U.S. Chamber of Commerce
Global Innovation
Policy Center

The True Cost of Price Controls

Patient Access Report 2024

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Executive Summary

In 2022, the United States Congress passed and President Biden signed into law the Inflation Reduction Act (IRA). The life sciences–related provisions of the IRA mark a sharp and stunning departure from existing practice and long-term precedent. Unlike many other high-income Organisation for Economic Co-operation and Development (OECD) economies, the U.S. federal government has not historically imposed national price controls or other restrictions and market-access barriers on health technologies, including life sciences and medical devices. Instead, the U.S. framework has relied on competition, rather than government price-setting, to contain the prices associated with innovative medicines. In contrast, the IRA—which purports to provide the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) with the authority to "negotiate" the price Medicare will pay for a set number of medicines without generic or biosimilar competition—grants such sweeping novel powers unilaterally to the Secretary of Health and Human Services and imposes such punitive damages on manufacturers that fail to agree to or abide by the price-setting mechanism, that it is a de facto control of expenditure and price.

Report objective

National price and reimbursement controls impose a fundamental market-access barrier and restriction on the ability of life sciences manufacturers to exercise their commercial rights fully and freely. Historically, such policies have had a direct and negative impact on the availability of new, innovative, and life-altering medicines and medical technologies for patients and consumers in the affected market.

The purpose of this report is twofold:

1. **Empirically measure and benchmark the current life sciences market access environment in the U.S. and compare it with that of eight developed high-income comparator OECD economies (Australia, Canada, France, Germany, Italy, Japan, South Korea, and the UK) through the creation of a Patient Access Matrix.**

2. **Show the real-world negative consequences of imposing price controls through the IRA on patient access to new life sciences innovation and technologies in the U.S.**

Key Findings

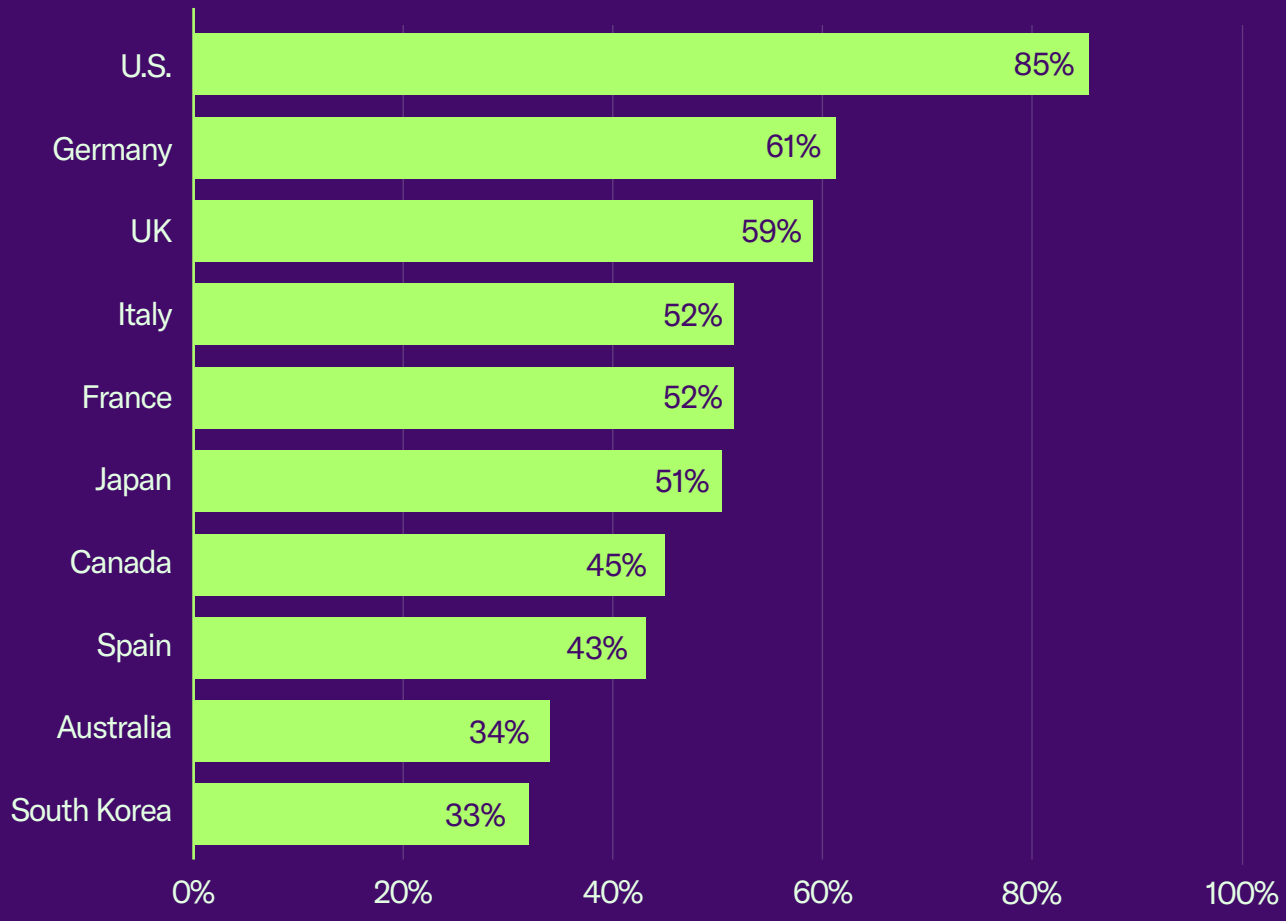
This report makes three key findings.

Key finding 1:

Between the U.S. and other advanced OECD member states with a history of pricing and reimbursement policies in place, a large disparity exists in product launches and market availability of new medicines.

Just like the long-term historical record, the most recent product launch and availability data show how economies with price controls and a more challenging life sciences market access environment consistently see substantially lower levels of product penetration and medicine availability for patients. Many new health technologies and medicines are never launched in economies that have strict pricing and reimbursement controls in place.

Percentage of New Active Substances Launched, 2012–2021, Selected Economies



Key finding 2:

The Patient Access Matrix shows the substantial negative impact that the IRA has had on the American life sciences market access environment.

Up until the passage of the IRA, the U.S. stood out as the sole economy in the Patient Access Matrix that did not impose direct national pricing and reimbursement controls. The IRA has had a direct and negative impact on U.S. performance in the Patient Access Matrix. Instead of being rated as the highest-performing economy included in the Patient Access Matrix, the U.S. is now, post-IRA, roughly commensurate with European Union (EU) member states, Australia, and Canada.

Patient Access Matrix, Results

	Dimension 1: National life sciences pricing policies	Dimension 2: Health system prioritization	Dimension 3: Systemic governance
U.S., pre-IRA	Attractive	Attractive	Mixed
UK	Challenging / highly challenging	Challenging	Mixed
France	Highly challenging / challenging	Challenging	Mixed
Germany	Highly challenging	Highly challenging / challenging	Mixed
Italy	Highly challenging	Highly challenging / challenging	Mixed
Australia	Highly challenging	Highly challenging	Mixed
U.S., post- IRA	Highly challenging	Challenging	Highly challenging
Canada	Highly challenging	Highly challenging	Highly challenging
South Korea	Highly challenging	Highly challenging	Highly challenging
Japan	Highly challenging	Highly challenging	Highly challenging

Key finding 3:

The IRA is projected to cut the number of new products launched in the U.S. by between 29% and 44%.

Based on two separate sets of averages and indirect comparisons to the experiences of all eight economies sampled in the Patient Access Matrix, our estimates suggest that the IRA will have a highly negative impact on the number of products developed and/or launched in the U.S.—in the range of 29% to 44% fewer products.

Critically, these estimates are in line with other research conducted on the potential impact of the IRA on life sciences research and development (R&D). For example, in June 2023, the health economics research consultancy Vital Transformation estimated that the IRA could, over a 10-year period, result in a reduction of 40% in approvals from the U.S. Food and Drug Administration (FDA). Similarly, a 2021 University of Chicago research paper estimating the impact of HR 5376—the draft bill that became the IRA—found that life sciences R&D spending was likely to fall by 18.5% and that this cut in investment would result in 135 fewer new medicines being developed.

U.S. Post-IRA Projection, Product Launches and Launch Delays

Patient Access Matrix performance	Percentage of new medicines launched by G20 country (of all 460 new medicines launched from 2012 to end of 2021)
Average group 1 (UK, France, Germany, and Italy)	56%
Average group 2 (Australia, Canada, Japan, and South Korea)	41%
U.S., pre-IRA	85%
U.S., post-IRA (projection)	41%–56% range (Equates to 29%–44% fewer products)

Discussion and conclusions

These are sobering findings. As the federal government moves forward with its plans for implementing the IRA, it should pause and consider the full ramifications of its pending actions. All health systems struggle with rising costs; this is not a uniquely American phenomenon. Imposing a system of "take it or leave it" price controls targeting medicines will, inevitably, reduce patient access to new life sciences products and technologies. Regardless of where the post-IRA experience of the U.S. falls on the spectrum of that of other OECD economies, one undeniable conclusion is that the imposition of national pharmaceutical price and reimbursement controls invariably comes at a cost: fewer new, lifesaving, and life-altering medicines and longer wait times. That cost is very clear—regardless of whether it's the experience of the UK, Germany, France, or Japan. Furthermore, because it reduces the life sciences research industry's resources to invest in R&D, the IRA will directly undermine the ability of our life sciences innovation ecosystem to continue to function at a high level. If the COVID-19 pandemic taught us anything, it is the value of having an advanced, research-based life sciences industry.

At over 15 billion doses produced, the global manufacturing and supply of COVID-19 vaccines today outstrips global demand. Also, a range of in- and outpatient treatments and therapies is available to patients today that was not on the market at the beginning of the pandemic. It is impossible to overstate the enormity of these accomplishments.

Yet the scientific and technological capacity that has allowed industry, public research organizations, and academic epidemiologists to achieve this technological miracle is based on decades of scientific study, innovation, and billions of dollars in sustained R&D investment. It is highly doubtful that in a post-IRA world this capacity can be maintained at a similar level of effectiveness.

Introduction

Turning gold into lead: The Inflation Reduction Act and the introduction of life sciences price controls in the U.S.

In 2022 the U.S. Congress passed and President Biden signed into law the Inflation Reduction Act (IRA). The IRA is a sprawling piece of legislation affecting many disparate parts of the U.S. economy, and the provisions that relate to the American health and life sciences market constitute a sharp and stunning departure from existing practice and long-term precedent. The U.S. federal government, unlike the governments of many other high-income OECD economies, has not historically imposed national price controls or other restrictions and market access barriers on health technologies, including life sciences and medical devices. Instead, the U.S. has relied on competition, including in the pharmacy space, to drive down the cost of innovative medicines.

This has now changed with the passage of the IRA, which marks a sharp departure in U.S. health and life sciences policy. Previous federal efforts to impose national price controls or other government-mandated expenditure containment efforts were unsuccessful.

For example, the Trump administration introduced several reform initiatives aimed at lowering the price of prescription medicines. In 2018, the Council of Economic Advisers released Reforming Life Sciences Pricing at Home and Abroad, an analysis of the global life sciences market. The HHS also announced a set of reforms in the blueprint document American Patients First. The Trump administration also announced a plan to build an International Pricing Index and develop a most-favored-nation (MFN) model to be used by Medicare Part B. This plan was formalized in 2020 by HHS and the Centers for Medicare and Medicaid Services (CMS). The MFN model would benchmark the price of a basket of 50 life sciences products in the U.S. against the government set price of the same products in a sample of OECD economies. These economies were chosen based on OECD membership and per capita gross domestic product (GDP) at purchasing power parity (PPP) of 60% or above that of the U.S. After several court rulings in 2021, the CMS formally rescinded the proposed MFN model.

Congress has introduced similar proposals for artificially controlling expenditures on prescription medicines through government price controls. In 2019 and 2021, members of Congress introduced H.R.3–Elijah E. Cummings Lower Drug Costs Now Act.

Like the MFN model, the bill introduced an international reference pricing framework whereby the price of medicines in the U.S. would be determined based on the average price of a basket of products from a selection of high-income OECD economies.

Each of these failed policy proposals was founded on the same false premise that underpins the IRA: that the prices charged by developers and producers for innovative medicines are unnaturally high. Accordingly, the law includes a series of fundamental changes to the pricing framework for medicines covered under Medicare Parts B and D. Purporting to provide the HHS and CMS with the authority to "negotiate" the price for certain medicines without generic or biosimilar competition, the law grants such sweeping powers to the HHS Secretary and imposes such punitive damages on manufacturers that fail to "agree" (or, more accurately, acquiesce) to the price-setting mechanism, that it does not in any way constitute a negotiation. Instead, the law is simply a de facto price-control plan. The legislation uses the nonfederal average manufacturer price available for a given medicine, adjusted based on the percentage increase in the consumer price index, as the basis for a government-set price.

Through a convoluted process the so-called maximum fair price (MFP) established for negotiated products must be equal to or less than this price—what is termed a "ceiling price." This ceiling price is a set percentage for each product (75%, 65%, or 40%) and depends on how long a given product has been on the market, with the lowest percentages applying to the oldest products. Furthermore, the IRA distinguishes between small- and large-molecule products, with small-molecule entities subject to negotiations at a much earlier date. Although the IRA excludes certain orphan disease treatments from negotiations, this exclusion is narrow and applies only to products used exclusively to treat one condition/disease. The legislation also caps the out-of-pocket cost that Medicare patients pay for insulin at $35 per month. The IRA also includes the option to divide annual out-of-pocket expenses into a monthly amount (so-called smoothing). At the time of research, HHS and CMS were in the process of finalizing implementing regulations with an initial guidance document issued in March 2023 and a revised document published in June. In late August 2023, the administration released the list of 10 initial medicines subject to these new powers and price-control measures.

