Pricing pressures rising globally, threats of impacts on R&D innovation worldwide

Accelerating medicines spending

Drug spending and growth is expected to accelerate globally over the next few years but varies across countries.[1] Spending for medicines is largely correlated with degrees of economic development and should be considered in the context of a country's overall health care expenditures[2] and health expenditures in the context of GDP.[3] Use of medicines is typically higher in higher income countries than in lower income countries (figure 1).[4]

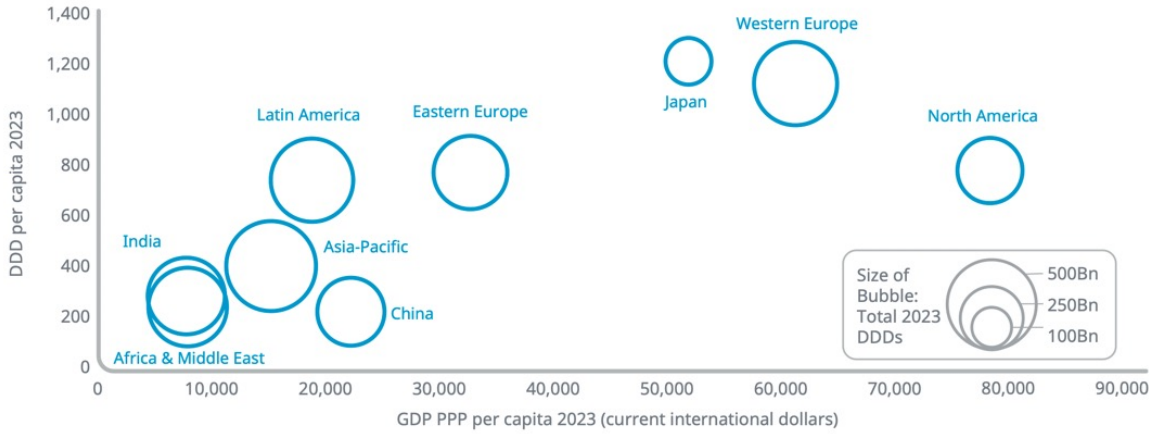
Some countries are more volume driven, while others are focused on the adoption of innovation in medicines.[5]

Specialty medicines are projected to represent more than 40% of global spending by 2028, with more than half of total spending in leading developed markets.[6]

Both population-driven volume growth—and a shift in the mix of medicines to higher cost products—is expected in North America, Eastern and Western Europe, Latin America, Africa, and the Middle East over the next five years. At the same time, China's drug spending looks to be less volume-oriented and more focused on expanding access to novel drugs, while Japan's spending is not likely to change as innovation is offset by annual price cuts.[7]

Figure 1. Per capita use of medicines

Defined Daily Doses (DDD) per capita by region compared to per capita gross domestic product (PPP), current international dollars



Source: IQIVIA Institute, December 2023; The World Bank, July 2023; International Monetary Fund, October 2023

Drug pricing pressures worldwide

Drug pricing and value continue to come under scrutiny as pricing pressures are being felt globally.[8] In 2024, government-mandated pricing pressure and controls are expected to play an increased role in the affordability and accessibility of certain medicines.[9] It's a complex topic, governed in wide ranging ways across the world, and requires taking multiple stakeholder perspectives in balance.

Direct drug pricing negotiations by the US government are underway for the first time in the US.[10] While the US government has a range of policy initiatives aimed at addressing drug pricing, the health care provisions of the Inflation Reduction Act (IRA)[11] are raising concerns among some drugmakers.[12]

In Europe, there is similar price consciousness. For example, in the UK, a new price regulation agreement–the voluntary scheme for branded medicines pricing and access (VPAS)—was reached to control the level of spending on innovative drugs.[13] VPAS sets a cap on the total allowed sales value of branded medicines to the UK National Health Service (NHS) on an annual basis.[14] The cap grows at an agreed rate of 2% per annum, but any medicine sales above the cap are required to be paid back to the UK Department of Health and Social Care (DHSC) via a levy.[15]

In Asia, Japan has steadily reduced prices every other year, ranging from around 2% to 9.4% after the latest fiscal year-over-year (FYoY) 2023 review.[16] China is leveraging its large population for its volume-based procurement strategy, significantly reducing prices while saving approximately US$36.3 billion at the end of 2021.[17]

Developed-world concerns around drug pricing are pushing the unaffordability of medicines to the top of the global health agenda as discussed at the World Health Assembly (WHA) in 2023.[18] Less-developed countries have voiced concerns over unaffordability of medicines for their health systems for decades. In 2024, the Access to Medicines Foundation is enhancing regulatory coordination in low- and middle-income countries (LMICs). The organization's updated biennial report is expected in 2024 and is expected to assess how pharma companies monitor the number of patients with access to their essential health care products in LMICs.

Implications of the US Inflation Reduction Act

The impact of pricing and access to medicines leads the list of concerns of more than half of US life sciences companies in 2024, according to a survey by Deloitte US.[19] Over the next five years, the IRA is expected to have implications for how the industry makes decisions and allocates resources in both research and development (R&D) and commercial efforts with corresponding implications for access to drugs across the world. The US holds almost a 43% share of the global pharma market and is home to some of the largest pharma companies worldwide.[20]

The IRA may have a positive effect for patient affordability given reduced out-of-pocket expenses for patients in Medicare Part D, and negotiated drugs are expected to be provided to patients at the negotiated price. Furthermore, smoothing is slated to begin in 2025, capping Medicare Part D out-of-pocket prescription drug costs at $2,000 annually.[21] As a result, it's anticipated that there may be major changes to commercial insurance design over the next few years, including pressures to incorporate patient out-of-pocket costs on net vs. list prices.

There can be material implications for drug companies with respect to gross-to-net, total molecule value—particularly for negotiated assets, price adjustments, and capital allocation for R&D and business development (BD).

