



U.S. Chamber of Commerce
Global Innovation
Policy Center

Patient Access Report

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U.S. Chamber of Commerce

The U.S. Chamber of Commerce's Global Innovation Policy Center (www.theglobalipcenter.com) is working around the world to champion intellectual property rights as vital to creating jobs, saving lives, advancing global economic growth, and generating breakthrough solutions to global challenges.

The U.S. Chamber of Commerce is the world's largest business federation representing the interests of more than 3 million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations.



This report was conducted by Pugatch Consilium, (www.pugatch-consilium.com) a boutique consultancy that provides evidence-based research, analysis, and intelligence on the fastest growing sectors of the knowledge economy. Authors of this report are Meir Pugatch and David Torstensson.

Professor Meir Pugatch, Managing Director and Founder | Prof. Pugatch is the Managing Director of Pugatch Consilium – a boutique consultancy that provides evidence-based research, analysis and intelligence on the fastest growing sectors of the knowledge economy. He is an IPKM Professor of Valorisation, Entrepreneurship and Management at the University of Maastricht in the Netherlands; as well as a Professor at the School of Public Health, University of Haifa in Israel, in which he acts as the Chair of the Health Management Division since 2019. Prof. Pugatch specializes in innovation strategies, organizational entrepreneurship, intellectual property management, pharmacoeconomics, pricing and reimbursement, and the management of public health systems. He is the author and editor of an extensive number of publications and serves as a referee and editorial board member of numerous peer review journals.

David Torstensson, Partner | Dr. Torstensson specializes in innovation, tax and intellectual property policy, with a particular focus on the health care, information and communication technology and content industries. He has wide experience in policy and economic analysis, as well as data sampling and creation of strategic operational and advocacy plans. He is the author of a number of academic and commissioned reports and publications and is the co-author of all ten editions of the U.S. Chamber International IP Index.

Executive Summary

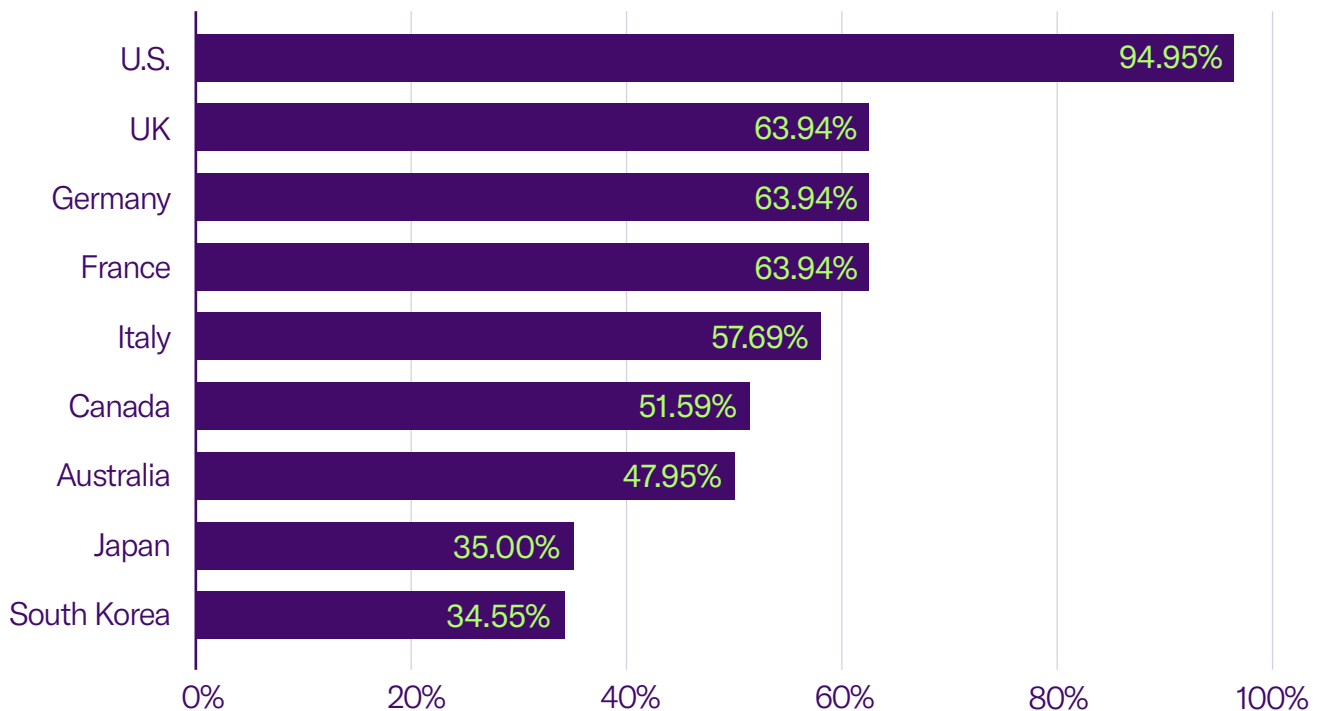
Countries with the right public policy frameworks in place can create an ecosystem where innovation can thrive. Free market frameworks, underpinned by effective intellectual property protection, have fostered life sciences innovation in key global markets. For that innovation to continue, countries must continue to allow marketplace competition to support the development of lifesaving treatments and cures.

The imposition of price controls creates a fundamental market access barrier that deters future innovation. Research published by the Chamber in 2019 highlighted how a country's legal and

regulatory framework can hinder the creation of and access to innovative goods and services in key global markets.

Legal and regulatory frameworks have changed in many countries since the onset of the COVID-19 pandemic. The 2023 *Patient Access Report* ("Report") examines the national biopharmaceutical market for nine Organisation for Economic Co-operation and Development (OECD) economies and assesses the impact of their policies on access to innovative medicines. The updated report illustrates how countries that impose price controls have less access to lifesaving treatments and cures. The overall scores for the 2023 Report are include in Figure 1 below.

Figure 1: Patient Access to the Latest Medicines: (Pricing, Reimbursement, and Access Regulation to a National Biopharmaceutical Market, 2022)



Key Findings

Strict price controls are widely used in most OECD economies:

Before the passage of the Inflation Reduction Act, the U.S. was the sole economy included in the Report that did not impose direct national price controls or other policies adopted in the name of biopharmaceutical cost containment. Consequently, the U.S. achieves an overall score of 94.95%, as indicated by Figure 1 above. However, following the implementation of the IRA, the U.S. score will fall dramatically and be more in line with OECD economies where the government intervenes to set the price of medicines.

Countries that use price controls see the following:



Fewer overall biopharmaceutical product launches:

Canada, Japan, South Korea, Australia, and European Union (EU) member states have seen significantly fewer overall biopharmaceutical product launches than the United States has over the past 20 years.



Fewer biologics:

Countries with the most severe price controls in place, including South Korea and Australia, have seen fewer than half of new biologics launched in the same period. Only 49% of new biologics launched in the U.S. over the last 20 years were available in South Korea, while only 38% of those biologics were launched in Australia.



Fewer oncology products:

Out of 104 new oncology products launched globally since 2017, 80% were launched in the U.S., but only 56% were launched in Europe.



Delayed access to treatments:

The long lag time between market authorization and inclusion for government reimbursement delays access to the newest innovative medicines. In Germany, patients wait an average of 133 days to access new treatments; in Spain, the delay is as long as 500 days.

The price controls included in the Inflation Reduction Act will have a detrimental impact on biopharmaceutical innovation. Government intervention in price setting undermines the innovation ecosystem that empowered the U.S. to become one of the most innovative countries in the world. The price control provisions could lead to fewer new products and medicines developed and introduced in the United States.

Government officials must carefully consider the implications of price controls for patients, as well as litigation risk and other practical considerations, before proceeding with the implementation of a legally problematic framework that would jeopardize U.S. leadership on biopharmaceutical innovation and patient access to treatments.



Introduction and Briefing Document Objective

From a Free Market to Command and Control? Introduction of Biopharmaceutical Price Controls in the United States

Historically, the provision of health care in the United States 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 biopharmaceutical market has been predominantly market based. Private payers, including insurers, managed care organizations, and pharmaceutical benefit managers, aggregate various health plans and purchase biopharmaceuticals on behalf of their members. Private 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 biopharmaceutical manufacturers and pharmacies. Individual hospitals and other health care institutions are also increasingly using formularies to manage costs.

However, unlike many other high-income OECD economies, the U.S. federal government has not imposed national price controls or other restrictions and market access barriers on health technologies, including biopharmaceuticals and medical devices. This may now be changing.

The Trump administration introduced several reform initiatives aimed at lowering the cost of prescription medicines. In February 2018 the Council of Economic Advisers released *Reforming Biopharmaceutical Pricing at Home and Abroad*, an analysis of the global biopharmaceutical market. A few months later the Department of Health and Human Services also announced a set of reforms in the blueprint document *American Patients First*. In late 2018 the administration announced a plan to build an International Pricing Index and to develop a most-favored-nation (MFN) model to be used by Medicare Part B. This plan was formalized in late 2020 by the Department of Health and Human Services and Centers for Medicare and Medicaid Services (CMS). The MFN model would benchmark the price of a basket of 50 biopharmaceutical products with

the price for the same products in a sample of OECD economies.¹ The comparator 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 United States. After several court rulings in late 2021, the CMS formally rescinded the proposed MFN model.