From leading the fight against COVID-19 to facing government price controls: Understanding the drivers of life sciences R&D

The COVID-19 pandemic displayed the immense and direct value of the research-based life sciences industry to global health. Developing new medicines is a long-term, high-risk, resource-intensive process. The fixed costs in terms of laboratory, research facilities, and researchers are high. In 1979, the total cost of developing and approving a new medicine stood at $138 million. Almost 25 years later, in 2003, this figure was estimated at $802 million.[1] More recent research from Tufts University suggests that it costs $2.6 billion, on average, to develop a new medicine.[2] On average, only one to two of every 10,000 synthesized, examined, and screened compounds in basic research will successfully pass through all stages of R&D and be approved by regulatory authorities. Historically, developing a new medicine would take a decade or more. Up until the COVID-19 outbreak, this timeline was the norm for vaccine development and the life sciences R&D process in general. Within this historical context, the speed at which COVID-19 vaccines and treatments were developed is truly breathtaking. It is impossible to overstate the enormity of these accomplishments. It shows the extensive scientific, commercial, and logistical capacity developed by the life sciences industry and the biotechnology community to rapidly understand an emerging threat, develop multiple vaccines and treatments, and scale production in record time to respond effectively to a novel virus not prevalent in human beings prior to 2019.

What the research-based life sciences industry together with its partners in academia and the public sector were able to achieve at a scientific, manufacturing, distribution, and organizational level amounts to a modern-day miracle. Yet the science and technological capacity that has allowed industry, public research organizations, and academic researchers to carry out this development is based on decades of R&D investment, experience, and innovation.

It is highly unlikely that this life sciences R&D would have taken place without the necessary enabling environment in place in the United States. These technologies and products are the fruit of our country's long-standing innovation ecosystem, which is centered and built on intellectual property (IP) rights. Without strong, clear, and secure IP rights it is unlikely that any of those medicines, products, and technologies—or the underlying science—that have been so essential to keeping societies functioning and fighting the COVID-19 pandemic would exist today.

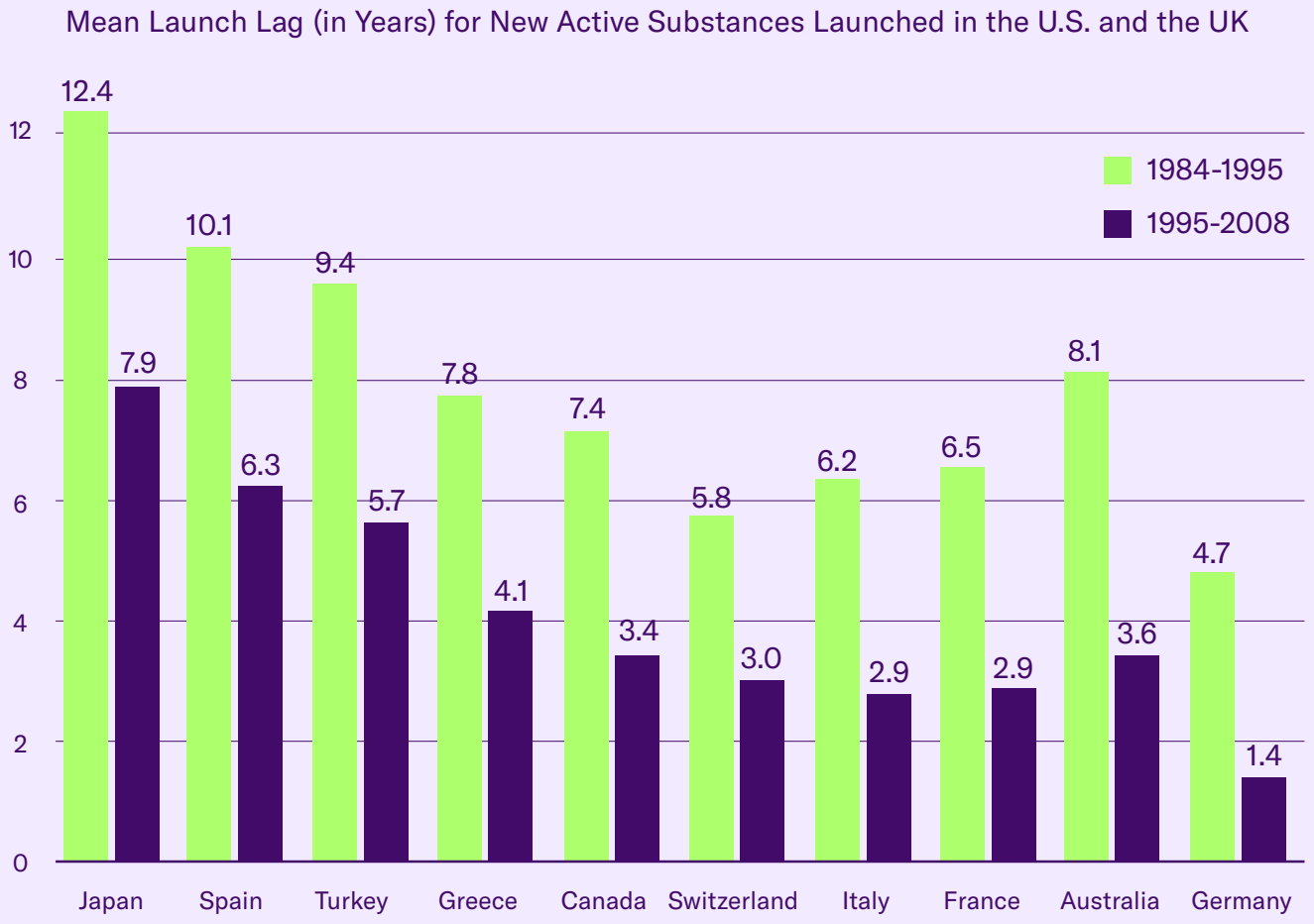
Fewer Medical Choices and Longer Wait Times: The Collective International Experience of Pharmaceutical Price Controls and Reimbursement Policies

The historical record shows unequivocally how the imposition of price controls and reimbursement policies has a direct impact on how and when patients can access medicines and medical products as well as what types are available in a given health system. The following subsection summarizes the data and analysis presented in our briefing document The Road Toward Deterring Innovation and R&D: The U.S. and Pharmaceutical Price Controls from earlier this year (the Patient Access Report, Phase One). Following this historical analysis, new data are presented using new findings published by PhRMA and IQVIA .

Several studies examining the availability of innovative medicines show a distinct disparity between those economies with market access and regulatory environments that balance maintaining financial stability with rewarding innovation, and economies with more stringent pharmaceutical pricing and reimbursement environments. For instance, a 2008 study of medicine launches by the National Bureau of Economic Research suggested that economies with market-based pricing have historically had a greater number of launched innovative medicines than have countries with a more challenging P&R environment. For the period examined, Germany (as is detailed in Section 5: Economy Overviews, 2010 reforms changed the German life sciences policy environment dramatically but during the time period studied the P&R system was based more on market-based pricing) and the U.S. had a larger number of launched

medicines for innovative medicines subclasses (88 and 86, respectively), while Japan, Portugal, and France—all of which had in place strict price regulations—saw fewer molecules launched (53, 62, and 69 respectively).[3] Similarly, statistical modeling investigating the impact of price controls on product launches in several OECD and middle-income economies found that, historically, price controls (and other supply-side controls) have had a significant impact on potential product entry, reducing the likelihood of entry by roughly 75% compared with a market with no price controls.[4] Finally, a large study conducted in 2010 by researchers at the London School of Economics and Political Science examined historical trends in launch lags of 495 innovative medicines in 20 economies; it suggested that economies with more challenging regulatory and market access environments experience far longer delays in accessing new innovative medicines. Figure 1 shows the time lags in market access for two of the time periods studied: 1984–95 and 1995–2008.

Figure 1: Historical Trends in Launch Lags of Innovative Medicines, Comparison between 1984–95 and 1995–2008, Selected Economies[5*]



*The term "mean launch lag" refers to the average time (in years) between first global launch (indicated by first sales in IMS database) and first sales in a given economy for 194 new molecules approved for marketing in the U.S. and the UK between 1984 and 1995, and 266 new molecules approved for marketing in the U.S. and the UK between 1995 and 2008.

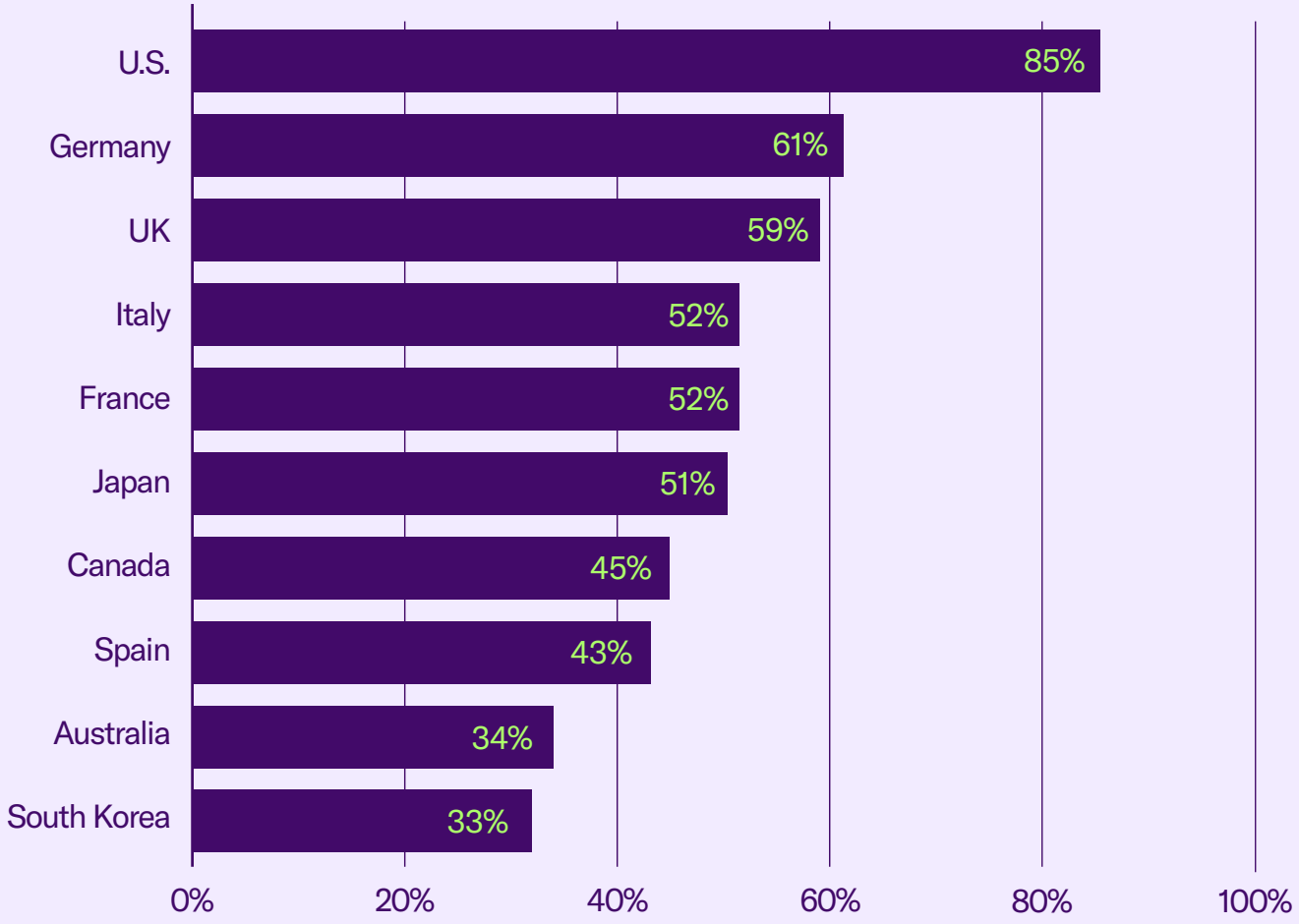
As Figure 1 shows, Japan, Australia, Spain, Turkey, and Greece have, historically, had medicine launches delayed far behind those in other markets. Many of the lags—particularly in earlier period of 1984 to 1995—can be attributed to the global trading environment at the time and the lack of truly integrated global life sciences supply chains. Still, it is noteworthy that many of these barriers and relative delays in access persist. For example, Japan maintained the longest lag time of all economies examined—at a full 12.4 years in the 1984–95 decade, dropping only to 7.9 years in the 1995–2008 period.

Although these academic studies focused on the long-term historical launch and medicine availability record, launch lags and differences in product availability among different markets are still common today.

As with the long-term historical record, the most recent launch and product availability data show how economies with price controls and a more challenging life sciences market access environment consistently see substantially lower levels of product penetration and medicine availability for patients. There is a large—and growing—disparity in product launches and market availability of new medicines between the U.S. and other advanced OECD member states with a history of price and reimbursement controls in place.

For example, evidence collected by IQVIA on the availability of new medicines launched in the 2012–21 decade and published by PhRMA in 2023 shows that many new health technologies and medicines are never launched in economies with strict price and reimbursement controls in place.[6] These innovations include treatments for critical diseases such as cancer. This is a significant lesson when evaluating the direct impact of introducing price and reimbursement controls: new products and medical innovations never make it into markets with these government policies. As Figure 2 shows, historically, developed OECD economies such as Canada, Japan, South Korea, Australia, and EU member states have seen significantly fewer overall life sciences product launches than has the U.S.

