PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)

SPECIAL 301 SUBMISSION 2025

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PhRMA 2025 SPECIAL 301 OVERVIEW

PhRMA 2025 SPECIAL 301 SUBMISSION

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide this submission for the *2025 Special 301 Report*. The Special 301 Report provides the Administration with a critical opportunity to confirm its strong commitment to defend American innovation in overseas markets and is a critical tool to address damaging intellectual property and market access barriers abroad that harm America's innovative and creative industries and the 63 million jobs that they support across the country.[1]

The United States leads the world in the research and development of valuable new medicines and vaccines. However, foreign trading partners that deny adequate and effective protection of intellectual property rights, or deny fair and equitable market access, significantly threaten the ability of our member companies and their workers to develop and export life-saving treatments and cures. PhRMA urges USTR to address the many significant trade barriers that foreign governments impose against biopharmaceuticals innovated and manufactured in the United States, consistent with President Trump's objective to eliminate unfair trade practices abroad and ensure that U.S. trade agreements benefit the United States.[2]

Urgent action is required to address serious intellectual property and market access barriers in the overseas markets named in this submission. Medicines discovered and manufactured by PhRMA member companies are the constant target of compulsory licensing and other harmful practices that deny the most basic intellectual property protections necessary to drive discovery and bring new treatments and cures to patients around the world. Also, as explained further below, biopharmaceutical innovators in the United States face a wide array of damaging government pricing policies abroad.

Many foreign trading partners subject to existing commitments to protect American innovation continue to deny basic intellectual property protections and market access to U.S. innovators. For example: **Mexico** and **Canada** have yet to implement key intellectual property provisions consistent with the United States-Mexico-Canada Agreement; **China** has yet to fully implement intellectual property commitments in Phase One of the Economic And Trade Agreement between our two countries and continues not to provide regulatory data protection; **Korea** has failed to adopt market access policies that are transparent and appropriately value American-made innovative medicines as required by the U.S. Korea Free Trade Agreement; **Australia** has yet to implement critical patent enforcement provisions of the U.S.-Australia Free Trade Agreement; and others. Similarly, USTR should also prioritize actions to address intellectual property barriers

[1] U.S. Dep't of Commerce, "Intellectual Property and the U.S. Economy: Third Edition," Mar. 2022, available at https://www.uspto.gov/sites/default/files/documents/uspto-ip-us-economy-third-edition.pdf (last visited Jan. 26, 2025).

[2] Memorandum on America First Trade Policy, Jan. 20, 2025, available at https://www.whitehouse.gov/presidential-actions/2025/01/america-first-trade-policy (last visited Jan. 26, 2025).

including compulsory licensing threats in **Colombia**; pending proposals in the **European Union** seeking to introduce a pan-EU compulsory licensing mechanism and conditioning intellectual property incentives on product launches in all EU member states; and longstanding systemic intellectual property failures, including restrictive patentability criteria, in **India**.

Egregious and discriminatory pricing policies in several markets, including **Canada**, **Japan** and **Korea**, continue to undervalue American innovation, threaten billions of dollars in lost sales and put American competitiveness, jobs and exports at risk. Government price controls imposed in many markets are non-tariff barriers to trade that substantially eliminate incentives to invest in the development of new medicines for patients. They deny American inventors and workers the ability to compete on fair and equitable terms in foreign markets, undermine the expected benefit of intellectual property protections and exacerbate the U.S. trade imbalance by inappropriately raising barriers in their own markets, while their own inventors enjoy access to the U.S. market. Ending damaging pricing policies in these markets and others could add billions of dollars to research and development for new medicines and lower overall health care costs in the United States and around the world, while supporting U.S. competitiveness and jobs.[3]

Unfortunately, the Biden Administration demonstrated limited ambition in addressing foreign intellectual property and market access barriers that impede U.S. biopharmaceutical research, manufacturing and exports. Instead, it departed from longstanding and bipartisan U.S. trade objectives by deprioritizing, and in certain instances proactively opposing, the very trade policies that best promote U.S. workers in this important sector. In 2022, the Biden Administration contradicted longstanding U.S. policy when it agreed to "waive" certain obligations of foreign governments to protect intellectual property on COVID-19 vaccines under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) – a deeply unnecessary decision that directly harmed American workers and innovators. Moreover, the Biden Administration did not implement a single commercially meaningful trade agreement with a new or existing partner and failed to adequately enforce existing commitments to protect American innovation, allowing harmful policies in key jurisdictions to go unaddressed. It is critical that the new Administration correct course by vigorously defending, enforcing and strengthening intellectual property protections and market access for U.S. innovations abroad.

