trillion in 2018 and is set to exceed $1.5 trillion by 2023.
- Invoice spending in the United States is expected to grow at 4–7% to $625–655 billion across all channels, but net manufacturer revenue is expected to be 35% below invoice and have growth of 3-6% as price growth slows on both an invoice and net basis.
- Net drug prices in the United States increased at an estimated 1.5% in 2018 and are expected to rise at 0–3% over the next five years.
- China reached $137 billion in medicine spending in 2018, but will see growth slow to 3-6% in the next five years as central government reforms to expand insurance access to both rural and urban residents, as well as expansions and modernizations of the hospital system and primary care services have been largely achieved and efforts shift to cost optimization and addressing corruption.
- Medicine spending in Japan totaled $86 billion in 2018, however spending on medicines is expected to decline from -3 to 0% through 2023, due to the effect of exchange rates and continued uptake of generics and offset by the uptake of new products.
- The number of new products launched is expected to increase from an average of 46 in the past five years to 54 through 2023, and the average spending in developed markets on new brands is expected to rise slightly to $45.8 billion in the next five years, but represent a smaller share of brand spending.
- The impact of losses of exclusivity globally is expected to be $121 billion between 2019 and 2023, with the United States accounting for just under 80% at $95 billion.
- By 2023, biosimilar competition in the biologics market will be nearly three times larger than it is today, but the key events are underway from earlier patent expiries, except the expected 2023 entrance of biosimilars to adalimumab (Humira) in the United States.
- Specialty share of total medicine spending will reach 50% by 2023 in most developed markets as the majority of new medicines have been and will continue to be in specialty classes.

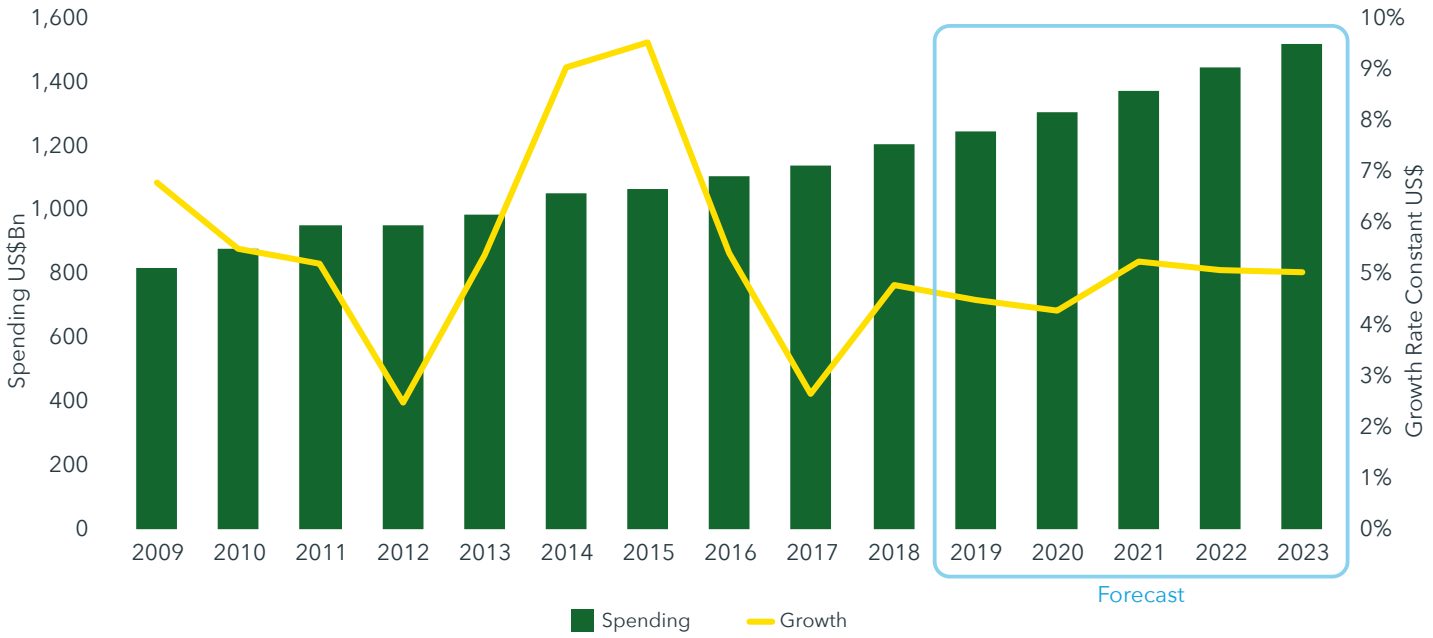
Note on pricing levels

This analysis of medicine spending is based on prices reported in IQVIA audits of pharmaceutical spending that are in general reported at the invoice prices wholesalers charge to their customers including pharmacies and hospitals. In some countries, these prices are exclusive of discounts and rebates paid to governments, private insurers or the specific purchasers. In other countries, off-invoice discounts are illegal and do not occur. The mix of true prices and opaque pre-discounted prices means the invoice-level analyses in this report do not reflect the net revenues of pharmaceutical manufacturers. As a part of this report, the IQVIA Institute has compared audited spending data to reported sales, net of discounts, reported by publicly traded companies and made estimates of future off-invoice discounts and rebates, and net manufacturer revenue.

Global market

Global spending on medicines reached $1.2 trillion in 2018, up from $1.1 trillion in 2017, and is set to be just under $1.3 trillion by 2019, with 4–5% growth globally. Global spending is expected to exceed $1.5 trillion by 2023 as the market grows in mid-single digits (see Exhibit 1).

Exhibit 1: Global Medicine Spending and Growth 2009–2023

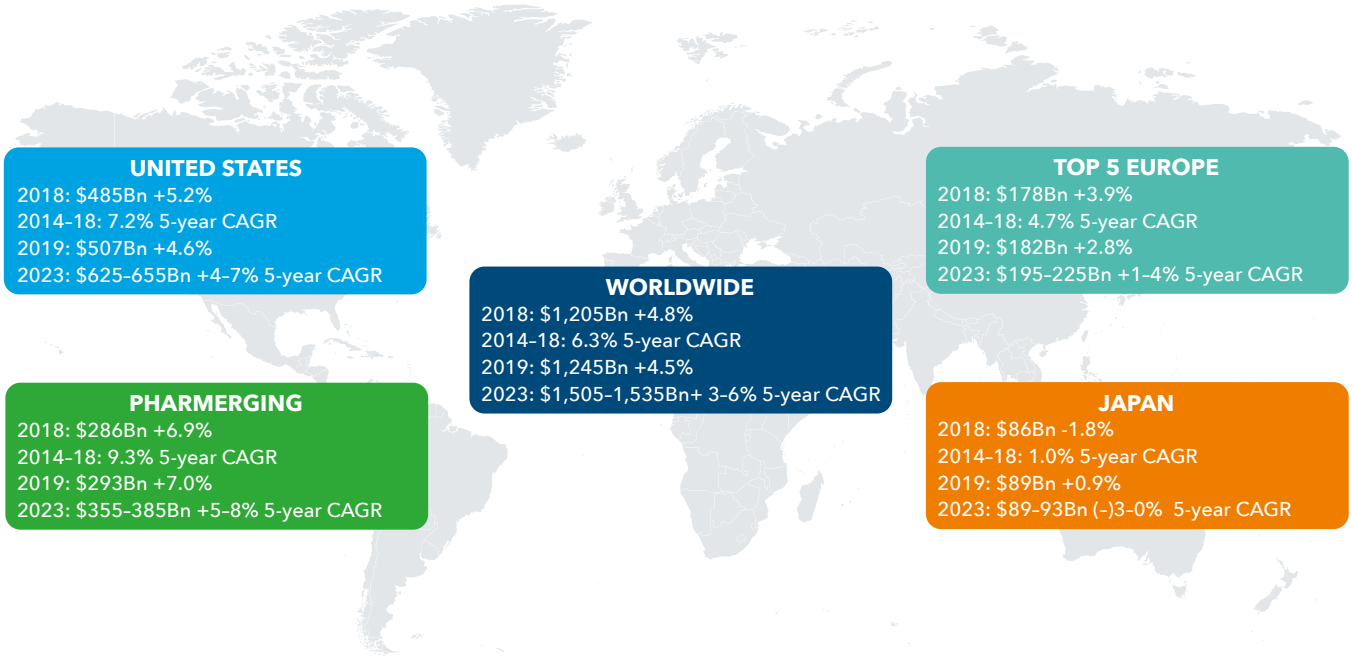


Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018

Global growth of medicine spending through 2023 will primarily be driven by developed markets and their adoption of a wave of newly launched innovative products. Global growth will be driven to a lesser extent by expanded access and use of medicines in pharmerging markets, with China alone approaching the combined spending level of the five major European markets. Growth in the United States will be driven by new products and (at a lower level than prior years) by pricing shifts, and will be offset by losses of exclusivity along with the emergence and growth of biosimilars. In Europe cost-containment measures and less growth from new products contribute to slower growth of 1–4%, compared to the 4.7% compound annual growth seen over the past five years (see Exhibit 2) that was significantly lifted by spending from new products, especially oncologics and viral hepatitis treatments.

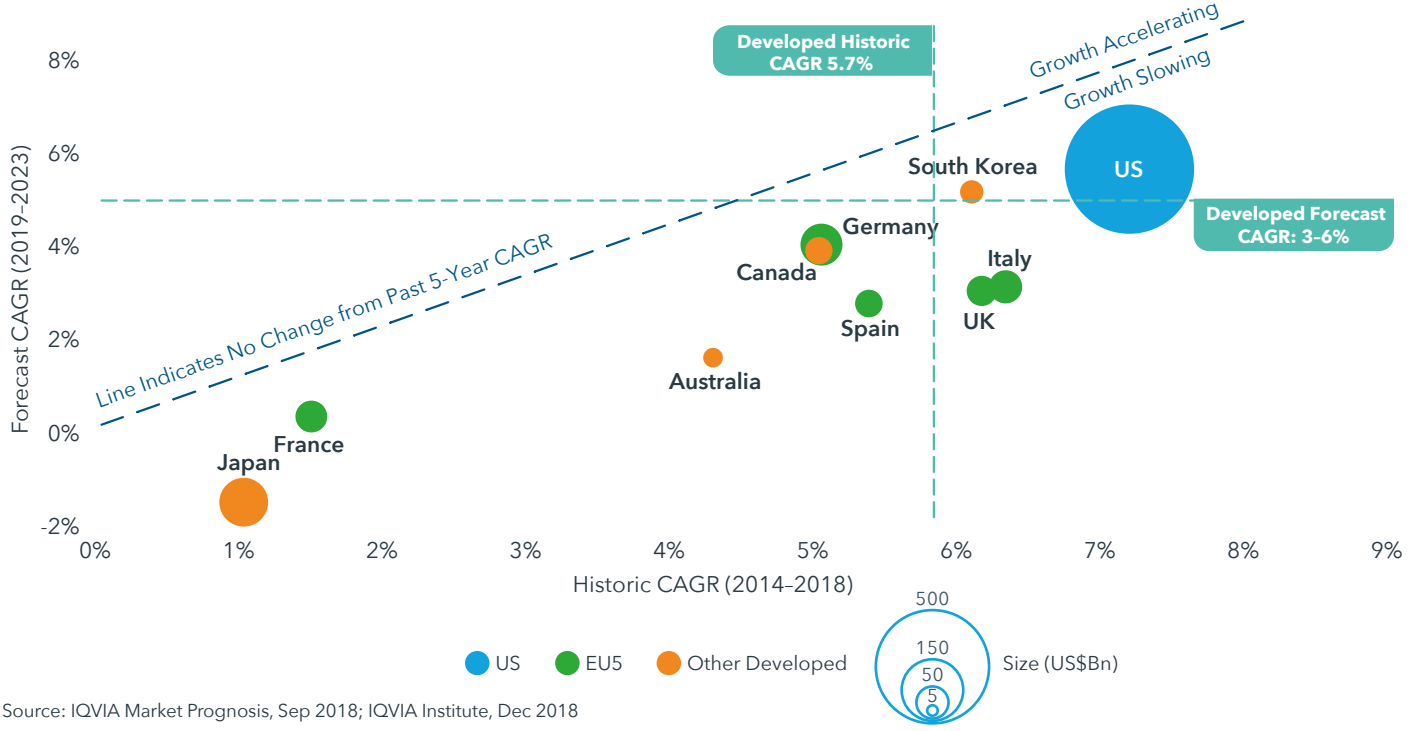
Medicine spending growth in the United States will be higher than the top five European countries, while Japan's overall growth will be the slowest among the developed markets. All developed countries will show slower growth over the next five years than in the past five (see Exhibit 3).

Exhibit 2: Global Medicine Spending and Growth in Selected Regions, 2018–2023



Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018
Notes: Market sizes shown in US$ with actual and forecast exchange rates; growth shown in constant dollars at Q2 2018 exchange rates; Japan growth decline on constant dollar basis is due to exchange rate dynamics

Exhibit 3: Developed Markets Historic and Forecast Spending Growth by Country

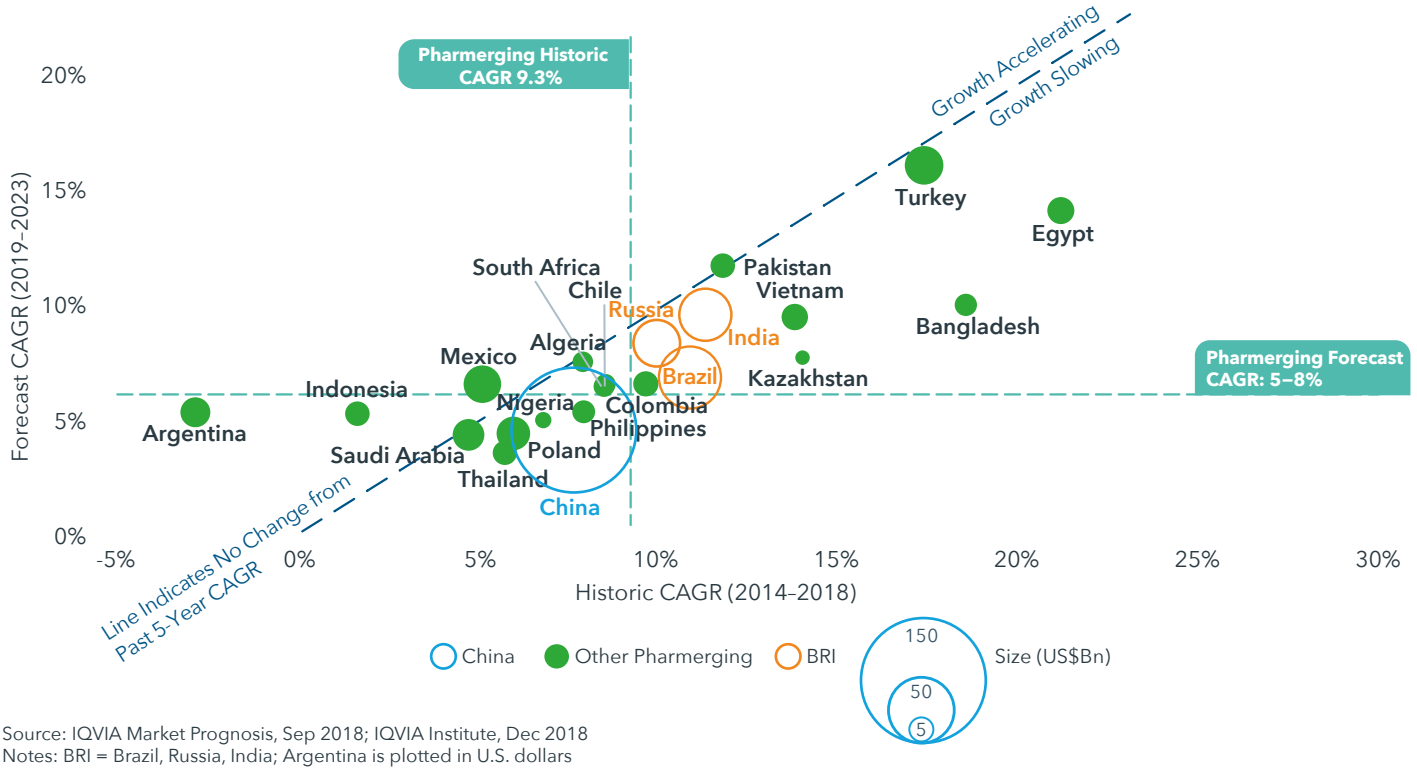


Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018

Medicine spending growth in the pharmerging markets continues to slow compared to the past five years and is projected to grow at 5–8% through 2023. Although China, Brazil and India have the greatest medicine spending within the pharmerging markets, Turkey, Egypt and Pakistan are forecast to have the greatest growth between 2019 and 2023 (see Exhibit 4).

Pharmerging market growth continues to derive primarily from increasing per capita use, but some markets are seeing wider uptake of newer medicines as patients' ability to afford their share of costs improves with economic growth.

Exhibit 4: Pharmerging Markets Historic and Forecast Spending Growth by Country

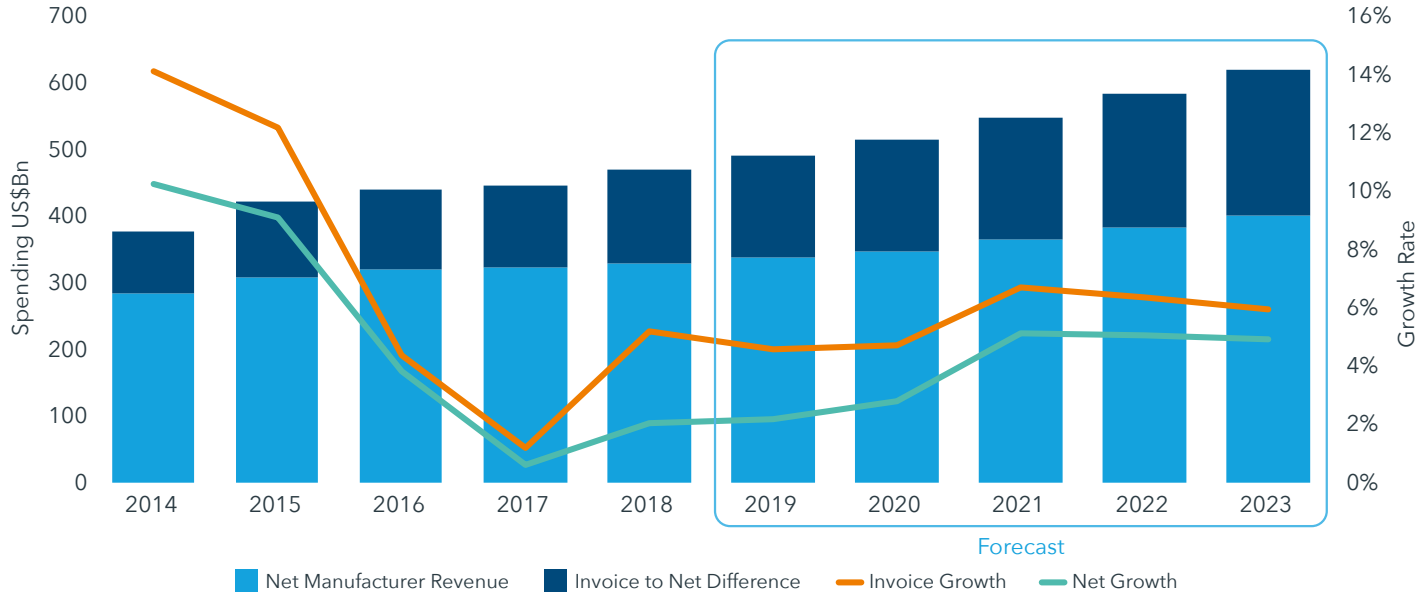


Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018
Notes: BRI = Brazil, Russia, India; Argentina is plotted in U.S. dollars

U.S. market

Spending on medicines is expected to reach over $600 billion on an invoice basis in 2023, including spending in all channels (e.g., retail pharmacies, hospitals, doctors' offices), and on all product types (e.g.,small molecules, biologics, brands, generics, biosimilars). As invoice spending does not reflect off-invoice discounts and rebates, the trend looking at invoice prices can differ substantially from the trend after deducting those discounts and rebates. Net manufacturer revenue growth in the U.S. market is expected to be 2–3% in 2019, down from a high of 10.3% and 9.1% in 2014 and 2015, respectively. Overall invoice spending growth is expected to rebound in 2023 to 6.0% up from a low of 1.2% in 2017, although net manufacturer revenue growth is expected to be 1–2% lower than invoice growth at this time (see Exhibit 5).