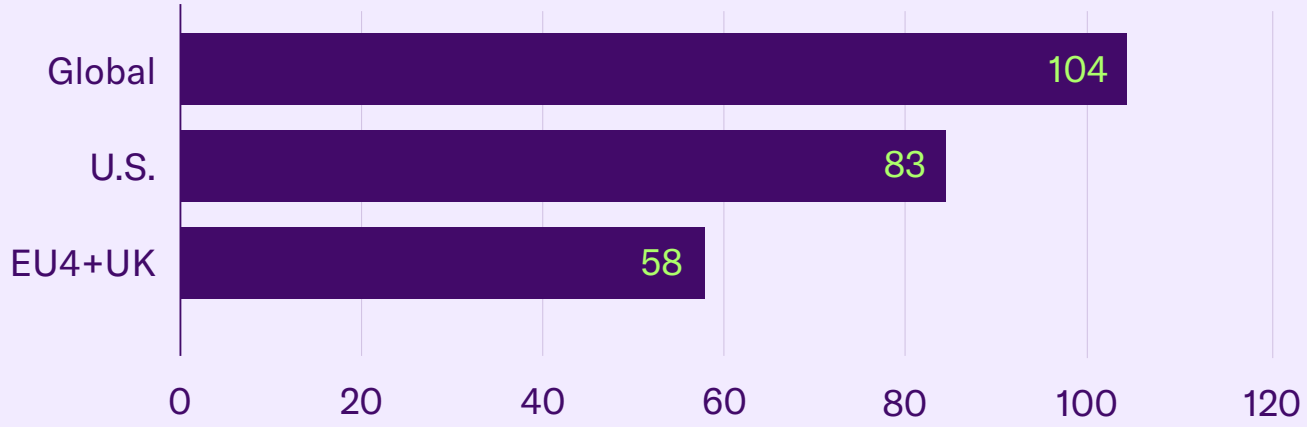
Figure 2: Percentage of New Active Substances Launched, 2012–21, Selected Economies[7]



This disparity between the U.S. and other developed OECD economies is even more pronounced in the availability of certain medicines in specific therapeutic areas. For instance, the most recent data on the launch of new cancer medicines echo these broader findings and demonstrate how even Germany and the UK are now falling behind the U.S. In the past, these two countries were closest to it. IQVIA's Global Oncology Trends 2022 report shows how the disparity in product launches between the U.S. and other economies with national price and reimbursement controls in place is, in fact, growing.

Figure 3 displays the total number of new oncology active substances launched in the past five years (2017–21) and the proportion available in the U.S. compared with that available in the EU and the UK. As Figure 3 shows, out of 104 new products launched globally since 2017, 80% were launched in the U.S. but only 56% were launched in Germany, France, Italy, and the UK.

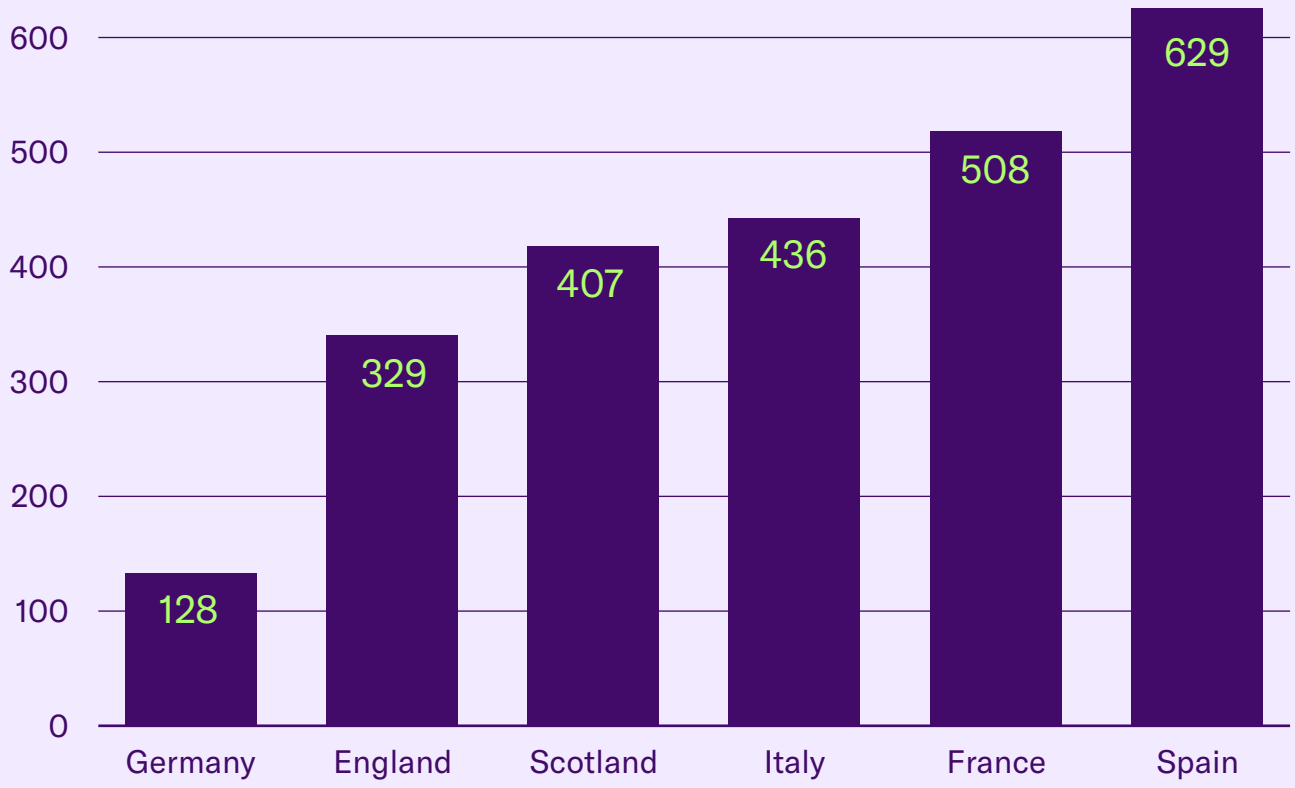
Figure 3: Number of New Oncology Active Substances Launched Globally, 2017–21, Selected Regions[8]



In addition to seeing fewer product launches, patients in economies with national price and reimbursement controls in place tend to wait longer for access to new medicines in their respective national health systems. This is due to the length of time taken by the formulary and reimbursement process. These delays can amount to several years of patients waiting to access new treatments. Many national payers have an elaborate evaluation to determine whether a product should be included on a given formulary and at what rate it should be reimbursed.[9] Such evaluations restrict access to national health systems through reimbursement limits, health technology and cost effectiveness assessments, and reference pricing. France, Italy, Germany, Spain, and the UK all make use of such tools, as do Australia, Canada, Japan, and South Korea. Critically, there can be a long lag between market authorization—that is, the date by which a new product is approved by medicine regulators for use—and the date on which it is approved and included on a national formulary for public reimbursement.

For health systems that are predominantly publicly funded and organized, it is the latter date that determines when most patients can access a new product, not the market authorization date. A concrete illustration of what this means in practice comes from the annual Patients W.A.I.T. (Waiting to Access Innovative Therapies) survey, conducted by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and IQVIA. This survey measures the rate of availability and patient access to new and innovative medicines in Europe.[10] As Figure 4 shows, the number of days that patients in Europe's largest economies wait to access new innovative life sciences is considerable.

Figure 4: Time from Market Authorization to Availability, 2018–21 (Number of Days from Market Authorization and Availability to Patients, through Public Reimbursement)[11]



As Figure 4 makes clear, apart from Germany, patients in Europe's largest economies must wait almost a year or more before they can access new medicines. Long delays are pronounced in France and Spain where patients, on average, wait 500 to 600 days.

These delays are typical of health systems with national price and reimbursement controls. In Australia, for instance, a 2018 study found that only 46% of all medicines registered in Australia between 2012 and 2017 were reimbursed (with a similar share for first-in-class medicines). On average, the reimbursement evaluation for the products studied took 426 days—considerably longer than the OECD average for this period. The results are similar in Canada. For example, a 2016 report conducted by IMS Health Canada for Innovative Medicines Canada attested to how Canadian patients have access to fewer innovative treatments than do patients in other OECD economies.[12] The study found long lags between market authorization and inclusion for public reimbursement. On average, for the period studied (2010–14) it took 449 days from market authorization to reimbursement. Looking at access across all Canadian provinces—formulary and reimbursement decisions are made provincially in Canada—the study found that only 37% of medicines were reimbursed and available to 80% or more of the population. There were pronounced gaps in availability for more advanced treatments, including cancer medicines and biologic products. Only 59% of cancer medicines were available to 80% or more of the population. For new biologics, this figure was even

lower, at 23%. More recent data suggest that time taken for reimbursement evaluation in Canada has gotten longer. Data compiled by Innovative Medicines Canada suggest that for the 2012–18 period, it took 632 days, on average, from market authorization to reimbursement.[13]

What do these aggregated data add up to in terms of real-life experiences? A 2018 study examining the availability of 46 new cancer medicines in four EU member states (Belgium, Estonia, Scotland, and Sweden) between 2000 and 2014 found large discrepancies with respect to both the number of products launched in each economy and when products were made available within each health system.[14] In no economy were all 46 new products launched. In Estonia, for instance, almost half of the sample (19 medicines out of 46) were never launched.[15] Similarly, in all the economies for all the medicines launched, it took, at best, more than a year for these new products to reach patients. Sweden, which on launch time performed best of the four, still took, on average, 14.3 months from time of EU market authorization to first product usage within the health system. In Belgium, this lag was, on average, more than two years (26.8 months), and in Estonia it was even longer: over five years (63.9 months).

Similarly, in terms of access to orphan drugs and new medicines for rare diseases, evidence suggests that considerable variation exists in levels of access across the EU. For example, a 2017 study by the Office of Health Economics (a British research institute) compared access to 143 orphan products that were approved for marketing in the EU between 2000 and 2016 across the then EU-5 (including a division between England, Scotland, and Wales).[16] Overall the study found that access to authorized orphan products through public reimbursement varied substantially between the sampled EU member states, ranging from 93% in Germany to 33% in Wales. Similarly, the average duration between the granting of marketing authorization by the EMA and reimbursement decision by the national authority was 23.4 months—nearly two years. That duration was also considerably longer for orphan medicines than for non-orphan medicines. For example, in the UK, the median number of months between the marketing authorization and the first National Institute for Health and Care Clinical Excellence (NICE) appraisal was 20.2 months for orphan medicines and 12.7 months for non-orphan medicines.

Given the impact of price controls on cancer drugs and rare disease drugs, it is likely that there will be similar impact on availability of chronic disease medications in the U.S. because of the shortened time frame for applying price controls to small-molecule drugs and the approach to aggregating drugs by active moiety/active ingredient. Most drugs for chronic disease are small molecule, and many subsequent indications for new patient populations and additional disease areas resulted from ongoing research on an approved drug. Because these medicines can be selected for negotiation so early, companies may be discouraged from R&D investment in the years following a medicine's initial FDA approval. Post-approval R&D often includes lengthy, costly, and labor-intensive clinical trials, resulting in additional discoveries into new treatment areas with unmet patient needs and a lack of effective therapies.

Summing up the historical and comparative record

The record shows unequivocally how the imposition of price controls and reimbursement policies has historically had a direct impact on how, when, and what type of medicines and medical products patients can access in a given health system. Fewer innovative medicines and longer wait times are the direct consequences of price controls and life sciences cost containment policies. The bottom line is that the price controls included in the IRA are likely to have the same direct and indirect negative impact in the U.S. over time: fewer medicines will be introduced to the market, and patients will need to wait longer to access the latest lifesaving and life-altering life sciences innovations.

Measuring Access Barriers to the Life Sciences Market: The Patient Access Matrix

Compare and contrast:
Building a Patient Access Matrix

The Patient Access Matrix is a new social scientific tool that measures how different economies manage their life sciences market access environments through price and reimbursement controls and other related policies. The Patient Access Matrix measures and benchmarks this environment in the U.S. and eight developed, high-income OECD economies: Australia, Canada, France, Germany, Italy, Japan, South Korea, and the UK. All national health systems are different; consequently, all national life sciences cost and expenditure containment systems are different. The Patient Access Matrix allows users to more systematically catalog, measure, and classify those differences.

Methodological overview

The Patient Access Matrix (Matrix) consists of 10 distinct indicators divided into three separate dimensions that benchmark different parts of the national life sciences market access environment. Each dimension evaluates a particular part of the life sciences market access environment and benchmarks levels of performance. Table 1 lists the 10 indicators included in the Matrix and the three dimensions. (The appendix at the end of this report contains a full explanation and definition of each individual indicator listed and the types of sources used.)

Table 1: Patient Access Matrix, List of Indicators

Dimension 1: National life sciences pricing policies
Direct national price controls
Imposition of mandatory price cuts, freezes, and/or rebates and discounts
Frequency of downward price revisions
Price linkage and price caps
Dimension 2: Health system prioritization
Overarching philosophy and direction of national health and life sciences system
Pricing and reimbursement decision-making process and methodology
Availability of new, innovative life sciences treatments and products
Time to effective patient access
Dimension 3: Systemic governance
Systemic transparency
Stakeholder engagement

The Matrix uses the following four-level performance scale to assess the environment in each economy:

1. **Attractive**
2. **Mixed**
3. **Challenging**
4. **Highly challenging**

Patient Access Matrix results

Table 2 shows the overall results of the Matrix for the nine economies included. The U.S. environment has been benchmarked twice; one assesses the environment prior to enactment of the IRA and the other considers the impact of the IRA.