[3] *See* Council of Economic Advisers, "Reforming Biopharmaceutical Pricing at Home and Abroad," Feb. 2018, available at https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf (last visited Jan. 26, 2025); and U.S. Dep't of Commerce, Int'l Trade Admin., "Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation," Dec. 2004, available at https://web.archive.org/web/20190414170009/https://2016.trade.gov/td/health/DrugPricingStudy.pdf (last visited Jan. 26, 2025).

I. The Innovative Biopharmaceutical Sector

The U.S. biopharmaceutical industry is the world leader in medical research.[4] Innovators in this critical sector depend on strong intellectual property protection and enforcement, and on fair and equitable access to overseas markets. With the right policies and incentives in place at home and abroad, they can continue to bring valuable new medicines to patients, contribute powerfully to the American economy and jobs and open markets to U.S. exports.

A. Biopharmaceutical innovation delivers value for patients and economies

PhRMA member companies are devoted to inventing, manufacturing and distributing valuable medicines that enable people to live longer, healthier and more productive lives. The U.S. biopharmaceutical industry is the world leader in medical research – producing more than half the world's new molecules in the last decade. Pioneering work by biopharmaceutical innovators in the United States contributes significantly to economic growth and supports good-paying jobs in all 50 states. As a key component of America's high-tech economy, the research-based biopharmaceutical sector supports over 4.9 million jobs across the economy, including more than one million direct jobs, and contributes more than $1.65 trillion in economic output on an annual basis when direct, indirect and induced effects are considered.[5]

In 2022, 34 percent of U.S. biopharmaceutical industry employees were engaged in manufacturing at over 1,500 manufacturing plants across the country, nearly 39 percent were engaged in biopharmaceutical R&D, 24 percent were engaged in distribution and three percent were engaged in corporate administration.[6] These important members of the U.S. innovative biopharmaceutical workforce partner with universities, clinical researchers, patient organizations, health care providers and others to bring new treatments and cures to patients who need them at home and abroad – introducing nearly 680 new therapies since 2000[7] and investing in many of the over 8,000 new drugs

[4] Ezell S, "Ensuring U.S. Biopharmaceutical Competitiveness," July 2020, available at https://www2.itif.org/2020-biopharma-competitiveness.pdf (last visited Jan. 26, 2025).

[5] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf (last visited Jan. 26, 2025).

[6] *Id.*

[7] U.S. Food and Drug Administration, "New Drugs at FDA: CDER's new molecular entities and new therapeutic biological products," available at https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products (last visited Jan. 26, 2025); and U.S. Food and Drug Administration, "Biological approvals by year," available at https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biological-approvals-year (last visited Jan. 26, 2025).

currently in development worldwide,[8] with about three quarters having the potential to be first-in-class treatments.[9]

Our sector also continues to be one of the most research-intensive, manufacturing-intensive and export-intensive in America, annually investing an estimated $122.2 billion in researching and developing new medicines.[10] With the right policies and incentives in place at home and abroad, our member companies can continue to bring valuable new medicines to patients around the world. In 2023, U.S. biopharmaceutical goods exports exceeded $101 billion.[11] The biopharmaceutical sector was the largest exporter of goods among the most R&D-intensive industries in 2023 – which in addition to biopharmaceuticals included navigational equipment, semiconductors and other electronic components, medical equipment and supplies, and communications equipment.[12]

The U.S. biopharmaceutical industry also is among the top five employers of U.S. manufacturing jobs, with more Americans directly employed in pharmaceutical manufacturing than in manufacturing in several other manufacturing industries, including each of the following: iron and steel products, aerospace products and parts, petroleum and coal products, and electric equipment and appliances.[13]

Even more important than the biopharmaceutical sector's role in the U.S. economy is its contribution to global patient health. Biopharmaceutical innovation extends lives, improves worker productivity and cuts health care costs. Between 1950 and 2016, life expectancy for women and men in the United States increased by more than a decade[14] – adding trillions of dollars to the U.S. economy.[15] New medicines are responsible for much of this increase. According to a National Bureau of Economic Research working

[8] PhRMA analysis of Citeline Pharmaprojects database (last accessed Oct. 16, 2024).

[9] Long G, "The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development" Analysis Group, 2017.