Similar proposals for controlling expenditure on prescription drugs through price controls have been introduced in Congress. In 2019 and 2021, members of Congress introduced H.R.3–Elijah E. Cummings Lower Drug Costs Now Act. Similar to the CMS’ 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 in a selection of high-income OECD economies.

In 2022, Congress passed the Inflation Reduction Act of 2022.² The legislation included a series of fundamental changes to the pricing framework for medicines covered under Medicare Part B and Part D in the United States. Among other things, the legislation (1) empowers the Secretary of Health and Human Services (HHS) to use what the law refers to as a “negotiation” process to set the price of an expanding number of medicines that are covered under Medicare; and (2) requires manufacturers to pay the federal government a “rebate” if they raise their prices for a large number of medicines covered by Medicare at a rate that is higher than the rate of inflation.



Briefing Document Objective

The imposition of price controls—including international reference pricing—constitutes a fundamental market access barrier and deters future innovation. Such policies have historically had a direct and negative impact on the availability of innovative drugs and medical technologies for patients and consumers in the affected market. Simply put, economies that impose price controls see fewer innovative products on the market, and patients are less likely to be able to access the latest drugs and medical technologies. This fact is not sufficiently recognized or considered in any of the previously described reform proposals in the United States.

Biopharmaceutical innovation does not take place in a vacuum. Like all high-tech industries, the life sciences sector relies on an ecosystem and set of enabling conditions that encourage research and development (R&D) and the development of new products. Human capital, adequate R&D infrastructure, strong and targeted intellectual property (IP) protection, transparent and effective regulations and administration, a technology transfer framework that encourages innovation and the translation of R&D into actual products and full commercialization, a predictable legal environment, and a stable commercial environment are all key factors and enablers of biopharmaceutical innovation.

The purpose of this briefing document is twofold:

1. Empirically measure and quantify the biopharmaceutical market access environment as currently constituted in the United States compared with a selection of high-income OECD economies.
2. Show the real-world negative consequences of imposing price controls on patient access to biopharmaceutical innovation and technologies.

Measuring Biopharmaceutical Market Access Barriers

First launched in 2019, the Patient Access Report (Report) is a unique social scientific tool dedicated to measuring the extent to which products, innovations, and creative works are allowed to gain access to their intended markets. The Report seeks to translate information tracked by international institutions (such as the World Trade Organization [WTO] and OECD) and large trading partners into a quantifiable economy-to-economy comparison and index measuring real-world market access environment for knowledge-intensive and intellectual property-based products and services.³

The Report consists of 16 individual indicators across four separate categories. The 2019 edition of the Report covered 20 economies: the 19 individual economies of the Group of Twenty (G20) and Algeria. One-quarter of the 2019 Report—Category 4: Pricing, reimbursement, and access regulation to a national biopharmaceutical market—is dedicated to measuring the extent to which national biopharmaceutical regulations, including pricing and reimbursement (P&R) policies, limit access to a domestic market and provide preferences for local producers.⁴

Rebenchmarking the Report in a Post-COVID-19 World

Since the results of the Report were published in 2019, the world has fundamentally changed. The COVID-19 pandemic reshaped how many governments and policymakers view public health and access to medical technology, including biopharmaceuticals. The pandemic illustrated the immense and direct value of the research-based biopharmaceutical 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 immense. In 1979, the total cost of developing and approving a new drug stood at USD138 million. Almost 25 years later, in 2003, this figure was estimated at USD802 million.⁵ More recent research from Tufts University suggests that it costs USD2.6 billion, on average, to develop a new drug.⁶ On average, only one to two of

every 10,000 synthesized, examined, and screened compounds in basic research will pass through all stages of R&D and go on to become a marketable drug. Developing a new medicine can take a decade or more. Up until the COVID-19 outbreak, this timeline was the norm for vaccine development and the biopharmaceutical R&D process in general.

Within this historical context the speed with which COVID-19 vaccines and treatments have been developed over the last two years has been truly breathtaking, and it is impossible to overstate the enormity of these accomplishments. It shows the extensive scientific capacity developed by the biopharmaceutical industry and the biotech community and the ability to scale up quickly and decisively to understand and develop a treatment for a novel virus that was not prevalent in human beings 24 months earlier. At the scientific, manufacturing, distribution, and organizational levels, what the industry together with its partners in academia and the public sector has been able to achieve amounts to a modern-day miracle. Yet the science and technological capacity that allowed industry, public research organizations, and academic researchers to carry out this development are based on decades of investment in R&D experience and innovation. Just as for other forms of technological innovation, it is highly unlikely that this biopharmaceutical R&D would have taken place without the right enabling environment in place.

These technologies and products are the fruits of a preexisting innovation ecosystem that is centered on IP rights, which provide innovators with an opportunity to earn a return on investment and establish a vehicle for knowledge-related commercial transactions. Without strong and clear IP rights and the economic functionality they provide, it is

unlikely that any of those products and technologies—or the underlying science—that have been so essential in keeping societies functioning and fighting the COVID-19 pandemic would exist today. The IP-enabled technologies used to fight COVID-19 will also further the development of the next generation of breakthrough treatments and cures. While a patent entitles the innovator to a 20-year term of protection, upon expiration, the knowledge included in the patent becomes available for anyone in the public to use to further their own innovation. In this way, patents further the public consumption of knowledge and ensure that future innovators can benefit from the research of their predecessors.

Given this new global context and the looming introduction of national biopharmaceutical price controls in the United States, the U.S. Chamber of Commerce has rebenchmarked nine of the original 20 economies against the four indicators included in Category 4: pricing, reimbursement, and access regulation to a national biopharmaceutical market. The results of an economy's score on these four indicators comprise their overall score in the Report. The nine economies benchmarked—Australia, Canada, France, Germany, Italy, Japan, South Korea, the UK, and the U.S.—play an outsized role in determining the viability of the economic environment for new drug development.

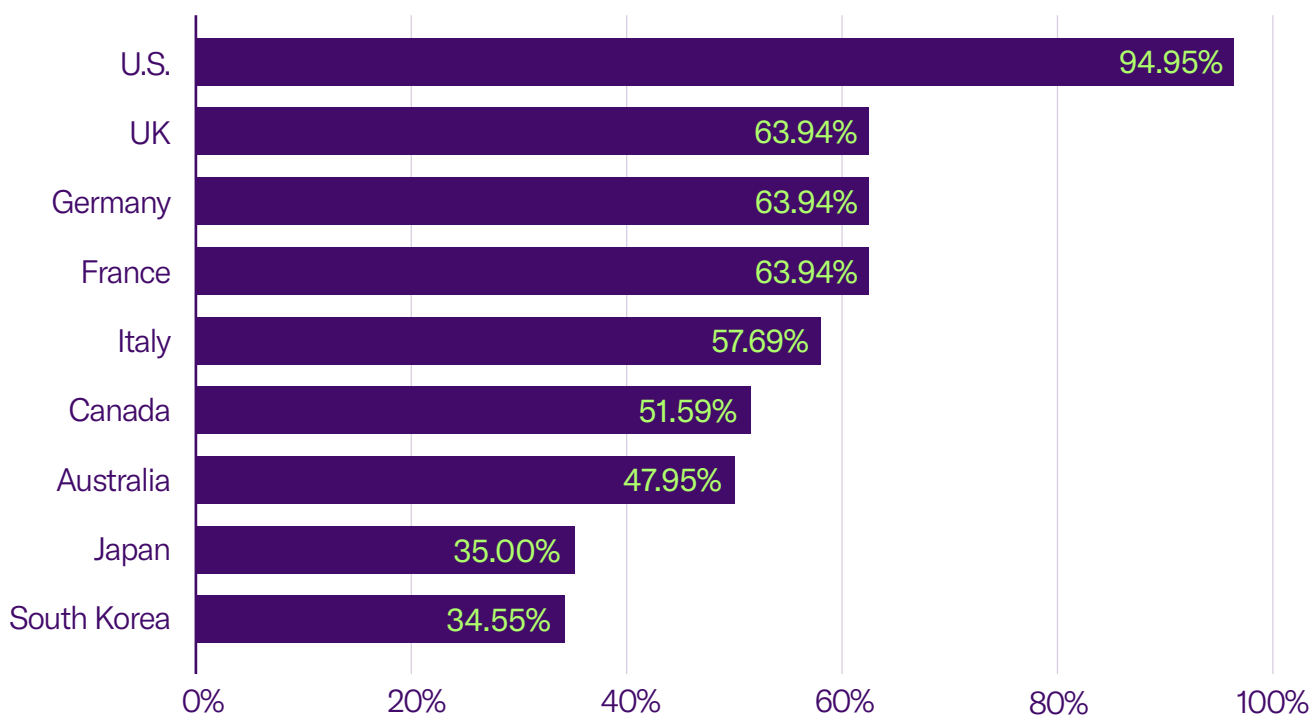
The updated research makes clear for politicians, policymakers, and stakeholders the differences in how these economies have regulated access to their biopharmaceutical markets through national pricing, reimbursement, and procurement policies, as well as the direct and highly negative consequences for medical innovation and patient access to new products and technologies associated with many of these approaches.