Table 2: Patient Access Matrix, Results

	Dimension 1: National life sciences pricing policies	Dimension 2: Health system prioritization	Dimension 3: Systemic governance
U.S., pre-IRA	Attractive	Attractive	Mixed
UK	Challenging/highly challenging	Challenging	Mixed
France	Highly challenging/challenging	Challenging	Mixed
Germany	Highly challenging	Highly challenging/challenging	Mixed
Italy	Highly challenging	Highly Challenging/challenging	Mixed
Australia	Highly challenging	Highly challenging	Mixed
U.S., post- IRA	Highly challenging	Challenging	Highly challenging
Canada	Highly challenging	Highly challenging	Highly challenging
South Korea	Highly challenging	Highly challenging	Highly challenging
Japan	Highly challenging	Highly challenging	Highly challenging

What stands out from these results? First, and foremost, there are significant price controls and other cost-cutting tools in place and adopted widely in all the OECD economies sampled. France, Italy, Germany, and the UK all impose direct or indirect controls on the price of life sciences products. Access to national health systems is also restricted via reimbursement limits, health technology and cost effectiveness assessments, and reference pricing.

Similarly, Australia, Canada, and Korea impose harsh price controls and cost-cutting tools. As Section 5 discusses, although most sampled economies provide a theoretical basis for rewarding life sciences innovation through price premiums and/or other commercial incentives, in practice few do.

In this sense, the biggest takeaway from the results of the Matrix is that all major OECD economies sampled could improve their national policy environments. The research and innovation that make the development of new life sciences products and technologies possible do not take place in a vacuum; it requires a complex ecosystem of enabling policies at both macro- and microlevels. These range from the institutional and eco-system level——such as levels of tertiary education, technical skill, and the IP rights environment—to factors that are more life sciences specific. The latter includes the type of life sciences and biotechnology R&D infrastructure an economy has in place, the availability of technology transfer laws and mechanisms, and the commercial environment for life sciences–based products and technologies, including medicines. Within this ecosystem, market and commercial incentives are critical in determining the extent to which private- and public-sector entities can continue to invest in R&D and develop new life sciences products and health technologies. In the U.S., historically, one of the strongest drivers of life sciences innovation has been the existence of a relatively free market in the pricing and sale of new medicines and life sciences technologies. The IRA does not improve this environment. Instead, the price controls included in the IRA are likely to have over time in the U.S. the same direct and indirect negative impact as they have had across the world: fewer medicines will be introduced to the market, and patients will need to wait longer to access the latest lifesaving and life-altering life sciences innovations. There is also likely to be a sustained direct and indirect negative impact on rates of R&D expenditure and, consequently, long-term rates of life sciences innovation and access to new forms of treatments. The research and innovation that makes the development of new life sciences products and technologies possible does not take place in a vacuum. It requires a complex ecosystem of incentives and enabling policies at both the macro and micro levels. These range from the institutional and eco-system level – such as levels of tertiary education, technical skill and intellectual property rights environment – to the more life sciences-specific. The latter includes what type of life sciences and biotechnology R&D infrastructure does an economy have in place, the availability of technology transfer laws and mechanisms, and the commercial environment for life sciences-based products and technologies, including medicines. Within this ecosystem, market and commercial incentives are critical factors in determining the extent to which private and public sector entities can continue to invest in R&D and develop new life sciences products and health technologies. In the U.S. one of the strongest drivers of life sciences innovation has historically been the existence of a relatively free market in the pricing and sale of new medicines and life sciences technologies. By reducing the life sciences research-based industries resources to invest in R&D, the IRA will directly undermine the ability of our life sciences innovation ecosystem to continue to function at a high level.

Second, the Matrix shows the substantial negative impact that the IRA has had on the American life sciences market access environment. Up until the passage of the IRA, the U.S. stood out as the sole economy included that did not impose direct national price or reimbursement controls. The IRA has had a direct and negative impact on U.S. performance on the Matrix. Instead of being the highest-performing economy, the U.S. environment performs now, post-IRA, roughly the same as the environments of EU member states, Australia, and Canada.

Finally, as demonstrated by the results in Dimension 3 (Systemic Governance), all economies sampled struggle with levels of transparency and/or effectively and meaningfully engaging with key stakeholders. This finding is somewhat surprising given that all sampled economies are developed, high-income OECD economies with clear rules and regulations requiring substantial levels of public transparency in all facets of public policymaking as well as defined stakeholder engagement throughout this process, regardless of industry or economic sector regulated. Yet in all economies, there are challenges related to how life sciences market access policies are conceived, how pricing and reimbursement decisions are made, and how much relevant authorities meaningfully engage with stakeholders and take their concerns into account.

In fact, in a growing number of the sampled economies, instead of constructively working together toward reaching compromise and consensus, stakeholders have been reduced to taking legal action to defend their interests. In the U.S., the research-based life sciences industry successfully challenged proposals for the introduction of international reference pricing put forth by the Trump administration, and there are, today, several pending legal challenges filed about the price control provisions under the IRA.

Similarly, in Canada the research-based industry had to pursue a legal challenge against proposals for evaluating and pricing patented medicines through a new evaluation methodology presented by the government; this is discussed in more detail in Canada's Economy Overview.

Estimating the IRA's Impact on Access to New Life Sciences Innovation in the U.S.

How will the IRA affect patients in the U.S.?[17]

The previous sections show a clear and robust relationship between an economy's performance on the Matrix and the availability of new life sciences innovation. Economies that impose price and reimbursement controls see fewer innovative products on the market, and patients are less likely to access the latest medicines and medical technologies in a timely fashion. Following implementation of the IRA, this is likely to be the case in the U.S. too. Historically, the U.S. has been the global leader in all types of life sciences R&D and innovation, with strengths in areas of cutting-edge research relating to cancer, Alzheimer's disease, diabetes, obesity, cardiovascular disease, and biologics.

These areas of research require significant investments and affect millions of patients. Without the ability to invest in innovative products, patients will have access to fewer advancements that address unmet patient needs in the future.

But with fewer resources—as a direct result of the IRA—life sciences research entities will have less to invest in R&D and, consequently, will be less likely to develop new medicines and health technologies at the same rate as in the past.

What's more, the design of the IRA itself, coupled with policy decisions made by CMS, make it likely that the detrimental effects of the IRA may have a disproportionate impact on certain disease areas, particularly chronic disease. For the first two years of the new Medicare negotiation program, CMS may negotiate only drugs reimbursed under Part D—that is, drugs that are self-administered. Negotiation of infused and provider-administered drugs, typically reimbursed under Part B, are not permitted until the third year of the program. Many drugs payable under Part D treat chronic diseases for large patient populations.

Additionally, CMS chose to identify negotiation-eligible drugs based on total Medicare gross spending—excluding the value of manufacturer rebates—which resulted in a greater proportion of highly rebated drugs being represented on CMS's selected drug list.

Highly rebated drugs in Medicare Part D tend to reside in competitive classes that treat chronic diseases. A recent analysis of the drug list for the first year of the negotiation program found that products treating cardiovascular disease, autoimmune conditions, diabetes, and chronic kidney disease are the most heavily represented.[18]

This will have consequences both for the U.S. and for other nations, which are likely to see a substantial reduction in new product development and/or launches. As discussed later, in June 2023, the health economics research consultancy Vital Transformation estimated that the IRA could, over a 10-year period, result in a reduction of 40% in FDA approvals.

Modeling the impact of the IRA on future product availability in the U.S.

Indicators 7 and 8 of the Matrix measure the availability of new, innovative life sciences treatments and products and the time it takes until new products reach patients, on average, in each of the individual economies. The heat map in Table 3 compares the Matrix's nine sampled economies across four different dimensions:

1. Matrix performance

2. Product availability, measured as a percentage of the total number of medicines launched globally in the decade 2012–21 (Indicator 7 on the Matrix)

3. Product availability, standardized to the number of products launched of the total number of medicines launched globally in the decade 2012–21

4. Time to effective patient access, as measured by the average number of months from global first launch to local launch and/or public reimbursement (Indicator 8 on the Matrix)

Table 3: Patient Access Matrix Performance and Availability of New Medicines[19]

Patient Access Matrix performance, highest to lowest	Percentage of new medicines launched by G20 country (of all 460 new medicines launched from 2012 to end of 2021)	Normalized to number of medicines	Average number of months from global first launch to local launch and/or public reimbursement
U.S., pre-IRA	85%	391	4
UK	59%	271	27
France	52%	239	34
Germany	61%	281	11
Italy	52%	239	38
Australia	34%	156	47
U.S., post-IRA			
Canada	45%	207	52
South Korea	33%	152	46
Japan	51%	235	17

As Table 3 shows, an almost stepwise relationship exists between an economy's performance on the Matrix and rates of life sciences product availability and launch delays. The worse an economy performs on the Matrix, the lower its rate of product availability and the longer it takes, on average, for new products to reach patients.

Because we can expect much of this logic to hold true in a post-IRA policy environment in the U.S., the results of this comparison give us a sense of what the impact of the IRA will be. Up until the enactment of the IRA, the U.S. stood out as the sole economy included in the Matrix that did not impose direct national price or reimbursement controls or other related policies. As the results of the Matrix show, post-IRA, the life sciences market access environment in the U.S. is now roughly on par with that of Australia and Canada. If we were translating Matrix results on a like-for-like basis and using U.S. performance to project future levels of product availability and launch lags, then we would expect the U.S. future performance to be comparable with that of Australia and Canada. But the U.S. market is not Australia and Canada. It is, by far, the largest life sciences market in the world. The latest estimates from IQVIA attest to this fact. In 2022, total expenditure on all medicines in the U.S. was $629 billion, over one third of the total global market of $1.5 trillion.[20] Consequently, the market and commercial dynamics are different. Even with the fundamental changes to the underlying forces of the U.S. market introduced by the IRA, it is more likely than not that the U.S. would remain one of the world's premier life sciences markets.

Taking this into account, it makes more sense to try to forecast the impact of the IRA using a range of comparisons. For example, the number of new medicines launched in a given market is the product of many factors; two of the most fundamental are (1) the total number of new medicines launched globally in a given year and (2) the attractiveness of a given national market. The consequence of the IRA's price and expenditure control mechanisms is to reduce the resources available to life sciences manufacturers and research organizations (whether public or private). With fewer resources available, these entities will naturally have less to invest in life sciences R&D. And, as a result, they will be less likely to develop and launch new products than in the past. But the IRA will also decrease the commercial attractiveness of the U.S. market. As identified previously, there is an almost stepwise relationship between an economy's performance on the Matrix and rates of life sciences product availability. The worse an economy performs on the Matrix, the lower its rate of product availability. The result will be that not only will fewer new medicines get developed and launched globally because of fewer resources to invest in innovation and R&D, but also the U.S. will be less likely to see the same proportion of those new products launched and available as in the past. In this respect, the experience of the basket of OECD comparator economies is instructive and suggestive of what such an impact could look like.

For example, excluding the results for the U.S., the eight remaining economies sampled in the Matrix can be divided into two equal groups of four according to levels of performance:

- **Group 1:**
  UK, France, Germany, and Italy
- **Group 2:**
  Australia, Canada, Japan, and South Korea

Calculating a set of averages for these two groups allows us to make a projection of the IRA's impact on product availability, based on two separate sets of averages and indirect comparisons between the experiences of all eight economies sampled. The heat map in Table 4 presents the averages calculated for both groups and compares these averages with current performance in the U.S. The difference between these three numbers gives us a projected impact range from the IRA.

Table 4: U.S. Post-IRA Projection—Product Launches and Their Delays

Patient Access Matrix performance	Percentage of new medicines launched by G20 country (of all 460 new medicines launched from 2012 to end of 2021)
Average group 1	56%
Average group 2	41%
U.S., pre-IRA	85%
U.S., post-IRA (projection)	41%–56% range (Equates to 29%–44% fewer products)

As Table 4 demonstrates, based on the average calculated for both groups of comparator economies, the IRA is set to have a highly negative impact on the estimated number of products launched. These impacts range from a severe drop of 44% fewer products on the U.S. market to a less severe, but still very substantial, 29% fewer products. In raw numbers, this means that the future development and/or commercialization of over 100 new medicines would be at risk.

Critically, these estimates on the negative impact of the IRA on future life sciences innovation and access in the U.S. are in line with other, similar research. For example, in June 2023, the health economics research consultancy Vital Transformation estimated that the IRA could, over a 10-year period, result in a reduction of 40% in FDA approvals.[21] Similarly, a 2021 University of Chicago research paper estimating the impact of the HR 5376, the draft bill that became the IRA, found that life sciences R&D spending was likely to fall by 18.5% and that this cut in investment would result in 135 fewer new medicines.[22]

Discussion and conclusions

These are sobering projections. As the federal government moves forward with its plans to implement the IRA, it should pause and consider the full ramifications of its pending policy actions. All health systems struggle with rising costs; this is not a uniquely American phenomenon. Imposing a system of "take it or leave it" price controls targeting medicines will, inevitably, reduce patient access to new life sciences products and technologies. Regardless of where the U.S. post-IRA experience falls on the spectrum of that of other OECD economies, one undeniable conclusion is that the imposition of national price and reimbursement controls invariably comes at a cost: fewer new medicines and longer wait times. That cost is very clear, regardless of whether it's the experience of the UK, Germany, France, or Japan.

Furthermore, by reducing the resources that life sciences research–based industries have to invest in R&D, the IRA will directly undermine the ability of our life sciences innovation ecosystem to continue to function at a high level. If the COVID-19 pandemic taught us anything, it is the value of an advanced research-based life sciences industry. Today, more than 2,000 active clinical trials are taking place globally to test treatments and potential vaccines for COVID-19. At over 15 billion doses produced, the global manufacturing and supply of COVID-19 vaccines today outstrips global demand.

Also, a range of in- and outpatient treatments and therapies is available to patients today that was not on the market at the beginning of the pandemic. It is impossible to overstate the enormity of these accomplishments. The speed at which this research has taken place is unprecedented. Yet the scientific and technological capacity that has allowed industry, public research organizations, and academic researchers to achieve this technological miracle is based on decades of scientific study, innovation, and billions of dollars in sustained R&D investment. It is highly doubtful that this capacity will remain in place in a post-IRA world. Consequently, not only will Americans experience reduced availability of innovative product launches as a result of IRA price controls, the entire world will see fewer new treatments and cures in absolute terms.