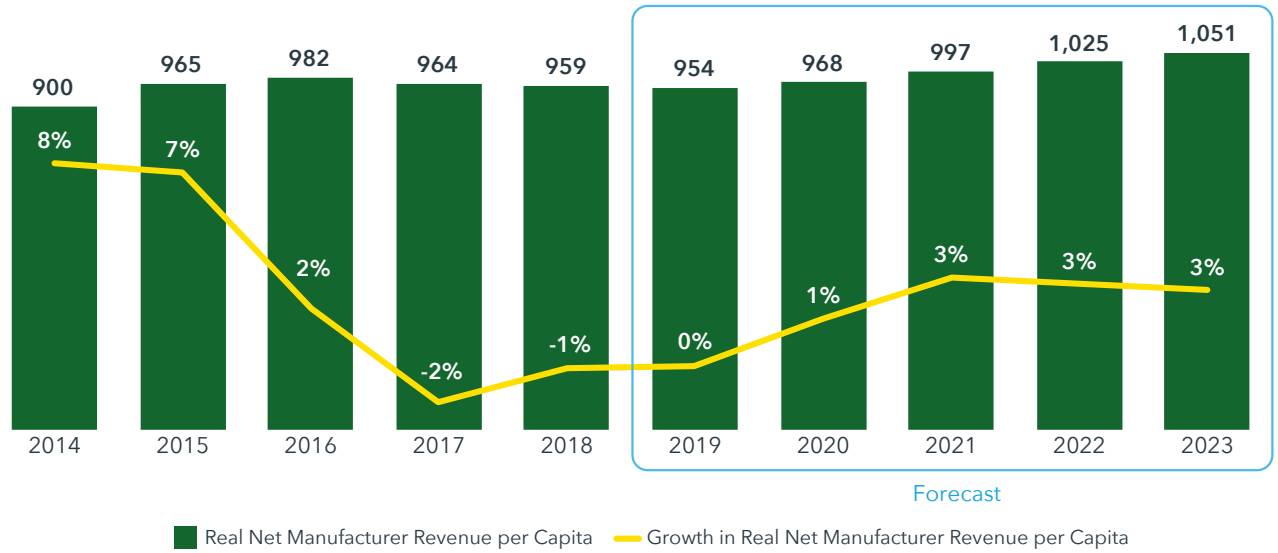
Exhibit 5: U.S. Invoice Spending on Medicines and Net Manufacturer Revenue and Growth US$Bn



Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018

This increase in spending growth is expected to be driven by a substantial rise in the number of launches of new medicines, but will be offset by losses of market exclusivity of branded products. Real net per capita medicine spending is expected to grow at 0–3%, about a percentage point lower than the 2.8% growth seen over the prior five years when adjusted for population, economic growth and manufacturer concessions (see Exhibit 6).

Exhibit 6: U.S. Real Net Manufacturer Revenue per Capita and Growth US$



Source: IQVIA Market Prognosis, Sep 2018; US Census Bureau, US Bureau of Economic Analysis (BEA), Dec 2018; IQVIA Institute, Dec 2018
Notes: Real net manufacturer revenue reflected in 2015 US$; See Methodology for estimated manufacturer net revenue

U.S. pricing trends

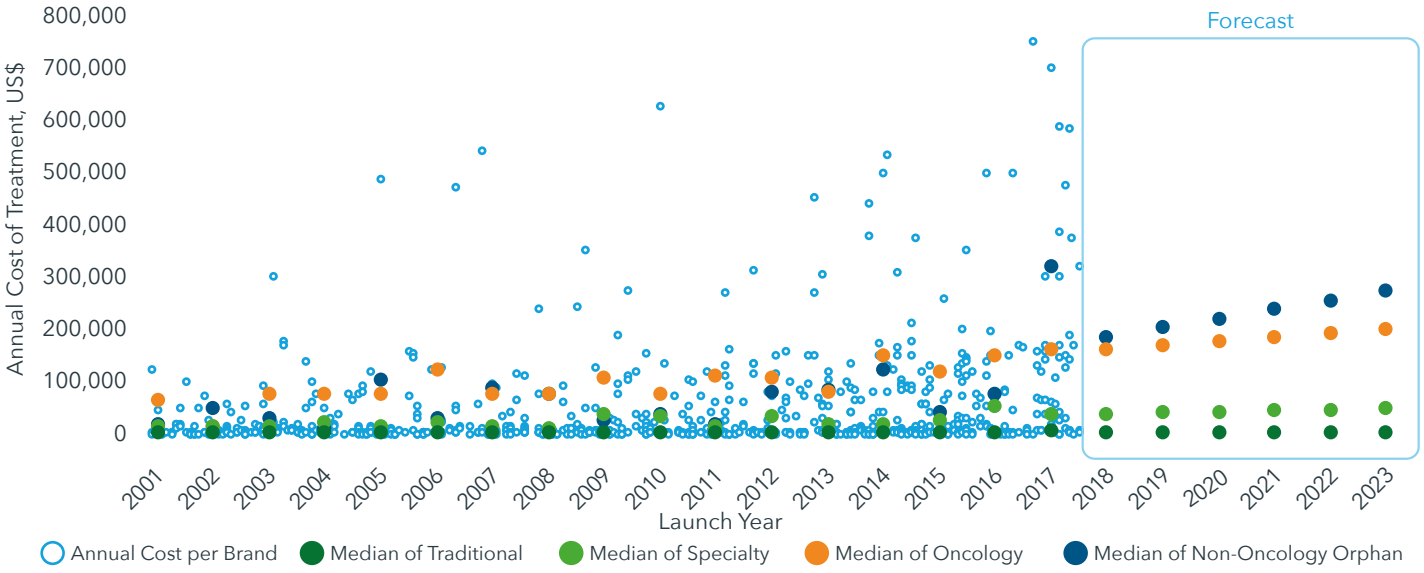
Drug pricing in the United States is a complex interaction between the prices set by manufacturers, negotiation with payers, competition between both branded and generic products and the design of public and private insurance programs that ultimately determine how much is paid by patients, payers and the government. These dynamics include both the prices set at launch and price changes that occur yearly (or more frequently) and the statutory and negotiated concessions manufacturers make afterwards.

There has been significant attention given to the list prices of recently launched drugs, especially with the shift in innovation to specialty, orphan and oncology areas that often have higher prices. The median annual cost for new medicines in many of these therapy areas have risen to tens or hundreds of thousands of dollars in recent years and, in particular, oncology and orphan drugs can be expected to have median prices well above $100,000 per year by 2023 (see Exhibit 7). In the next five years, it is expected that launch prices could increase at a slower rate through a combination of factors including:

- Price competition with other innovative brands as seen already in hepatitis C and PCSK9 therapeutic classes
- Independent review of pricing from bodies like the Institute for Clinical and Economic Review (ICER) or others with similar impact, and the effect of price transparency initiatives more generally
- Recent level of breakthrough (e.g., CAR-T therapies, immune checkpoint inhibitors, etc.) will not be repeated as much as in past five years, i.e., breakthroughs will be more incremental

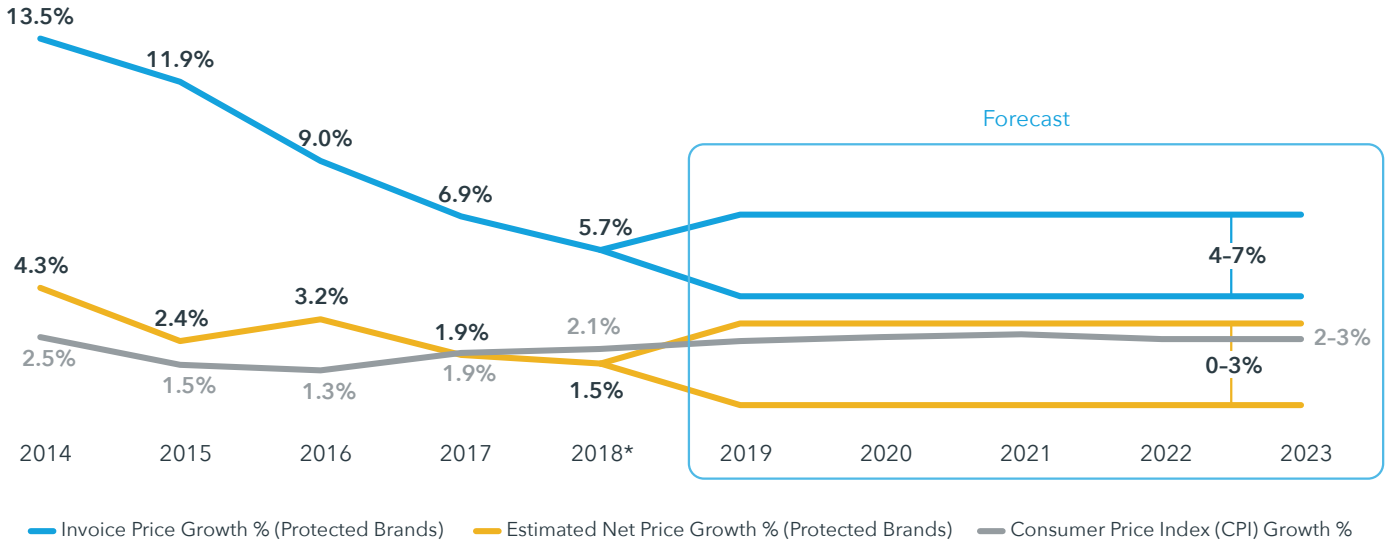
Price increases by manufacturers on established products have drawn public attention, as some have been deemed excessive by the public and policy makers. In the past two years, a range of companies made commitments to reduce list price increases for branded medicines, which are now below 6% per year on average, and are expected to remain in the 4–7 percent range within the next five years (see Exhibit 8). The net prices manufacturers receive for these drugs have grown more slowly as off-invoice discounts, rebates, statutory payments under the affordable care act and the value of patient coupons have offset invoice price growth. Net prices increased at an estimated 1.5% in 2018 and are expected to rise at 0–3% over the next five years. Included in this overall average are the potential for some companies and products to have net price declines in the face of competitive markets. Additionally, net price growth was below inflation in the wider economy in 2018; an occurrence expected to continue for the next five years.

Exhibit 7: Annual and Median Costs of U.S. Brands by Type and Launch Year US$



Source: IQVIA National Sales Perspectives, Dec 2017; IQVIA Institute, Dec 2018
Notes: Annual costs based on invoice prices, with overall invoice-level spending divided by estimated numbers of patients. Patient estimates are based on audited volumes assuming all patients use the drug according to the approved label. Products are included in medians based on segment assignments. Oncology includes both orphan and non-orphan products. All other products that have orphan indications are grouped together and some products have both orphan and non-orphan indications in this group. Specialty and traditional products exclude orphan or oncology products but are otherwise defined according to IQVIA definitions. Projected median costs are based on simple extrapolation of the medians in the prior ten years.

Exhibit 8: U.S. Price Growth Comparing Protected Brands Invoice Price and Net Price Growth, 2014–2023



Source: IQVIA National Sales Perspectives, Sep 2018, CPI projections from Economist Intelligence Unit (EIU), Aug 2018; IQVIA Institute, Dec 2018
Notes: 2018 Invoice price growth to YTD September 2018; Estimated net price growth in 2018 and forecast periods based on expected base case scenarios and interim review of selected company financial results; Protected Brands excludes new brands marketed less than 24 months in each year as price growth cannot be calculated.

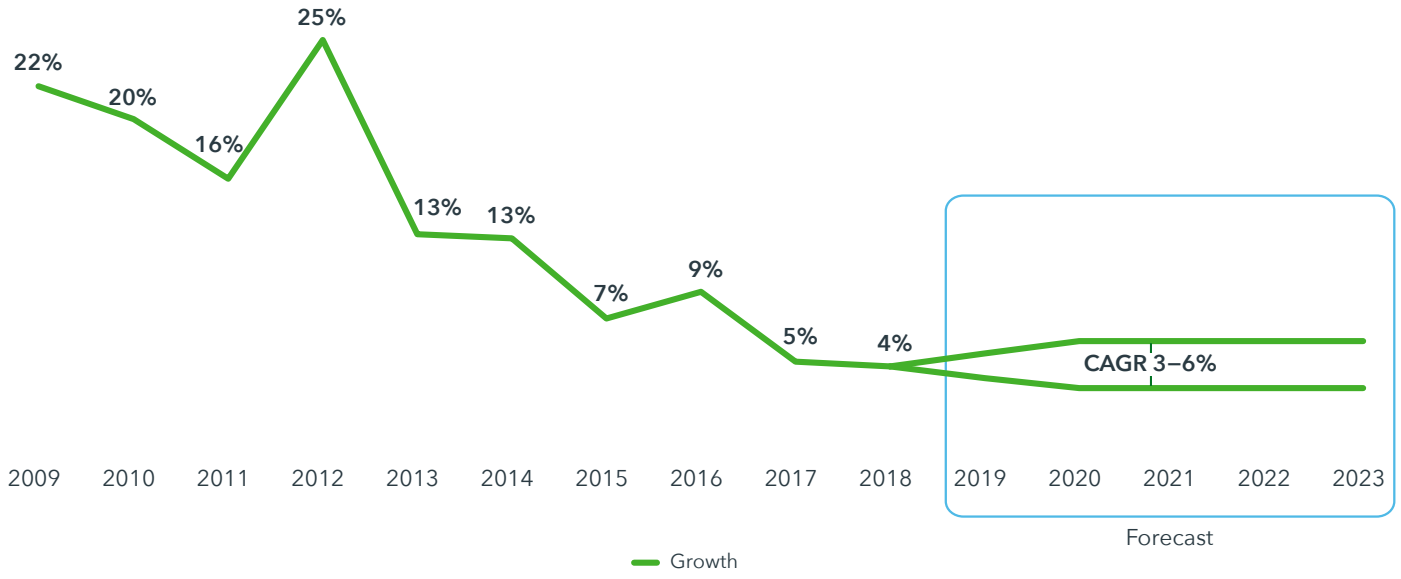
China market

China has expanded to be the second largest pharmaceutical market globally with $137 billion in total spending in 2018, but growth has slowed in the past five years from a 19% CAGR in 2008–2013 to an 8% CAGR in 2013–2018. Growth is expected to continue to decline to 3-6% through 2023 (see Exhibits 9 and 10).

Much of the growth in the past decade has been driven by central government reforms to expand insurance access to both rural and urban residents, as well as to expand and modernize the hospital system and better integrate primary care services (see Exhibit 11). Broader economic growth has enabled more Chinese patients to access and afford medicines, and per capita rates of use and spending have risen significantly. In order to manage affordability for government programs and the population generally, the Chinese government has focused on managing drug pricing through the use of an Essential Drug List (EDL) and a National Reimbursement Drug List (NRDL). Both require manufacturers to offer substantial discounts, while listing on the NRDL offers wider access to the population in return. The NRDL had been updated periodically: in 2001, 2004, and 2009 with the most recent in 2017 after an eight-year gap. The adoption of newer medicines from this updated reimbursement list will drive significant growth for novel brands, while unbranded generic medicines and locally manufactured non-original brands are expected to grow more slowly.

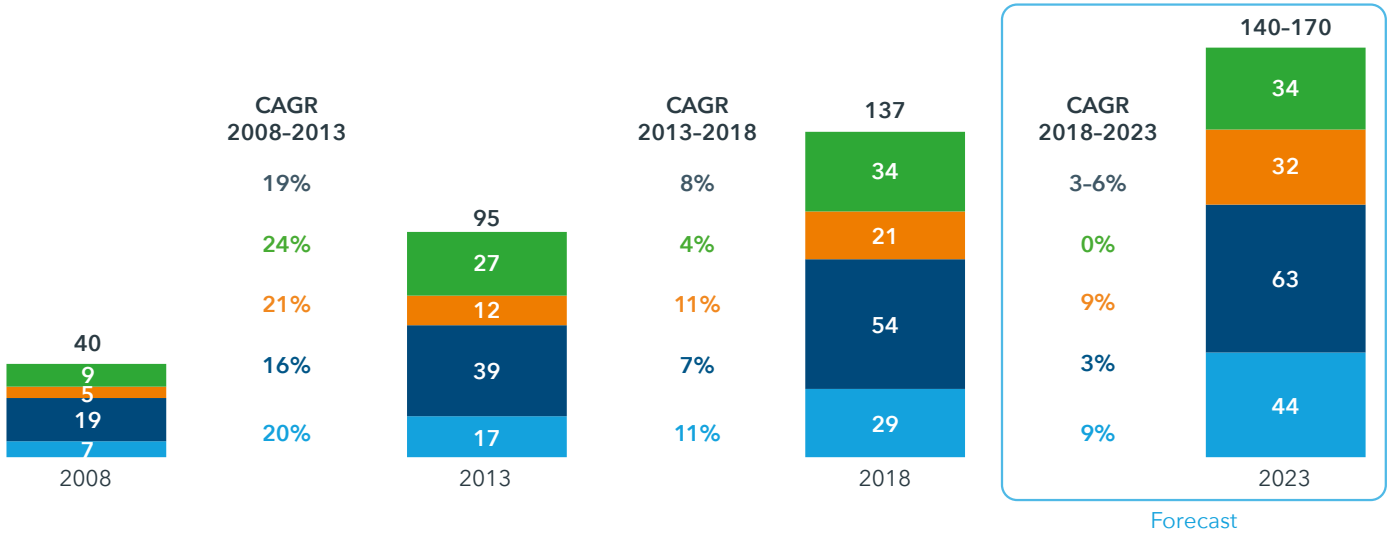
Underpinning the average 11% growth in the past five years for original brands are a range of national reforms aimed at reducing corruption and improving the efficiency of state agencies. The Chinese Food and Drug Administration (CFDA) has been replaced with the State Drug Administration (SDA), while the State Medical Insurance Administration (SMIA) becomes a combined insurance agency overseeing both urban and rural insurance and the reimbursement lists. In addition, reforms to hospital tendering will drive greater competitiveness for generics and off-patent brands, while removing some incentives for hospitals around these purchases that were ultimately inflationary. Overall, patient out-of-pocket spending will decline as insurance assumes a larger portion of spending.