[10] Research!America, "U.S. Investments in Medical and Health Research and Development, 2016-2020," 2022, available at https://www.researchamerica.org/wp-content/uploads/2022/09/ResearchAmerica-Investment-Report.Final_.January-2022-1.pdf (last visited Jan. 26, 2025).

[11] U.S. Bureau of Economic Analysis, International Accounts Products for Detailed Goods Trade Data, available at https://www.bea.gov/international/detailed-trade-data.

[12] Analysis of National Science Foundation and Business Research and Development Survey (BRDIS) data by ndp | analytics.

[13] U.S. Bureau of Labor Statistics, Current Population Survey (CPS) Labor Force Statistics, available at https://www.bls.gov/cps/home.htm (last visited Jan. 26, 2025).

[14] U.S. Dep't of Health and Human Services, Centers for Disease Control and Prevention, Nat'l Center for Health Statistics, Health, United States, 2017, Table 15, May 2018, available at https://www.cdc.gov/nchs/data/hus/2017/015.pdf (last visited Jan. 26, 2025).

[15] Between 1970 and 2000, increased longevity added about $3.2 trillion per year to national wealth in the United States. *See* Murphy, KM, Topel RH, "The Value of Health and Longevity," Nat'l Bureau of Econ. Res., June 2005, available at http://www.nber.org/papers/w11405 (last visited Jan. 26, 2025).

paper, new treatments accounted for three-quarters of life expectancy gains in the United States and other high-income countries between 2000 and 2009.[16]

For example, the AIDS death rate has dropped nearly 87 percent since the approval of antiretroviral treatments in 1995.[17] Today, a 20-year old diagnosed with HIV can expect to live another 50 years.[18] New medicines have cut heart disease deaths by 38 percent, according to the Centers for Disease Control and Prevention.[19] More than 80 percent of the increase in life expectancy of cancer patients since 1980 is attributable to new treatments.[20] New hepatitis C therapies approved since 2013 cure over 90 percent of patients – a more than two-fold increase from previously available treatment options.[21]

PhRMA member companies are building on these achievements and pioneering new treatments and cures for some of the world's most devastating diseases. Researchers are developing more than 500 new medicines for infectious diseases, including viral, bacterial, fungal and parasitic infections such as the most common and difficult-to-treat form of hepatitis C, a form of drug-resistant malaria, a form of drug-resistant MRSA, and a novel treatment for smallpox.[22] Advances in biotechnology and genomics are propelling the discovery of new medicines to treat a range of chronic and infectious diseases. Made using living organisms, biologic medicines are revolutionizing the treatment of cancer and autoimmune disorders. Biologics are critical to the future of the industry and promise progress in the fight against conditions like Alzheimer's, a

[16] Lichtenberg, FR, "Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-income Countries, 2000-2009," National Bureau of Economic Research, July 2012, available at http://www.nber.org/papers/w18235 (last visited Jan. 26, 2025).

[17] U.S. Dep't of Health and Human Services, Centers for Disease Control and Prevention, Nat'l Center for Health Statistics, Health, United States, 2014, Table 29, May 2015, available at http://www.cdc.gov/nchs/data/hus/hus14.pdf (last visited Jan. 26, 2025).

[18] *Id.*

[19] U.S. Dep't of Health and Human Services, Centers for Disease Control and Prevention, "New CDC Vital Signs: CDC finds 200,000 heart disease deaths could be prevented," Dec. 2013, available at https://www.cdc.gov/media/releases/2013/p0903-vs-heart-disease.html (last visited Jan. 26, 2025); and U.S. Dep't of Health and Human Services, Centers for Disease Control and Prevention, "Vital Signs: Avoidable Deaths from Heart Disease, Stroke, and Hypertensive Disease—United States, 2001-2010," Sept. 2013, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a4.htm (last visited Jan. 26, 2025).

[20] Sun E, Lakdawalla D, et al., "The determinants of recent gains in cancer survival: an analysis of the surveillance, epidemiology and end results [SEER] database," J. Clinical Oncology, 2008, available at http://ascopubs.org/doi/abs/10.1200/jco.2008.26.15_suppl.6616 (last visited Jan. 26, 2025); A more recent article by the American Cancer Society (dated Jan. 8, 2019) reported that cancer death rates have been reduced 27 percent since 1991. Available at https://www.cancer.org/latest-news/facts-and-figures-2019.html (last visited Jan. 26, 2025).