Report Results and Key Takeaways

Figure 1 shows the results of the re-benchmarking of the four indicators included in Category 4: pricing, reimbursement, and access regulation to a national biopharmaceutical market

for the original nine high-income OECD Members included in the 2019 Report: Australia, Canada, France, Germany, Italy, Japan, South Korea, the UK, and the U.S.

Figure 1: Overall Scores, Category 4: Pricing, Reimbursement, and Access Regulation to a National Biopharmaceutical Market



As Figure 1 shows, strict price controls are in place and widely used in most OECD economies. In Europe, France, Italy, Germany, and the UK all impose direct or indirect controls on the price of biopharmaceuticals. Access to national health systems is also restricted by reimbursement limits, health technology and cost effectiveness assessments, and reference pricing. Similarly, Australia, Canada, and Korea all impose harsh price controls.

Until 2022, the U.S. was the sole economy included in the Report that did not impose direct national price controls or other policies adopted in the name of biopharmaceutical cost containment. Consequently, the U.S. achieves an overall score of 94.95%. This is more than 30 percentage points higher than France, Germany, and UK; all tied at 63.94%. Notably, almost half the sampled economies—Canada, Australia, Japan, and South Korea—achieve a score of around

50% or less; Canada scored the highest of those four economies at 51.59%. However, following the implementation of the IRA, the U.S. score will decrease significantly as a result of the new price control provisions. As a result, U.S. consumers will face less choice of new medicines, similar to consumers in other OECD economies.

Review of the four individual indicators that together constitute Category 4: pricing, reimbursement, and access regulation to a national biopharmaceutical market echoes these broader findings. Table 1 shows the individual scores for the economies sampled for each of the four underlying indicators that together make up the category.

Table 1: Individual Indicator Scores, Category 4: Pricing, Reimbursement, and Access Regulation to a National Biopharmaceutical Market⁷

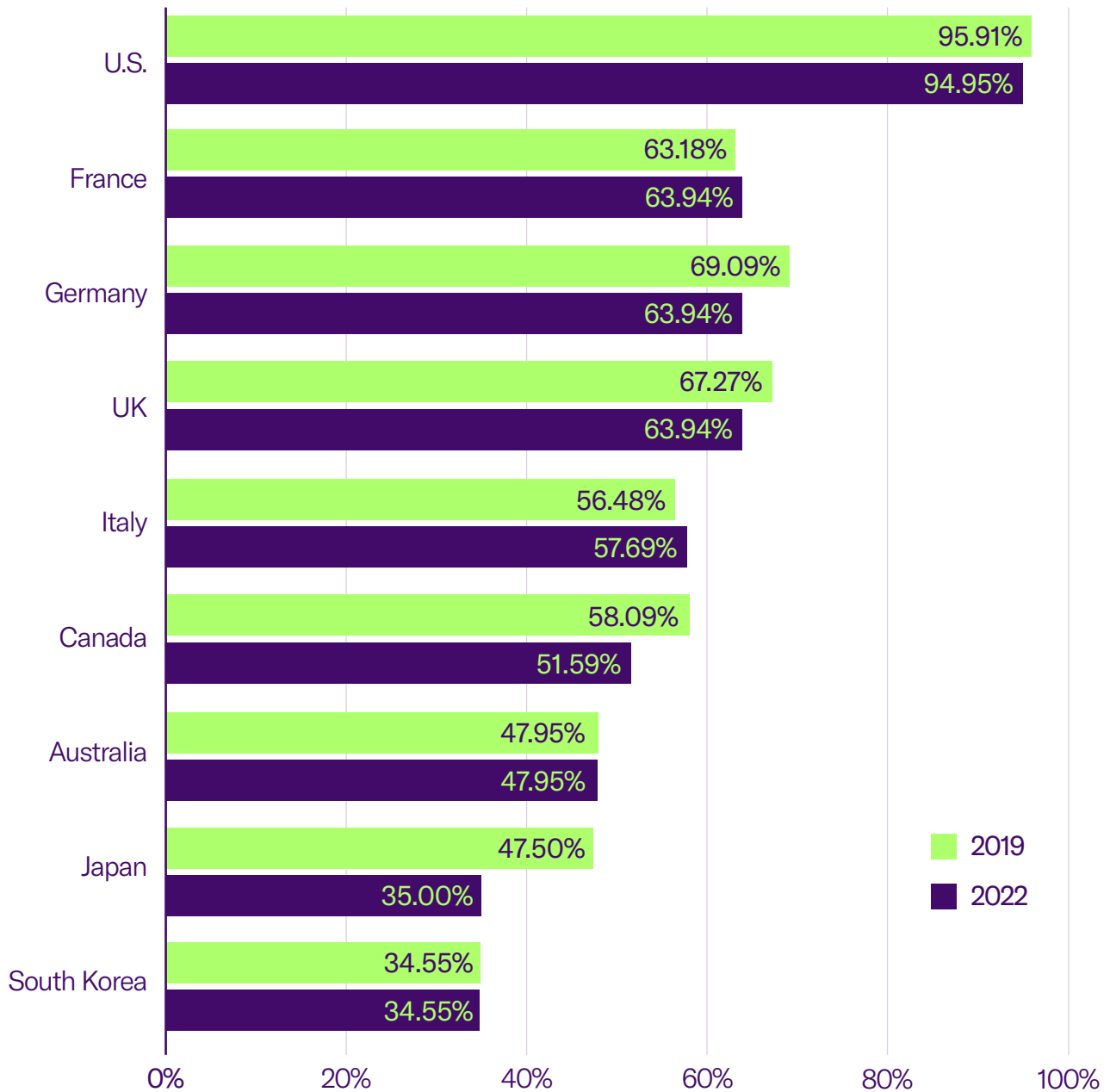
	Overarching philosophy and direction of health and biopharmaceutical system: cost cutting versus recognizing and incorporating new products and biopharmaceutical innovation	Pricing and reimbursement decision-making and process	Biopharmaceutical-specific procurement preferences	Availability of new, innovative biopharmaceutical treatments and products
Australia	25%	25%	100%	42%
Canada	25%	25%	100%	56%
France	50%	50%	100%	56%
Germany	50%	50%	100%	56%
Italy	50%	25%	100%	56%
Japan	25%	0%	75%	40%
South Korea	0%	0%	100%	38%
UK	50%	50%	100%	56%
U.S.	100%	100%	100%	80%

Table 1 shows how challenging the market access environment is for biopharmaceutical rightsholders as measured by the individual indicators. For example, apart from procurement preferences—where only Japan scores less than 100%—all economies bar the United States score 50% or less on indicators measuring the pricing and reimbursement environment. South Korea and Japan stand out. Both economies score poorly on the overarching philosophy and direction of their health and biopharmaceutical systems.

Similarly, the P&R process in both economies remains opaque with little in the way of meaningful opportunity and engagement with nongovernment stakeholders.

Comparing the 2022 Report with the 2019 scores shows that the biopharmaceutical market access environment in many economies has deteriorated. Figure 2 compares the nine sampled economies’ 2022 and 2019 scores.

Figure 2: 2022 Versus 2019 Results, Category 4: Pricing, Reimbursement, and Access Regulation to a National Biopharmaceutical Market



As Figure 2 shows, most of the nine sampled OECD economies have seen their scores drop over the last two years. Notably, Japan and Canada’s scores decreased substantially, with decreases of 12.50% and 6.50%, respectively.

In Japan, this steep drop was driven by the finalization and adoption of a new biopharmaceutical cost-benefit assessment system, price preferences for locally developed products, and a lack of meaningful consultation and engagement

with relevant stakeholders in developing these new policies.⁸ Specifically, a new health technology assessment (HTA) procedure became operational and has become an integral part of the national pricing and reimbursement process. This new HTA system is primarily focused on cost as a basis for analysis. It includes rigid selection criteria and focuses almost exclusively on high-cost products. Additional socioeconomic impact analysis does not form part of the assessment criteria. Similarly, changes to eligibility and evaluation criteria relating to the Price Maintenance Premium program—an initiative introduced in the early 2010s aimed at rewarding innovation through additional price premiums—now provide indirect price preferences for products developed in Japan. Both the U.S. government and the research-based biopharmaceutical industry have noted the lack of transparency and meaningful stakeholder involvement in developing these new policies.