Exhibit 9: China Spending Growth Rate Constant US$Bn 2009–2023



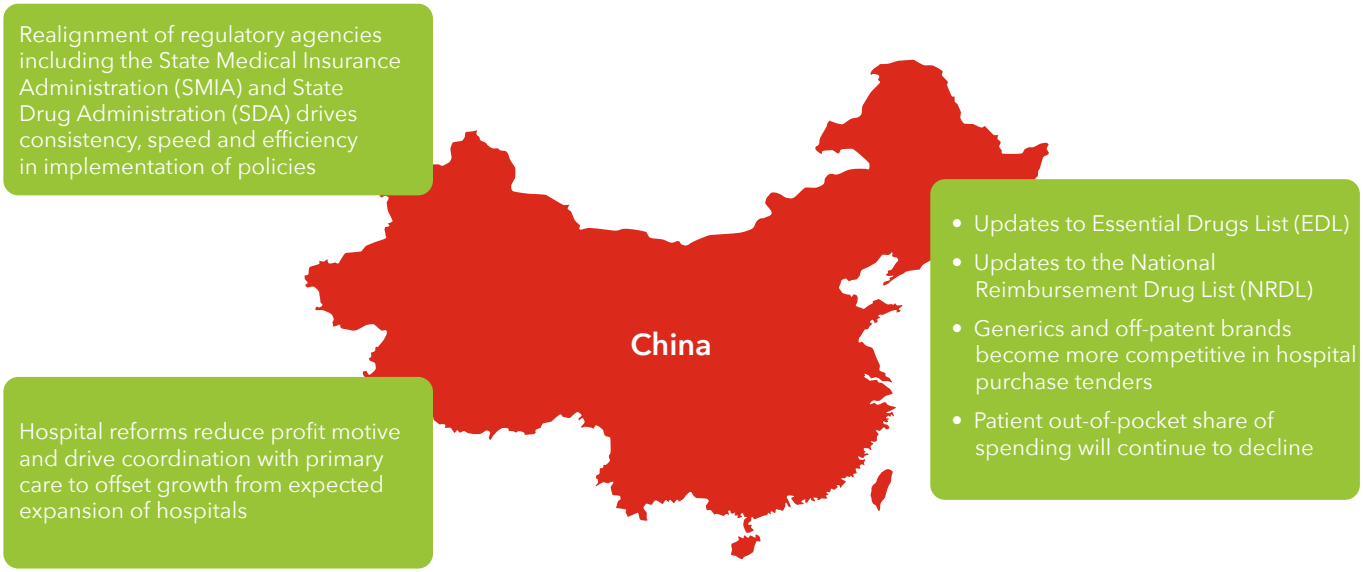
Source: IQVIA Market Prognosis, Sep 2018

Exhibit 10: China Spending 2008–2023 and Compound Annual Growth Constant US$Bn



Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018
Notes: OTC = Over-the-counter

Exhibit 11: China's Market Reforms

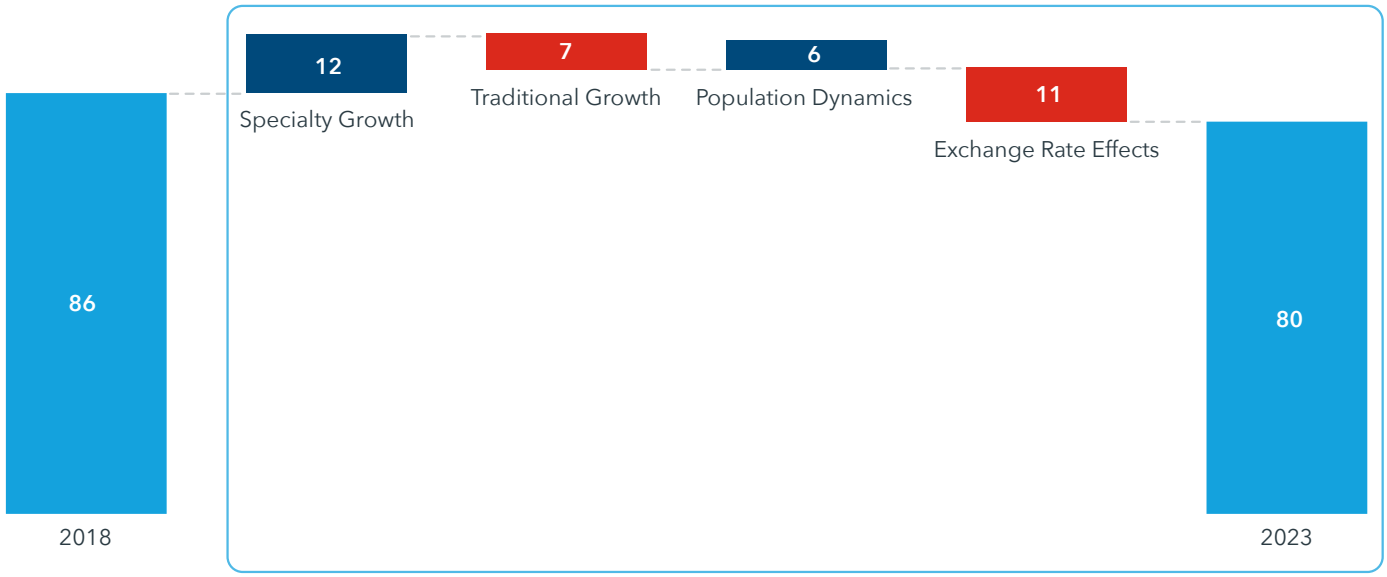


Source: Market Prognosis China, Sep 2018

Japan market

Japan has been the second largest branded pharmaceutical market for many years, mostly due to a historic lack of policies to encourage generic use. Growth has been consistently lower than other developed markets through a system of biennial drug price cuts. The centralized budgeting in the Ministry of Health Labor and Welfare (MHLW) has largely maintained the overall spending trend but has shifted focus in recent years to achieve greater access to novel medicines within this low-growth trend. Spending in Japan totaled $86 billion in 2018, but over the next five years, spending on medicines in Japan is expected to decline from -3 to 0% on a constant dollar basis but grow by about 1% on a variable dollar basis, due in large part to exchange rate dynamics that are expected to have a significant effect (see Exhibit 12). The largest drivers of growth are forecast to be a shift in spending to specialty drugs, including oncology medicines, as well as an aging population. Although the Japanese population is declining, there is a greater per capita use of medicines by older patients that tempers the downward pressure of an uptake in the use of generics and exchange rate effects (see Exhibit 12).

Exhibit 12: Japan Spending Growth Dynamics 2018–2023 Constant US$Bn

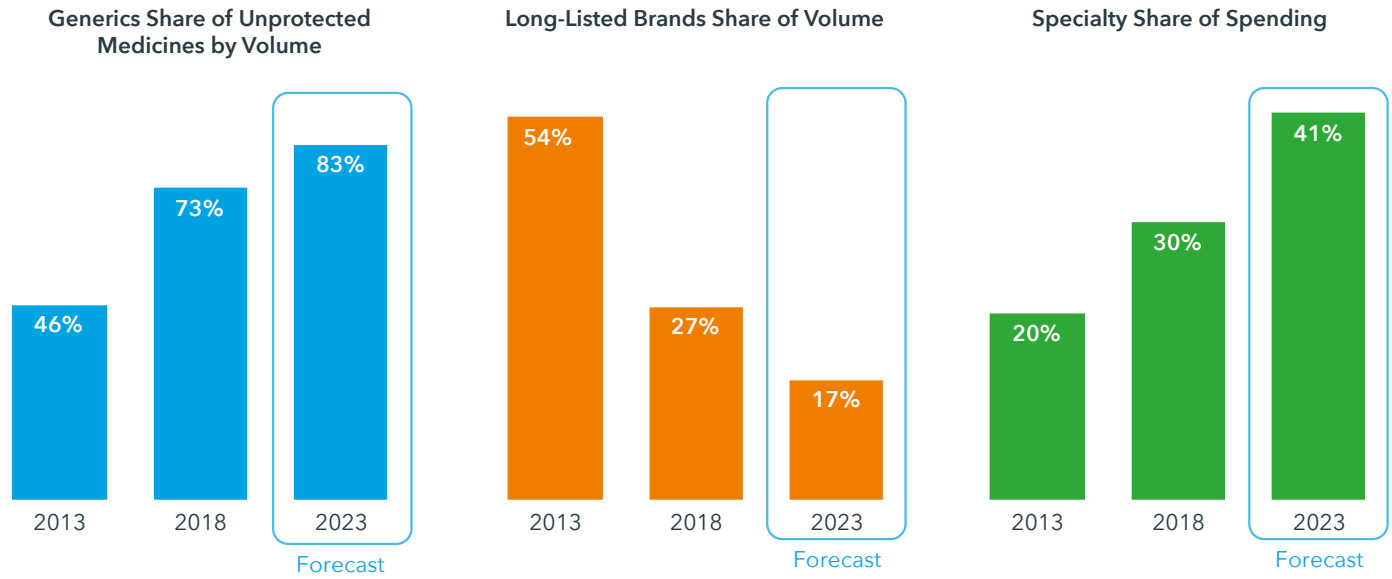


Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018

Traditional drugs will contribute to slowing growth that is strongly linked to the shift from older off-patent medicines – termed 'long-listed brands' locally – to unbranded generics. The MHLW's stated goal in 2014 was to achieve a rate of 80% of prescription volume of unbranded generics in the unprotected market by 2021, but it is expected that this will be achieved in 2020 as incentives have driven commercial activity into this area. The greater savings from generics is enabling a greater shift to specialty medicines without overall budget impact and the share of specialty spending is expected to rise from approximately 30% in 2018 to 41% in 2023 (see Exhibit 13).

While the policies around biennial price cuts and price setting from the MHLW have been largely effective at ensuring access to new medicines and controlling growth, there are continuing refinements to the current every-other-year system. These include ongoing reforms to the eligibility requirements for a new and innovated drug to achieve a price maintenance premium (PMP), which protects against repricing. Since 2010, the MHLW's focus on granting price protection based on the degree of clinical benefit is rewarding innovative products and is at the core of the ministry's policies to support both improved access and maintain overall growth over the next five years. It remains possible that further adjustments to the system could be implemented, including shifting to annual price cuts for certain medicines, but these would likely only occur if spending were to exceed ministry targets on a consistent basis.

Exhibit 13: Drivers of Spending Growth Dynamics in Japan

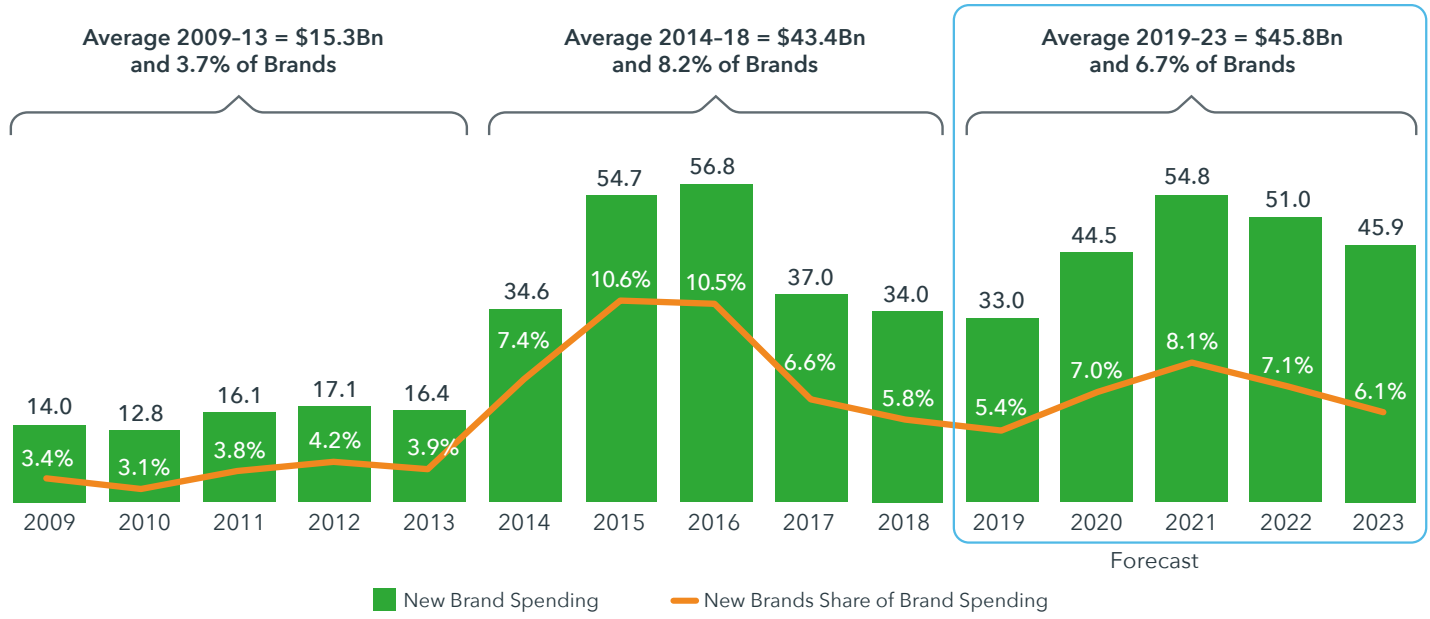


Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018

New products

Globally over the past five years there has been a significant increase in the number of and spending on new active substances, particularly in the developed markets where they have historically launched first. Between 2014 and 2018, the average spending on new branded medicines was $43.4 billion. New products launching between 2019 and 2023 are expected to have a slightly higher overall level of spending, approximately $45.8 billion, but will likely represent only 6.7% brand spending, down from 8.2% between 2014 and 2018 (see Exhibit 14). There are a wide range of particularly important treatments expected to be launched in 2019 and 2020, with the biggest impact of those launches in the subsequent year.

Exhibit 14: Developed Markets New Brand Spending and Share of Total Brand Spending Constant US$Bn

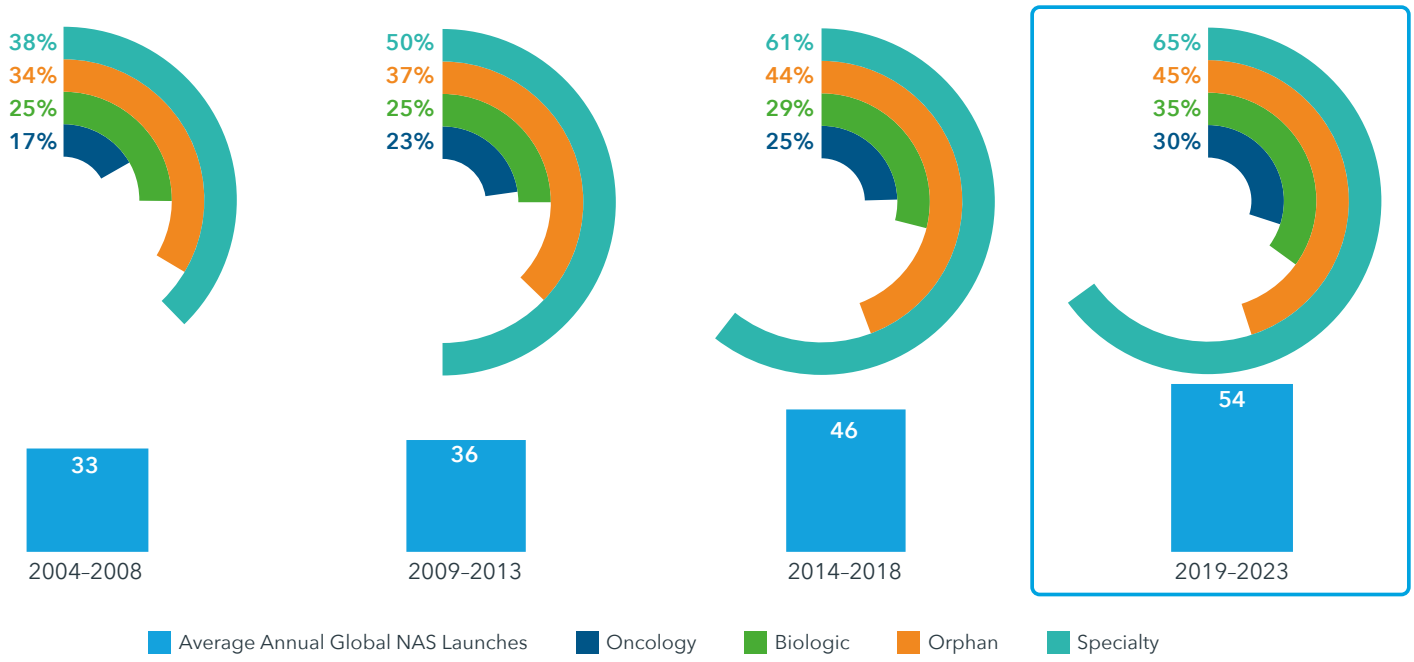


Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018
Notes: Developed markets include: U.S., Japan, Germany, France, Italy, U.K., Spain, Canada, S. Korea, Australia; New Brands defined as those launched less than two years previously, measured separately in each country as launches of the same products are at different times.

Along with the increasing number of launches, the type of products continues to shift to specialty, orphan, biologic and oncology products. Specialty is expected to represent nearly two-thirds of newly launched medicines over the next five years, and oncology approximately 30% (see Exhibit 15). Orphan drugs could represent 45% of new active substances should the level of FDA orphan designations for in-progress research and breakthrough designations produce successful launches at current, historic rates. With these shifts in the type of products launching, price per patient is likely to be increasingly high, while the number of patients treated by these therapies will be fewer. The increasing use of biomarkers to segment and treat appropriate patients will characterize more launches, and while not all products can be categorized as precision medicines, there will be more precision treatments in specialty, orphan and oncology therapeutic areas.

The oncology pipeline includes 748 drugs in late-stage clinical development, including over 300 mechanisms of action and 53 Next-Generation Biotherapeutic projects. It is likely that 70–90 oncology products will launch in the next five years, which would be a significant increase over the 57 launched in the past five years. New drugs could emerge for a range of other diseases with large unmet needs, such as Alzheimer's disease, but recent setbacks in this therapy area suggest the likelihood is low. Other notable areas include first-time treatments for diseases like nonalcoholic steatohepatitis (NASH), novel approaches to migraines (including the CGRP inhibitors), neuromuscular diseases,[3] autism and other developmental disorders, and a range of molecular targets for cell and gene therapies.