[21] *See*, *e.g.*, "FDA approves Viekira Pak to treat hepatitis C," Dec. 19, 2014, available at https://www.formularywatch.com/fda/fda-approves-viekira-pak-treat-hepatitis-c (last visited Jan. 26, 2025).

[22] PhRMA, "2020 Medicines in Development – Infectious Diseases Report," July 2020, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/MID_2020_InfectiousDiseases_DrugList.pdf (last visited Jan. 26, 2025).

debilitating disease affecting millions.[23] The mRNA technology platforms, which are the backbone of the most effective COVID-19 vaccines, could potentially revolutionize vaccinology and help fight cancer, immune-mediated diseases and rare diseases.[24]

New medicines can lower the overall cost of treating these and other devastating diseases by reducing medical complications, hospitalizations and emergency room visits. For example, the use of cholesterol-lowering statin drugs has cut hospitalizations and saved the U.S. health care system at least $5 billion.[25] Every $24 spent on new medicines for cardiovascular diseases in OECD countries saves $89 in hospitalization costs.[26] Treating high blood pressure according to clinical guidelines would result in annual health system savings of about $15.6 billion.[27] In addition to lowering overall health care costs, appropriate use of medicines can increase worker productivity by reducing rates of absenteeism and short-term disability.[28] A 2012 study demonstrated that appropriate use of diabetes medicines saved 15 percent and 20 percent per month in medical spending after one year of initiating treatment[29] and an estimated reduction of more than one million emergency department visits and hospitalizations annually, for an annual savings of up to $8.3 billion.[30]

PhRMA members are working to overcome significant systemic challenges that can prevent the poorest patients from accessing medicines. Together with governments, academia and others, they are leading more than 300 initiatives with more than 1,000 partners to help shape sustainable solutions that improve the health of all people.[31] In

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[23] *Id.*

[24] Sanofi, "mRNA Technology: Vaccines and Beyond," Nov. 2021, available at https://www.sanofi.com/en/science-and-innovation/research-and-development/technology-platforms/mrna-technology-platform (last visited Jan. 26, 2025).

[25] Grabowski D, Lakdawalla D, et al., "The Large Social Value Resulting From Use Of Statins Warrants Steps To Improve Adherence And Broaden Treatment," Health Aff., Oct. 2012, available at https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.1120 (last visited Jan. 26, 2025).

[26] Lichtenberg FR, "Have newer cardiovascular drugs reduced hospitalization? Evidence from longitudinal country-level data on 20 OECD countries, 1995-2003," National Bureau of Economic Research, May 2008, available at http://www.nber.org/papers/w14008 (last visited Jan. 26, 2025).

[27] Cutler DM, Long G, et al., "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation," Health Aff., Jan. 2007, available at https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.26.1.97 (last visited Jan. 26, 2025).

[28] Carls GS, Roebuck MC, et al., "Impact of medication adherence on absenteeism and short-term disability for five chronic diseases," J. Occupational and Envtl. Med., July 2012, available at http://journals.lww.com/joem/Abstract/2012/07000/Impact_of_Medication_Adherence_on_Absenteeism_and.7.aspx (last visited Jan. 26, 2025).

[29] Jha AK et al., "Greater adherence to diabetes drugs is linked to less hospital use and could save nearly $5 billion annually," Health Aff., Aug. 2012, available at https://www.healthaffairs.org/doi/10.1377/hlthaff.2011.1198 (last visited Jan. 26, 2025).

[30] Slejko JF et al., "Adherence to statins in primary prevention: yearly adherence changes and outcomes," J Manag. Care Pharm., Jan. 2014, available at https://www.jmcp.org/doi/10.18553/jmcp.2014.20.1.51 (last visited Jan. 26, 2025).

[31] *See* Global Health Progress, available at http://www.globalhealthprogress.org (last visited Jan. 26, 2025).