Similarly, in Canada, the biopharmaceutical market access environment has deteriorated since 2019. Over the past several years, Canadian authorities have reformed how patented medicines are evaluated and priced through the Patented Medicine Prices Review Board's (PMPRB) evaluation methodology. These reform efforts have focused almost exclusively on cost and expenditure reduction. While successful legal challenges have limited the scope of

some of these proposals, the changes to the basket of economies the PMPRB uses for international price comparisons have been retained and are now in effect. Specifically, the reforms have expanded the size of the basket and removed the United States and Switzerland as comparator economies. New economies added are Australia, Belgium, Japan, the Netherlands, Norway, and Spain. Given the strict price controls in these new economies and the removal of the United States and Switzerland as comparator economies, these changes will substantially lower the overall price comparisons and thus the overall biopharmaceutical price level in Canada. These changes came into force on July 1, 2022.

Germany and the UK have also seen their scores drop by 5.15% and 3.33%, respectively. This drop was driven by a decrease in the availability of new oncology medicines in both economies compared with those of the U.S. The latest available data on the launch of new oncology products show how substantially fewer innovative medicines have been launched in Europe in the last five-year period than in previous reporting periods measured in the 2019 Report. Specifically, the Global Oncology Trends 2022 report—published by IQVIA in May 2022—shows how out of 104 new products launched globally since 2017, 80% were launched in the U.S., but only 58% were launched in Europe, including both Germany and the UK.

Fewer Innovative Medicines and Longer Wait Times

The True Cost of Price Controls

The imposition of price controls have a direct impact on how, when, and which medicines and medical products are available to patients in a given health system.

For instance, a 2018 study examining the availability of 46 new cancer medicines in four EU Member States (Belgium, Estonia, Scotland and Sweden) between 2000-2014 found large discrepancies with respect to both the number of products launched in each country and when products were made available within each health system. In no country were all 46 new products launched. In Estonia, for instance, almost half of the sample (19 medicines out of 46) were never launched. Similarly, in all of the countries for all of the medicines launched it took, at best, more than a year for these new products to reach patients. In Sweden, which on launch time was the best performing of the four, it still took, on average, 14.3 months from time of EU market authorization until the product was first used within the health system. In Belgium this was, on average, over two years (26.8 months) and in Estonia it was even more – over five years (63.9 months).

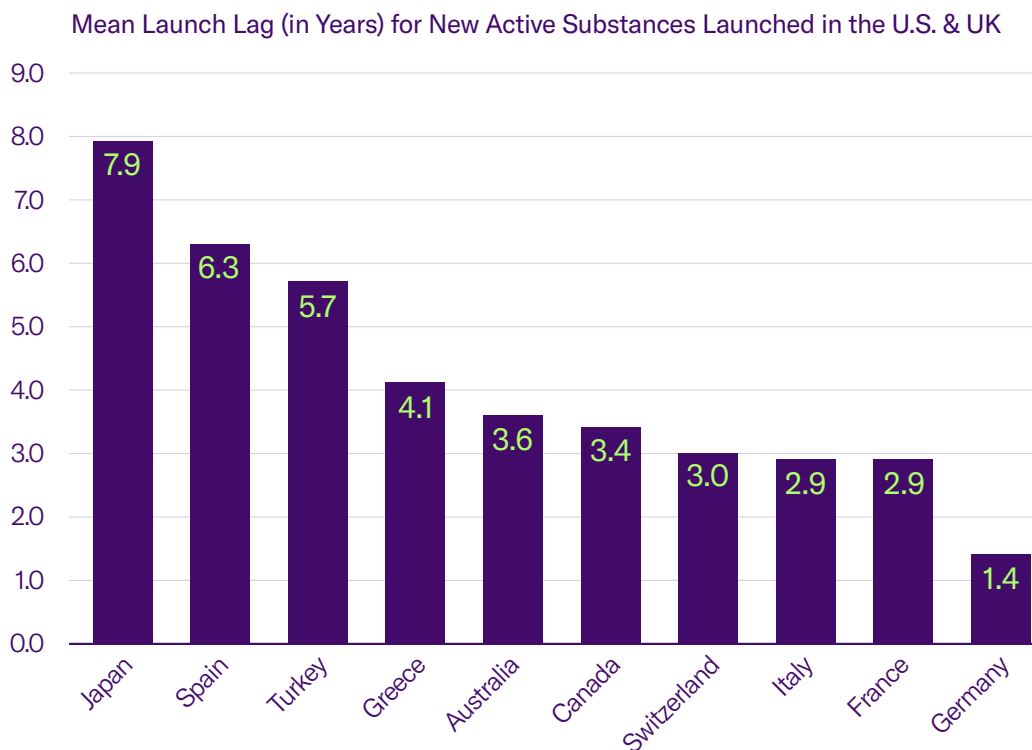
Similarly, looking at access to orphan drugs and new medicines for rare diseases, evidence suggests that there is considerable variation in levels of access across the EU. For example, a 2017 study by the Office of Health Economics (a British research institute) compared access to 143 orphan products 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 that comprises the UK). Overall, the study found that access to authorized orphan products through public reimbursement varied substantially between the sampled 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. The duration was considerably longer for orphan medicines when compared to non-orphan medicines. For example, in the UK, the median number of months between the marketing authorization and the first NICE appraisal was 20.2 months for orphan medicines compared to 12.7 months for non-orphan medicines.

Indeed, the historical data and evidence is very clear on this.

Several studies examining the availability of innovative drugs show a distinct disparity between (1) economies with market access and regulatory environments that seek to strike a balance between maintaining financial stability and rewarding innovation and (2) more restrictive economies that prioritize policies adopted in the name of biopharmaceutical cost containment. For instance, a 2008 study by the National Bureau of Economic Research concerning drug launches suggests that free-pricing countries historically have a larger number of launched innovative drugs than countries with a more challenging P&R environment. For the period examined (1992–2003), Germany⁹ and the U.S. had a larger number of launched drugs for subclasses of innovative drugs (88 and 86, respectively), while Japan, Portugal, and France, which all had in place strict price

regulations, saw fewer molecules launched (53, 62, and 69 respectively).¹⁰ Similarly, statistical modeling investigating the impact of price controls on product launches in several OECD and middle-income economies found that price controls (and other supply-side controls) have a significant impact on potential product entry, reducing the likelihood of entry by roughly 75% compared with a market having no price controls.¹¹ A large 2010 study from the London School of Economics and Political Science examining historical trends in launch lags of innovative drugs in 20 economies suggests that economies with more challenging regulatory and market access environments have longer delays in accessing innovative drugs. Figure 3 shows the time lags in market access for the latest period studied, 1995–2008.

Figure 3: Historical Trends in Launch Lags of Innovative Drugs, 1995–2008, Select Economies^{12*}



*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 266 new molecules approved for marketing in the U.S. and UK in 1995–2008.

As Figure 3 shows, markets like Japan, Australia, Spain, Turkey, and Greece have historically had longer lags than other markets.

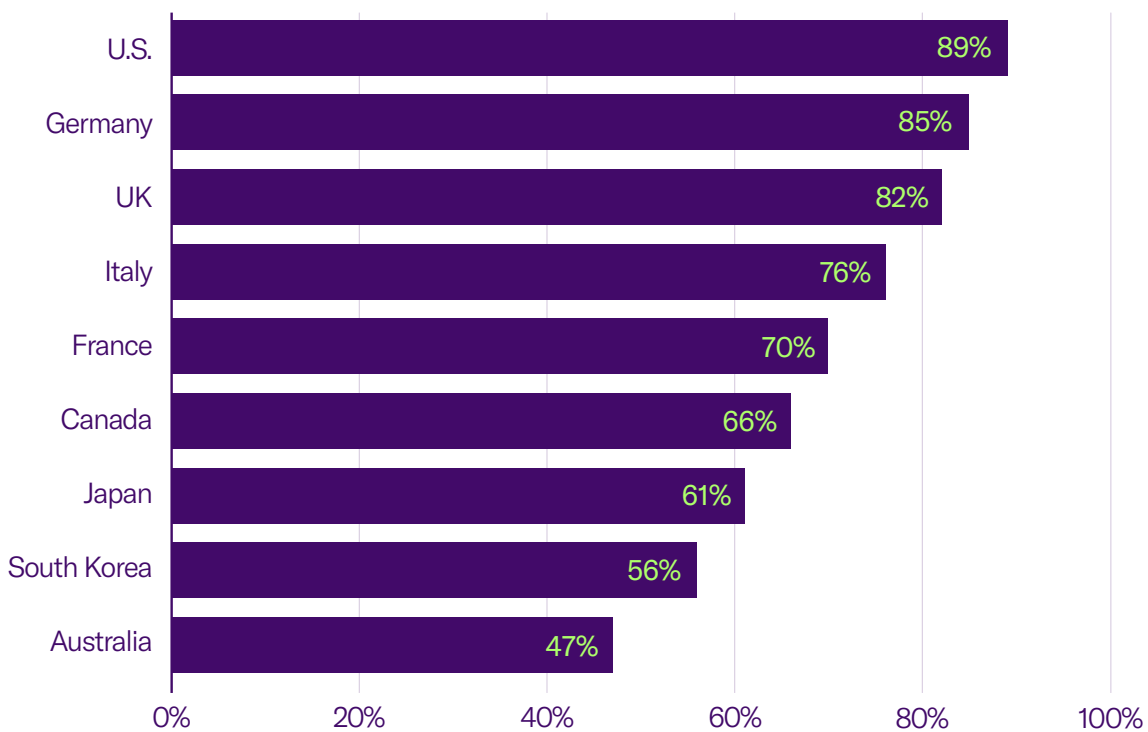
While these academic studies focus on the long-term historical launch and drug availability records, launch lags and differences in product availability between markets are still common today. In fact, despite globalization, global regulatory harmonization, and improved access to global biopharmaceutical supply chains, these lags in availability are, in some ways, even more pronounced today. This is particularly the case for more technically complex and innovative drugs such as biologics and cancer medicines.