A downstream effect is expected from the IRA on the operations and financials of health insurance plans, pharmacy benefit managers (PBMs), pharmacies, employers, hospitals, health systems, and other providers in the US. The price-negotiation provisions, for example, will likely impact the drug-acquisition price for providers and pharmacies and their reimbursement rates, in addition to rebates. Amongst all the players, the effects of lower negotiated prices put pressure on business practices.[22]

There may also be unintended consequences, such as differences for small molecule vs. biologic drugs as well as orphan drug dynamics (multiple vs. single orphan drug exclusion). Several negotiated drugs expect to have generics/biosimilars introduced within 12-24 months or less. In order to not create financial incentives that could deter biosimilars from entering the market, the IRA provides for a delay in selecting drugs for negotiation.[23]

Government's in-depth reviews on the drugs selected

An in-depth review of the first 10 drugs selected for negotiation is provided by the US Department of Health and Human Services (HHS)—the "Medicare Drug Price Negotiation Program: Understanding Development and Trends in Utilization and Spending for the Selected Drugs." Drugs selected represent nearly 20% of spending in the Medicare Part D drug benefit and were approved by the FDA more than seven years ago.[24]

According to the report, prices for the 10 drugs selected had more than doubled from 2018 to 2022, from US$20 billion to about US$46 billion, an increase of 134%.[25] In addition, the rate of growth in spending for these 10 drugs was more than three times as fast as for all Medicare Part D drugs over the same period.[26] List prices being negotiated factor into both insurance premiums and patient out-of-pocket costs.[27]

First 10 drugs selected for price negotiations

Drugs selected represent nearly 20% of spending in the Medicare Part D drug benefit and were approved by the US Food & Drug Administration (US FDA) more than seven years ago.[28] In 2024, the US administration is moving forward on seeking price cuts for 10 drugs covered by US Medicare that are commonly prescribed to older and disabled Americans; another 60 will be negotiated by 2029 (figure 2).[29] The first round includes medications for diabetes, heart-failure, arthritis, psoriasis, Crohn's disease, ulcerative colitis, blood thinners, and treatment for blood cancers. "Orphan" drugs for rare diseases, which treat conditions affecting fewer than 200,000 people, were excluded.

Drugs purchased at pharmacies under Medicare Part D are part of the first two years of negotiations, with Medicare Part B drugs, those administered by doctors, being added in 2028. Prices for the first 10 drugs are expected to be revealed by September 2024.[30]

In addition to the drug negotiation program, the IRA requires drugmakers that sell drugs through Medicare to pay rebates to the US government for drugs increasing in price faster than the rate of consumer inflation. As part of the rebate provision, prices for 48 prescription drugs included in Medicare Part B beneficiary coinsurances may be lower starting between 1 January 2024–31 March 2024.[31]

Government view, focus on cost savings

The drug negotiation program is estimated to potentially save Medicare US$100 billion[32] of the US$237 billion in overall savings projected for the IRA's drug pricing provisions over the next decade.[33] The US government believes Americans should not be paying two to three times more than what people

Figure 2. First 10 drugs up for Medicare price negotiation cuts in 2024

Drug	Type of medication	Pharma company
Eliquis	Blood thinner	Pfizer and Bristol Myers Squibb
Xarelto	Blood thinner	Janssen Pharmaceuticals, Inc., part of Johnson & Johnson, and Bayer
Jardiance	Diabetes, heart failure	Boehringer Ingelheim and Eli Lilly
Januvia	Diabetes	Merck & Co.
Farxiga	Diabetes, chronic kidney disease	AstraZeneca and Bristol Myers Squibb
Novolog	Diabetes	Novo Nordisk
Enbrel	Arthritis, psoriasis	Immunex, a subsidiary of Amgen
Stelara	Psoriasis, Crohn's disease, ulcerative colitis	Janssen Biotech Inc., part of Johnson & Johnson
Entresto	Heart failure	Novartis
Imbruvica	Cancers of the blood	Pharmacyclics, an AbbVie Company, and Janssen Biotech Inc., part of Johnson & Johnson

Source: US Department of Health and Human Services

in other Organisation for Economic Co-operation and Development (OECD) countries pay for the same drugs—even when accounting for rebates and discounts.[34]

A recent US Senate Health, Education, Labor, and Pensions (HELP) Committee staff report highlighted the high cost of drugs in the US compared to other countries.[35] The issue is complex, and there are many variables to consider. For example, HELP's focus is on gross prices that are part of the negotiations. Manufacturer gross drug prices for brand name originator drugs are significantly higher in the US than other countries—422 percent of prices in comparison countries in 2022.[36]

What the drug manufacturer receives, the "net" price, can be up to 75% less. Negotiated and statutory rebates to third-party payers are the largest share of gross-to-net differences.[37] In the first three quarters of 2023, net prices for brand-name drugs dropped for the sixth year in a row, with real, inflation-adjusted net prices falling -7.4% in 2023.[38]

Comparisons of gross prices shape public perception, and for 158 million Americans with employer-based plans, premium contributions and out-of-pocket costs, like those for prescription drugs, are taking up an increasing portion of US household budgets.[39] The US government increases demand for prescription drugs by subsidizing employment-based health insurance in addition to being the primary funder of basic research in biomedical sciences.[40]

Pharma industry view, focus on pharmacy benefit manager reform

Drug manufacturers point to PBMs as needing significant reform.[42] A concern for the Pharmaceutical Research and Manufacturers of America PhRMA is that the US government's policy presents barriers to transparency and accountability. Prescription drugs are the only part of the US health care system where the difference between list and net prices is monetized as rebates that are redistributed via intermediaries to payers.[43] PhRMA President and CEO Stephen Ubl says reforms should shift focus to ensure that rebates companies negotiate with intermediaries (like PBMs) are passed onto patients at the pharmacy counter.[44]

PBMs were introduced into the system to manage benefits for health plans, and while they were

Where does the money go? Gross-to-net price differences

A drug's net price represents the actual revenues that a manufacturer earns from a drug after paying rebates, applying discounts, and other reductions.[41] Gross-to-net price differences for brand-name drugs include:

- Rebates, discounts, and fees to commercial payers and plans
- Rebates and coverage gap discounts in Medicare Part D
- Rebates to the Medicaid program
- Discounts under the 340B Drug Pricing Program
- Manufacturers' payments to drug channel participants, including administrative and other fees to PBMs as well as fees and discounts to pharmacies, wholesalers, and other purchasers
- Patient assistance and copayment support funds

supposed to lower health care costs,[45] manufacturers' list prices actually increased to accommodate rebates.[46] PBMs' use of pharmaceutical rebates allows multiple players in the supply chain to potentially benefit financially at the expense of patients and control patients' access to certain drugs.[47] In addition, PBMs own their own pharmacies, and many believe this ownership creates huge conflicts of interest—hurting competition and distorting pricing.[48]

The US House of Representatives launched a report in 2023 that found:

- PBMs often require burdensome prior authorization that may cause lengthy delays to approve prescriptions.
- With lengthy delays, some patients may suffer, and even die, while they await authorization.[49]
- Some patients first have to fail to respond to a more expensive drug, even if a cheaper alternative exists because the PBM may have a financial incentive to compel the more expensive drug.[50]

Provisions in the US Department of Health & Human Services (HHS) November 2020 final rule on pharmacy benefit managers' rebates should eliminate rebates in favor of point-of-sale discounts in the Medicare Part D and Medicaid managed care organization programs.[51] Essentially, the rule is designed to remove the anti-kickback safe harbor for rebates.[52] However, implementation of the rule was deferred, and the IRA has extended the time to implement the rule until 2032. [53]

Industry stakeholders are also concerned about the disproportionate power and influence of the three largest PBMs that control over 80% of all prescription drug access and reimbursement in the US.[54] In 2022, these PBMs excluded more than 1,150 medicines from their standard commercial insurance formularies, representing a nearly 1,000% increase in exclusions since 2014, including medicines that would provide patients needed treatments at lower costs.[55]

Experts say out-of-pocket costs for many patients have risen as leading PBMs logged double-digit profit growth.[56] Enforcers, like the US Federal Trade Commission (FTC), and lawmakers in Congress have started focusing on PBMs with hearings and bills, and PBMs will likely remain on the hot seat.[57]

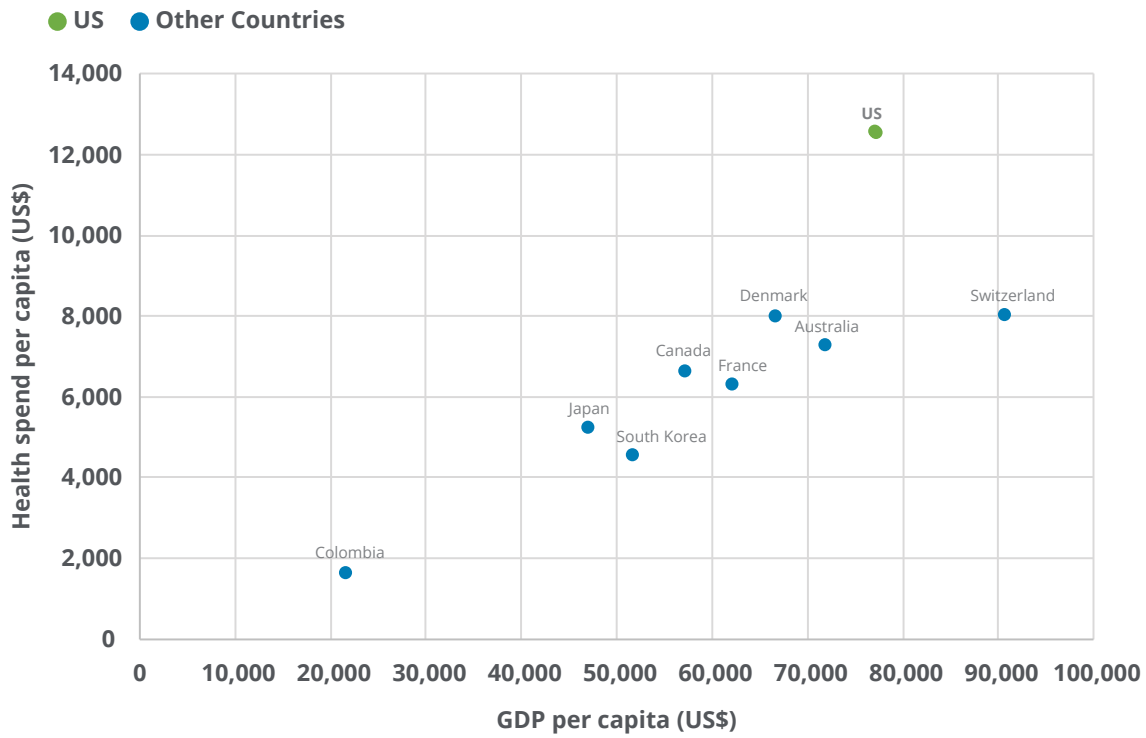
"The US is the only country where our members are capturing less than 50 cents on the dollar of the list price of the medicine, with the rest being absorbed very efficiently by other actors in the supply chain."

—Stephen Ubl, president and CEO of PhRMA[58]

Drug pricing in the context of per capita health expenditures and GDP

The US spends considerably more per capita on health expenditures than peer nations, spending about US$12,500 in health expenditures per capita, with a GDP per capita of approximately US$77,000 in 2022 (figure 3).[59] Switzerland and Germany have the next highest health expenditures per capita, at about US$8,000 each per capita in 2022; GDP per capita in 2022 was higher for Switzerland at about US$90,000, and close to US$67,000 in Germany.[60]

Figure 3. GDP per capita and health consumption spending per capita, US dollars, 2022 (current prices and PPP adjusted),



Source: Petersen KFF Health Tracker, analysis of OECD data

As an example of the wide range in prices paid for essential medicines across the world, in 2019, the median price paid for 60 tablets of the blood thinning medication Eliquis by a sample of private health insurers was US$440 in the US, US$162 in Switzerland, and US$96 in Germany in 2019 (figure 4).[61] The price in the US was 4.5 times more than in Germany.[62]