Exhibit 15: Average Number of Global NAS Launches Annually per Period and Percentage of Launches by Type

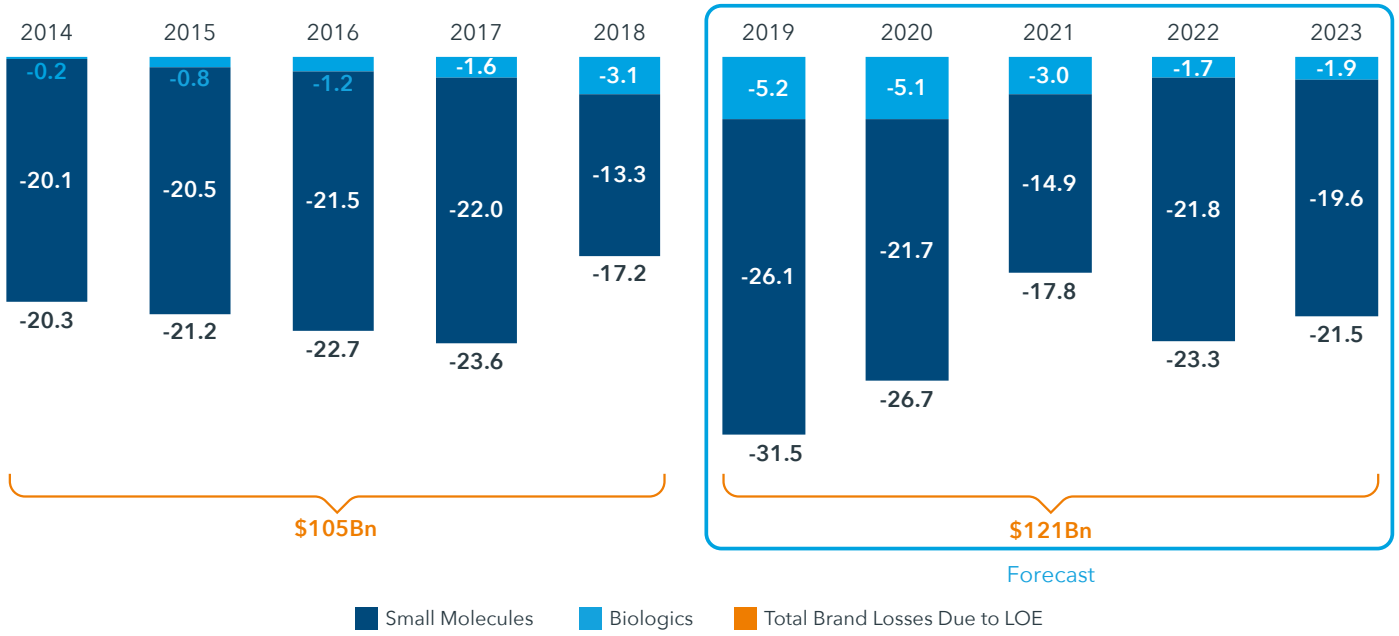


Source: IQVIA Institute, Dec 2018
Notes: Percentages do not sum as segments are not mutually exclusive. NAS = new active substance

Losses of exclusivity

The expected impact of losses of exclusivity (LOE) for branded medicines in the developed markets is expected to peak in 2019 and will be driven by events in 2018 as in 2019 including the U.S. approval for seven biosimilars in 2018 (see Exhibit 16).[4] Overall, the impact of LOE is greater for small molecules versus biologics, although the impact of biosimilar competition will grow significantly for biologics through 2023. For example, the impact of LOE in developed markets for small molecules will be larger in the next five years at $121 billion compared to $105 billion from 2014–2018, a 15% increase (see Exhibit 16). However, the impact of LOE for biologics is expected to increase two-and-a-half-times to approximately $17.0 billion from 2019 to 2023, up from $6.9 billion in the period 2014–2018. The impact of biosimilars has been driven by continued uptake in Europe to-date, but the introduction of biosimilars in the United States has accelerated since late 2013, and an even greater impact is expected through 2023. For example, the leading product by global revenue, adalimumab (Humira), is currently facing biosimilar competition in Europe and will see biosimilar competition in the United States in 2023. By the end of 2023, only two of the current top 20 original brands, nivolumab (Opdivo) and pembrolizumab (Keytruda), will not be facing generic or biosimilar competition.

Exhibit 16: Developed Markets Impact of Brand Losses of Exclusivity 2013-2022, US$Bn

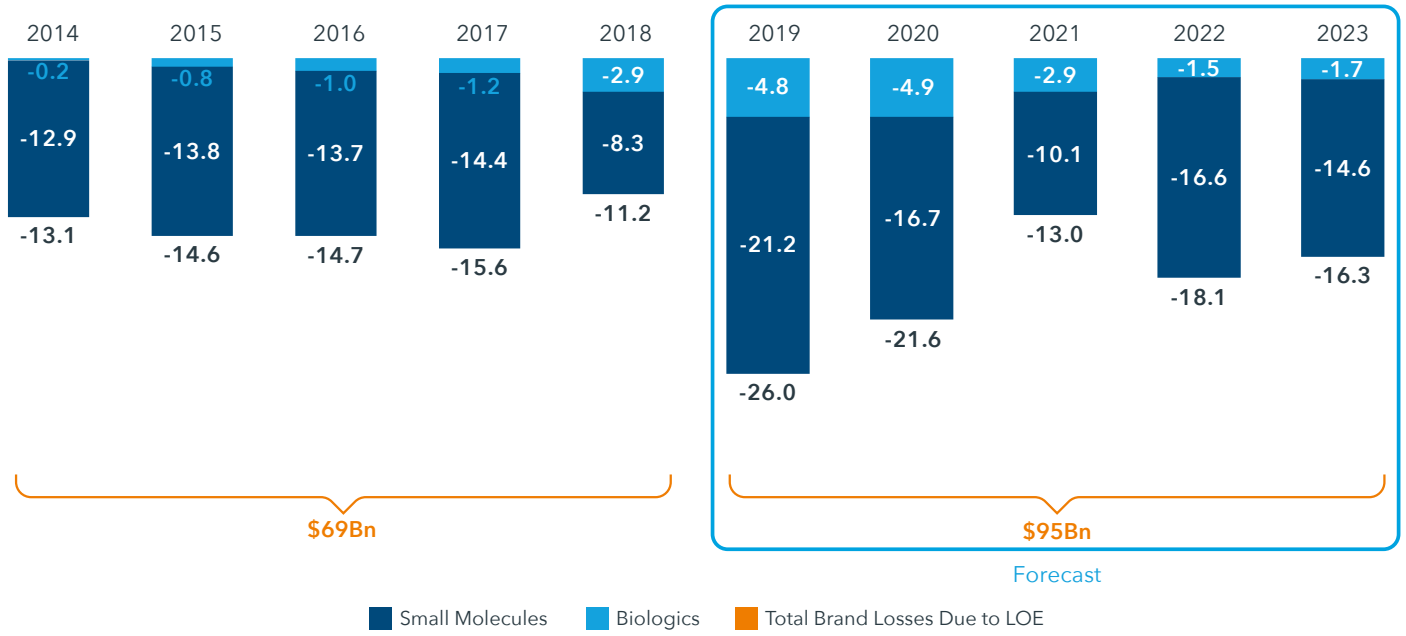


Source: IQVIA Market Prognosis, Oct 2018; IQVIA Institute, Dec 2018

In total, much of the LOE impact through 2023 derives from the U.S. market, which is expected to account for $95 billion of the approximately $121 billion in brand LOE (see Exhibits 16 and 17). The largest individual product to face LOE in the United States is expected to be adalimumab (Humira), with estimated biosimilar entries expected in late 2023, which will delay the bulk of the impact into 2024 and beyond.

Despite a larger absolute amount of impact on brand spending as a result of market growth, the impact of LOE on a percentage basis will be about the same in the United States over the next five years as it was between 2014 and 2018: 4.1% of the branded market. In the overall developed group of countries, the impact of LOE will decline from 3.9% of brands in the past five years to 3.6% in the next five. This difference in impact belies the differing dynamics and timing of LOE in the United States compared to the other countries.

Exhibit 17: U.S. Impact of Brand Losses of Exclusivity 2013–2022, US$Bn



Source: IQVIA Market Prognosis, Oct 2018; IQVIA Institute, Dec 2018

*Somatropin (Omnitrope) was approved prior to the creation of the abbreviated licensure pathway for biological products in the United States

Biosimilars

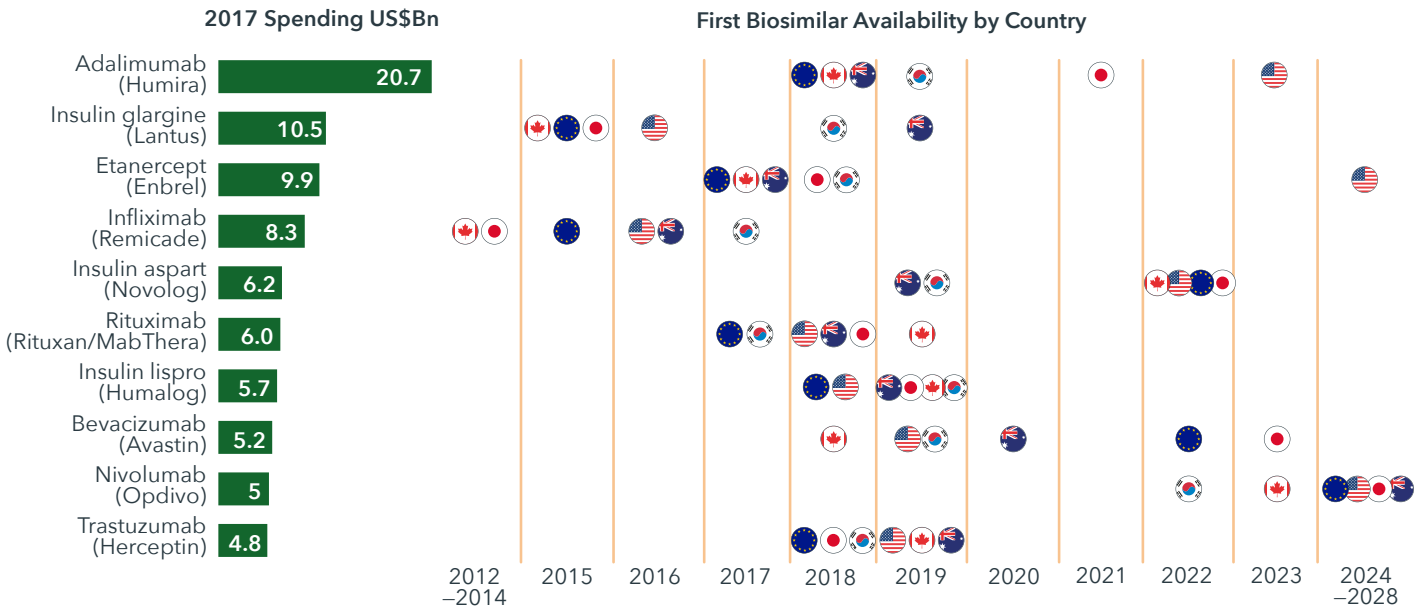
Across developed markets, the bulk of the biosimilar impact has been outside the United States. Biosimilar dynamics in the next five years will be driven by molecules that already have or will soon have competition, with the introduction of new competitors and further market penetration of existing biosimilars. The adoption and introduction of biosimilars in Europe will continue at a faster pace than in the United States until later in the decade. Across developed markets, there will be fewer losses of exclusivity and associated market entry by biosimilars after 2019, until the next major event with the entrance of adalimumab (Humira) biosimilars in the United States in 2023 (see Exhibit 18). By 2023, U.S. policies are expected to encourage more biosimilar applicants to file and to reshape reimbursement dynamics that have hampered early uptake of some molecules.

In order to maximize savings, countries will need to ensure that incentives for challengers to enter the markets are substantial enough, and that policies that encourage providers and patients to use biosimilars are sufficient, while maintaining safety.[5] The relatively slow adoption of biosimilar policies in the United States has delayed the potential savings from these medicines, but the larger delays have come from the patent protections for major originator biologics and the lack of development challenges associated with smaller revenue molecules. There are currently $11.3 billion in spending in the United States for biologics launched more than ten years ago, and there is little prospect that any of these products will face biosimilar competition in the next fifteen years as their revenues are each below $1 billion and/or below $150 million per year (see Exhibit 19). However, biosimilar competition is expected for some biologic molecules launched in the past ten years despite having no announced biosimilar research to date.

Competition for these molecules is likely because their revenues currently total $81.6 billion and could grow further before they face biosimilar competition, and is spread relatively evenly in the years between 2024 and 2033.

While biosimilar introductions in the United States have lagged behind Europe, and only five originator biologics have seen biosimilars launched in the United States by 2018 (somatropin*, filgrastim, infliximab, insulin glargine, pegfilgrastim), many more are expected over the next five years. To date, biosimilars in the United States have generated some

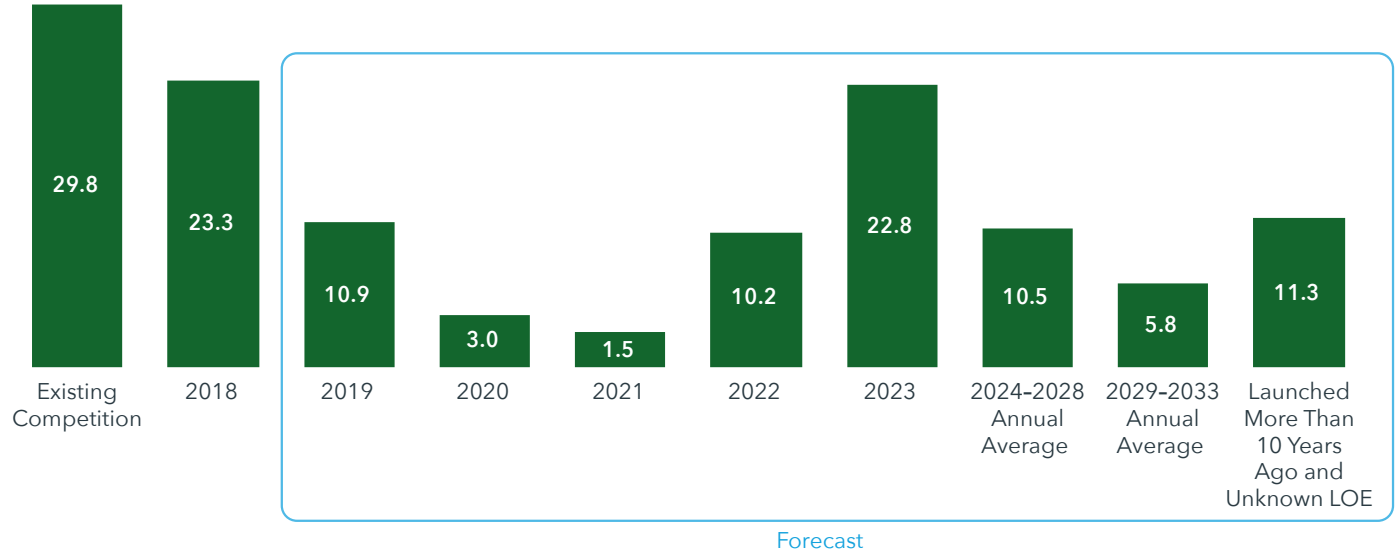
Exhibit 18: Developed Markets Spending on Top Ten Biotech Medicines and Expected First Biosimilar Availability



Source: IQVIA MIDAS, MAT Jun 2018; ARK Patent Intelligence, IQVIA Institute, Dec 2018
Notes: Developed markets include: U.S., Japan, Germany, France, Italy, U.K, Spain, Canada, S. Korea, Australia.

systemic savings, but greater savings will require more competitors per molecule and more molecules facing competition. By 2023, the part of the biologic market with competition from biosimilars will be nearly three-times larger than it is today, and the presence of that competition will result in nearly $160 billion in lower spending over the next five years, or about 10% of the cumulative spending that would have been in that period, if the expected new biosimilars did not reach the market (see Exhibit 20).

Exhibit 19: Amount of Biotech Medicine Spending Newly Exposed to Biosimilar Competition Over Time, 2018 Values US$Bn

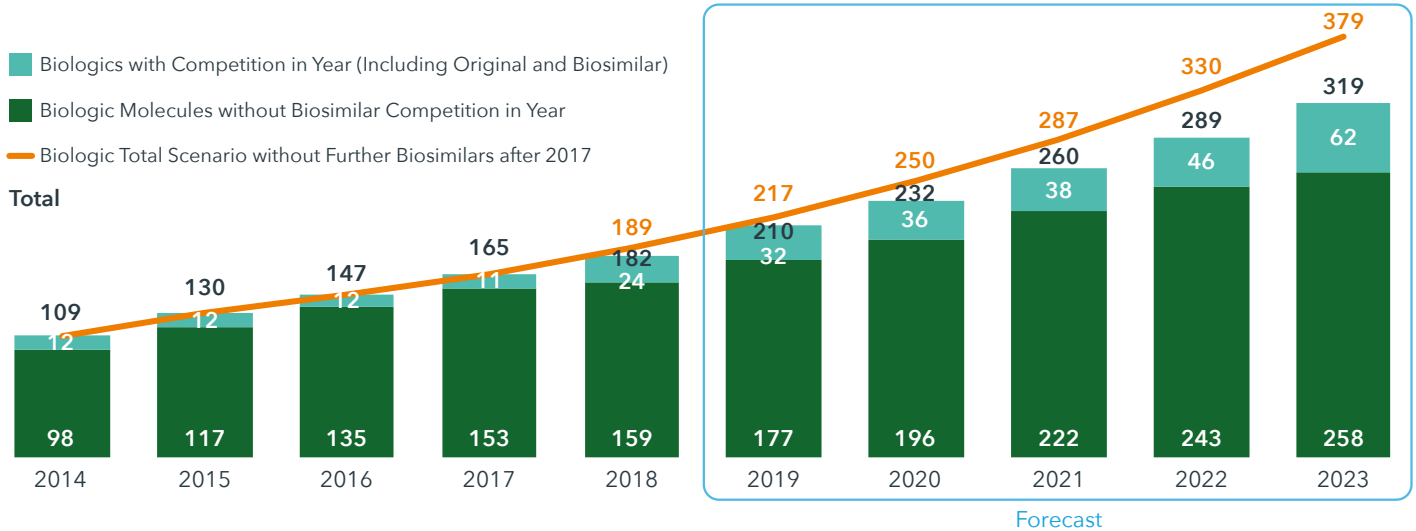


Source: IQVIA MIDAS, MAT Jun 2018; ARK Patent Intelligence, IQVIA Institute, Dec 2018

Notes: Developed markets include: U.S., Japan, Germany, France, Italy, U.K, Spain, Canada, S. Korea, Australia

LOE = loss of exclusivity. MAT June 2018 sales assigned by period of expected first year of competition by country. Expected biosimilar entry based on lapse of relevant exclusivities and patents where information is available. For biologics launched in the past 10 years it is assumed that they will eventually face competition and in the absence of patent information, LOE is set as launch plus 15 years. For biologics launched before 2009, with no patent information and no reported biosimilar development activity, no further assumptions have been made about their expected competition dates.