Just like the long-term historical record, 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.

For example, evidence collected by IQVIA and published by Life Sciences Ontario in 2020 shows that many new health technologies and medicines are never launched at all in economies with strict price controls in place. This is a critical takeaway when examining the true cost of introducing price controls: Many new products and medical innovations never make it onto the market. As Figure 4 shows, markets like Canada, Japan, South Korea, Australia, and EU member states have seen significantly fewer overall biopharmaceutical product launches than the United States over the past 20 years.

Figure 4: Percentage of New Active Substances Launched, 2000–2019, Select Economies¹³

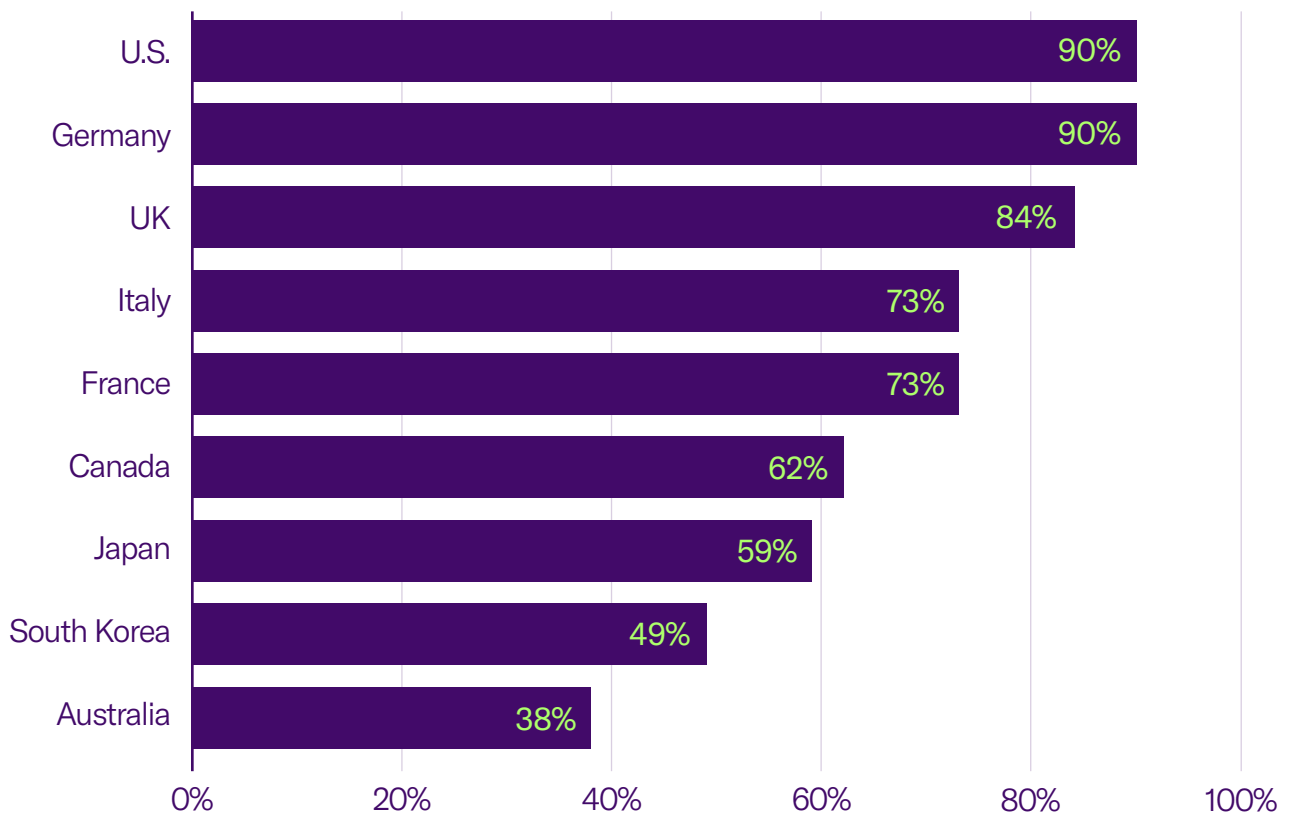


This disparity between the U.S. and other developed OECD economies is even more pronounced when looking at more advanced and specialist products such as biologics and oncology drugs.

Figure 5 shows the percentage of new biologic products launched in individual economies between 2000 and 2019. Apart from Germany and the UK, economies such as France, Italy, Canada, Japan, South Korea, and Australia have seen significantly fewer biologics launched than the United States had over the past 20 years. Moreover, economies with the

most severe price controls in place—such as South Korea and Australia—have seen fewer than half of new biologics launched in the same period. Australia, in particular, stands out. Over the 20-year period studied, only 38% of new biologics were launched in Australia. Apart from South Korea (at 49%), this rate is not comparable to other high-income economies. Instead, it is closer to the launch rate of developing and emerging markets such as Argentina (35%) and Thailand (40%), both of which have far less purchasing power and far fewer resources invested in their health systems.

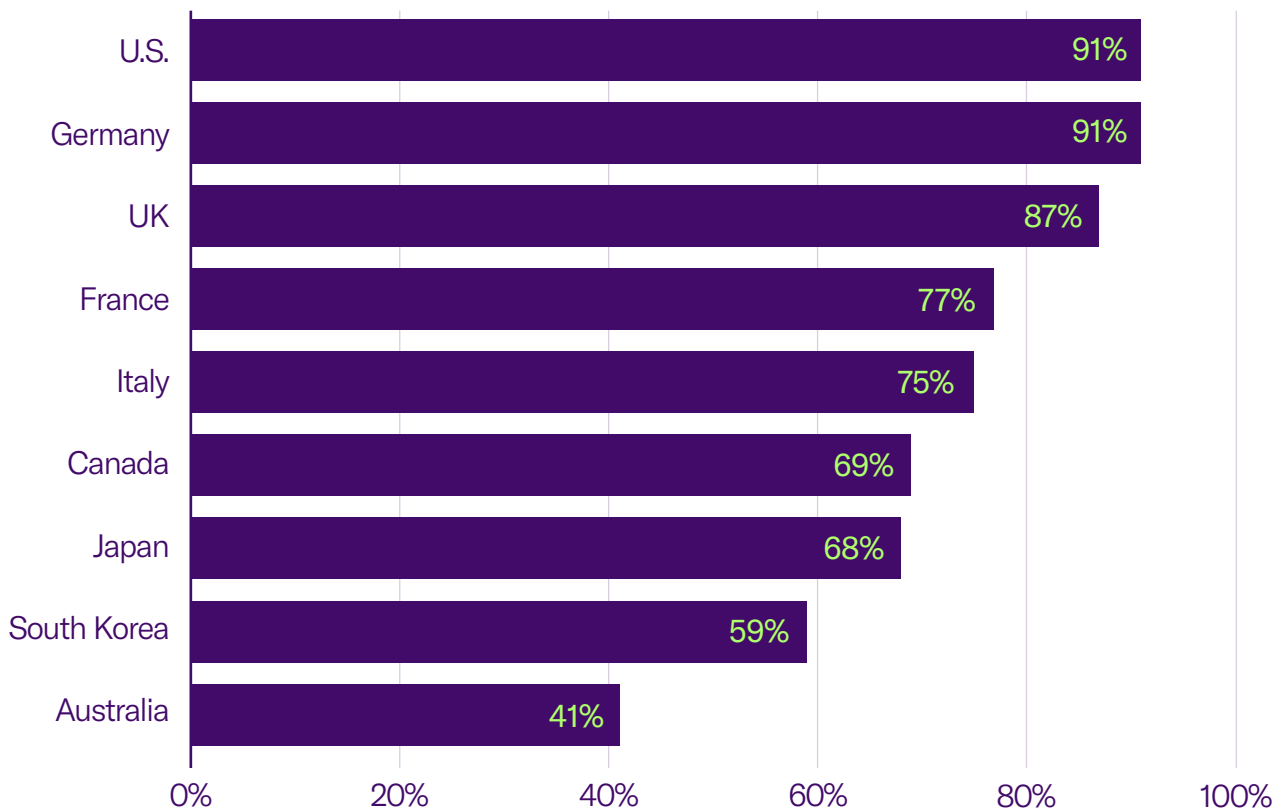
Figure 5: Percentage of New Biologic Active Substances Launched, 2000–2019, Select Economies¹⁴



Furthermore, there is a similar disparity for oncology products between the U.S. and economies with biopharmaceutical price controls in place. Figure 6 shows the percentage of new oncology products launched in the sampled economies between 2000 and 2019. Apart from Germany and the UK, economies such as France, Italy, Canada, Japan, South Korea, and Australia

have seen significantly fewer oncology products launched than the U.S. had over the past 20 years. Moreover, just as with biologics, economies with the most severe pricing, reimbursement, and price controls in place—such as South Korea and Australia—have seen substantially fewer oncology products launched during the same period.