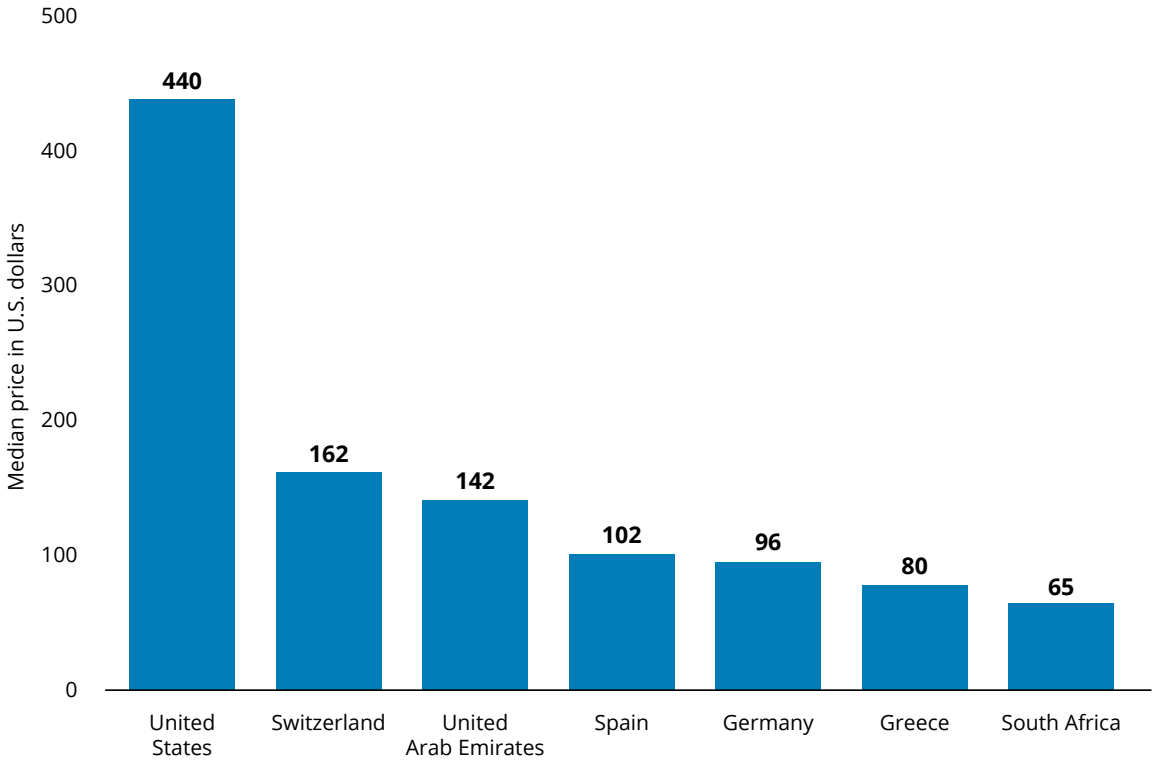
The Bristol Myers Squibb (BMS) customer savings and support webpage promotes that Eliquis is covered by 90% of commercial and Medicare Part D plans, but out-of-pocket copays vary. The webpage offers a US$10 copay card to apply towards any copay for patients deemed eligible to receive it, which could be those who have insurance and still have a copay or those without insurance.[63]

Discounted prices advertised for 60 tablets of Eliquis by GoodRX, available to consumers from leading pharmacies in the US, are in the range of about US$592 to US$626—a savings of 9% to 17% off the retail price.[64] GoodRX's discount and coupon prices are

based on contracts between a pharmacy (or pharmacy purchasing group) and a PBM that provide the prices and are a best estimate.[65] Some patient assistance programs (PAPs) also provide those with limited incomes access to free or low-cost prescription drugs from the drug manufacturer.[66]

As we point out in the patient section of this outlook, some patients do not even know who manufactures their drugs, and more than one company is associated with many drugs. Finding the best available price and discount is not just a patient problem, it can become an administrative cost and burden on health care professionals (HCPs), pharmacists, communities, and the health care system as a whole if patients cannot afford the medicines they need and risk suffering additional health consequences.[67]

Figure 4. Median prices paid for Eliquis by a sample of private health insurers in select countries in 2019



Notes: Prices are for Eliquis (apixaban 5mg) – 60 pills. The source compared the median prices paid by a sample of private health insurance companies for 34 specific health care services in 11 countries in 2019. Health cost comparisons among various countries are complicated by differences in sectors, fee schedules, and prices may not be representative of prices paid by other plans in that market. The limitations were minimized by selecting services with very specific definitions and wording survey questions to match the procedures that are the basis of the US payment system.

Source: Statista, 12 August 2022

CMS hosts patient "listening sessions" in support of Medicare negotiations

Concern about high copays were expressed at the patient listening session for Eliquis—hosted by the US Centers for Medicaid and Medicare Services (CMS)—and open to the public online.[68] These live-streamed listening sessions are opportunities for patients, patient advocacy groups, caregivers, and others to provide feedback on the values of particular drugs.[69] Ten sessions were held in Q4 2023, one for each drug being negotiated.[70]

Transcripts for the sessions are available on the CMS website,[71] including a transcript for the Eliquis session.[72] One medic, representing Doctors for America as its Vice Chair for Access to Affordable Care, points out that high copays for Eliquis are not insignificant for seniors on a fixed income.[73]