Economy Overviews

Introduction

This section presents an overview and analysis of each individual economy's performance and classification on all 10 indicators in the Patient Access Matrix (Matrix). Each economy is assessed on all 10 indicators according to the performance scale outlined previously:

1. **Attractive**
2. **Mixed**
3. **Challenging**
4. **Highly challenging**

Specific challenges, debates, and issues relating to the national life sciences market access environment in each individual economy, as captured in the Matrix, is discussed in more detail in the subsection "Spotlight on the Life sciences Market Access Environment."

Australia

Patient Access Matrix

	Indicators	Performance classification	Dimension overall performance classification
Dimension 1: National life sciences pricing policies	1. Direct national price controls	Highly challenging	Highly challenging
	2. Imposition of mandatory price cuts, freezes, and/or rebates and discounts	Highly challenging	
	3. Frequency of downward price revisions	Highly challenging	
	4. Price linkage and price caps	Highly challenging	
Dimension 2: Health system prioritization	5. Overarching philosophy and direction of national health and life sciences system	Highly challenging	Highly challenging
	6. Pricing and reimbursement decision-making process and methodology	Highly challenging	
	7. Availability of new, innovative life sciences treatments and products	Challenging	
	8. Time to effective patient access	Highly challenging	
Dimension 3: Systemic governance	9. Systemic transparency	Challenging	Mixed
	10. Stakeholder engagement	Attractive	

Spotlight on the National Life Sciences Market Access Environment

Dimension 1: National life sciences pricing policies

Within the Australian health system is a strong focus on cost control and minimizing overall life sciences spending. Section 8 of the National Health Act grants the Minister of Health broad powers to negotiate and set the price of any life sciences product to be provided through the national health service, Medicare, and listed on the national formulary, the Pharmaceutical Benefits Scheme (PBS). Under this statutory pricing system, innovative products are subject to significant price reductions upon market entry of a follow-on product. Mandatory price reductions are also triggered by 5-, 10-, and 15-year anniversaries of product listing. Although some recent changes to the magnitude of these reductions have been made—with the 10-year anniversary price reductions decreased and the 15-year anniversary increased substantially—they remain in place. Additionally, innovative products included in the PBS are subject to additional adjustments by the Department of Health as well as further downward price pressure from a therapeutic group reference pricing system, which uses the lowest-priced product in the group. There are also rolling and automatic price reductions in place for listings on the F2 formulary through statutory "price disclosure reductions."

Dimension 2: Health system prioritization

Rewarding innovation is not a central feature of the overarching policy environment. With respect to reimbursement and pharmacoeconomic evaluation, Australia has had in place for a long time an HTA mechanism for all new product listings. This process has historically been long and drawn out, resulting in reimbursement decisions taking extensive time and delayed patient access. On average, it takes 47 months from global launch of a product to a reimbursement listing in Australia. More than half of this time is spent in review, after a product has been launched locally. Similarly, there is a high rate of rejections; few new products are appraised as being cost effective. Compared with other OECD peers, the PBS sees fewer innovative products launched and listed; they are, in effect, never made available to Australian patients. For example, of the 460 new medicines launched between 2012 and 2021 (and measured in Indicator 7 of the Matrix), Australian patients had access to only 156, or 32%, of them. This compares with 391 of the 460 products available in the U.S. (85%).

Dimension 3:
Systemic governance

The existing HTA mechanism does not officially disclose the cost-effectiveness thresholds used; practice suggests that recommendations for reimbursement coverage of high-cost medicines are rare. On a positive note, the Australian research-based life sciences industry association, Medicines Australia, has since 2010 concluded several consecutive strategic agreements with the Australian government, the latest of which has been in effect since 2022. As part of this latest agreement, the government agreed to a review of the HTA process. At the time of research, a reference committee had been established and a “terms of reference” document had been published. Modernizing the HTA process and review mechanism of new medicines so that more products are made available on a timelier basis would be a substantial improvement to Australia’s life sciences market access environment.

Canada

Patient Access Matrix

	Indicators	Performance classification	Dimension overall performance classification
Dimension 1: National life sciences pricing policies	1. Direct national price controls	Highly challenging	Highly challenging
	2. Imposition of mandatory price cuts, freezes, and/or rebates and discounts	Highly challenging	
	3. Frequency of downward price revisions	Highly challenging	
	4. Price linkage and price caps	Highly challenging	
Dimension 2: Health system prioritization	5. Overarching philosophy and direction of national health and life sciences system	Highly challenging	Highly challenging
	6. Pricing and reimbursement decision-making process and methodology	Highly challenging	
	7. Availability of new, innovative life sciences treatments and products	Challenging	
	8. Time to effective patient access	Highly challenging	
Dimension 3: Systemic governance	9. Systemic transparency	Challenging	Highly challenging
	10. Stakeholder engagement	Highly challenging	

Spotlight on the National Life Sciences Market Access Environment

Dimension 1: National life sciences pricing policies

At the national level, the Patented Medicine Prices Review Board (PMPRB) monitors and sets the price of patented medicines, judging whether a price is "excessive" for new and existing patented medicines. The PMPRB is mandated to continually review the price of patented medicines, with patentees required to submit pricing information regularly after a listing price has been set. If prices are found to be excessive, the PMPRB has the authority to impose rebates. It uses a two-step process to set and review prices for new patented medicine products: (1) scientific review and (2) price review. The purpose of the scientific review is to establish the "level of therapeutic improvement of a patented medicine product." There are four categories of therapeutic improvement, ranging from "breakthrough" to "slight or no improvement." The level of therapeutic improvement is used to determine if a price is judged as being "excessive." Over the past several years, Canadian authorities have been reforming how patented medicines are evaluated and priced through a new evaluation methodology. These reform efforts have focused almost exclusively on cost and expenditure reduction and had little regard for a product's level of innovation. These reforms have (1) expanded the size of the basket and (2) removed the U.S. and Switzerland as comparator economies. New economies that have been added include Australia, Belgium, Japan, the Netherlands, Norway, and Spain. Given the strict price and expenditure controls in place in most of these new economies, and the removal of the U.S. and Switzerland as comparator economies, these changes will substantially lower the overall price comparisons and thus the overall life sciences price level in Canada—while adding more layers of complexity to the pricing and reimbursement process.

Dimension 2: Health system prioritization

Overall, there is a strong focus on cost control and minimizing overall life sciences spending within the Canadian health system. Canada has in place a traditional single-payer, tax-funded national health insurance program called Medicare. The central government sets insurance standards through the Canada Health Act, and provincial and territorial health insurance plans implement this law and offer actual coverage and medical services. Consequently, downward cost pressure on life sciences is exerted at both federal and provincial levels. With respect to pricing and reimbursement policies for life sciences, pricing review takes place at the central level, whereas formularies and decisions on reimbursement take place at the individual provincial/territorial level. The Canadian pricing and reimbursement process is long and drawn out, resulting in reimbursement decisions taking extensive time and delaying patient access.

On average, it takes 52 months from the global launch of a product to a reimbursement listing in Canada. Almost two-thirds of this time (34 months) is spent in review, after a product has been launched locally. Compared with other OECD peers, Canada sees fewer innovative products launched and listed. For example, of the 460 new medicines launched between 2012 and 2021 (and measured in Indicator 7 of the Matrix), Canadian patients had access to only 207, or 45%, of them. This compares with 391 of the 460 products available in the U.S. (85%).

Dimension 3: Systemic governance

Different price comparisons and methodologies are made, depending on the assessed level of therapeutic improvement. These include comparisons based on international reference pricing as well as internal reference pricing through therapeutic class comparisons. Overall, relatively few products are assessed as being of "breakthrough" status, with most products assessed appraised at the lowest level of therapeutic improvement. For example, at the time of research, the latest available annual report published by the PMPRB was for 2021. Out of a total of 876 products reviewed in the 2012–21 period, only 19 were assessed as achieving "breakthrough" status—0.6% of the total. Most products for which the review process had been completed (76.8%) were assessed as having a therapeutic level of "slight or no improvement." Equally, meaningful stakeholder engagement is limited. Local industry was forced to initiate legal action against proposed reforms to the PMPRB pricing methodology proposed by Health Canada. These successful legal challenges have limited the scope of some of the proposals.

France

Patient Access Matrix

	Indicators	Performance classification	Dimension overall performance classification
Dimension 1: National life sciences pricing policies	1. Direct national price controls	Challenging	Highly challenging/ challenging
	2. Imposition of mandatory price cuts, freezes, and/or rebates and discounts	Highly challenging	
	3. Frequency of downward price revisions	Challenging	
	4. Price linkage and price caps	Highly challenging	
Dimension 2: Health system prioritization	5. Overarching philosophy and direction of national health and life sciences system	Challenging	Challenging
	6. Pricing and reimbursement decision-making process and methodology	Challenging	
	7. Availability of new, innovative life sciences treatments and products	Challenging	
	8. Time to effective patient access	Highly challenging	
Dimension 3: Systemic governance	9. Systemic transparency	Mixed	Mixed
	10. Stakeholder engagement	Mixed/challenging	

Spotlight on the National Life Sciences Market Access Environment

Dimension 1: National life sciences pricing policies

In terms of pricing policy, price regulations are in place for virtually all life sciences on the French market. (Free pricing does exist for nonreimbursed products and products included in the early entry schemes—formerly the so-called ATU—with the proviso that a proportion of any "excess" price over a subsequently negotiated price will be returned by the manufacturer.) The price of a new product is based on an internal evaluation and direct negotiations with the manufacturer. The French health system has in place a long-standing and elaborate system of clawbacks and mandatory rebates, depending on sales volume and growth. Specifically, a preset universal budget as well as predetermined life sciences annual spending growth rates act as de facto cost and expenditure control mechanisms. The French pricing and reimbursement system also imposes automatic price cuts on loss of exclusivity, and the price of follow-on products is set at a percentage of the originator's price; different percentages apply, depending on in- or outpatient usage.

Dimension 2: Health system prioritization

Overall, there is a strong emphasis on containing cost and the growth of life sciences spending within the French health system. All innovative medicines that have received marketing approval must undergo a pharmacoeconomic and HTA evaluation by the Haute Autorité de Sante (HAS). The purpose of the assessment is to determine (1) whether a given product should be included in the national reimbursement list, (2) the rate of reimbursement, and (3) the listing price. HAS conducts two separate evaluations of a new medicine's benefit: the clinical benefit (Service Médical Rendu, SMR) and improvement in actual clinical benefit (Amélioration du Service Médical Rendu, ASMR). There have, historically, been long delays in the reimbursement appraisal and product evaluation process. On average, it takes 34 months from the global launch of a product to a reimbursement listing in France. Just over a year of this time (15 months) is spent in review, after a product has been launched locally. Furthermore, compared with other OECD peers, France sees fewer innovative products launched and listed. For example, of the 460 new medicines launched between 2012 and 2021 (and measured in Indicator 7 of the Matrix), French patients had access to only 239, or 52%, of them. This compares with 391 of the 460 products available in the U.S. (85%).

Dimension 3: Systemic governance

Both the SMR and ASMR rating affect the price and level of reimbursement for a given product. Although not frequently used, it is primarily within this appraisal process and the ASMR rating that there is a theoretical scope for recognizing and rewarding innovation through a "premium." However, relatively few products are rated as achieving a high ASMR rating and showing a "major clinical improvement." Consequently, few new products are awarded an innovation premium. For example, appraisal data between 2014 and 2020 show that a total of 146 products were submitted for reimbursement and pricing evaluation (SMR and ASMR). Only 6.1% of the products assessed received the highest ASMR rating of I ("important"). Most products received an ASMR of III or IV, and the clinical added value was rated as "minor" or "no clinical improvement." This stands in contrast with the SMR rating for the same products, which found that most of them achieved a clinical benefit rating of I ("important"). To address challenges of access to new innovation, the French government has launched several different initiatives—most notably Healthcare Innovation 2030.

This flagship policy includes a strong focus on expanding and accelerating access to new life sciences innovation within the context of both growing the economic footprint of the health care sector—including through increased levels of clinical research and biomedical R&D—and improving the overall provision and delivery of health care services. Section 4 of the plan contains specific objectives for improved patient access to new medicines. Modernizing the French pricing and reimbursement process so that more products are made available on a timelier basis would be a substantial improvement to France's life sciences market access environment.

Germany

Patient Access Matrix

	Indicators	Performance classification	Dimension overall performance classification
Dimension 1: National life sciences pricing policies	1. Direct national price controls	Challenging	Highly challenging
	2. Imposition of mandatory price cuts, freezes, and/or rebates and discounts	Highly challenging	
	3. Frequency of downward price revisions	Highly challenging	
	4. Price linkage and price caps	Highly challenging	
Dimension 2: Health system prioritization	5. Overarching philosophy and direction of national health and life sciences system	Highly challenging	Highly challenging
	6. Pricing and reimbursement decision-making process and methodology	Highly challenging	
	7. Availability of new, innovative life sciences treatments and products	Mixed	
	8. Time to effective patient access	Highly challenging	
Dimension 3: Systemic governance	9. Systemic transparency	Mixed	Challenging
	10. Stakeholder engagement	Mixed/challenging	

Spotlight on the National Life Sciences Market Access Environment

Dimension 1: National life sciences pricing policies

Traditionally, Germany had in place a "free pricing model" for its life sciences market; manufacturers of new innovative products entering the market were able to decide and set their own prices relatively freely. In 2011, this changed with the Arzneimittelmarktneuordnungsgesetz law (AMNOG). This law retained an element of free pricing but introduced a national process whereby all new innovative products introduced into the German retail market undergo a pharmacoeconomic evaluation and HTA of the medicine's therapeutic benefit over existing treatments. The price of innovative medicines that demonstrate added therapeutic benefit is set through negotiations between manufacturers and the health insurance funds. Innovation price premiums are available for products that receive the highest therapeutic benefit assessment; see next section for a detailed discussion. The AMNOG also introduced a price freeze that remained in effect throughout 2022.