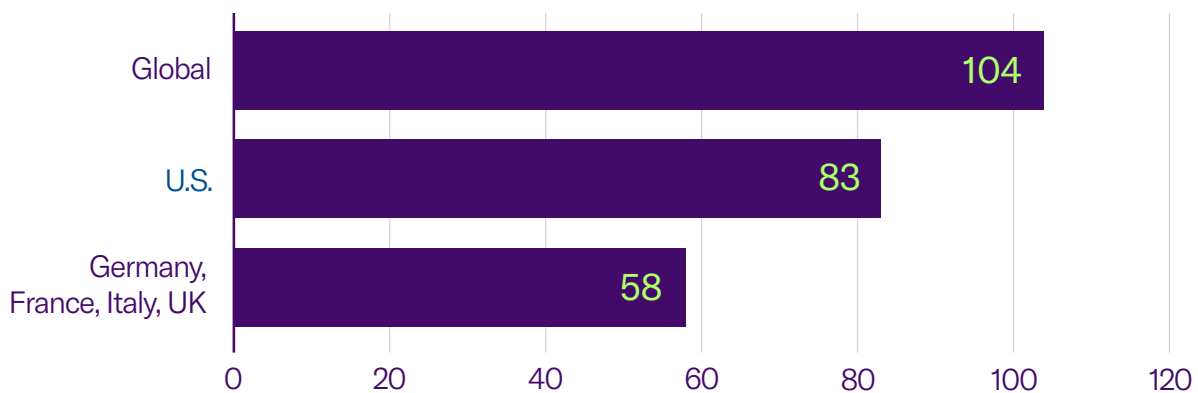
Figure 6: Percentage of New Oncology Active Substances Launched, 2000–2019, Select Economies¹⁵



The most recent data on the launch of new cancer medicines echo these findings and show how even Germany and the UK—which in the past have been the closest—are falling behind the U.S. IQVIA’s latest Global Oncology Trends 2022 report published in May 2022 shows how the disparity in product launches between the U.S. and other economies with national price controls in place is, in fact, growing.

Figure 7 shows the total number of new oncology active substances launched in the past five years (2017–2021) and the proportion available in the U.S. compared with those in the EU and the UK. As Figure 7 shows, out of 104 new products launched globally since 2017, 80% were launched in the U.S., but only 58% were launched in Germany, France, Italy, and the UK.

Figure 7: Number of New Oncology Active Substances Launched Globally, 2017–2021, Select Regions¹⁶



These data paint a clear picture: There is a large disparity in product launches and availability of new medicines between the U.S. and other OECD member states that have national price controls in place.

However, the launch of a product on a given market does not always equate to actual patient access. In addition to setting and controlling prices, an important barrier to free and fair market access consists of reimbursement evaluation. Many payers (whether public or private) have an elaborate evaluation to determine whether a product should be included on a given formulary and the rate of reimbursement. In a growing number of health systems, the reimbursement

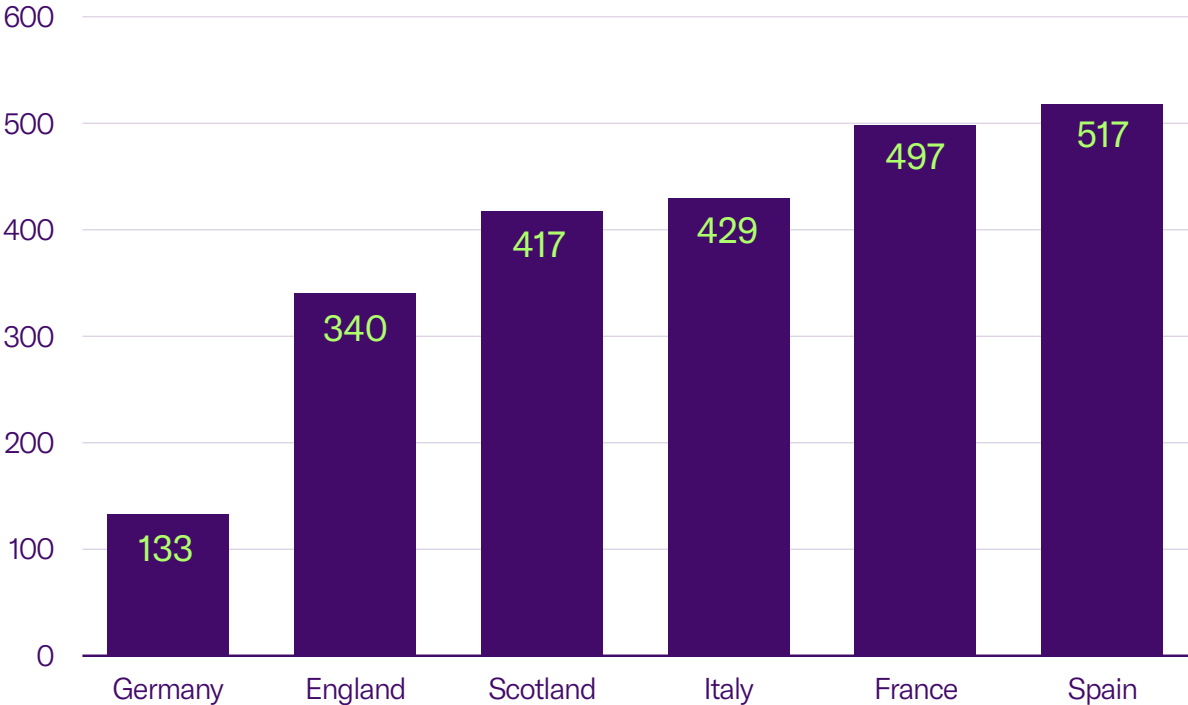
process often involves a pharmacoeconomic or HTA evaluation that assesses a given product’s cost effectiveness. Depending on the design and function of the HTA body and underlying assessment methodology used, this assessment can include a cost-effectiveness threshold and benchmark to assess the cost effectiveness of new products through quality-adjusted life years (QALYs). A QALY is a matrix that measures the value of a given product based on two dimensions: the time added to patients’ lives due to the use of a given product and the quality of life experienced during these years. Outside of the U.S., most governments restrict access to their respective national health systems through reimbursement

limits, health technology and cost-effectiveness assessments, and reference pricing. In Europe, France, Italy, Germany, and the UK all make use of such tools, as do Australia, Canada, and South Korea. Critically, there can be a long lag between market authorization—that is, the date by which a new product is approved for use and launched in an economy—and inclusion for public reimbursement. For health systems that are predominantly publicly funded and organized, the latter date, not the product launch date, determines when most patients can actually access a new product.

Looking at the available data and evidence, it is clear that many economies have a