Area of high public interest and opinion

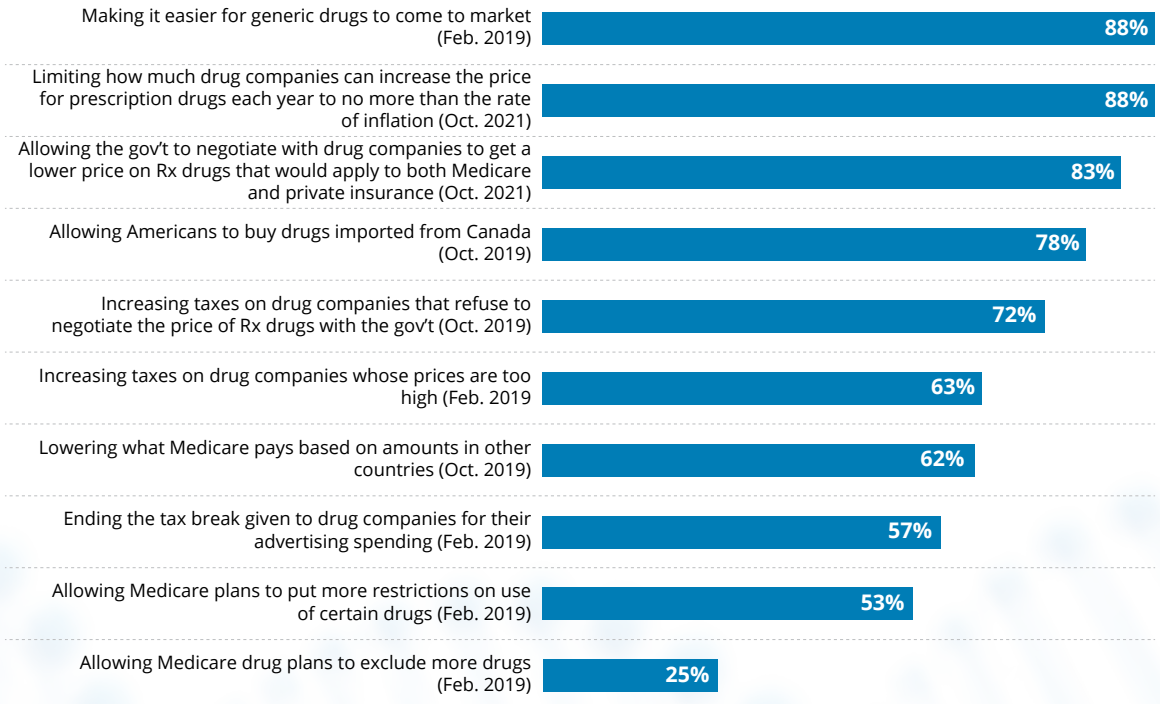
The pharma sector faces growing public scrutiny and media attention regarding drug pricing transparency and affordability.[74] More than 900 name brand drugs have price increases taking affect at the beginning of 2024.[75] But the median wholesale acquisition cost (WAC) increase of 4.7% is now the lowest percentage increase in more than a decade, down 0.1% from 2023.[76]

Many believe the pharmaceutical industry is viewed unfavorably due to the rising (and total) cost of prescription drugs.[77] Research organizations have been polling public opinion in the US for decades,[78] and 93% of Americans feel drugmakers would still make enough money if prices were lowered.[79]

A 2023 poll found that 82% say the cost of prescription drugs is unreasonable, and almost three-quarters of Americans feel there should be more regulation to limit the price of drugs.[80] An end of the year 2022 poll queried Americans regarding support of various proposals for lowering drug costs (figure 5).[81]

Figure 5. Tracking US public opinion on drug cost regulation, November-December 2022

Percent who favor each of the following actions that would keep prescription drug costs down:



Source: KFF Health Tracking Poll (29 November-8 December 2022)[82]

Reducing the price differences between the US and other countries

Reductions in administrative burdens and drug costs could substantially reduce the difference between US and peer nation health spending.[83] While drug manufacturers say price cuts can negatively affect innovation,[84] the US government's view is that companies spend more on stock buybacks and dividends than they do on research and development (R&D).[85] Accordingly, the IRA has tax implications, including a 1% share buyback excise tax and a corporate alternative tax of 15% for companies meeting the thresholds.[86]

Pharma industry view, focus on innovation

According to PhRMA, members want to get patients access to the medicines they need, but believe the IRA is a threat to innovation and collaboration.[87] PhRMA member companies have more than doubled their annual investments in the search for new treatments and cures over the last decade.[88]

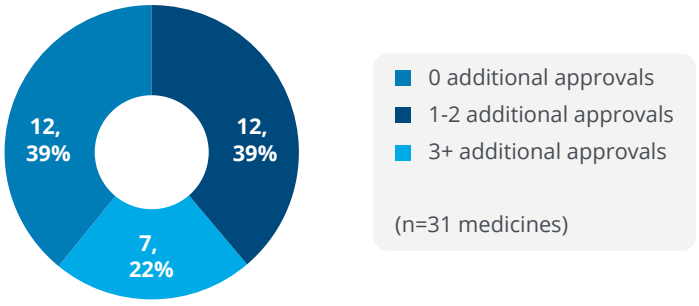
From discovery to launch, drug manufacturers spend an average of US$2.3 billion to bring a new drug to market.[89] The top 20 global pharmaceutical companies collectively spent US$139 billion on R&D in 2022.[90]

PhRMA states that the IRA ignores the nature of the R&D process by not considering:

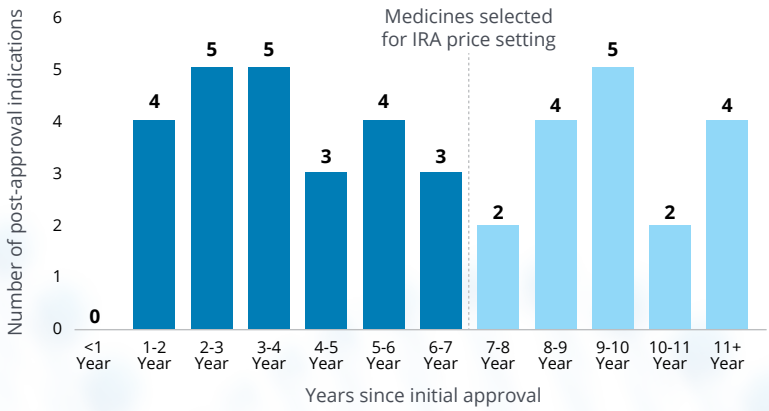
- Innovations that occur past the time of their first USFDA approval (figure 6)—new uses for medicines, new patient populations, new formulations, and new dosage forms.
- The real-life impact new drugs and treatments can have on patients.
- The increase in therapeutic value over time as medicines are approved for new uses—such as in new patient populations, for use with new diseases or new stages of disease.[91]

Figure 6. IRA's price setting impact on cancer medicines, research from the Partnership for Health Analytics and Research (PHAR)