Dimension 2: Health system prioritization

At the systemic national level and in its day-to-day technical operations, the German health system has since 2011 moved away from a policy environment promoting access to new life sciences innovation and toward a greater focus on cost and expenditure containment. The AMNOG is overseen by the German medicine regulatory authority, the Gemeinsamer Bundesausschuss, with the HTA usually carried out by the German national HTA authority Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Prior to the AMNOG reforms, Germany had a rate of new product listings that was among the highest in the world and comparable with that of the U.S. Today, a gap is there—and growing. For example, of the 460 new medicines launched between 2012 and 2021 (and measured in Indicator 7 of the Matrix), German patients had access to only 281, or 61%, of them. This compares with 391 of the 460 products available in the U.S. (85%).

Dimension 3: Systemic governance

As mentioned, the AMNOG provides the theoretical possibility of innovation price premiums based on therapeutic benefit. Therapeutic benefit is assessed on a scale of 1 to 6, from “major additional benefit” to “no additional benefit proven” and “the benefit is less than those of the comparator.” As of late 2022, most therapeutic assessments (61%) concluded that the evaluated product provided no additional benefit. Moreover, appraisals of therapeutic benefit in patient subpopulations found even fewer additional benefits. Between 2011 and 2017, a major additional benefit was found in less than 1% of the patient population groups studied. Following the COVID-19 pandemic and accompanying budgetary pressures on the German health system, a financial stabilization package was enacted in late 2022 to shore up the funding for all statutory health insurance funds: the GKV Financial Stabilization Act. This package includes several notable measures targeting life sciences that further erode German patients’ access to new medical innovation. To begin with, the law tightened eligibility criteria for innovation price premiums and introduced new mandatory budget caps and so-called price-volume agreements.

Existing mandatory rebates were increased and a new 20% rebate on combination products introduced. The GKV also halved the period of free pricing on an initial product listing from 12 to 6 months.

Overall, this latest legislative package did not address, or even recognize, the long-term negative impact of the decade-old AMNOG reforms on the research-based industry and German patients’ access to new medicines and products. Instead, the new reforms have simply erected additional barriers and imposed more cost and expenditure containment.

Italy

Patient Access Matrix

	Indicators	Performance classification	Dimension overall performance classification
Dimension 1: National life sciences pricing policies	1. Direct national price controls	Highly challenging	Highly challenging
	2. Imposition of mandatory price cuts, freezes, and/or rebates and discounts	Highly challenging	
	3. Frequency of downward price revisions	Challenging	
	4. Price linkage and price caps	Highly challenging	
Dimension 2: Health system prioritization	5. Overarching philosophy and direction of national health and life sciences system	Challenging	Highly challenging/ challenging
	6. Pricing and reimbursement decision-making process and methodology	Highly challenging	
	7. Availability of new, innovative life sciences treatments and products	Mixed	
	8. Time to effective patient access	Highly challenging	
Dimension 3: Systemic governance	9. Systemic transparency	Mixed	Challenging
	10. Stakeholder engagement	Challenging	

Spotlight on the National Life Sciences Market Access Environment

Dimension 1: National life sciences pricing policies

Italy has, historically, had one of the most restrictive pricing and reimbursement systems in Europe. The Italian health system is a publicly funded universal national health service (Servizio Sanitario Nazionale). Although the health system is decentralized and implemented at the regional level, Italy operates for life sciences a national formulary, the Prontuario Farmaceutico Nazionale. The Italian medicine regulatory authority AIFA (Agenzia Italiana del Farmaco) oversees pricing and reimbursement as well as the administration of the life sciences system. AIFA negotiates directly with manufacturers on rates of reimbursement and the price of a product. Price cuts and so-called paybacks have been in place for years and are aggressively applied. Under this scheme, manufacturers can choose to pay back a given percentage of spending on their products or accept a unilateral cut in prices. These policies are applied to both in- and outpatient sectors. Given that most modern high-cost treatments are provided within a hospital and clinical setting, a disproportionate amount of these paybacks come from the inpatient sector. Other policies have also targeted internal reference pricing whereby products are grouped together and compared based on therapeutic equivalence—including comparisons between products under exclusivity and follow-on products as well as products with different active ingredients.

Dimension 2: Health system prioritization

Cost remains a primary guidepost—with only limited room for recognizing innovation. Budget targets set by the central government tie pharmaceutical expenditure to overall levels of health expenditure. There is some scope for recognizing innovation within the health system, with a specific budget allocated for innovative treatments: the Innovative Medicine Fund launched in 2017. Products supported by this budget are funded separately, gain immediate access to all regions in Italy, and are exempt from mandatory discounts. To qualify for reimbursement under this fund, a new treatment must show that there is (1) unmet medical need, (2) an additional therapeutic benefit, and (3) a high level of robustness to the supporting clinical evidence. At the time of research, this fund had an allocated budget of €1 billion, virtually unchanged since its launch. More broadly, the reimbursement process is marred by delays and is longer than that of many other OECD economies. On average, it takes 38 months from the global launch of a product to a reimbursement listing in Italy. A year and a half of this time (18 months) is spent in review after a product has been launched locally. Compared with other OECD peers, Italy sees fewer innovative products launched and listed. For example, of the 460 new medicines launched between 2012 and 2021 (and measured in Indicator 7 of the Matrix), Italian patients had access to only 239, or 52%, of them. This compares with 391 of the 460 products available in the U.S. (85%).

Dimension 3: Systemic governance

There is a long-standing issue of price cuts and “paybacks” policies being applied equally to the in- and outpatient sectors, with limited meaningful change over time. Given that most modern high-cost treatments are provided within a hospital and clinical setting, a disproportionate amount of these paybacks come from the inpatient sector. Despite this long-standing challenge having been identified by the research-based industry, this practice remains largely unchanged. Pre-COVID data suggest that very few products are included in the fund and thus granted additional commercial benefits. In the fund’s first three years of operation, only a handful of new medicines were included every year: 0 in 2017, 9 in 2018, and 6 in 2019.

Japan

Patient Access Matrix

	Indicators	Performance classification	Dimension overall performance classification
Dimension 1: National life sciences pricing policies	1. Direct national price controls	Highly challenging	Highly challenging
	2. Imposition of mandatory price cuts, freezes, and/or rebates and discounts	Highly challenging	
	3. Frequency of downward price revisions	Highly challenging	
	4. Price linkage and price caps	Highly challenging	
Dimension 2: Health system prioritization	5. Overarching philosophy and direction of national health and life sciences system	Highly challenging	Highly challenging
	6. Pricing and reimbursement decision-making process and methodology	Highly challenging	
	7. Availability of new, innovative life sciences treatments and products	Mixed	
	8. Time to effective patient access	Highly challenging	
Dimension 3: Systemic governance	9. Systemic transparency	Highly challenging	Highly challenging
	10. Stakeholder engagement	Highly challenging	

Spotlight on the National Life Sciences Market Access Environment

Dimension 1: National life sciences pricing policies

Historically, Japan's life sciences market has had high barriers to entry. Japanese medicine regulations mandated local clinical trials as part of the medicine approval process, and market access was further restricted through a system of strict price controls and systematic price cuts. The result of these barriers was that Japan was in many ways closed off to foreign life sciences, and new medicines took longer to reach patients in Japan than in any other developed OECD economy. In the decade between the mid-1980s and mid-1990s this launch lag was estimated at over 12 years. Although by the mid-2000s this lag had declined to just under eight years, it was still longer than that found in other comparable economies. During the late 2000s and mid-2010s, Japan introduced several measures to reduce these barriers and improve product access and availability. Chief among these were the elimination of much of the local clinical trials requirement, the acceptance of ICH standards on the recognition of international trials data, and key changes to the pricing and reimbursement system. The centerpiece of the latter was a greater focus on recognizing innovation through the introduction of the Price Maintenance Premium (PMP) program, accelerating all relevant approval timelines and introducing additional price premiums based on levels of innovation (including through the Sakigaki program). The PMP program limited the impact of cost-control mechanisms in place, which mandated a cut in prices every two years. Additional reforms aimed to improve and expand the uptake of generic medicines within the health system. (Unlike in the U.S. and many other OECD economies, the prescription of generic and follow-on products makes up only a small proportion of overall volume of medicines dispensed in Japan.) Together these reforms marked a paradigm shift and suggested that the life sciences market access environment in Japan had fundamentally changed. However, since 2016, many of these positive reforms have been rolled back and/or replaced by blunt-cost and expenditure containment measures. To begin with, the eligibility criteria for receiving the PMP have been tightened, with the number of companies eligible reduced. Industry reports suggest that these reforms have resulted in reducing the number of eligible products by 50%, and so the number of innovative medicines receiving a PMP has fallen dramatically. Similarly, a system of biennial price revaluations and cuts was in 2021 replaced with a move to repricing annually. (National price controls are in place for all products eligible for reimbursement and listed on the national formulary, the Japanese "Medicines List.") Ad hoc substantial price cuts are also in place for fast-selling, costly products that exceed expected sales volume—the "huge seller" rule. Under this rule, an innovative medicine with sales of ¥35 billion or higher is subject to a price review quarterly and a price reduction. Furthermore, innovative medicines with annual sales between ¥100 billion and ¥150 billion may be subject to an immediate price cut between 25% and 50%, depending on how much their projected sales volume outpaces initial estimates. Price caps and linkage mechanisms are also in place for follow-on products.

Dimension 2: Health system prioritization

Japan's policy environment is characterized by a focus on drastic price and reimbursement controls, with limited to no scope for recognizing levels of life sciences innovation and a strong focus on blunt-cost and expenditure containment measures. In 2016, Japanese authorities introduced a pilot HTA procedure; it was subsequently adopted on a permanent basis in 2019 and is actively applied today. The Japanese HTA program is almost exclusively focused on cost effectiveness and the specific thresholds in place. Unlike HTA mechanisms in many other economies, the Japanese system is narrowly based on achieving budget efficiencies and expenditure control, with limited systematic effort to understand or map the greater health and socioeconomic value of an appraised product. The result is that Japanese patients have less access to innovative treatments than do patients in other high-income OECD economies. On average, it takes 17 months from the global launch of a product to a reimbursement listing in Japan. Furthermore, compared with other OECD peers, Japan sees fewer innovative products launched and listed. For example, of the 460 new medicines launched between 2012 and 2021 (and measured in Indicator 7 of the Matrix), Japanese patients had access to only 235, or 51%, of them. This compares with 391 of the 460 products available in the U.S. (85%).

Dimension 3: Systemic governance

Since 2016 and throughout the pricing and reimbursement system's reform process to the Japanese life sciences market access environment and pricing and reimbursement regulations there has been little meaningful engagement between the relevant health authorities and the affected research-based life sciences industry. Specifically, industry reports suggest there are only limited ways of formally engaging with the relevant Japanese health authorities and that, since 2016, there has been a lack of transparency with both proposed and implemented changes to the pricing and reimbursement environment.

South Korea

Patient Access Matrix

	Indicators	Performance classification	Dimension overall performance classification
Dimension 1: National life sciences pricing policies	1. Direct national price controls	Highly challenging	Highly challenging
	2. Imposition of mandatory price cuts, freezes, and/or rebates and discounts	Highly challenging	
	3. Frequency of downward price revisions	Highly challenging	
	4. Price linkage and price caps	Highly challenging	
Dimension 2: Health system prioritization	5. Overarching philosophy and direction of national health and life sciences system	Highly challenging	Highly challenging
	6. Pricing and reimbursement decision-making process and methodology	Highly challenging	
	7. Availability of new, innovative life sciences treatments and products	Challenging	
	8. Time to effective patient access	Highly challenging	
Dimension 3: Systemic governance	9. Systemic transparency	Highly challenging	Highly challenging
	10. Stakeholder engagement	Highly challenging	

Spotlight on the National Life Sciences Market Access Environment

Dimension 1: National life sciences pricing policies

National price controls are in place for all life sciences products to be included in the national formulary. Prices are set through a mix of external reference pricing, therapeutic comparisons, and cost-effectiveness studies. Mandatory price cuts have been instituted through a therapeutic reference pricing system that places innovative and generic medicines in the same baskets, with prices set based on the average price in the basket. The innovative or therapeutic value of a given product is not factored into the price. This system is complemented by other measures including rebates associated with price-volume agreements and post-listing repricing. These post-listing price reductions and reviews can take place in four ways: (1) price-volume cuts based on product sales exceeding the pre-market entry negotiated estimate, (2) transaction-based investigations in which market/transaction prices are investigated (these can lead to 10% reductions), (3) new indications for a medicine (which can lead to application of a discount rate of between 1% and 5%), and (4) loss of exclusivity (which leads to price cuts of 70% for a reference product).

Dimension 2: Health system prioritization

Overall, the Korean life sciences policy environment is characterized by a focus on drastic price and reimbursement control, with limited scope for recognizing levels of innovation. Approval for reimbursement is dually determined by a ruling of cost effectiveness by the Health Insurance Review and Assessment Service and price negotiations with the National Health Insurance Corporation. Korea has also introduced several changes to its pricing and reimbursement policies that favor local manufacturers and penalize foreign companies. This includes the de facto granting of price preference to locally developed innovative medicines and discrimination against foreign manufacturers. Specifically, the terms of a premium pricing policy were in 2018 the basis for discussions and renegotiations under KORUS; however, subsequent changes to the policy framework did not improve foreign manufacturers' ability to gain eligibility to price premiums. The result of these challenges is that Korean patients have less access to innovative treatments than do patients in other high-income, OECD economies. On average, it takes 46 months from the global launch of a product to a reimbursement listing in Korea. A year and a half of this time (18 months) is spent in review after a product has been launched locally. Furthermore, compared with other OECD peers, South Korea sees fewer innovative products launched and listed. For example, of the 460 new medicines launched between 2012 and 2021 (and measured in Indicator 7 of the Matrix), Korean patients had access to only 152, or 33%, of them. This compares with 391 of the 460 products available in the U.S. (85%).