Exhibit 20: U.S. Biologic Spending by Competitive Status and Scenario without Future Biosimilar Molecules US$Bn



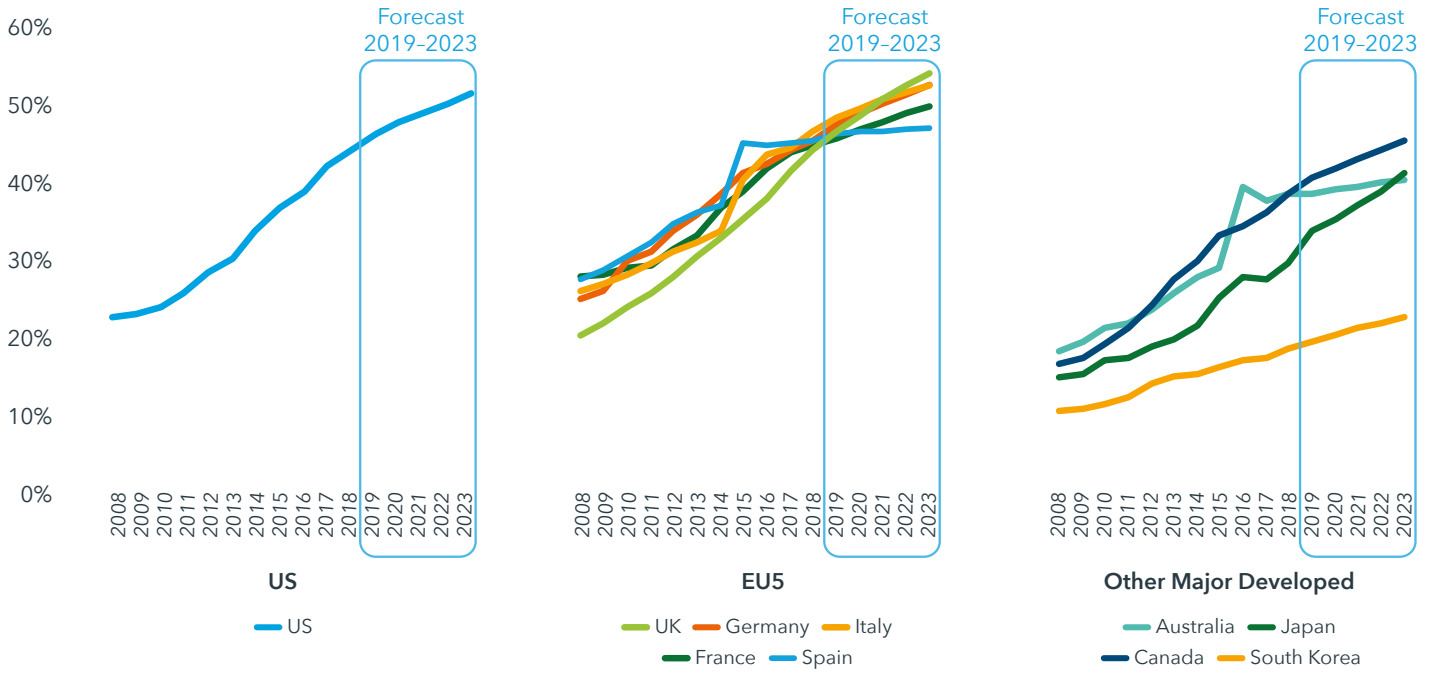
Source: IQVIA MIDAS, Jun 2018; IQVIA Institute, Dec 2018

Notes: Line on chart represents biologic spending using average growth of molecules not facing competition in 2017 continued to 2023 to represent what spending would have been without new molecules facing biosimilar competitors. Segments for biologics with and without competition are modeled using the average historic growth rates and expected entrance of biosimilars and price and volume changes associated with biosimilar entry.

Specialty products

Specialty medicines spending will reach $475–505 billion in developed markets by 2023. Specialty medicines are those that treat chronic, complex or rare diseases and are costly, either directly or through the distribution, care-delivery or follow-up treatments required (see Methodology for details). The specialty share of total medicine spending will approach 50% by 2023 in most developed markets (see Exhibit 21) as the majority of new medicines have been and will continue to be in specialty classes. Some developed markets, notably Spain and Australia, continue to focus on efforts to contain the growth in specialty medicine spending. Most markets are balancing specialty growth with offsetting savings in traditional products and are achieving lower overall growth rates.

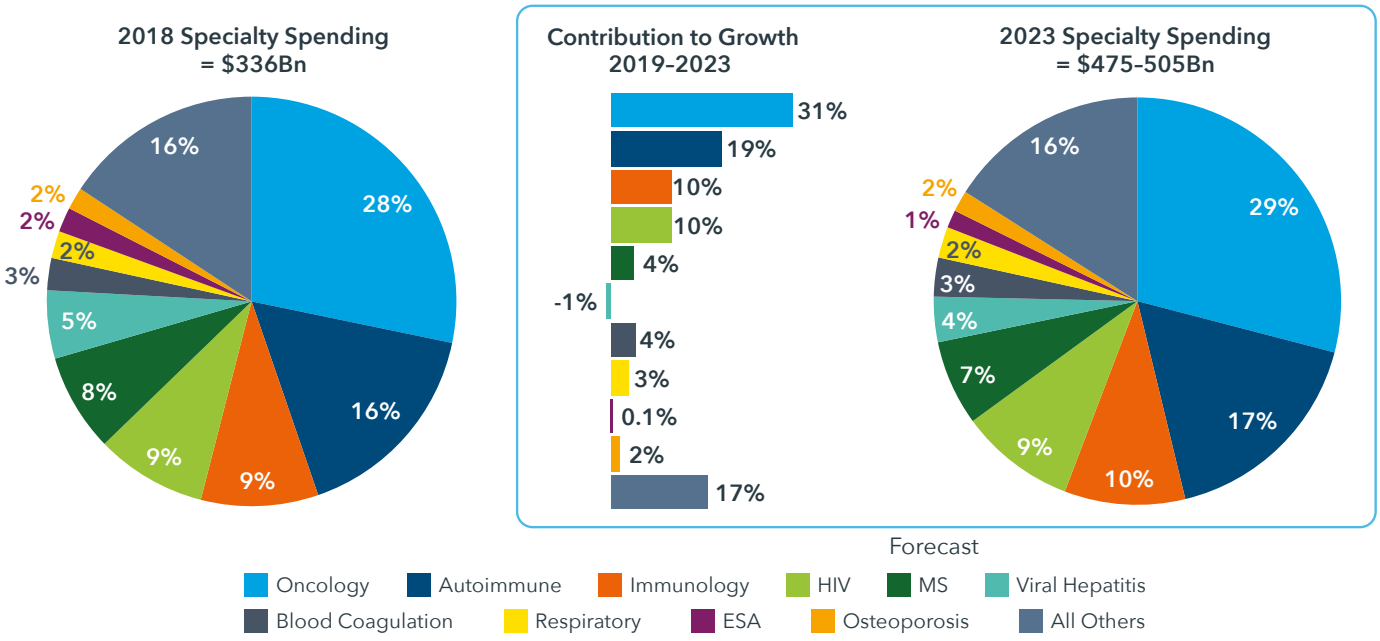
Exhibit 21: Specialty Medicines Share of Spending by Country, 2008–2023



Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018

The growth in specialty spending is expected to increase spend across developed markets from $336 billion in 2018 to $475–505 billion in 2023 (see Exhibit 21). The ten developed markets represent 66% of global spending with specialty share of spending across the countries rising from 42% in 2018 to 50% in 2023. The growth will be disproportionately driven by the five largest specialty therapeutic classes: oncology, autoimmune, immunology (which includes interferons, immunosuppressants and immunoglobulins), HIV and multiple sclerosis. These five classes will drive 74% of specialty growth over the five year period (see Exhibit 22). Specialty represents a smaller share in pharmerging markets, averaging 13% in 2018 and rising to 14% through 2023.

Exhibit 22: Specialty Medicines Spending and Growth in Developed Markets



Source: IQVIA Therapy Prognosis Global, Jun 2018, IQVIA Institute, Dec 2018
Notes: Therapy shares based on eight developed markets: U.S., Japan, Germany, France, Italy, Spain, U.K., Canada; MS = multiple sclerosis; ESA = erythropoiesis stimulating agent

What to watch 2019 to 2023

- A range of novel technologies, such as induced pluripotent stem cells (iPSC) and CRISPR/Cas9, and others involving modified cells or gene-modification tools are under development, will treat limited patient populations and raise important questions for healthcare stakeholders around cost and accessibility.
- Mobile apps are increasingly submitted to the FDA for clearance or approval. These prescription digital therapeutics (DTx) are a new emerging treatment modality with indications and disease-specific treatment effectiveness claims in their prescribing labels.
- In the past decade, philanthropic organizations focused on neglected tropical diseases have made significant progress and many of the clinical development programs they have started or supported are beginning to result in drug approvals.
- Over the next five years, life sciences companies will continue to develop and invest in artificial intelligence, machine learning and deep learning programs leading to breakthroughs impacting the discovery and development of medicines.
- Manufacturers of new medicines where safety has been well demonstrated, but additional or alternative uses of drugs have not yet been approved, will incorporate real-world evidence to support approval for novel indications.
- Pharmaceutical companies will continue hiring specialists in patient care and patient advocacy, building health advocacy roles internally with most of the top 20 pharma companies having a senior level patient advocacy role by 2019.
- In response to stakeholder perceptions in the United States that they are paying inappropriately high costs for medicines, the federal government has proposed a sweeping set of pricing reforms for government programs with varying levels of impact and probability of being enacted.
- There will be more emerging biopharma companies (EBP) launching new medicines in the next five years, due to shifts in strategy as well as the rising absolute number of active R&D compounds, with more than one-third of drugs launched in the next five years brought to market by EBP companies.
- The next five years likely pose a number of challenges to biopharmaceutical companies, with payer actions on prices looming, and it remains to be seen whether these companies can repeat their past successes in terms of revenues and cost management.
- Existing policies and new legislation will likely impact opioid prescribing and use through 2023, and the dynamics around prescription opioids, and issues around illicit drug use and overdoses, will remain complex and challenging to address. A range of likely scenarios around opioid prescribing trends include a continuation of the ongoing rapid declines in use or a pattern of convergence around current lower-use states.

Next-Generation Biotherapeutics: expanding use and new approvals

Nine cell-based therapies, gene therapies and regenerative medicines [i.e., Next-Generation Biotherapeutics (NGBs)][6] have launched globally, and a growing number of these are in active clinical research across therapy areas from ophthalmology to oncology. These include direct gene replacement and the widely noted CAR-T therapies, which are associated with significant rates of remission for some blood cancers. A range of other novel technologies using induced pluripotent stem cells (iPSC), CRISPR/Cas9, modified cells and gene-modification tools are also under development.

WHAT TO WATCH

The drugs launched to date in this category have been notably high-cost and have either treated limited patient populations or had to offer some sort of outcomes-based contract to gain reimbursement. Forthcoming changes in the number of drugs and their potential budget impacts for healthcare stakeholders include:

- Increasing levels of use and reimbursement for existing NGBs, subsequent regulatory approvals and new indications that will have associated budget implications for payers.
- Five to eight new NGBs will be approved by regulators over the next five years, a substantially lower rate of approvals than previously predicted, but offering substantial clinical benefits.
- Rapid clinical trial progress will be seen for a range of technologies that are currently in early-stage trials and could bring entirely new, high-value treatment options to the market very quickly and unexpectedly.

IMPLICATIONS

For healthcare stakeholders to benefit from these therapies, some obstacles must be overcome, namely that:

- High list prices and smaller patient populations create unique challenges. For example, the gene therapy Strimvelis was approved in Europe in 2016 but has treated only four patients to date, and the first gene therapy to be approved, Glybera, was withdrawn from the market in 2017 with the company citing low use.[7,8]
- The bioethics surrounding CRISPR gene editing technology are evolving. A recent example of twin babies born in China with CRISPR gene modifications occurred without significant oversight, rigor, and long-term tracking of patients that has increased public scrutiny of the technology and could potentially delay future developments.
- Drugs providing full therapeutic impact after a single patient treatment, or limited period, concentrate costs over time. This may pose challenges for some payers and will require adjustments from traditional payment models.
- The manufacturing and distribution challenges in making NGBs will also limit the number of competitors, and it is expected that there will be only a few companies driving most of the activity in NGBs over the next five years.

Prescription digital therapeutics gain FDA clearance with clinical evidence

A new treatment modality is emerging as mobile apps are increasingly submitted to the U.S. FDA for clearance or approval and come to market as prescription digital therapeutics (DTx). These new mobile or software applications will come to market as prescription devices with indications and disease-specific treatment effectiveness claims in their software labels.

WHAT TO WATCH

The first DTx launched in November 2018, reSET, was approved for the treatment of substance use disorder (SUD) and will be the first of many digital therapeutic apps with novel uses to launch in the United States.[9,10,11] Many of these novel apps will initially seek FDA clearance through the De Novo pathway providing clinical evidence of outcomes and come to market with prescription labeling like medicines.[12] The following are expected to apply:

- Cognitive pathways and behavioral drivers of health are likely targets for these apps. ADHD, major depressive disorder and schizophrenia apps are among late-stage pipelines and may be early market entrants (see Exhibit 23).[39] Some apps, like the DTx Freespira for PTSD that was FDA cleared in December, may meet large unmet needs.
- To optimize returns, digital therapeutic developers may seek partnerships with pharmaceutical companies whose expertise complements their own. Pear Therapeutics has launched apps including reSET and reSET-O in partnership with Sandoz, which is expected to supply sales forces to educate clinicians and bring expertise in payer negotiation.[22]
- Pharma and biotech manufacturers are now seeing opportunities for therapeutics to be defined not only as molecule-based but also as digital therapeutics. Over the next five years, the extent to which they will pursue mobile apps to improve outcomes in their own right (not only to provide patient support

Exhibit 23: Examples of Digital Therapeutics in Late-Stage Pipelines Likely to be Dispensed by Prescription

DEVELOPER	PRODUCT	THERAPEUTIC AREA	RECENT CLINICAL PROGRAM
Pear Therapeutics and Novartis	PEAR-004 (psychosocial intervention/CBT)	Schizophrenia	Will be tested in a 102-participant sham-controlled pivotal study as an adjunct to standard of care with antipsychotic medications to further reduce symptoms of schizophrenia.[13]
Click Therapeutics	CT-152 /Click-EFMT	Major depressive disorder in adults	Multi-center, randomized, controlled, parallel-group, pivotal FDA registration trial with 348 participants[14] for the treatment of major depressive disorder in adults using a cognitive-emotionl training Emotional Faces Memory Task (EFMT).[15]
Akili Interactive Labs	AKL-T01	Pediatric ADHD	The STARS-ADHD multi-center, randomized, double-blind, active-controlled pivotal study of AKL-T01 videogame-like digital monotherapy to improve attention and symptoms of pediatric ADHD has been completed and the app submitted to the FDA. It will now also be tested as an adjunctive treatment to stimulant medication in a 203-participant single group assignment trial with one arm with and one without stimulants.[16]
DTHera	DTHR-ALZ	Alzheimer's disease	App with Breakthrough Device designation granted by the FDA[17] uses 'reminiscence therapy' psychosocial intervention, artificial intelligence and biofeedback to mitigate symptoms of agitation and depression.

Source: Clinicaltrials.gov;[13,14,16] Peer reviewed literature;[15] Company websites and public releases[17,18,19,20,21]

as drug companion apps), or will adopt these as a saleable therapeutic product for their sales forces to promote, will become clear.

- The commercialization approaches that digital therapeutic developers decide to use – how DTx are priced, whether they are successfully able to gain reimbursement from payers, and how they deploy support services to their customers – are all likely to determine whether this business model will be profitable.

- Review of regulatory submissions for software as a medical device (SaMD) may be further accelerated by the FDA's Software Precertification (Pre-Cert) Pilot Program, which enables app developers to be 'excellence-appraised' ahead of submission.[23]

IMPLICATIONS

Stakeholders are cautiously observing developments in DTx as the new modality could bring benefits, but their use must be carefully weighed against the evidence for existing options. Where drug therapy alone has left unmet needs, particularly in the areas of behavioral health and cognition, these new technologies promise substantial benefits.

- DTx may offer new therapeutic choices to individuals where medicines are not an ideal option, or for whom formal behavioral/psychological interventions are out of reach. For example, parents of children with ADHD may lean away from pharmaceutical intervention towards apps if they prove similarly effective, and medications may slowly slip from being the recommended first-line treatment.

- DTx are prescribed by physicians and reimbursed by insurers, which makes them practically no different than a drug for healthcare providers, however, the use of software-as-a-medical-device will be new to most physicians, and learning how to prescribe and interact with these apps will require education and therefore a salesforce.

- Adoption success is likely to be driven by the strength of clinical evidence and outcomes data, the simplicity for channels of distribution, ease-of-use and awareness strategies. Additionally, since app prescriptions are not sent to pharmacies to dispense, companies must build infrastructure, such as a patient and physician support centers, to help guide the patient through downloading and using the app and empower physicians to engage with any dashboards or data collected for their patient.[24]

- The shift to including clinical outcomes data in regulatory premarket applications for digital health apps reflects the growing innovation that such apps are now bringing to healthcare and to patients, and the need of app developers to now demonstrate patient outcomes to secure both approval and reimbursement. As these novel apps raise the bar on proving clinical effectiveness, an increasing number of clinical trials are likely to be run on apps in the future.

- DTx apps may provide a way to combat health disparities. For those in underserved areas where it is difficult to obtain access to treatment or in locations where seeking help for mental health still carries taboos, such apps may bring scientifically validated models of treatment to populations that otherwise would not have access.

Global health: new approaches to addressing neglected tropical disease

Neglected tropical diseases (NTDs) affect more than a billion people across 149 countries and cost upwards of a billion dollars per year.[25] These diseases have a disproportionate impact on persons living in low and middle-income countries of Africa, Asia and Latin America – particularly in areas without adequate sanitation and in close contact with infectious vectors – even though relatively basic remedies could eradicate some diseases for less than a dollar per day per person.[26,27] A number of NTDs, as well as other diseases that disproportionally affect developing nations, are considered 'tool deficient' and would benefit from significant investment, especially in drug development.

WHAT TO WATCH

Over the past decade, philanthropic organizations focused on NTDs have made considerable progress and many of the clinical development programs they started or have supported are beginning to result in drug approvals:

- There will be 5–10 new products launched in the next ten years, but most will offer incremental improvements in efficacy and tolerability versus existing treatments with only a few offering wholly new approaches or mechanisms.
- For new medicines to reach patients, governments and other stakeholders, coordination between actors will need to improve, primary care systems will need to be strengthened and financial and geographic challenges that limit the functioning of health systems in developing countries will need to be addressed.
- Continued investment by international organizations and philanthropic organizations, such as the Bill and Melinda Gates Foundation, the Global Fund and the Carter Center, could help to eradicate at least one of these neglected diseases, such as Guinea worm disease,[28] by 2020.

IMPLICATIONS

The late-stage development (Phase II and Phase III) pipeline for NTDs is primarily focused on tool-deficient NTDs that have already approved treatments or vaccines (e.g., Dengue and rabies), along with malaria, sickle-cell disease and tuberculosis (see Exhibit 24). The decision to fund research in these diseases and place them among the first priorities of philanthropic organizations derives from the perception that near-term solutions could be found and would benefit millions of people. The next wave of research funding and priorities will determine which diseases have the chance to see a first treatment, improved outcomes or even eradication.