Number of cancer medicines by number of post-approval indications
For small molecule oncology medicines receiving initial FDA approval between 2006-2012



Timing of post-approval indications
For small molecule oncology medicines receiving initial FDA approval between 2006-2012



Source: PhRMA, research from PHAR

Lawsuits argue the constitutionality of the pricing negotiation framework

As part of the IRA, a new US excise tax, ranging from 65%-95% on all US sales by a pharmaceutical manufacturing company, may potentially be applicable to pharmaceutical manufacturers who do not enter into a negotiation program with the US government to determine maximum prices.[92]

While all the companies representing the first 10 drugs selected signed agreements to negotiate,[93] PhRMA, drugmakers, some patient advocacy groups, and others, initiated lawsuits against the constitutionality of the measure. [94] The Global Colon Cancer Association (GCCA) joined PhRMA's lawsuit because it believes that the IRA could thwart progress in colon cancer research that is affecting more Americans under 50.[95] According to GCCA Executive Director Andrew Spiegel, "The IRA is implementing a process where patient voices and concerns have no real seat at the table." [96] He says patients deserve better, and that's why GCCA joined in the lawsuit.[97]

As of 1 May, the courts have rejected the PhRMA lawsuits including one brought by AstraZeneca[98]—signaling that the pharmaceutical manufacturers may not secure legal protections. However, PhRMA filed an appeal,[99] and a federal judge in New Jersey is permitting four other drugmakers—BMS, Novo Nordisk, Novartis, and Johnson & Johnson—to combine their arguments.[100] Additional lawsuits are still pending.[101]

Impacts on portfolio strategies

Will less revenue mean less drug innovation?[102] Lowering US drug prices may impact incentives to innovate because drugmakers are likely to be less profitable.[103] The IRA is already affecting R&D decision-making and portfolio strategies as there is uncertainty around planning. Some companies are rethinking R&D investments—shifting away from small molecule investments.[104]

In a survey of 25 participating PhRMA members, three-quarters say early-stage pipeline projects are likely to be cancelled and two-thirds say pipeline projects that are planned, but not yet in clinical development, will likely no longer be pursued. More than half expect to reduce spending on new scientific platforms that may take many years to develop.[105]

Nonetheless, recent research by the Congressional Budget Office (CBO) expects that about 13 out of 1,300 new drugs, or 1%, over the next three decades would not make it to market as a result of changes brought about by the IRA.[106] Other experts say novel discoveries are mostly the result of taxpayer investments in academic research and startups.[107] However, how those new discoveries are accelerated and studied is predominantly funded by the pharma sector, not biotechs, given the cost.

Acumen Pharmaceuticals is an innovative biotech company specializing in novel Alzheimer's disease therapeutics, with a focus on toxic amyloid beta oligomers. Acumen received funding from the US Department of Health & Human Services (HHS),[108] and recently was awarded "[the 2023] Monoclonal Antibody Solution of the Year" by the BioTech Breakthrough Awards program. [109] Acumen CEO Daniel O'Connell says that in order to really bring attention to Alzheimer's disease, and meet the market's needs, it will require the support of large pharma companies.

"We are in the early days of launching disease modifying treatments for Alzheimer's disease patients. Large pharma companies, like Biogen, Eisai and likely Eli Lilly are helping to establish the market. Over the next few years, with additional data and time, opportunities will start to open up. Buyers are trying to assess how big the Alzheimer's market is really going to be. Large pharma companies, like Biogen and Eli Lilly have added to the mix. Depending on the drug growth trajectory with those initial products, companies like Merck, maybe AbbVie and BMS, will be looking for their play. That is going to contribute to some level of partnering and M&A that will further catalyze growth of the Alzheimer's space.

Knowing the mindset within the business leadership of these big pharma companies right now, there is a "wait and see, show me" kind of attitude for Alzheimer's disease. For Acumen, and our mAb (monoclonal antibody), it's a greenfield; there is no prior precedent. The field is in the process of establishing the patient journey, the infrastructure, etc. It's going reasonably well, and by this time next year, we're going to be convinced that the commercial possibilities are very real and growing. It'll be an important time for us to continue to position our asset and program as one with attractive differentiation and long-term potential. And there's an important role for the larger pharmaceutical companies to play in bringing these innovations to commercialization and ultimately have the envisioned patient impact."

—**Daniel O'Connell**, CEO at Acumen Pharmaceuticals
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IRA impact requires a balanced view from stakeholders

In 2024, pharmaceutical leaders should consider ways to make products more commercially accessible through different payment schema. In the next few years, patients may lose out for niche indications as the IRA is discouraging the development of some types of medicines and treatments for certain patient populations. These effects are likely to spread throughout the world as the US leads transformative innovation.

No doubt the impacts of the IRA will be profound in the US as well as globally, but the precise impact and timing is still unfolding. All sides present strong arguments. Pharma wants to keep innovating—and be incentivized to do so. Patients want fair prices and HCPs want patients to be able to afford their necessary medicines. And the US government wants more equitable prices—as it is carrying a large share of the burden to make these drugs available globally.

Pricing pressures challenge Japan's innovative reputation in medicines

While Japan is known for developing innovative medicines, recent pricing pressures, akin to those in other parts of the world, are also driving reforms.[111] Reforms are creating uncertainty for pharmaceutical companies in the world's third-largest pharma market as well as concerns over the future of innovation.[112]

The Japanese government reimburses patients for drugs at prices specified in the Drug Price Standard (DPS). The DPS covers all medications dispensed by the National Health Insurance (NHI) and stipulated by Japan's Ministry of Health, Labour and Welfare (MHLW).[113]

Health care funding sources, public vs. private

Health care in Japan is publicly funded, while health care delivery is primarily done through private institutions.[114] In the UK, the health care system is mostly public, while predominately private in the US (figure 7).