Dimension 3: Systemic governance

Despite the aforementioned long-standing challenges having been identified by both the research-based industry and the U.S. government, the Korean pricing and reimbursement process remains largely unchanged. More broadly, there is little concrete and meaningful engagement between the Korea authorities and the research-based industry. Specifically, industry reports suggest that there are only limited ways of formally engaging with the relevant authorities and that there is a lack of transparency with both proposed and implemented changes to Korea's pricing and reimbursement environment.

United Kingdom

Patient Access Matrix

	Indicators	Performance classification	Dimension overall performance classification
Dimension 1: National life sciences pricing policies	1. Direct national price controls	Challenging	Challenging/ highly challenging
	2. Imposition of mandatory price cuts, freezes, and/or rebates and discounts	Highly challenging	
	3. Frequency of downward price revisions	Highly challenging	
	4. Price linkage and price caps	Mixed	
Dimension 2: Health system prioritization	5. Overarching philosophy and direction of national health and life sciences system	Challenging	Challenging
	6. Pricing and reimbursement decision-making process and methodology	Challenging	
	7. Availability of new, innovative life sciences treatments and products	Mixed	
	8. Time to effective patient access	Highly challenging	
Dimension 3: Systemic governance	9. Systemic transparency	Mixed	Mixed
	10. Stakeholder engagement	Challenging	

Spotlight on the National Life Sciences Market Access Environment

Dimension 1: National life sciences pricing policies

Unlike most European economies, the UK does not have in place direct price controls for most medicines. Instead, its primary system of price regulation is indirect, governed by the Voluntary Scheme for Branded Medicines Pricing and Access 2019–2023, which replaced the long-standing Pharmaceutical Price Regulation Scheme (PPRS). (There is also a separate Statutory Scheme whereby manufacturers not willing to participate in the Voluntary Scheme have their products priced directly with the Department of Health through a mixture of negotiation and price and profit product comparisons.) Under the Voluntary Scheme, price negotiations take place between the Department of Health and manufacturers. Free pricing is allowed during the first 36 months for "new active substances." However, price increases are controlled within both the Voluntary and Statutory Schemes through a mandatory clawback mechanism. The National Health Service (NHS) has a predetermined budget capped at 2% annual growth for life sciences expenditure. Under this system, manufacturers make direct payments throughout the year to the Department of Health to make up for any spending above this limit. As of 2022, these rebate payments amounted to 15% of net sales under the Voluntary Scheme and 14.3% under the Statutory Scheme. As such, these payments fundamentally act as a blunt expenditure control tool; they do not differentiate between types of products, consider the value of innovation, or seek to accelerate access to new products and technologies.

Dimension 2: Health system prioritization

The UK's overarching policy framework is a mix of blunt-price and reimbursement controls and policies aimed at accelerating the uptake of new life sciences innovation. The UK has had in place since the early 2000s a system of HTA overseen by the National Institute for Health and Care Clinical Excellence (NICE). NICE appraises new life sciences products on the UK market and recommends whether a product should be reimbursed and the extent of its availability to patients through the NHS. Industry reports suggest that almost half (49%) of the products appraised by NICE since 2000 have not been recommended for full use within the NHS in line with the marketing authorization application. For oncology treatments, this percentage was largely the same, with 52% not recommended in line with marketing authorization. Like many HTA bodies, NICE uses a cost-effectiveness threshold and benchmark to assess the cost effectiveness of new products through quality-adjusted life-years (QALYs). QALY is a kind of Patient Access Matrix that measures the value of a given product based on two dimensions: (1) the life-years that are added to the patient due to the use of a given product and (2) the quality of life experienced during those years. NICE has used the same cost-effectiveness threshold of £20,000 to £30,000 per QALY since it became operational in the early 2000s. In 2022, after an official review of NICE procedures and appraisal standards, a slight modification to this cost-effectiveness threshold was introduced,

with the possibility of using a higher cost-effectiveness threshold under specific circumstances. Historically, the UK's pricing and reimbursement process has been drawn out, resulting in reimbursement decisions taking extensive time and delayed patient access. On average, it takes 27 months from the global launch of a product to a reimbursement listing in the UK. Just over a year of this time (15 months) is spent in review, after a product has been launched locally. Furthermore, compared with OECD peers, UK sees fewer innovative products launched and listed. For example, of the 460 new medicines launched between 2012 and 2021 (and measured in Indicator 7 of the Matrix), UK patients had access to only 271, or 59%, of them. This compares with 391 of the 460 products available in the U.S. (85%).

Dimension 3: Systemic governance

NICE's remit has gradually been widened from cost effectiveness to include budget impact. Specifically, in 2017, NICE was charged with making a Budget Impact Test for all new products covered by the NHS and expected to exceed a cost threshold of £20 million. Under this test, the NHS could delay the funding of new products even after receiving a positive recommendation from NICE. At the time of introduction, this was criticized for adding an additional layer of cost and expenditure containment into what should be a pharmacoeconomic and cost-effectiveness analysis. Given the relatively low access rate, a range of government-supported programs have over the last decade been introduced to effectively bypass NICE and the national pricing and reimbursement process—and enable accelerated access to new medicines and technologies. In 2011, the Cancer Medicines Fund was introduced to provide dedicated funding for new, innovative oncology treatments. (The fund's remit was changed in 2016 with a fixed budget introduced and all decisions for reimbursement to be made by NICE.) In 2021/22, plans for a new additional supplementary fund, the Innovative Medicines Fund, were announced. Its purpose is to accelerate patient access to new non-cancer treatments. More broadly, the 2021 Life Sciences Vision, which lays out the British government's view on the life sciences sector going forward, includes a dedicated focus on improving the pricing and reimbursement environment and expanding patient access to new medical innovation. Specifically, the Vision document states that it seeks to create "a forward-thinking commercial environment where the NHS can strike flagship deals and where proven, clinically [effective] and cost effective innovations are rapidly adopted and spread across the country to bolster the health of the nation, deliver greater value for the taxpayer, and stimulate economic growth." Modernizing the British pricing and reimbursement process so that more products are made available on a timelier basis would be a substantial improvement to the UK's life sciences market access environment.

United States, pre-IRA

Patient Access Matrix

	Indicators	Performance classification	Dimension overall performance classification
Dimension 1: National life sciences pricing policies	1. Direct national price controls	Attractive	Attractive
	2. Imposition of mandatory price cuts, freezes, and/or rebates and discounts	Attractive	
	3. Frequency of downward price revisions	Attractive	
	4. Price linkage and price caps	Challenging	
Dimension 2: Health system prioritization	5. Overarching philosophy and direction of national health and life sciences system	Attractive	Attractive
	6. Pricing and reimbursement decision-making process and methodology	Attractive	
	7. Availability of new, innovative life sciences treatments and products	Attractive	
	8. Time to effective patient access	Mixed	
Dimension 3: Systemic governance	9. Systemic transparency	Mixed	Mixed
	10. Stakeholder engagement	Challenging	

United States, post-IRA

Patient Access Matrix

	Indicators	Performance classification	Dimension overall performance classification
Dimension 1: National life sciences pricing policies	1. Direct national price controls	Highly challenging	Highly challenging
	2. Imposition of mandatory price cuts, freezes, and/or rebates and discounts	Highly challenging	
	3. Frequency of downward price revisions	Challenging	
	4. Price linkage and price caps	Challenging	
Dimension 2: Health system prioritization	5. Overarching philosophy and direction of national health and life sciences system	Challenging	Challenging
	6. Pricing and reimbursement decision-making process and methodology	Highly challenging	
	7. Availability of new, innovative life sciences treatments and products	Attractive	
	8. Time to effective patient access	Mixed	
Dimension 3: Systemic governance	9. Systemic transparency	Challenging	Highly challenging
	10. Stakeholder engagement	Highly challenging	

Spotlight on the National Life Sciences Market Access Environment

Dimension 1: National life sciences pricing policies

Historically, the provision of health care in the U.S. has been based on a health insurance model principally managed via private funding and private delivery. Health care facilities—including hospitals and clinics—are mainly privately owned and operated. The elderly, those with low income, military personnel, and public-sector employees are eligible for public coverage of health care (either full or subsidized) via Medicare, Medicaid, and other programs that are run by the federal and state governments. Similarly, the life sciences market has been predominantly market based. Private payers, including insurers, managed care organizations, and pharmaceutical benefit managers, aggregate various health plans and purchase life sciences on behalf of their members. Payers often employ formularies, differential cost sharing (including tiered copayments), and other methods to influence prescribing practices. In doing so, they can negotiate discounted prices from life sciences manufacturers and pharmacies. Individual hospitals and other health care institutions are also increasingly using formularies to manage costs. Unlike many other high-income OECD economies—including all economies sampled in this Matrix—the U.S. federal government has never imposed national price controls or other restrictions and market access barriers on health technologies, including life sciences and medical devices. This has now changed with the passage of the IRA. The law includes a series of fundamental changes to the pricing framework for medicines covered under Medicare Parts B and D. Purportedly providing the HHS and CMS with the authority to negotiate the price of a set number of medicines without generic or biosimilar competition that are covered under Medicare, the law grants such sweeping powers to the Secretary of HHS, and imposes such punitive damages on manufacturers that fail to agree or abide by the price setting mechanism, that it is a de facto national expenditure and price control. The legislation uses the non-federal average manufacturer price available for a given medicine, adjusted based on the percentage increase in the consumer price index, as the basis for a government-set price. Through a convoluted process the so-called maximum fair price (MFP) established for negotiated products must be equal to or less than this price—what is termed a “ceiling price.” This ceiling price is a set percentage for each product (75%, 65%, or 40%), depending on how long a given product has been on the market, with the lowest percentages applying to the oldest products. Furthermore, the IRA distinguishes between small- and large-molecule products, with small-molecule entities subject to negotiations at a much earlier date. Although the IRA excludes certain orphan disease treatments from negotiations, this exclusion is narrow and applies only to products used exclusively to treat one condition/disease. Moreover, the law introduces new mandatory discounts of 10% to 20% through a manufacturer medicine discount program.

The legislation also caps the out-of-pocket cost that Medicare patients pay for insulin at $35 per month. Finally, in a highly unusual departure from standard public administration and lawmaking practice, the IRA outlaws manufacturers' ability to challenge the major components of the program. Section 1198 simply states that "there shall be no administrative or judicial review" of the Secretary's authority and decisions relating to the selection of products subject to price controls, the determination of maximum fair prices, and which medicines will be subject to negotiations and renegotiations. At the time of research, HHS and CMS were in the process of finalizing implementing regulations, with an initial "guidance" document issued in March 2023 and a revised document published in June. The administration in late August 2023 released the list of 10 initial medicines subject to these new powers and price control measures.

Dimension 2: Health system prioritization

The U.S. life sciences policy framework has, historically, relied on competition, rather than government intervention, in the price-setting process to contain the prices of innovative medicines. This long-standing framework has resulted in patients having primary and extensive access to new lifesaving treatments and cures and has built a scientific and life sciences R&D infrastructure that is the envy of the world, consistently producing new lifesaving medical innovations and cutting-edge technologies—as demonstrated most notably during the COVID-19 pandemic. Both the long-term historical record and the most recent launch and product availability data show how economies with price controls and a more challenging biopharmaceutical market access environment consistently see substantially lower levels of product penetration and drug availability for patients. There is a large disparity in product launches and market availability of new medicines between the U.S. and other advanced OECD member states with a history of price and reimbursement controls in place.

Dimension 3: Systemic governance

The IRA grants such sweeping powers to the HHS Secretary, and imposes such punitive damages on manufacturers that fail to agree to or abide by the price setting mechanism, that it does not in any way constitute a negotiation. Instead, the law is simply a de facto expenditure and price control mechanism. Similarly, the IRA outlaws manufacturers' ability to challenge the major components of the program, eliminating any legal review of the federal government's authority and decisions relating to the selection of products subject to price controls, the determination of maximum fair prices, and which medicines will be subject to negotiations and renegotiations. In 2021, the research-based life sciences industry successfully challenged proposals for the introduction of an International Pricing Index and the development of a most-favored-nation (MFN) model to be used by Medicare Part B. This plan was formalized in 2020 by HHS and CMS. The MFN model would benchmark the price of a basket of 50 biopharmaceutical products against the price of the same products in a sample of OECD economies. The comparator economies were chosen based on OECD membership and per capita GDP, at PPP, of 60% or above that of the U.S. After several court rulings in 2021, the CMS formally rescinded the proposed MFN model. Today there are several pending legal challenges filed regarding the price control provisions under the IRA.supplementary fund, the Innovative Medicines Fund, were announced. Its purpose is to accelerate patient access to new non-cancer treatments.

More broadly, the 2021 Life Sciences Vision, which lays out the British government's view on the life sciences sector going forward, includes a dedicated focus on improving the pricing and reimbursement environment and expanding patient access to new medical innovation. Specifically, the Vision document states that it seeks to create "a forward-thinking commercial environment where the NHS can strike flagship deals and where proven, clinically [effective] and cost effective innovations are rapidly adopted and spread across the country to bolster the health of the nation, deliver greater value for the taxpayer, and stimulate economic growth." Modernizing the British pricing and reimbursement process so that more products are made available on a timelier basis would be a substantial improvement to the UK's life sciences market access environment.