- Investment decisions will be informed by the WHO's assessment of which diseases are neglected and/or tool-ready.
- Funding focus may shift to non-drug approaches to address root disease causes, such as sanitation or vector control, if this can lead to disease management.
- Several NTDs that have no late-stage candidates and are either treated with older, antibiotics or have no medicines would benefit from novel treatments.

Exhibit 24: Medicines for Neglected Tropical Diseases

	PHASE I	PHASE II	PHASE III AND PRE-REG	NUMBERS OF APPROVED THERAPIES
Tool-Ready NTD with Approved Therapy				
Lymphatic filariasis	2			1
Onchocerciasis (river blindness)	1			2
Schistosomiasis		1		1
Soil-transmitted helminthiasis (e.g., ascariasis, hookworm, and whipworm)				2
Taeniasis and cysticercosis				2
Tool-Ready NTD without Approved Therapy				
Dracunculiasis (guinea-worm disease)				
Echinococcosis				
Leprosy		1		
Trachoma				
Tool-Deficient NTD with Approved Therapy				
Chagas disease (American trypanosomiasis)		1		2
Dengue	2	1	1	1
Foodborne trematodiases (e.g., fascioliasis, paragonimiasis)				1
Human African trypanosomiasis (sleeping sickness)			1	4
Leishmaniasis		2		4
Rabies	1	3	1	3
Tool-Deficient NTD without Approved Therapy				
Buruli ulcer				
Mycetoma		1		
Yaws				
Other neglected diseases				
Cholera		1		4
Malaria	3	6	3	9
Sickle-cell disease	2	6	2	1
Tuberculosis	4	4	1	11
Typhoid	1	1		2

Phase I · Phase II · Phase III and Pre-Registration · Number of Approved Therapies · General Use Anti-Infective · Surgery or No Medicines

Source: IQVIA Pipeline Intelligence, Nov 2018; ClinicalTrials.gov, Nov 2018; World Health Organization. Neglected tropical diseases. Accessed Nov 2019. Available from: http://www.who.int/neglected_diseases/diseases/summary/en/; CDC. Neglected Tropical Diseases: Other NTDs. Accessed Nov 2018. Available from: https://www.cdc.gov/globalhealth/ntd/diseases/otherntds.html

Notes: NTD = neglected tropical diseases. The CDC defines tool-ready NTDs as those that can be controlled or even eliminated through mass administration of safe and effective medicines or other, effective interventions, such as vector control or sanitation. Tool-ready NTDs were identified by the WHO or CDC. In some cases, analysis of tool-readiness was estimated based on the following. Leprosy and Guinea worm disease are considered tool-ready in terms of preventative measures, not in terms of treatment with mass drug administration. Malaria and cholera can be considered tool-ready due to the availability of preventative measures, and medications to treat sickle-cell disease and tuberculosis are becoming increasingly available. Typhoid is considered tool-ready due to the availability of a vaccine and preventative measures. The number of approved therapies is based on publicly available information. Some NTDs are treated with older antibiotics even if there is no specifically approved drug for the specific indication. Pipeline information consists of active clinical programs.

Machine learning and artificial intelligence: applications expand

Big data analytics applied to large, complex healthcare databases can provide crucial knowledge, but there are challenges in linking these datasets and deriving useful insights. Artificial intelligence (AI) uses smart algorithms to analyze these datasets, and machine learning (ML), a subset of AI, goes a step further by using self-learning algorithms to refine the way big data is analyzed.

WHAT TO WATCH

Over the next five years, life sciences companies will accelerate their use of machine learning, leading to breakthroughs impacting the discovery and development of medicines and their appropriate use by patients.[29] In particular:

- Life Sciences companies will continue to develop and invest in AI, ML and deep learning programs to assess preclinical compounds, identify potential targets based on real-world data (RWD), and drive efficiencies in clinical development.
- In both commercial and clinical settings, predictive analytics powered by ML will be used to subdivide patient pools within datasets to help identify undiagnosed and untreated patients, predict the optimal timing to initiate or change patient treatment, and provide lower-cost monitoring of patient progress and selection of treatment of options over time.
- As the availability of large, complex datasets (e.g., biomarker results, pharmacokinetic profile data, electronic health records) grows, these will feed into existing applications of AI/ML and improve machine learning algorithms; however applications for personalized treatment decisions will not be routine within the next ten years.

IMPLICATIONS

While applications of AI and ML in healthcare have been developing slowly and inconsistently over the past several decades, an inflection point has been reached that will have important implications for healthcare stakeholders:

- The supply of healthcare-specific data scientists is expected to lag behind demand of companies or institutions seeking leadership or meaningful involvement in AI/ML, and so creating an attractive environment for these teams will need to be a top priority.
- New layers of complexity will be uncovered as ML is applied to new areas of science and healthcare. Some of this complexity will be unanticipated and in the near-term will lead to recognition of how little we understand about medical science, human behavior and optimizing decision-making, resulting in further expansion of efforts to apply AI and ML in even more creative ways.
- The application of AI and ML in healthcare will lead to heightened sensitivity around issues of appropriate use of personal health information, data security and patient privacy, as well as ownership and custody of data. These will be addressed differently around the world leading to a patchwork of approaches. In addition, the extent to which software will be linked directly to decision-making for patient care will raise inevitable moral and ethical issues. All participants will need to be prepared for challenges as these technologies are embraced.
- As AI and ML mature, there will be a growing thirst for ever more extensive and complex data sets, all of which must reach a standard of quality, connectedness and relevance. Although these elements are poorly defined today, the availability, curation and continued use of these very large datasets will trigger new business approaches and regulatory practices that are yet to be developed.

Real-World Evidence: expanding use and new trial designs

While randomized controlled trials (RCT) remain the gold standard for evidence in regulatory submissions, there has been increasing acceptance of the use of real-world evidence (RWE) and RWD by regulators. This has been seen in the recent approvals of avelumab (Bavencio) and blinatumomab (Blincyto), and RWE was also included in a labeling update for paliperidone palmitate (Invega Sustenna) in the United States.[30,31] In December 2018, the FDA issued a strategic framework for the expanded use of RWE in their review plans for small-molecules and biologics, as mandated by the 21st century cures act,[1] and interest in pragmatic clinical trials, which test medicines in routine clinical practice settings but at times leverage RWE, has also grown.

WHAT TO WATCH

Although RWE has been used for years in post-marketing studies and in certain rare disease trials,[32,33] there are key areas that can be expected to expand as a result of the confirmed FDA guidance, including:

- The number of trials that leverage RWE for indication expansions or product label updates will increase where there are practical reasons to conduct randomized studies in real-world circumstances. These include some pragmatic trials that combine RWE with the advantages of randomization.
- Manufacturers of therapies where safety has been well demonstrated, but additional or off-label uses of drugs have not yet been approved, will incorporate RWE to support approval for these indications.
- The use of RWE in comparative effectiveness assessments and as synthetic arms in rare disease trials will increase in cases where randomized trial requirements would harm patients due to delay or lack of access to new treatments.

IMPLICATIONS

The growing volume of RWD, as well as emerging standards for the use of these data, are building a stronger evidence-base for decisions by regulators. Use of this data could elucidate both positive and negative clinical outcomes related to medicines, and innovators, regulators, providers and patients all need to carefully assess how the evidence-basis is evolving as:

- Technology enabled trials, including apps and site-less clinical trials, along with RWE comparators could dramatically reduce research and development (R&D) costs, which can support industry or be returned to society in the form of lower drug prices.
- Approval of new indications based on RWE confirmatory evidence can increase confidence in the results or can improve the efficiency and speed of drug development, enabling new treatments to reach patients more rapidly.
- However, if new data contradict prior RCT results, it will likely not be accepted simply because the data are 'real', and will require a greater burden of proof, and likely further studies.
- Wide dissemination of trial results, along with RWE in the media (and 'Right to Try' legislation[34] that enables terminally ill patients to gain access to medications) serve to provide further evidence for decision-making by both patients and providers.

Patient engagement: pharma companies hiring patient advocacy leaders

As the U.S. market access environment has become more challenging, and company pipelines have shifted towards specialty pharmaceuticals and rare diseases (where the provision of patient support services is critical), pharmaceutical manufacturers have gradually expanded their business "beyond the pill" to build a stronger value story for payers. They have created support programs to help improve patient outcomes, improve patient adherence, reach rare patient populations and facilitate diagnosis and treatment. Pharmaceutical manufacturers have also sought to generate new evidence to show they are improving the lives of patients, their caregivers and families.[35] One aspect of this trend is the rise of senior patient affairs officers within pharma companies that has been growing since 2012.[36]

WHAT TO WATCH

Pharmaceutical companies will continue hiring specialists in patient affairs and patient advocacy, building roles internally with most of the top 20 pharma companies having a senior-level or C-suite patient role by 2019. Over the next five years, these roles intended to bring clinical and commercial efforts together, will lead to improvements in patient engagement and trial design. In particular:

- These roles will build the strength of the patient voice both within and outside the company by leading a number of initiatives focusing on patient experience, including building repositories of RWE and encouraging the growth of patient registries that can be used for partnerships (see Exhibit 25).

Exhibit 25: Roles Responsibilities and Approaches for Patient Advocacy Personnel

ROLE RESPONSIBILITIES	APPROACH
Understand patient needs, priorities and the patient journey	• Help set direction for research within the internal organization • Leverage social media to gain valuable patient journey insights • Uncover ways to enable patients to find and receive appropriate care
Help internal organization and/or external advocacy groups build RWE platforms and gain access to data	• Use big data from RWE and other sources to set metrics, provide insight and add value for patients
Drive change and patient focus throughout the organization	• Shift the mindset of the internal organization that everything focuses on the patient • Demonstrate the value patient centricity can bring to the business to encourage systemic adoption of new approaches
Build partnerships with patient advocacy organizations and patient opinion leaders	• Gain partners and support for therapeutic projects and understand how to improve care • Obtain aid in recruiting patients for clinical trials • Leverage advocacy organizations' abilities to build data repositories and discuss policy and access issues • Leverage organizations' abilities to lobby for patient interests
Facilitate patient input to clinical trial design, including patient-reported outcomes and trial environment	• Ensure clinical trials do not put undue burden on patients leading to high dropout rates and underpowered trials • Seek and incorporate patient input to maximize patient involvement, patient experience and outcomes measures important to the affected population
Support digital patient engagement and work with digital policy partners to leverage technology to serve patient needs in new ways	• Enhance therapeutic outcomes and solutions through digital or other services to support those needs better to keep patients enrolled • Build business value of patient support programs

Source: IQVIA Institute, Dec 2018
Notes: RWE = real-world evidence

- Digital, patient-facing technologies will continue to see uptake in both clinical protocols and patient therapeutic care, to the benefit of all stakeholders.[37] These patient-facing engagement technologies will be leveraged to more accurately measure patient outcomes and side effects, help provide emotional support and facilitate access-to-care for patients and care-givers.
- Use of patient-reported outcomes (PRO) data will continue to grow in clinical trials as it becomes more valued as a success measure for healthcare interventions and is understood to more fully reflect patient experience on medications.
- Payers and providers will increasingly be offered patient-centric outcomes measures rather than purely economic or clinical ones and these approaches may influence negotiated prices and market access.

IMPLICATIONS

With pharmaceutical companies better engaging external patient advocacy groups, this will have important implications across stakeholders:

- Manufacturers with a more patient-centric focus are likely to outperform otherwise equivalent competitors as they find ways to appeal to multiple stakeholders in otherwise undifferentiated therapy areas.
- Patients will be better served as these roles ensure clinical trial design meets the needs of the community and help PRO data gain further consideration by payers.
- As the people hired into patient care and patient advocacy roles will often come from the same non-profit and third-party organizations they seek to influence, pharma companies will gain a route to build better outreach to these patient populations and improve patient engagement.
- The Chief Patient Officer and the Chief Digital Officer may vie for control of digital tool development for patient engagement. Regardless of which role leads, the value of digital tools is still evolving, and by 2023 the use of apps and wearables to provide value in healthcare, both clinically and in R&D, will be routine.

Pricing environment: U.S. pricing policy reforms enacted

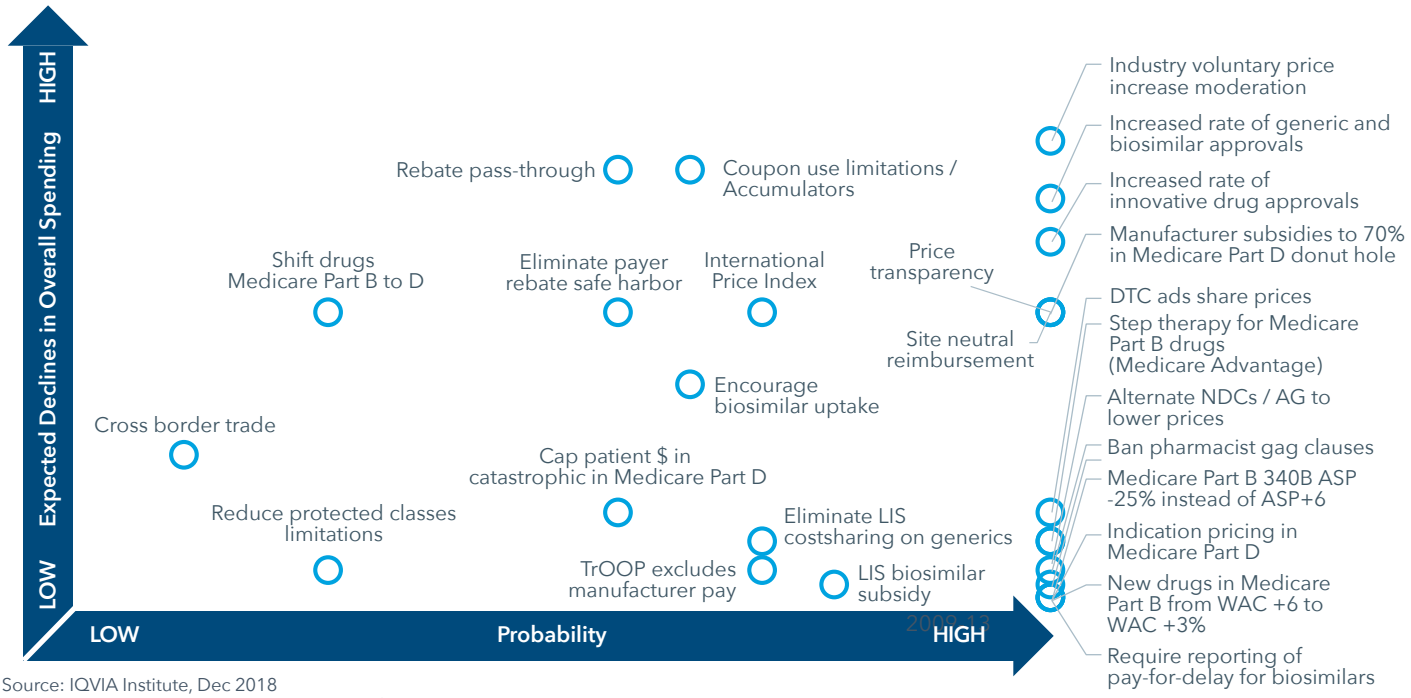
While manufacturers are free to set the prices of their drugs in the U.S. market, the ultimate prices paid by payers and patients are determined through a highly fragmented system of rules and negotiations for those with public or private insurance. Within this environment, commercial insurers and healthcare providers have continued to consolidate, building their negotiating power relative to each other and to manufacturers, and shifting the tools and mechanisms they use to influence medicine use and negotiate the prices paid for them.

WHAT TO WATCH

Over the past five years, a series of high-profile, widely-criticized examples of inappropriate drug pricing have shifted public perceptions of drug prices, and most stakeholders now believe that they are paying inappropriately high costs for medicines. The federal government has stopped short of government price controls but has proposed a sweeping set of pricing reforms for government programs with varying levels of impact and probability of being enacted (see Exhibit 26).

- Due to divided government in 2019, policies in the presidential administration's blueprint will be instituted largely through executive rulemaking authority in the Departments of Health and Human Services, Centers for Medicare & Medicaid Services or FDA.
- The effect of each of the policies on net spending by payers, net out-of-pocket costs, and net manufacturer revenue will all vary independently, in line with the complexity of the current system.
- The current gap between list and net prices could drop from the current $150 billion to from $75 to $100 billion with the difference returned to American consumers (or their employers) in the form of lower

Exhibit 26: U.S. Recent Policies and Proposals, their Impact and Probability



Source: IQVIA Institute, Dec 2018
Notes: ASP = average selling price; WAC = Wholesale Acquisition Cost; DTC = direct-to-consumer; LIS = low-income subsidy; TrOOP = true out-of-pocket; AG = authorized generics; NDC are unique drug identifiers

point-of-sale prices. These shifts are also likely result in lower intermediary profits, including managed care companies and healthcare providers, and potentially cause insurance premiums to rise.

- List price increases, and drug prices at launch, will be carefully managed to avoid the appearance of impropriety, but the shift to more specialty, niche and orphan drugs will continue the trend for headline-grabbing price points, potentially raising doubts about the efficacy of the reforms.

IMPLICATIONS

The discussion of drug pricing has evolved from an initial public outcry at price increases and the cost of a single year of therapy for a life-saving drug, to demands for transparency and calls for substantive action to reduce prices. The primary goal of the federal government's reforms is to address patient out-of-pocket costs, as well as Medicare and Medicaid exposure to costs, but there could be significant unintended consequences, including:

- At a time when commercial insurance markets are evolving rapidly, pharmacy benefit managers (PBMs) are integrating with payers, and plans are shifting to high-deductible, value-based and copay accumulator benefit designs, policy changes could be disruptive and add confusion for plan sponsors and patients.
- In a market rapidly shifting to remove or reduce rebates, the disruption from change, and its speed, could induce manufacturers into price competition where it has not existed and potentially reduce their margins. This is arguably a goal of the proposals.
- Each stakeholder in the U.S. healthcare system has a different exposure to the prices of medicines and each will have to examine the reforms carefully as they relate to their own book of business, portfolio or patient mix. Manufacturers will also have differing exposure to the various policies.

Emerging biopharma companies: growing influence in late-stage pipeline and launches

Emerging biopharma companies (EBP) are those with less than $500 million in revenue or with less than $200 million in R&D spending. Over the past decade, the percent of R&D activity being led by EBP companies has increased from 60% in 2009 to 72% through October 2018 (See Exhibit 27). Additionally, EBP companies are increasingly taking their products to market on their own, with the segment launching 68 New Active Substances (NAS) over the past five years, up from 47 in 2009 to 2013.