Japan's health care system is known for maintaining relatively low health care costs compared to other developed countries.[115] In 2022, its health expenditure per capita was US$5,250, less than half of that for the US.[116] While patients in Japan have copays, there are caps on out-of-pocket expenses.[117]

Figure 7. Countries' health care service provider and its financial resource

Country	Primary service provider	Financial source*2
	Private (Public: 5%)*1	**Public** (Public: 84%)
	Private (Public: 23%)*2	**Private** (Public: 51%)
	Public (Public: almost all)*2	**Public** (Public: 79%)
	Private (Public: 45%)*2	**Public** (Public: 77%)
	Private (Public: 25%)*2	**Public** (Public: 78%)

Note: *1=Japan's MHLW data, 2021; *2=OECD, data, 2020
Source: Deloitte analysis

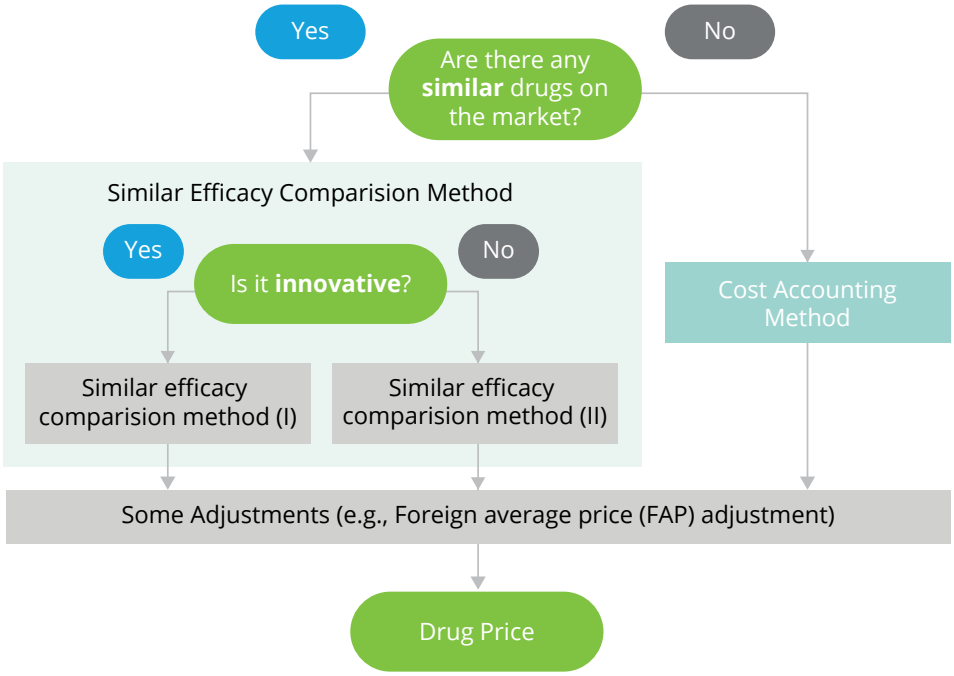
In FY2023, Japan's average drug price decreased 9.4% for 2,000 drugs in the DPS,[118] accounting for 36% of products increased in the FY2023 DPS.[119] This 9.4% decrease in 2023 for Japan's drug prices is twice the size of the 4.7% drug price increase in the US for 2024, reflecting some of the differences between countries with publicly funded health care systems and private.[120]

A new layer between market access and reimbursement

While the US government recently started considering value assessments through price negotiations, Japan was one of the first countries to introduce cost-effectiveness data for pricing new pharmaceutical products in 1992.[121] But a new Cost-Effectiveness Analysis (CEA) implemented in 2019 is testing the country's reputation for innovation.[122]

In a simplified overview, new drugs and treatments are originally evaluated for their similarity to other products in the market (figure 8). If similar and "innovative," the new product is priced comparably, according to Japan's Similar Efficacy Comparison Method (SECM) I. For less innovative products, SECM 2 adds premium adjustments for various values, like marketability and specific use. If there are no comparable drugs, a cost accounting method is used.[123] After the drug standard listing, drugs may be subject to a CEA or repricing over time.[124]

Figure 8. Pricing methods for new drugs in Japan



Source: ISPOR Asia Pacific, CRECON Medical Assessment Inc.

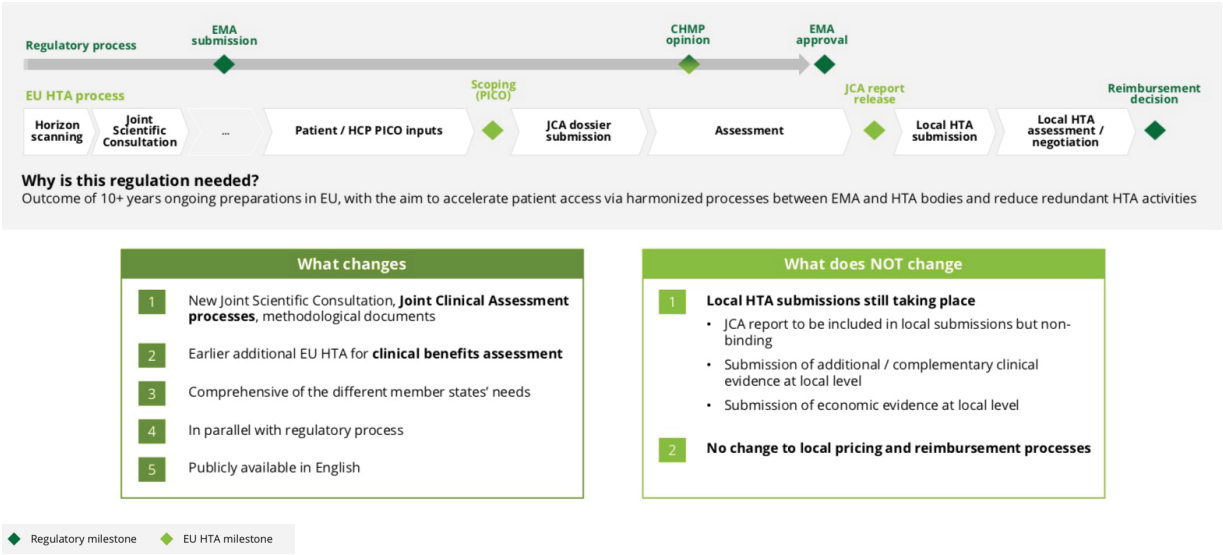
Drug manufacturers may be required to undergo a CEA for certain medicines and medical devices as part of the Health Technology Assessment (HTA) process.[125] HTAs aim to inform decision makers about relevant aspects of new health technologies, including pharmaceuticals, medical devices, surgical procedures, and other health care interventions.[126]

Experts say some of the challenges for drug manufacturers include assessing whether they will be subject to a CEA, and then ensuring they have the capabilities to show they meet CEA requirements. This extra step presents a delay in reimbursement and market access challenges.