Conclusion

The Patient Access Matrix shows the substantial negative impact that the IRA has had on the American life sciences market access environment. Instead of being rated as the highest-performing economy included in the Matrix, performance of the U.S. environment is now roughly commensurate with that of Australia and Canada.

As the federal government moves forward with its plans for implementing the IRA, it should pause and consider the full ramifications of its proposed policy actions. All health systems struggle with rising costs; this is not a uniquely American phenomenon. But the solution is not to impose a system of "take it or leave it" price controls that will, inevitably, reduce patient access to new biopharmaceutical products and technologies. Regardless of where on the spectrum the U.S. post-IRA experience falls relative to those of OECD economies, one undeniable conclusion is that the imposition of national price and reimbursement controls invariably comes at a cost: fewer new medicines and longer wait times. That cost is very clear, regardless of whether it's the experience of the UK, Germany, France, or Japan.

Appendix

Sources

The Patient Access Matrix is based on both qualitative and quantitative evidence. To provide as complete a picture as possible of an economy's life sciences market access environment, this evidence is drawn from a range of sources. All sources used are publicly available and freely accessible. The following is an outline of the types of sources used.

Government
Sources from government branches and agencies include the following:

- Primary legislation
- Secondary legislation (regulation) from executive, legislative, and administrative bodies
- Reports, rules, and published guidelines from government agencies (and, where relevant, parliamentary committees), in particular, government institutions dealing with health and pharmaceutical policy
- Internal departmental guidelines, assessment protocols, and policies

Legal
Sources from judicial authorities and legal practitioners include the following:

- Court cases and decisions
- Legal opinions written by judges
- Legal analysis and opinions written by legal practitioners

International institutions and third parties
These sources include the following:

- Data, studies, and analysis from international organizations such as the OECD, WTO, IMF, UNCTAD, and WIPO
- Publicly available reports, studies, and government submissions by industry organizations
- Reports from NGOs and consumer organizations

Academic
Academic sources include the following:

- Academic journals
- Legal journals

News
News sources include the following:

- Newspapers
- News websites
- Trade press

Indicators Explained

This Appendix explains how each of the indicators included in the Matrix is measured. All indicators included in the Matrix, except numerical indicators, examine de jure laws, regulations, rules, official guidelines, and/or de facto practices.

Dimension 1: National life sciences pricing policies

1. **Direct national price controls:** The extent to which an economy's national health and life sciences system (including de jure laws, regulations, rules, official guidelines, and/or de facto practices) imposes direct price controls on life sciences products and technologies.

2. **Imposition of mandatory price cuts,** freezes, and/or rebates and discounts: The extent to which an economy's national health and life sciences system (including de jure laws, regulations, rules, official guidelines, and/or de facto practices) imposes mandatory price cuts, freezes, and/or rebates and discounts on life sciences products and technologies.

3. **Frequency of downward price revisions:** The extent to which an economy's national health and life sciences system (including de jure laws, regulations, rules, official guidelines, and/or de facto practices) seeks to regularly reassess and revise downward the officially regulated and set price of life sciences products and technologies.

4. **Price linkage and price caps:** The extent to which an economy's national health and life sciences system (including de jure laws, regulations, rules, official guidelines, and/or de facto practices) links and/or caps the price of a follow-on life sciences product and technology (generics and biosimilars) to a fixed percentage or ratio of the price of the reference product and/or a basket of reference products.

Dimension 2: Health system prioritization

5. **Overarching philosophy and direction of national health and life sciences system:** The extent to which a given economy's national health and life sciences system (including de jure laws, regulations, rules, official guidelines, and/or de facto practices) is geared toward cost and expenditure containment versus recognizing innovation and actively seeking to incorporate new, innovative life sciences products and technologies into the health system.

6. **Pricing and reimbursement decision-making process and methodology:** The extent to which a given economy's existing national life sciences pricing and reimbursement process, decision-making, and assessment methodology (regardless of pricing and reimbursement system and assessment methodology used) are made based on reaching the lowest possible price or rate of reimbursement or retains and makes comparisons that retain and value the level of innovation of a given life sciences product or technology.

7. **Availability of new, innovative life sciences treatments and products:** Measured by the availability of new medicines launched in the period 2012 to 2021.[23] This is a numerical indicator.

8. **Time to effective patient access:** An indicator that examines the extent to which a given economy's post-marketing life sciences pricing and reimbursement procedures, decision-making, and assessment methodology (regardless of pricing and reimbursement system and assessment methodology used) function as a de facto barrier to patient access by delaying the availability of new life sciences products and technologies that have been approved for use in the health system and granted market authorization by the relevant medicine regulatory authorities. This is a numerical indicator.[24]

Dimension 3: Systemic governance

9. **Systemic transparency:** The extent to which an economy's life sciences pricing and reimbursement procedures, decision-making, and assessment methodology (regardless of pricing and reimbursement system and assessment methodology used) are transparent to all stakeholders.

10. **Stakeholder engagement:** The extent to which stakeholders are provided the opportunity to meaningfully engage with and comment on both existing pricing and reimbursement procedures, decision-making, and assessment methodology (regardless of pricing and reimbursement system and assessment methodology used) and, when applicable, propose changes to that policy framework.

Endnotes

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6. PhRMA. (2023, April). Global access to new medicines report [Slide presentation]. Slide 11: Percentage of new medicines launched by G20 country (of all 460 new medicines launched from 2012 to end of 2021). PhRMA, Washington, DC.
7. Ibid.
8. IQVIA: Institute for Human Data Science. (2022, May). Global oncology trends 2022: Outlook to 2026, p. 7.
9. In a growing number of health systems, the reimbursement process often involves a pharmacoeconomic or HTA evaluation, which assesses a given product's cost effectiveness. Depending on the design and function of the HTA body and underlying assessment methodology used, this assessment can include a cost-effectiveness threshold and benchmark to assess the cost effectiveness of new products through quality-adjusted-life-years (QALYs). A QALY is a type of patient access matrix that measures the value of a given product on the basis of two dimensions: the length of time added to patients' lives due to the use of a given product and the "quality of life" experienced during these years.
10. Newton, M., et al. (2023, April). EFPIA patients W.A.I.T. indicator 2022 survey. EFPIA & IQVIA.
11. Ibid, slide 13. This is IQVIA's description of its dataset: "The time to availability is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list). The marketing authorisation date is the date of central EU authorisation.... For France, the time to availability (508 days, n = 93 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer."
12. Medicines Australia. (2018). Comparison of access and reimbursement environments (4th ed.).
13. Innovative Medicines Canada & IMS Health Canada. (2016). Access to new medicines in public medicine plans: Canada and comparable countries, 5.
14. Innovative Medicines Canada. (n.d.). Canadian public reimbursement timelines. https://innovativemedicines.ca/resources/crt/
15. Ferrario, A. (2018) Time to entry for new cancer medicines: From European Union–wide marketing authorization to patient access in Belgium, Estonia, Scotland, and Sweden. Value in Health, 21, 809–821.

16. Ibid., 816. See also “Supplemental Material” for further information on the products mapped. The products never launched by brand name and INN in the sampled economies were Mekinist (trametinib), Panretin (alitretinoin), Foscan (temoporfin), Pixuvri (pixantrone dimaleate), Removab (catumaxomab), Trisenox (arsenic trioxide), Vargatef (nintedanib), Zydelig (idelalisib), Ameluz (5-aminolevulinic acid hydrochloride), Caprelsa (vandetanib), Erivedge (vismodegib), Firmagon (degarelix), Javlor (vinflunine), Kadcyla (trastuzumab emtansine), Lysodren (mitotane), Perjeta (pertuzumab), Stivarga (regorafenib), Tafinlar (dabrafenib), Targretin (bexarotene), Teysuno (tegafur / gimeracil / oteracil), and Zaltrap (aflibercept).

17. Zamora et al. (2017). Comparing access to orphan medicinal products (OMPs) in the United Kingdom and other European countries. Office of Health Economics.

18. What constitutes “access to medicines” in a given health system is a complex and technical topic. As demonstrated in Section 3, the first step to access is for a product to receive market authorization in a given legal jurisdiction and/or health system. But in addition to market authorization and sanitary product registration, there are substantial differences between health systems with respect to both the number of products publicly reimbursed and the average time it takes for patients to gain effective and meaningful access to them. A good example of what this means in practice is the EU. There, the majority of product registration and authorization takes place at the regional level, through the EMA. Once a product is approved and registered by this regional body, it is authorized for use throughout the EU. However, there are substantial differences between member states with respect to both the number of products publicly reimbursed and the average time it takes for patients to gain effective access to them. Each member state, through its broader health and biopharmaceutical policies, decides on market access policies and how to control the cost of medicines. Some member states and health systems seek to eliminate barriers to the introduction and utilization of new products and technologies; others focus solely on cost containment and do not prioritize patient access to new products and innovation. This takes place regardless of whether a given product has been approved and registered by EMA. In the U.S., decisions on access controls also take place at multiple legal and organizational levels. What is most critical is the extent to which patients can effectively and practically access the medicine or medical technology they require at the desired time of use.

19. Avalere. (2023, November 6). IRA negotiation creates ripple effects across drug markets. https://avalere.com/insights/ira-negotiation-creates-ripple-effects-across-drug-markets.

20. PhRMA. (2023). Global access, slides 11 and 18.

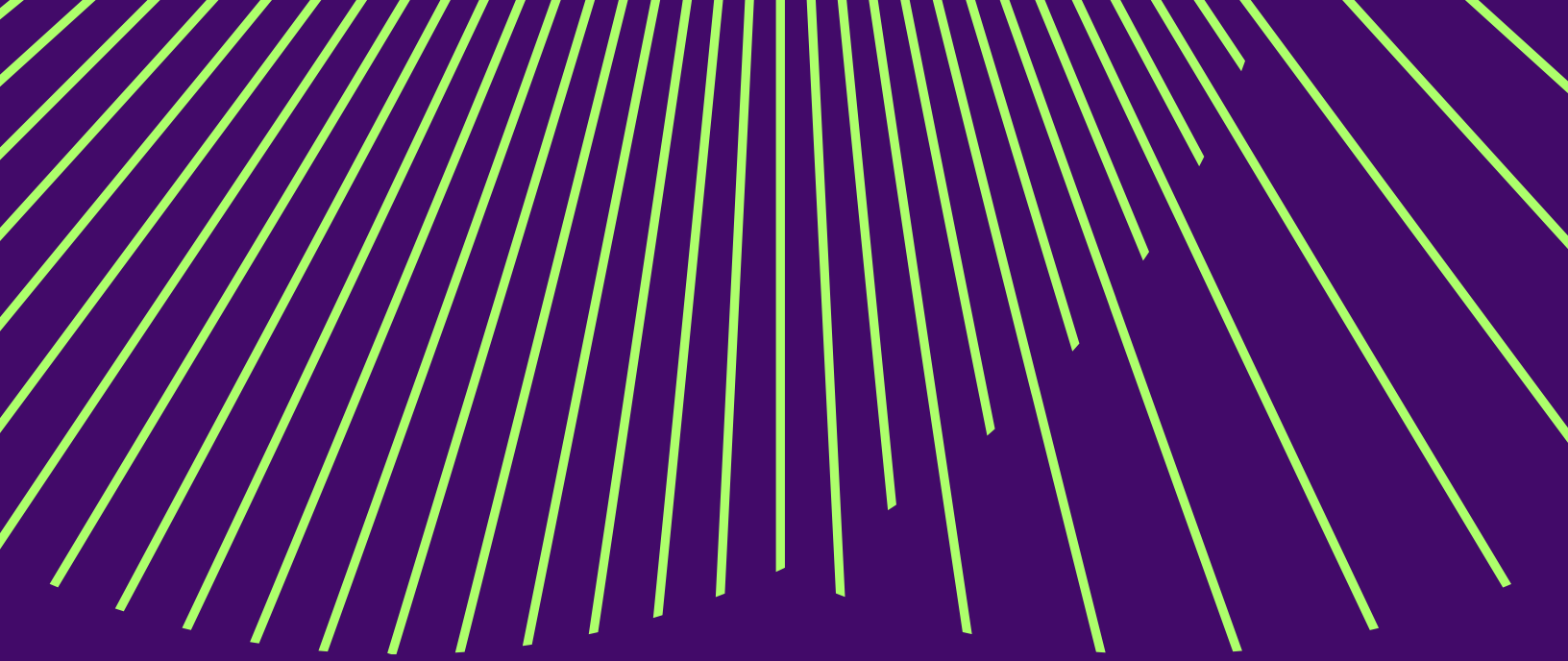
21. IQVIA: Institute for Human Data Science. (2023). Global use of medicines 2023: Outlook To 2027, 20¬–23.

22. Gassull, D., Bowen, H. & Schulthess, D. (2023). Slide 15: IRA’s impact on the US biopharma ecosystem. Vital Transformations.

23. Philipson, T. J., & Durie, T. (2021, November). Issue brief: The impact of HR 5376 on life sciences innovation and patient health. University of Chicago.

24. PhRMA. (2023, April). Slide 11.

25. This indicator posits that all post-marketing delays to patient access are negative in nature and detrimental to individual patients and public health. Consequently, all post-marketing delays in an economy will reduce its score on this indicator. Post-marketing delays and effective patient access are measured by the average number of days taken from medicine regulatory approval and market authorization to patient access, as represented by the inclusion and listing of a product or technology on the relevant public or national formularies and/or reimbursement lists. Any economy in which the average waiting period from the date of market authorization to patient access is equal to or exceeds one full year (365 days) will automatically receive a score of 0 on this indicator. If there are no post-marketing delays in an economy, the value it scores on this indicator is the maximum available score of 1.00. For delays of 1 to 364 days, the numerical formula used to calculate the impact of such delays is (364 – n days of delay) / 364.



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