WHAT TO WATCH

Over the next five years, the number of EBP-launched drugs will continue to increase due to shifts in company strategy as well as the rising absolute number of active R&D compounds. Specifically:

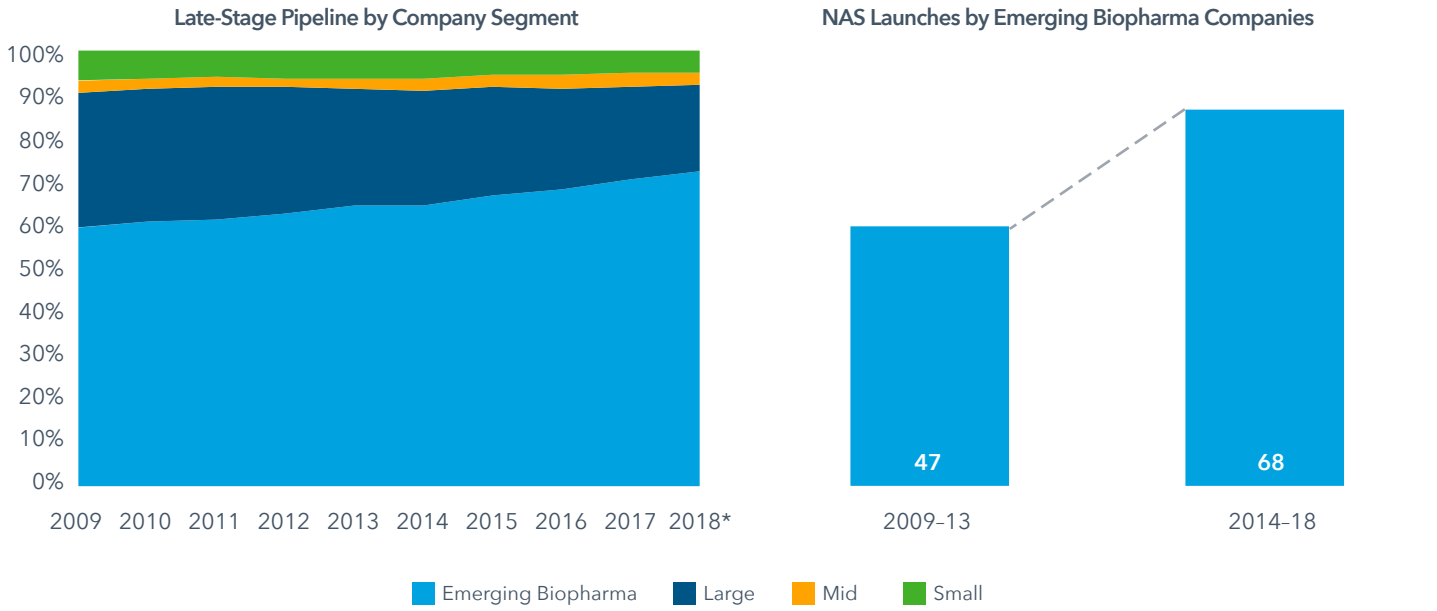
- More than one-third of drugs launched in the next five years will be brought to market by EBP companies.
- More EBP companies, seeking to maximize investor returns, will market their own developments without a large pharma partner.

IMPLICATIONS

Whether companies choose to partner, acquire or go to market alone will depend on how their individual assets are valued in the market by investors or potential partners. This is likely to continue current trends in mergers and acquisitions as well as partnering and other company commercial strategies including:

- Large pharma companies partnering with EBP companies rather than acquiring them, or encouraging incentive-based agreements that mitigate risks.
- New EBP companies being more aggressive commercially, amplifying competitive intensity in some therapy areas.

Exhibit 27: Emerging Biopharma Company Launches Over Time



Source: IQVIA Pipeline Intelligence, Oct 2018; IQVIA Institute, Dec 2018
Notes: *Reflects pipeline through October 4th 2018. Companies assigned to segments based on MAT Sep 2018 Revenues or 2017 R&D Spend. Segments defined at company level as: Large >$10Bn; Mid $5-10Bn; Small $500Mn-5Bn; Emerging Biopharma (EBP) <$500Mn OR R&D Spend <$200Mn. If multiple companies involved in a project, the larger segment takes precedence. Launches YTD December 5th 2018.

Large pharma margins: doubling down on innovation and technology-driven efficiencies

Biopharmaceutical companies have been aggressively reshaping their businesses after the patent cliff in the early 2000s, shifting their portfolios to more specialty and niche products and achieving operational efficiencies that enabled them to maintain operating margins.

WHAT TO WATCH

The next five years will likely pose a similar scale of challenges. With payer actions on prices looming, it remains to be seen whether companies can repeat their past successes in terms of revenue and cost management. In the face of these challenges:

- Companies both large and small will continue to adopt modern cloud-based and multi-channel marketing solutions to coordinate their stakeholder engagements in an increasingly complex and fast-changing marketplace.
- Companies will become more adept at predicting revenue and more rapidly right-size operational support for their products.
- Large companies will more often partner with emerging biopharma companies around launches rather than buying those assets outright when the commercial results are less certain, mitigating risks and enabling tighter control over operating costs and margins.
- Companies that fail to maintain current margins may have to make cuts to salesforces, R&D spend or may be acquired by other companies.

IMPLICATIONS

Rather than simply cutting costs, reducing salesforce sizes and outsourcing, companies are increasing their investments in technologies that enable their teams to work smarter. Opportunities remain to improve operations and costs with some caveats:

- If companies are faced with large scale price cuts from payers in major markets, there could be challenges in offsetting lower-than-expected revenues with cuts through investments in modernization.
- The investments in technology and efficiencies will likely not be enough to offset wholesale price adjustments that may come from major markets, particularly in the United States
- Those companies with weaker portfolios or lagging in the adoption of operational efficiencies may require more dramatic adjustments including cuts to R&D investment, as well as cuts to operating costs that could affect performance.

Opioid epidemic: declining role of prescription opioids

Prescription opioid use in the United States peaked in 2011 on a per capita morphine milligram equivalent (MME) basis and has now declined for seven consecutive years. The rate of decline in prescription opioid use has been variable across states due to a complex interplay of factors including uneven prevalence of chronic pain, as well as legal, regulatory and clinical practice guidelines, and socioeconomic and historical differences that surround both the pain-patient experience and the medicines they are prescribed.

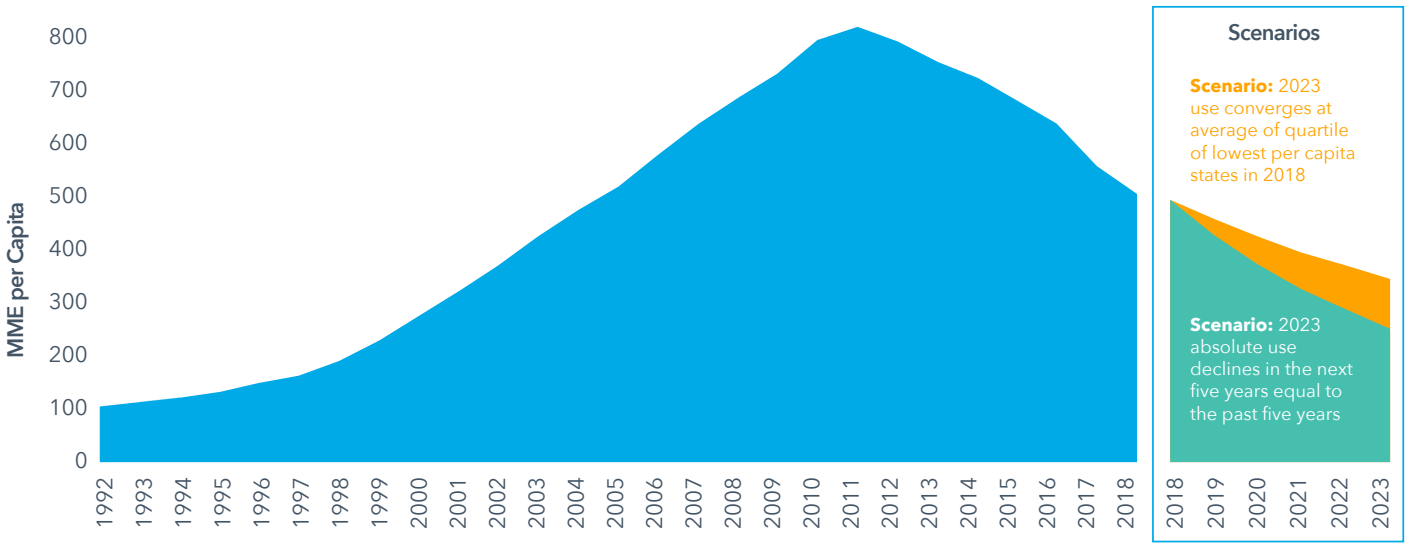
WHAT TO WATCH

It is likely that existing policies, as well as new legislation at both the state and federal levels, will impact opioid prescribing and use through 2023. However, the dynamics around prescription opioid use and issues around illicit drug use and overdose, will remain complex and challenging to address. Likely scenarios for levels of prescription opioid use include: a continuation of the ongoing rapid declines in use, or a pattern of convergence at the levels of current lower-use states. The level of MME per capita in these two scenarios would be approximately one-half to one-third the peak level measured in 2011, and approach levels seen in mid-2002 or mid-2000, respectively (see Exhibit 28).

In the scenario where opioid use continues to slow at the rate of the past five years, it will likely be the result of:

- Continued implementation and impact of policies, laws and practice guidelines introduced over the past two years, including the class-wide Risk Evaluation and Mitigation Strategy (REMS) introduced by FDA in 2018 for immediate and extended-release formulations.[38]

Exhibit 28: Scenarios for Prescription Opioid Volumes in the United States per Capita in Morphine Milligram Equivalents (MME)



Source: IQVIA "SMART – Launch Edition", Sep 2018; IQVIA Institute, Dec 2018
Notes: States with MME per capita below the average of the lowest quartile do not change in the convergence scenario.

- New state laws in states currently lacking restrictive opioid rules.
- More complete effects of the expanded funding for the opioid crisis passed by Congress in 2018.

In the alternative scenario, higher-use states adopt policies that enable them to converge at a lower level of prescription opioid use, but lower-use states will be unable to continue dramatic reductions in use.

- This would still lower use nationally by approximately 30% over the next five years.
- Use would drop to 2.4 times the 1996 level, which is often referred to as the point prior to the greatest escalations in prescription opioids.

IMPLICATIONS

Many cities and states are currently pursuing similar approaches to the opioid crisis (and have reduced prescription opioid levels dramatically) but are achieving wildly different results as measured by overdoses and deaths. The underlying variability in their outcomes suggests that there may be many different effective approaches and that each city or state's circumstance is unique. Agencies, regulators, legislators, advocates, healthcare providers and patients are expected to redouble their efforts to address the opioid crisis, but motivation may not be sufficient. To succeed:

- New policies and new coordination by multiple stakeholders, both public and private, will need to develop.
- New programs must be evaluated for their impact on many different processes and outcomes measures, including the rates of addiction, rates of overdoses and the quality of care of those with pain, as well as the cost of the programs.
- It will remain equally important for stakeholders to observe other programs and continually assess new options in an evidence-based way to make informed choices and build locally-adaptable approaches to address the opioid crisis.

Updates on past predictions

In last year's report *'2018 and Beyond: Outlook and Turning Points'* the Institute for Human Data Science originally predicted the following. Here are those predictions published in March 2018 and the current assessment:

1. FDA guides use of real-world data for medicines	
Prediction	**Assessment**
• In 2018, the FDA will release guidance for clarifying appropriate use of RWE in both approval and post-approval settings. • By 2022, proof cases of RWE use in regulatory decisions will be driving expanded roles and demand for RWE in supporting decision-making.	• The FDA announced their draft guidance in December as expected and continue to gradually evolve the standards and practices for the use of RWE in clinical trials, post-approval marketing and supportive studies to characterize and understand diseases.

2. Next-Generation Biotherapeutics move toward mainstream	
Prediction	**Assessment**
• In 2018, 5–8 new cell-based therapies, gene therapies, and/or regenerative medicines will be approved. • Over the next five years, up to 20% of innovative therapeutics will be Next-Generation Biotherapeutics.	• No new next-generation products were approved in 2018, however a previously approved medicine launched. • Over 100 such products are in active R&D with more than half in cancer, and the number of new products in early phase trials continues to increase, but 1–2 launches per year are expected through 2023.

3. Apps make their way into treatment guidelines	
Prediction	**Assessment**
• In 2018, over 300 digital health efficacy studies will be completed and published, strengthening the body of evidence to support new treatment guidelines that incorporate apps. • Major groups, such as the American College of Cardiology, will incorporate apps into clinical guidelines and protocols within five years, following the lead of the American Diabetes Association.	• Continued expansion of the number of active studies, as expected. • More institutions are recommending apps as part of protocols and prescribing them to patients. • A growing number of apps are being studied for health outcomes, and digital, prescription therapeutics are being approved (e.g., reSET).

4. Telehealth use broadens

Prediction	Assessment
• In 2018, nearly all commercially insured U.S. patients will have some form of telehealth service included in their plans. • Rapid adoption is expected as costs are so much lower than emergency room (ER) or office visits though challenges remain to assure appropriate.	• Despite widespread coverage under insurance and by employers, patient adoption of telehealth remains modest and slowed in 2018 relative to 2017. • Some experts suggest that the concept of meeting patients 'where they are' would be more appropriately served with pop-up kiosks in larger retailers, or the continued expansion of in-store clinics and urgent-care centers.

5. Branded medicine spending in developed markets falls

Prediction	Assessment
• In 2018, net manufacturer revenue for brands in developed markets will decline by 1–3% reducing net revenue by approximately $5 billion to approximately $391 billion. • Over the next five years, total net brand revenue will be flat: payers will spend the same in 2022 for brands as in 2017, despite the expected flow of new medicines.	• Early assessments suggest a very slow rate of net growth (0–2%), but faster than the previously expected slight decline.

6. Specialty medicines drive all spending growth in developed markets

Prediction	Assessment
• In 2018, specialty medicines will account for 41% of total medicine spending in developed markets and will drive all spending growth.	• Specialty medicines share exceeded 42% of total medicines spending in 2018 in developed markets. Furthermore, specialty medicines drove 92% of spending growth in 2018 and an expected 83% of the growth through 2023.

7. Slower growth in China and other pharmerging markets

Prediction	Assessment
• Growth of pharmerging markets in 2018 will be 7–8%, marking the third consecutive year of single-digits growth.	• Pharmerging growth was 6.9% in 2018 and is expected to slow to 5–8% through 2023.

UPDATES ON PAST PREDICTIONS

8. U.S. real net per capita spending on medicines steadies

Prediction	Assessment
• Medicine costs on a real net per capita basis will decline in 2018 and continue almost unchanged at about $800 per person through 2022. • Innovative medicines will enter the market at higher price levels but be offset by the impact of patent expiries and moderate levels of net brand price increases in the range of 2–5% annually.	• Real net per capita spending will grow at 1.8% over the next five years, slightly faster than forecast. • Net brand prices are expected to increase at 0–3% over the next five years compared to the 2–5% embedded in the past forecast, however new product growth is expected to increase to offset much of the effect.

9. Outcomes-based contracts find limited role

Prediction	Assessment
• Over 10 new outcomes-based contracts will be publicly announced in 2018. • By 2022, 30 out of the 50 top medicines will incorporate some outcomes measures in some or all of the contracts between manufacturers and payers.	• Through September 2018, there were nine newly announced contracts compared to the expected 12–15 per year.

10. New wave of biosimilar market opportunity emerges

Prediction	Assessment
• In 2018, $19 billion of current biotech spending will become exposed to biosimilar competition for the first time in one or more of the developed markets, up from the $3 billion that became exposed in 2017. • This signals the next large wave of biosimilar opportunity with an additional $52 billion of exposure added in 2019–2022.	• New biosimilar competition entered developed markets for $23 billion of current biotech spending. • Over $48 billion of current sales is expected to face competition between 2019 and 2023.

Notes on sources

THIS REPORT IS BASED ON THE IQVIA SERVICES DETAILED BELOW

National Sales Perspectives (NSP)™ measures spending within the U.S. pharmaceutical market by pharmacies, clinics, hospitals and other healthcare providers. NSP reports 100% coverage of the retail and non-retail channels for national pharmaceutical sales at actual transaction prices. IQVIA invoice prices reflect the drug prices as received on the direct sales transaction received by IQVIA. IQVIA invoice prices do not reflect off-invoice discounts and rebates separately paid to insurers, or other price concessions paid to patients or other health system participants.

"SMART – Launch Edition" is a service that allows users to study the market uptake and launch criteria, both of the marketplace and product, for branded and generic launches from 1992 to present-day.

IQVIA MIDAS™ is a unique data platform for assessing worldwide healthcare markets. It integrates IQVIA national audits into a globally consistent view of the pharmaceutical market, tracking virtually every product in hundreds of therapeutic classes and providing estimated product volumes, trends and market share through retail and non-retail channels. MIDAS data is updated monthly and retains 12 years of history.

IQVIA™ Market Prognosis is a comprehensive, strategic market forecasting publication that provides decision makers with insights on the drivers and constraints of healthcare and pharmaceutical market growth. This includes political and economic developments, alongside dynamics in healthcare provision, cost containment, pricing and reimbursement, regulatory affairs and the operating environment for pharmaceutical companies. Market Prognosis contains economic forecasts from the Economist Intelligence Unit and delivers in-depth analysis at a global, regional and country level, and analyzes dynamics at distribution channel, market segment and therapy class level.

IQVIA™ Pipeline Intelligence is a drug pipeline database containing up-to-date R&D information on over 40,000 drugs, and over 9,000 in active development worldwide. The database captures the full process of R&D, covering activity from discovery stage through preclinical and clinical development, to approval and launch.

Ark Patent Intelligence is a database of biopharmaceutical patents or equivalents worldwide and including over 3,000 molecules. Research covers approved patent extensions in 52 countries, and covers all types of patents including product, process, method of use and others.

IQVIA™ Therapy Prognosis Global covers ATC3 level sales forecasts for major therapy areas in 14 key markets, 8 developed (U.S., Japan, Germany, France, Italy, Spain, U.K., and Canada) and 6 pharmerging (China, Brazil, Russia, India, Turkey and Mexico) and includes interactive modeling and event-based forecasts and comprehensive market summary.

Appendix

Methodology

ESTIMATES OF NET MANUFACTURER REVENUE AND PRICES

IQVIA audits reflect invoice-based pricing derived from proprietary information gathered from wholesalers and company direct sales. While IQVIA invoice prices reflect supply-chain price concessions, they do not reflect the off-invoice discounts and rebates separately paid to insurers, or other price concessions paid to patients or other health system participants. Estimated net prices and revenue are projected from a sample of large and mid-sized companies analyzed from 2011–2017, and projections of expected future changes to volume and prices to 2023. Branded products are included in the sample if their net sales amount is disclosed in financial filings with the Securities and Exchange Commission (SEC) and if the volume of sales captured in IQVIA audits is consistent with information provided directly by manufacturers in support of IQVIA proprietary datasets. Net prices are calculated by dividing publicly reported net sales values by volumes for the same products reported to IQVIA. Estimated brand net price growth for the total market is projected from the analysis sample to the total market. Net prices represent an estimate of the average manufacturer realized price, reflecting any reductions in net revenues due to off-invoice discounts, rebates, co-pay assistance or other price concessions, and do not necessarily reflect the net costs paid by insurers, the federal government or patients, which all vary significantly and independently. For generic companies, a sample of five large generic companies' generic portfolios were analyzed in aggregate consistent with their SEC filings, as specific generic product analyses are not possible. See Medicine Use and Spending in the United States, April 2018 for more details.