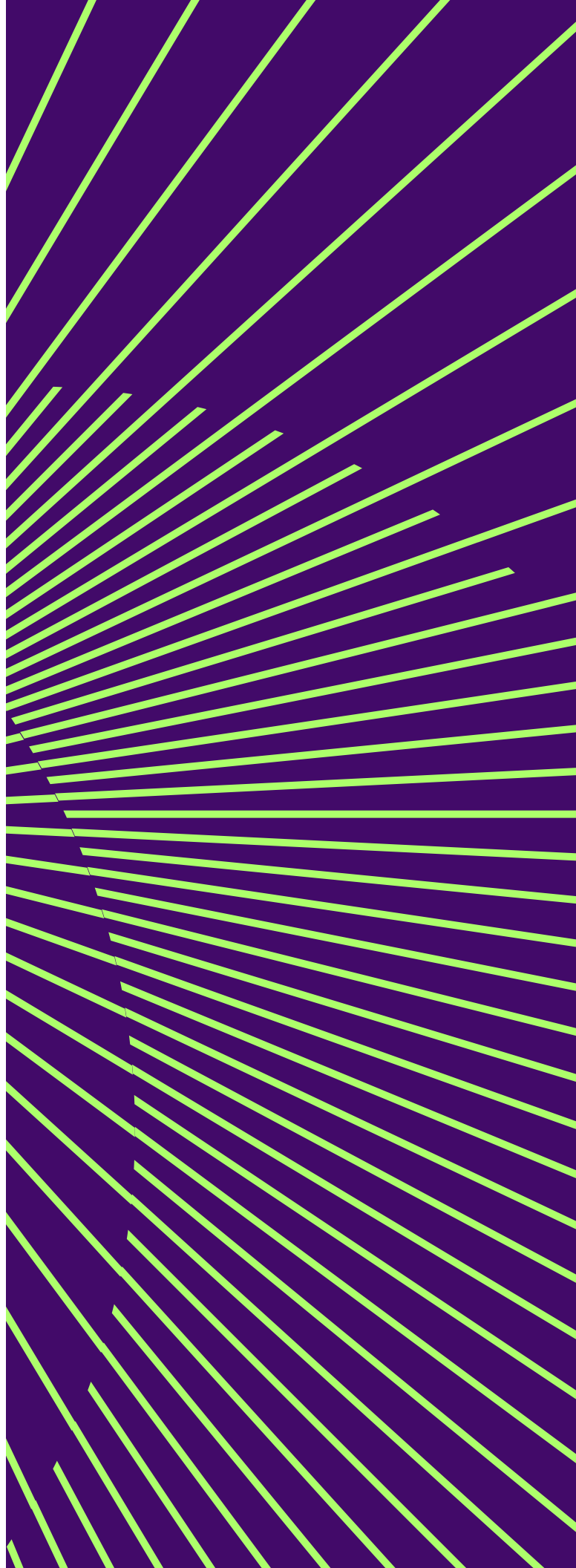
considerable lag between product launch and inclusion for public reimbursement. For example, Figure 8 shows the results of the European Federation of Pharmaceutical Industries and Associations’ (EFPIA) and IQVIA’s annual Patients W.A.I.T. (Waiting to Access Innovative Therapies) Survey from 2022. This survey measures the rate of availability and patient access to new and innovative medicines in Europe.¹⁷ As Figure 8 shows, the number of days patients in Europe’s largest economies (Germany, France, Italy, Spain, and the UK) wait, on average, to access innovative biopharmaceuticals is considerable. It ranges from 133 days in Germany as long as 500 days in Spain.

Figure 8: Time to Availability (Days From Market Authorization and Availability to Patients Through Public Reimbursement)¹⁸



As Figure 8 shows, 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 particularly more pronounced in France and Spain. Outside of Europe, there are also long access lags in both Australia and Canada.

In Australia, for instance, a 2018 study found that only 46% of all drugs registered in the country between 2012 and 2017 were reimbursed (with a similar share for first-in-class drugs).¹⁹ 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 shows how Canadian patients have access to fewer innovative treatments than in other OECD economies.²⁰ The study finds that there are long lags between market authorization and inclusion for public reimbursement. On average, for the period studied (2010–2014), 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 finds that only 37% of drugs were reimbursed and available to 80% or more of the population. There were particular gaps in availability for more advanced treatments, including cancer medicines and biologic products. Only 59% of new cancer medicines were available to 80% or more of the population. For new biologics, this ratio was even lower at 23%. More recent data suggest that the time taken for reimbursement evaluation in Canada has gotten longer. Data compiled by Innovative Medicines Canada suggest that for the period 2012–2018, the average time from market authorization to reimbursement in Canada was 632 days.²¹



Conclusion

As the 2022 results from the rebenchmarking of the Patient Access Report demonstrate, of the nine high-income OECD economies sampled, the U.S. was the sole economy that did not impose direct national price controls or other policies adopted in the name of biopharmaceutical cost containment. Prior to the implementation of the IRA, the U.S. achieves a score of 94.95%. However, following the implementation of government price controls, the U.S. score will fall notably, with U.S. patients suffering as a result. While the U.S. currently score, more than 30% higher than France, Germany, and the UK, the IRA price control provisions will result in U.S. consumers facing similar barriers to access as those in other OECD economies.

Price controls—including international reference pricing—impose a fundamental market access barrier. Such policies have a real and negative impact on the availability of new, innovative drugs and medical technologies for patients and consumers in the affected market. As this briefing document and the historical evidence demonstrate, an economy's score on the Barometer corresponds with access to and availability of medical innovation. 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 strict price controls in place.

The price controls included in the Inflation Reduction Act will have a detrimental impact on biopharmaceutical innovation, leading to fewer new products and medicines developed and introduced in the U.S. The research and

benchmarking that this briefing document are based on were conducted before the enactment of the Inflation Reduction Act. As the federal government moves forward with implementing the biopharmaceutical price controls provisions of the legislation in 2023, the U.S. Chamber of Commerce will recalibrate and rebenchmark the Report considering the full scope of these legislative and regulatory changes. An updated Report to be released in the second half of 2023 will provide stakeholders with an understanding of the negative impact that the Inflation Reduction Act has had on the biopharmaceutical policy environment in the United States.

U.S. leadership in biopharmaceutical innovation is a result of the robust free market framework and strong protection of intellectual property. The price control measures included in the Inflation Reduction Act—and any subsequent attempts to set the price of medicines via federal regulation—will undermine the innovative ecosystem that empowered the U.S. to become one of the most innovative countries in the world. Prior to 2022, the U.S. framework allowed competition, rather than government intervention in the price-setting process, to drive down the cost of innovative medicines. As this briefing document illustrates, the existing U.S. framework has resulted in patients having primary and extensive access to new lifesaving treatments and cures. Government officials must consider the implications of price controls on patients before proceeding with the implementation of a framework that would jeopardize U.S. leadership in biopharmaceutical innovation and patient access to treatments.

Appendix

Methodology, Sources, and Indicators Explained

The 2019 Report consisted of 16 indicators and four separate categories. For the purposes of rebenchmarking the Report in 2022, only the four indicators under Category 4: pricing, reimbursement, and access regulation to a national biopharmaceutical market are benchmarked in this document.

Indicators Explained

This section explains how each of the four indicators in the 2022 Report is measured and scored.

Category 4: Pricing, Reimbursement, and Access Regulation to a National Biopharmaceutical Market

Overarching philosophy and direction of health and biopharmaceutical system: cost cutting versus recognizing and incorporating new products and biopharmaceutical innovation—the extent to which a given economy’s health and biopharmaceutical system (including de jure laws, regulations, rules, official guidelines, and/or de facto practices) is geared toward cost cutting (regardless of pricing and reimbursement system and methodology used) versus recognizing and incorporating new products and biopharmaceutical innovation. The latter can be defined, for example, through market-based pricing or appropriate recognition

of innovation within an economy’s pricing and reimbursement system and decision-making process. This is a mixed indicator.

Pricing and reimbursement decision-making and process—the extent to which a given economy’s pricing and reimbursement process and decision-making (1) are transparent, (2) follow due process, and (3) use comparisons that are made (regardless of methodology used) on the basis of reaching the lowest possible price or rate of reimbursement or on a basis that values the level of innovation. This is a mixed indicator.

Biopharmaceutical-specific procurement preferences—the extent to which the procurement of biopharmaceutical products (including de jure laws, regulations, rules, official guidelines and/or de facto procurement practices) by public and/or private payers gives preference to local manufacturers. Examples of such preference include (but are not limited to) higher prices paid to local manufacturers, tendering preferences for local manufacturers, and restrictions on foreign vendors’ ability to participate in public procurement. This is a mixed indicator.

Availability of new, innovative biopharmaceutical treatments and products—measured by the availability of new cancer medicines on the domestic market. For the U.S., France, Germany, Italy, and the UK, this is measured using the Global Oncology Trends 2022 report published by IQVIA in May 2022. For the remaining economies where data are not available, this is measured by the original 2019 Report indicator (i.e., availability of new oncology products within two years of global launch between 2012 and 2016).²² This is a numerical indicator.

Scoring Methodology

The scoring methodology used in the original 2019 Report has been retained. Each indicator can score a value between 0 and 1, and the cumulative score of the Report ranges from a minimum of 0 to a maximum of 4. Indicators can be scored using two distinct methods: numerical and mixed.

Numerical indicators are those that are based on a quantitative source and compared to a baseline used. The score for each economy on this indicator is calculated by dividing the quantitative score for each economy by the relevant baseline using the numerical formula n quantitative score/the baseline used. The Report includes only one numerical indicator, which measures the percentage of availability of innovative oncology medicines in the economies benchmarked.

The remaining indicators that make up the rebenchmarked Report are mixed indicators. The final score for these indicators is based on an even split between these:

1. Primary and/or secondary legislation (regulation), relevant rules, and guidelines in place
2. The actual application and enforcement of the relevant primary and/or secondary legislation, rules, and guidelines in place

The use of mixed indicators provides flexibility when scoring and allows the Report to more effectively accommodate gray areas in economy performance for a given indicator. Specifically, it is possible to assign a partial score rather than only 0 or 1. Five possible scores are available within a mixed indicator: 0, 0.25, 0.5, 0.75, and 1. The range of scores available for mixed indicators means that greater nuance can be used when individual indicators are scored; the practical result is that economies can receive partial scores for an indicator, which in some cases are a better approximation of their given reality.

Sources

Scoring in the Report is based on both qualitative and quantitative evidence. To provide as complete a picture of an economy's market access environment as possible, this evidence is drawn from a range of sources. All sources used are publicly available and accessible to all. The following is an outline of the types of sources used.