Cross-country HTA collaborations, and value in the European Union (EU)

In many countries, HTA is used to inform reimbursement and pricing. New technologies, like Generative AI (GenAI), have the potential to improve HTA submissions. In the near future, cross-country HTA collaborations are expected to require more comparative clinical data for pricing and reimbursement decisions (figure 9).

Figure 9. Overview on European Union (EU) HTA process in parallel with European Medicines Agency (EMA) submission process*



Note: * Process and timeline are not final and expected to change until 2025

Source: Deloitte analysis

Providing evidence for value in the EU

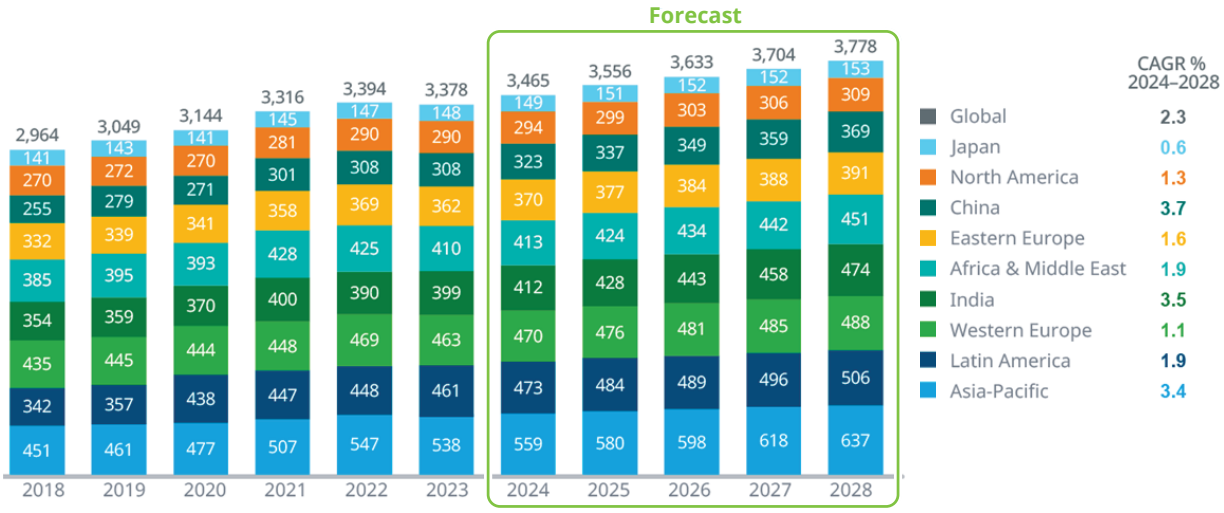
Evidence for a value-based system already has precedent in many other countries, particularly throughout the EU. Collectively, the EU plus the UK represent the second largest pharma market (33%), even though China is the second largest by country.

For example, Norway currently has a system that gives a drug its cost based on the patient's quality-adjusted life year. Their approach seeks to control costs by negotiating the prices of new drugs based on their cost-effectiveness and how health benefits are distributed.[127]

Rising use of medicines and calls for global pricing transparency

A good balance—between pharma cost containment measures, innovative medicine, and affordability—is critical to achieving optimal pricing and reimbursement, as the use of medicines is only expected to rise globally (figure 10)[128] along with global calls for pricing transparency. Many countries already require their manufacturers to declare ex-factory pricing—the manufacturer's selling price—in their initiatives (figure 11).

Figure 10. Historical and projected use of medicines by region, 2018–2028



Note: Forecasted Defined Daily Doses (DDF) in billions

Source: IQVIA, "Global Use of Medicines 2024, Outlook to 2028", January 2024.

Figure 11. Approaches used for drug price transparency by various countries

	Approach used on drug price transparency to government (through price declaration practices of pharma companies)				Drug price setting mechanism		Governing bodies for price setting mechanism
	Report other countries' price	*Ex-factory price*	*Distribution/ logistics fee/ wholesale*	*Pharmacy retail price/reimbursement list (RL)*	*Price referencing*	*Price negotiation*	
Canada	✓	✓		✓ (RL)	✓	✓	*Patented Medicine Prices Review Board*
China		✓	✓	✓	✓	✓	*National Development and Reform Commission*
Germany	✓	✓	✓	✓ (RL)	✓	✓	*Ministry of Health*
United Kingdom		✓	✓	✓ (RL)	✓	✓	*Pharmaceutical Price Regulation Scheme, Department of Health*
Netherlands	✓	✓		✓	✓		*Ministry of Health, Welfare and Sports*
United States		✓		✓ (RL)		✓	*Medicare, Department of Veteran Affairs, Medicaid, Health Maintenance Organization and Pharmacy Benefit Managers*

*Drugs covered under Medicare, Department of Veteran Affairs' health plans and Medicaid Best Price Program

Source: Deloitte analysis

In 2024, the US joined attempts by health systems around the world to control spending on new drugs, while also ensuring and improving access to innovative medicines for their populations. The IRA in the US is expected to have significant implications on how some of the largest pharma companies allocate funds for R&D and commercialize their drugs. Impacts on innovation and access could be felt globally.

In Europe, Japan, and China, the focus on how to evaluate the cost benefit of new medicines will likely continue—with new challenges. In particular, they will need to focus on how to value and price the benefits for cell and gene therapies as a class of expensive drugs with patient benefits over multiple years. Only through collaboration between industry and the health ecosystem can patients be assured that there is a win-win for finding cures and preventing and treating the diseases that affect all of us.

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