JAPAN ANALYSIS OF GROWTH DRIVERS:

Growth for specialty medicines and traditional medicines were first forecast on a variable exchange rate basis, and then only growth associated with changes in share of per capita spending were associated with specialty or traditional growth. Changes in per capita spending on a variable exchange rate basis are reflected as population dynamics. The difference in forecast growth on a variable exchange rate basis and forecast growth on a constant dollar basis is labeled as exchange rate effects. Overall growth over the five years declines on a constant dollar basis as illustrated in Exhibit 12, however spending grows 1.0% on a variable exchange rate basis. Exchange rates and population estimates provided by the Economist Intelligence Unit (EIU).

NEW ACTIVE SUBSTANCES:

Medicines are considered a NAS if at least one active ingredient has not been previously marketed globally. IQVIA analyzes launches globally and assigned NAS launches based on observed or reported launches rather than announced regulatory approvals alone. Predictions of future launches have been based on the success rates and durations of historic launches and R&D phase transitions and are informed by the actively researched R&D activity and historic launches around the world.

BIOSIMILAR MARKET ENTRY DATES:

Originator biologic medicines have been researched to determine the relevant dates of patent expiry or end of market exclusivity. In many cases, there are multiple patents, only some of which are expected to constrain biosimilar entry. Additional research has identified announced settlement of litigation and the associated biosimilar entry dates. Where an originator product

is expected to face biosimilar competition in some developed markets and no information is known in others, the subsequent five-year period is assumed for those unknown countries. For example, Exhibit 19 shows 2024–2028 or 2029–2033 as future five-year periods, and if a product is expected to see competition in 2022 but no information exists for other developed markets, those countries have been set to see competition in 2024–2028 for the purposes of assessing the scale of future competition. For originator biologics launched in the past 10 years (2009–2018) and with no known patent expiry information identified in the research, an assumed protected life of 15 years has been applied, resulting in all products seeing competition after 2024. For products launched more than ten years ago, and with no patent information and no announced biosimilar activity, no assessment of future biosimilar competition has been made.

OPIOID MARKET DEFINITIONS FOR ANALYSES

Prescription opioid use analyses have defined the market as treatments for pain management, and exclude treatments used exclusively to combat opioid use dependence, but does include medicines that are mostly used for pain treatment but have some use in opioid dependence. The Centers for Disease Control and Prevention (CDC) have defined factors to reflect the potency of different prescription opioids relative to 1 milligram of morphine.

Exhibit 29: Morphine Equivalency Segments and Factors

Low Equivalency (ME factor <1)	
Anileridine	0.25
Codeine	0.15
Dihydrocodeine	0.25
Meperidine	0.10
Pentazocine	0.37
Propoxyphene	0.06
Tapentadol	0.40
Tramadol	0.10

Equivalent (ME factor = 1)	
Hydrocodone	1
Morphine	1
Nalbuphine	1
Opium	1

High-Equivalency (ME factor 1.5–100+)	
Buprenorphine	10 or 75
Butorphanol	7
Fentanyl	10–100+
Hydromorphone	4
Levorphanol	11
Methadone	3
Oxycodone	1.5
Oxymorphone	3

Notes:
Fentanyl is commonly referred to as having an MME of 50 or higher, but the MME factors vary based on formulation for this drug. The most commonly prescribed fentanyl formulation (transdermal patch) has an MME factor of 100. Other forms, including injectables and oral formulations (spray, buccal, sublingual, lozenges) have MME factors with scale based on strength from 10 to over 200.

Source: Centers for Disease Control and Prevention (CDC)

SPECIALTY PHARMACEUTICALS

IQVIA defines specialty medicines as those that treat chronic, complex or rare diseases, and that have a minimum of four out of seven additional characteristics related to the distribution, care delivery and/or cost of the medicines.

- Chronic diseases are long-lasting and often without direct cure, and treatments are intended to be used for more than six months.
- Complex diseases have both environmental and genetic components, meaning they can may be hereditary and/or exacerbated by environmental factors (e.g., obesity, diet, etc.). Complex diseases can affect multiple organ systems and may be caused or be the cause of secondary diseases (e.g., diabetes can cause renal failure such that both are considered complex diseases).
- Rare diseases are defined as those with fewer than 200,000 new cases annually, equivalent to the U.S. definition of orphan diseases, but not exclusively linked to the granting of an FDA orphan drug designation.

Additional product characteristics, where a product must exhibit four of the seven to be considered specialty are:

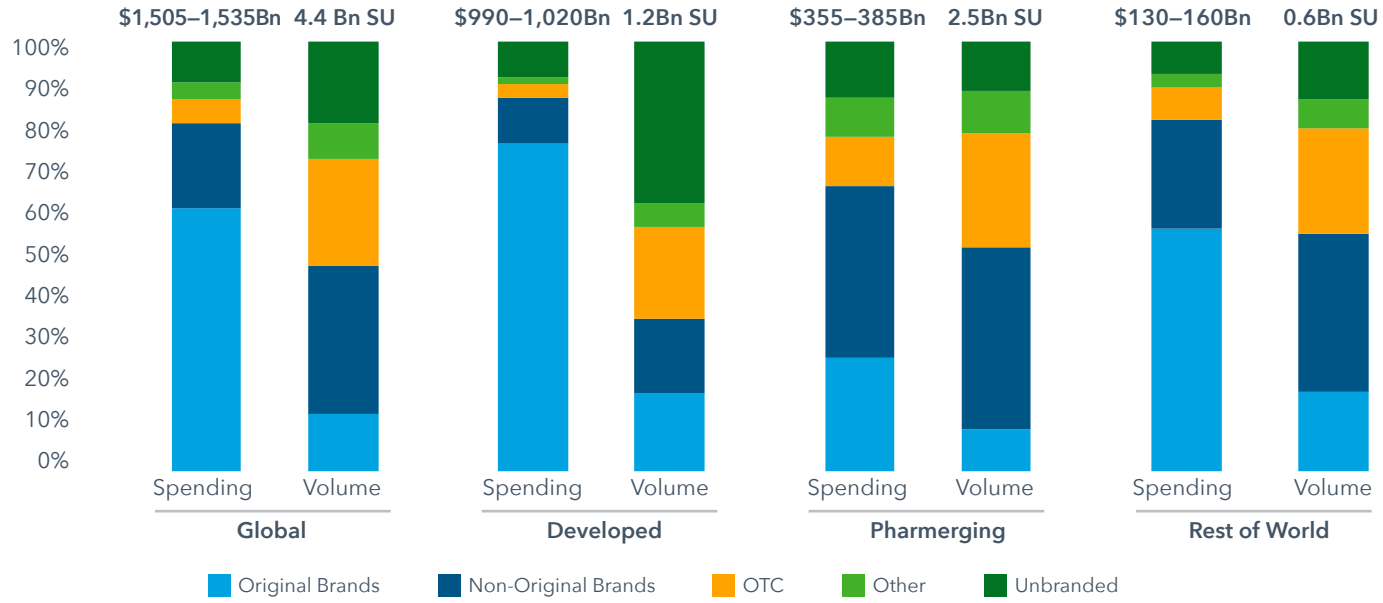
- Costly: list price is in excess of $6,000 per year
- Initiated/maintained by a specialist
- Requiring administration by another individual, or health care professional (i.e., not self-administered)
- Requiring special handling in the supply chain (e.g., refrigerated, frozen, chemo precautions, biohazard)
- Requiring patient payment assistance
- Distributed through non-traditional channels (e.g., 'specialty pharmacy')
- Medication has significant side-effects that require additional monitoring/counselling (including, but not limited to REMS programs) and/or disease requires additional monitoring of therapy (e.g., monitoring of blood/cell counts to assess effectiveness/side effects of therapy).

COMPANY SEGMENTATIONS

- Large: >$10bn in annual global revenue on audited basis from IQVIA MIDAS
- Mid-sized: between 5–10 billion in annual global revenue on audited basis from IQVIA MIDAS
- Small: between $500 million and 5 billion in annual global revenue on audited basis from IQVIA MIDAS
- Emerging biopharma: less than $500 million in annual global revenue on audited basis from IQVIA MIDAS or less than $200 million in R&D spending in latest year.

Appendix exhibits

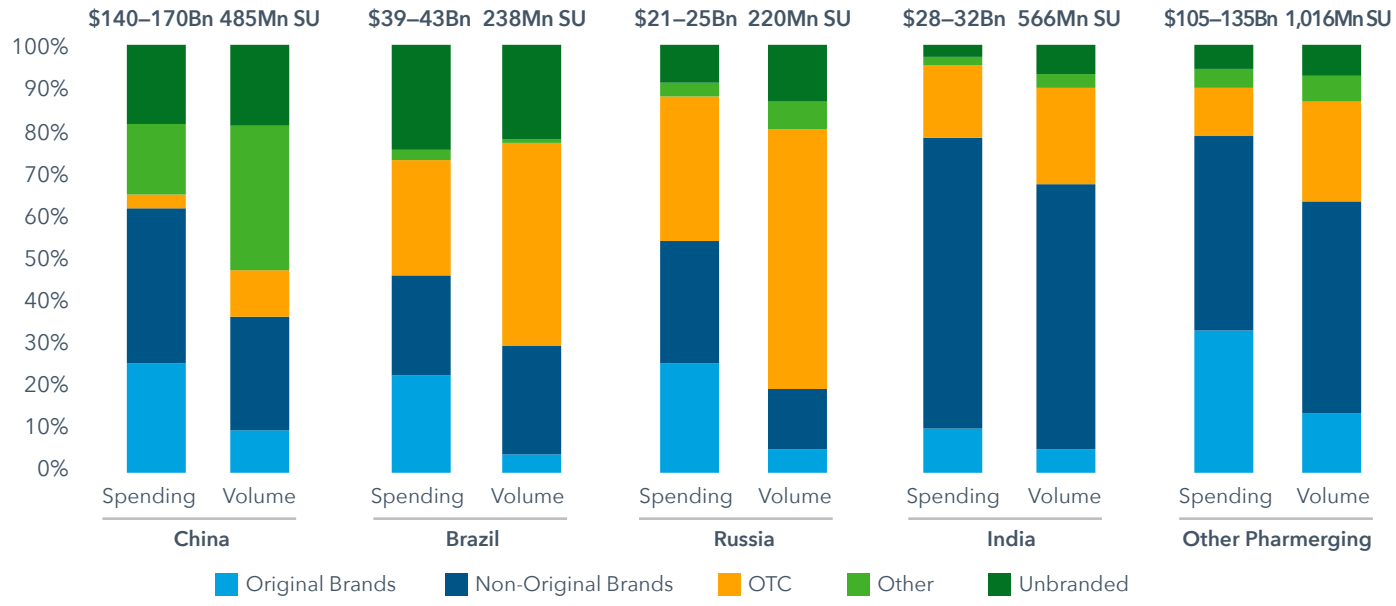
Exhibit 30: Global Medicine Spending and Volume by Region and Type, 2023



Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018

Notes: SU = Standard Units; OTC = Over-the-Counter; Spending in US$Bn. Developed markets include the United States, United Kingdom, Germany, Italy, Spain, France, Japan, Canada, South Korea and Australia. Pharmerging countries are defined based on per capita income below $30,000 and a five-year aggregate pharmaceutical growth over $1 billion.

Exhibit 31: Pharmerging Medicine Spending and Volume by Type, 2023



Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018

Notes: SU = Standard Units; OTC = Over-the-Counter; Spending in US$Bn. Pharmerging countries are defined based on per capita income below $30,000 and a five-year aggregate pharmaceutical growth over $1 billion.

APPENDIX EXHIBITS

Exhibit 32: Leading Therapy Areas Spending and Growth in Select Developed and Pharmerging Markets

THERAPY AREAS	2018 CONST US$ SPENDING	2014–18 CAGR CONST US$	2023 CONST US$ SPENDING	2019–2023 CONST US$ CAGR
Oncology	99.5	13.1%	140–150	6–9%
Diabetes	78.7	15.2%	115–125	7–10%
Respiratory	60.5	5.7%	70–80	2–5%
Autoimmune	53.5	15.4%	70–85	6–9%
Pain	39.7	0.9%	40–48	0–3%
Antibiotics and Vaccines	40.6	2.3%	40–48	0–3%
Mental Health	35.5	-2.6%	32–40	(-2)–1%
Blood Coagulation	39.8	13.1%	55–65	7–10%
Hypertension	29.9	-3.6%	27–31	(-2)–1%
Immunology	34.2	11.7%	45–55	6–9%
All Others	392.7	4.8%	440–470	1–4%

Source: IQVIA Therapy Prognosis, Sep 2018; IQVIA Institute, Oct 2018
Notes: Includes eight developed countries (United States, France, Germany, Italy, Spain, United Kingdom, Japan, Canada) and six pharmerging countries (China, Brazil, Russia, India, Turkey, Mexico). CAGR = Compound Annual Growth Rate.

Exhibit 33: Global Medicine Spending Share and Growth by Region and Product Type

SPENDING 2023 US$	ORIGINAL BRANDS	NON-ORIGINAL BRANDS	OTC	OTHER PRODUCTS	UNBRANDED	TOTAL US$BN
Global	61%	20%	6%	4%	9%	1,505–1,535
Developed	76%	10%	3%	2%	8%	90–1,020
Pharmerging	27%	40%	11%	9%	13%	355–385
Rest of World	56%	26%	7%	3%	8%	130–160

2019–2023 CAGR CONSTANT US$	ORIGINAL BRANDS	NON-ORIGINAL BRANDS	OTC	OTHER PRODUCTS	UNBRANDED	TOTAL GROWTH
Global	4–7%	5–8%	3–6%	0–3%	(-1)–2%	3–6%
Developed	4–7%	5–8%	0–3%	0–3%	(-5)–(-2)%	3–6%
Pharmerging	6–9%	5–8%	5–8%	0–3%	7–10%	5–8%
Rest of World	2–5%	3–6%	2–5%	2–5%	0–3%	2–5%

Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018
Notes: CAGR = Compound Annual Growth Rate; OTC = over-the-counter

Exhibit 34: Global Spending and Growth in Selected Countries

	2018 SPENDING US$BN	2014–2018 CAGR CONSTANT US$	2023 SPENDING US$BN	2019–2023 CAGR CONSTANT US$
Global	**1,204.8**	**6.3%**	**1,505–1,535**	**3–6%**
Developed	**800.0**	**5.7%**	**90–1,020**	**3–6%**
U.S.	484.9	7.2%	625–655	4–7%
EU5	177.5	4.7%	200–230	1–4%
Germany	53.5	5.0%	65–69	3–6%
France	36.8	1.5%	37–41	(-1)–2%
Italy	34.4	6.3%	40–44	2–5%
U.K.	28.4	6.2%	33–37	2–5%
Spain	24.6	5.4%	27–31	1–4%
Japan	86.4	1.0%	89–93	(-3)–0%
Canada	22.2	5.0%	27–31	2–5%
South Korea	15.8	4.7%	19–23	4–7%
Australia	13.1	4.3%	13–17	0–3%
Pharmerging	**285.9**	**9.3%**	**355–385**	**5–8%**
China	132.3	7.6%	140–170	3–6%
Tier 2	67.7	10.7%	91–95	7–10%
Brazil	31.8	10.8%	39–43	5–8%
India	20.4	11.2%	28–32	8–11%
Russia	15.5	9.9%	21–25	7–10%
Tier 3	85.9	11.3%	105–135	7–10%
Rest of World	**118.9**	**3.2%**	**130–160**	**2–5%**

Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018

Notes: Spending in US$Bn, CAGR = Compound Annual Growth Rate using Constant US$ with Q2 2018 exchange rates.

APPENDIX EXHIBITS

Exhibit 35: Global Top 20 Countries Ranking and Spending Relative to U.S.

2013				2018				2023			
RANK		COUNTRY	% OF U.S.	RANK		COUNTRY	% OF U.S.	RANK		COUNTRY	% OF U.S.
1		U.S.	100	1		U.S.	100	1		U.S.	100
2	▲1	China	28	2		China	28	2		China	27
3	▼1	Japan	24	3		Japan	18	3		Japan	12
4	▲1	Germany	12	4		Germany	11	4		Germany	10
5	▼1	France	10	5		France	7	5	▲2	Brazil	7
6		Italy	7	6		Italy	7	6		Italy	6
7	▲1	U.K.	6	7	▲1	Brazil	6	7	▼2	France	6
8	▲3	Brazil	5	8	▼1	U.K.	6	8		U.K.	5
9	▼2	Spain	5	9		Spain	5	9	▲2	India	5
10	▼1	Canada	5	10		Canada	5	10	▼1	Spain	4
11	▲3	India	3	11		India	4	11	▼1	Canada	4
12	▼2	South Korea	3	12		South Korea	3	12	▲1	Russia	4
13	▼1	Australia	3	13	▲1	Russia	3	13	▼1	South Korea	3
14	▲5	Russia	3	14	▼1	Australia	3	14	▲3	Turkey	3
15	▼2	Mexico	2	15		Mexico	2	15	▲4	Argentina	2
16	▲7	Saudi Arabia	2	16	▲1	Poland	2	16	▼2	Australia	2
17	▲1	Poland	2	17	▲9	Turkey	2	17	▼2	Mexico	2
18	▼1	Belgium	2	18	▼2	Saudi Arabia	2	18	▼2	Poland	2
19	▼3	Netherlands	2	19	▲27	Argentina	1	19	▼1	Saudi Arabia	2
20		Switzerland	1	20	▼2	Belgium	1	20	▲6	Vietnam	1

Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018

▲▼ Change in Ranking over Prior Five Years

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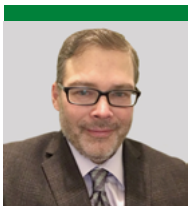

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About the Institute

The IQVIA Institute for Human Data Science contributes to the advancement of human health globally through timely research, insightful analysis and scientific expertise applied to granular non-identified patient-level data.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved human outcomes. With access to IQVIA's institutional knowledge, advanced analytics, technology and unparalleled data the Institute works in tandem with a broad set of healthcare stakeholders to drive a research agenda focused on Human Data Science including, including government agencies, academic institutions, the life sciences industry and payers.

Research Agenda

The research agenda for the Institute centers on 5 areas considered vital to contributing to the advancement of human health globally:

- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing the performance of health systems by focusing on patient centricity, precision medicine and better understanding disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.
- Understanding the future role for biopharmaceuticals in human health, market dynamics, and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.
- Researching the role of technology in health system products, processes and delivery systems and the business and policy systems that drive innovation.

Guiding Principles

The Institute operates from a set of Guiding Principles:

- Healthcare solutions of the future require fact-based scientific evidence, expert analysis of information, technology, ingenuity and a focus on individuals.
- Rigorous analysis must be applied to vast amounts of timely, high quality and relevant data to provide value and move healthcare forward.
- Collaboration across all stakeholders in the public and private sectors is critical to advancing healthcare solutions.
- Insights gained from information and analysis should be made widely available to healthcare stakeholders.
- Protecting individual privacy is essential, so research will be based on the use of non-identified patient information and provider information will be aggregated.
- Information will be used responsibly to advance research, inform discourse, achieve better healthcare and improve the health of all people.

The IMS Institute is now the IQVIA™ INSTITUTE for Human Data Science

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