Government (Legislative/Regulatory)

Sources from legislative and executive 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), including in particular government institutions dealing with foreign investment rules and restrictions
- Internal departmental guidelines, assessment protocols, and policies

Judicial/Legal

Sources from judicial authorities and legal practitioners include the following:

- Court cases and decisions, including:
 - » 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

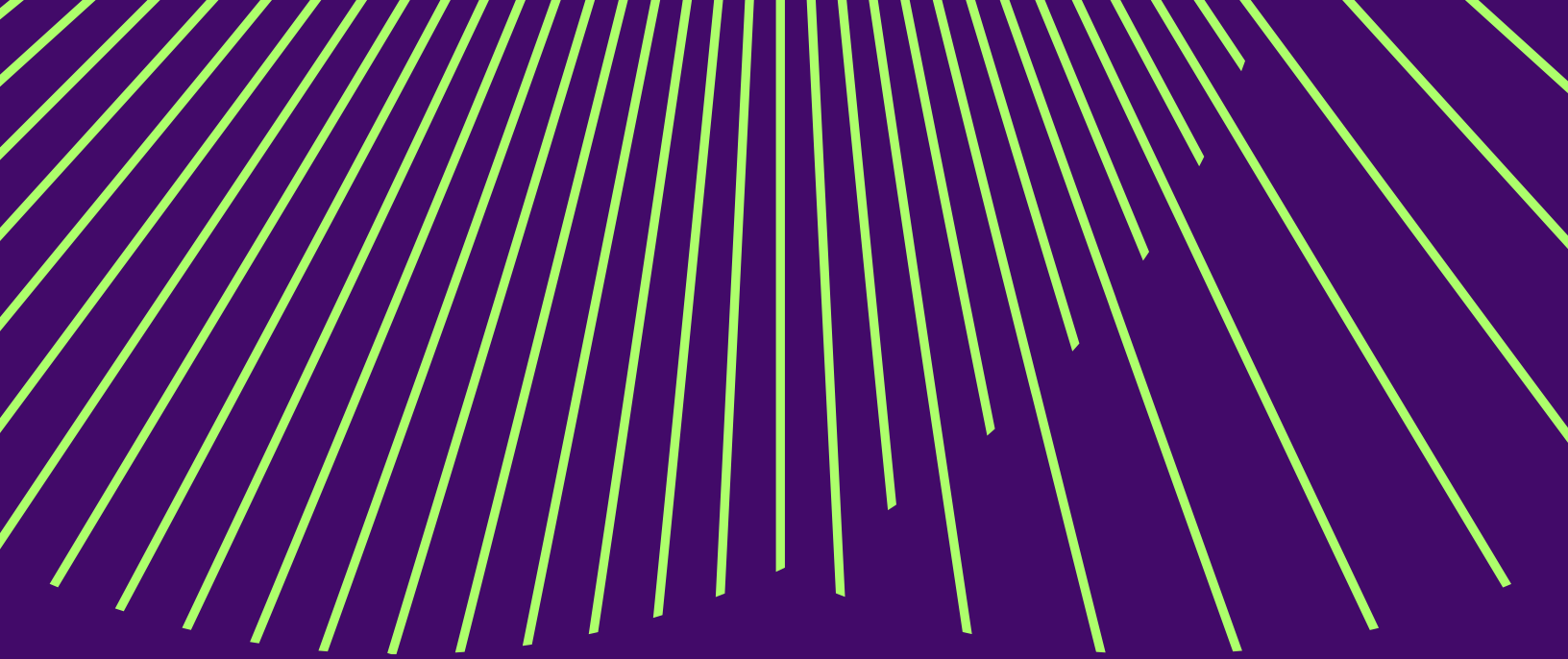
News sources include the following:

- Newspapers
- News websites
- Trade press

Endnotes

1. See Department of Health and Human Services, Centers for Medicare & Medicaid Services (2020, November 27), 42 CFR Part 513 [CMS–5528–IFC], RIN 0938–AT91.
Most Favored Nation (MFN) Model, Federal Register, vol. 85, Rules and Regulations. The economies included in the basket for the first year of analysis were Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, and the UK.
2. See H.R.3–117th Congress (2021–2022): Elijah E. Cummings Lower Drug Costs Now Act, introduced April 2021, Sponsor Rep. Pallone, Frank, Jr. [D-NJ-6].
3. Large trading partners, including the U.S. and EU, keep detailed records of the major market access trading barriers in place around the world. In the U.S., the United States Trade Representative (USTR), Department of Commerce, and State Department all independently and jointly provide thorough assessments of the international trading environment through the National Trade Estimate Report on Foreign Trade Barriers, Investment Climate Statements, and Country Commercial Guides. Similarly, the European Commission lists barriers to trade in its Market Access Database (MADB). Major international institutions track barriers to trade and foreign direct investment. For example, the OECD has developed an FDI Regulatory Restrictiveness Index (FDI Index), which measures the extent to which foreign direct investment is limited through foreign equity limitations; screening or approval mechanisms; restrictions on the employment of foreigners as key personnel; and operational restrictions, e.g., restrictions on branching and on capital repatriation or on land ownership (see B. Kalinova et al. (2010) OECD’s FDI Restrictiveness Index: 2010 Update, OECD Working Papers on International Investment 2010/03). The WTO allows for the recording and tracking of trade disputes, the registration of nontariff measures, and other trade related information.
4. For full details of the indicators included in the Report and methodology, see the appendix.
5. J.A. DiMasi et al. (2003). The price of innovation: New estimates of drug development costs. *Journal of Health Economics* 22(2): 151–185.
6. J.A. DiMasi, H.G. Grabowski, and R.W. Hansen (2016). Innovation in the biopharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*, 47, : 20–33.
7. A full description and definition of each of these indicators are available in the appendix.
8. See USTR (2022), 2022 National Trade Estimate Report on Foreign Trade Barriers, 302–303; PhRMA (2022), 2022 Special 301 Report, 45–57. A Towse (2019), “HTA in Japan: Failing to Meet International Good Practice?” OHE News, March 15, 2019; M Hasegawa et al. (2020), “Formal Implementation of Cost-Effectiveness Evaluations in Japan: A Unique Health Technology Assessment System,” *Value in Health*, January 2020, 23(1), pp. 43–51.
9. 2010 reforms changed the German biopharmaceutical policy environment dramatically, but during the period studied, the P&R system was based more on market-based pricing.
10. P.M. Danzon and A.J. Epstein (2008), “Effects of Regulation on Drug Launch and Pricing in Interdependent Markets,” *National Bureau of Economic Research*, May 2008.
11. M. Kyle (February 2007), *Pharmaceutical Price Controls and Entry Strategies*, *Review of Economics and Statistics*, 89(1): 88–99.
12. N. Varol, J. Costa-Font, and A. McGuire (2010), *Do International Launch Strategies of Pharmaceutical Corporations Respond to Changes in the Regulatory Environment?* LSE Health, Working Paper No. 19/2010. See appendix.
13. Life Sciences Ontario (2020), “New Medicine Launches: Canada in a Global Context,” slide 29, June 22, 2020. Based on a sample of 516 global launches between January 1, 2000, and December 31, 2019. Data extracted and provided to Life Sciences Ontario by IQVIA.
14. Ibid. Slide 34. Based on a sample of 164 global launches between January 1, 2000, and December 31, 2019. Data extracted and provided to Life Sciences Ontario by IQVIA.

15. Ibid. Slide 36. Based on a sample of 122 global launches between January 1, 2000, and December 31, 2019. Data extracted and provided to Life Sciences Ontario by IQVIA.
16. IQVIA Institute for Human Data Science (2022), Global Oncology Trends 2022, Outlook to 2026, May 2022, IQVIA, 7.
17. M. Newton et al. (April 2022), “EFPIA Patients W.A.I.T. Indicator 2021 Survey,” EFPIA & IQVIA.
18. Ibid. Slide 12. This is IQVIA’s description of its data set: “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.” The number of days estimated for France is based on products included under the ATU system.
19. Medicines Australia (2018), Comparison of Access and Reimbursement Environments, 4th ed.
20. Innovative Medicines Canada & IMS Health Canada (2016), Access to New Medicines in Public Drug Plans: Canada and Comparable Countries: 2016 Annual Report, 5.
21. Innovative Medicines Canada, Canadian Public Reimbursement Timelines, pCPA Trends Update page. <https://innovativemedicines.ca/resources/crt/>
22. This assessment is based on market availability data and assessment by IQVIA Institute for Human Data Science. For the period 2017–2021 this assessment is based on 104 oncology products launched globally. For the period 2012–2016 this assessment is based on 55 oncology products launched globally. Availability is based on sales in the market irrespective of formulary (private or payer) inclusion. See IQVIA (2022), Global Oncology Trends 2022, 7.; and IQVIA (2018), Global Oncology Trends 2018, IQVIA Institute, 24.



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