2017, more than 20 biopharmaceutical companies joined the World Bank and the Union for International Cancer Control to launch Access Accelerated – a first-of-its-kind global initiative to address cancer and other non-communicable diseases that cause more than 28 million deaths per year in low and lower-middle income countries.[32]

Between 2000 and 2011, biopharmaceutical innovators contributed an estimated $98.4 billion dollars toward achieving health-related Millennium Development Goals.[33] Despite a three percent drop in public funding for neglected disease (excluding Ebola) research and development in 2014, biopharmaceutical industry funding increased by 28 percent during the same period.[34]

B. Policies that power prevention, treatments and cures

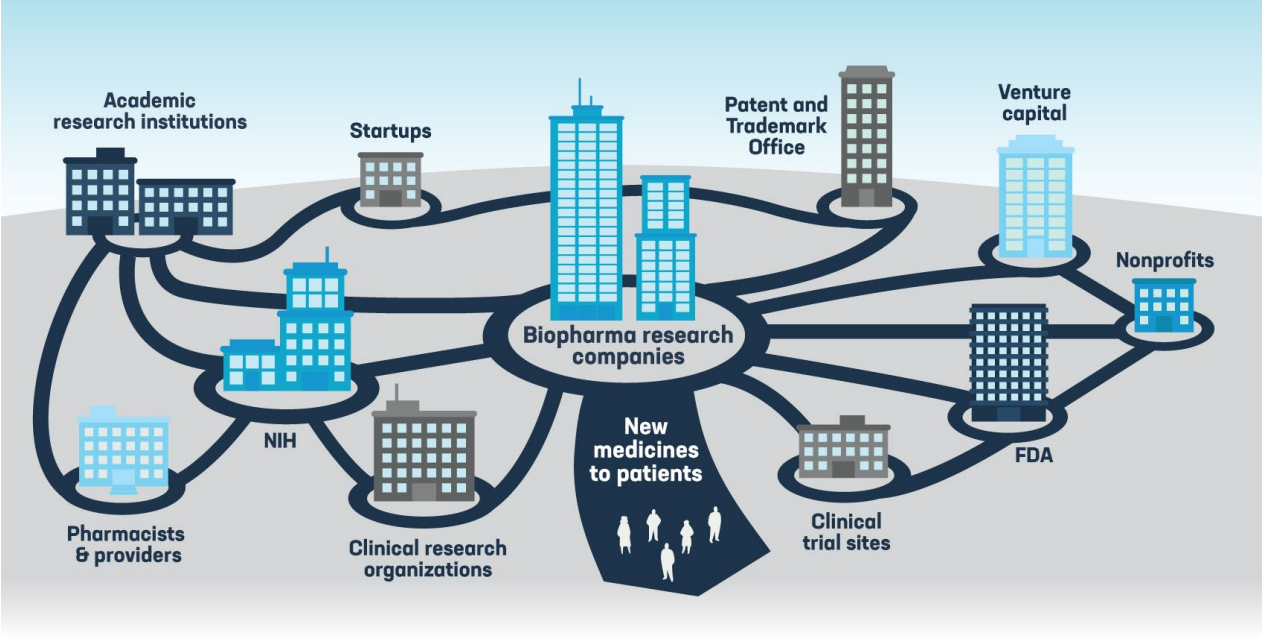
Fair and transparent access to overseas markets and strong protection and enforcement of patents, regulatory test data and other intellectual property provide powerful incentives that drive and sustain substantial investments in valuable treatments and cures. Where markets are open, innovation is valued and intellectual property is protected and enforced, biopharmaceutical innovators have the predictability and certainty that they need to collaborate with partners, compete successfully and accelerate the launch of new medicines.

[32] Access Accelerated, "22 Biopharma Companies Partner and Launch Access Accelerated," Jan. 2017, available at https://accessaccelerated.org/news-and-events/test-post-f/ (last visited Jan. 26, 2025).

[33] Morris J et al., "The Pharmaceutical Industry's Contributions to the United Nations Millennium Development Goals," Hudson Inst., May 2013, available at https://www.yumpu.com/en/document/read/22352783/the-pharmaceutical-industrys-contributions-to-hudson-institute (last visited Jan. 26, 2025).

[34] Global Funding of Innovation for Neglected Diseases: G-Finder, available at https://gfinder.policycuresresearch.org/ (last visited Jan. 26, 2025).

Figure 1: Collaboration and the biopharmaceutical R&D process



As highlighted in Figure 1 above, research, development and distribution of innovative medicines increasingly involves collaboration and the exchange of commercially sensitive information among multiple partners across borders and around the world. Strong intellectual property protection and enforcement enable innovators to license their patented inventions to others with the certainty that valuable information disclosed is secure. Thanks to the technology transfer framework established by the Bayh-Dole Act, voluntary licensing of intellectual property is also enabling collaboration among industry, university and public sector researchers in the development of new medicines and other products – adding as much as 1 trillion to the U.S. economy and as many as 6.5 million American jobs over the last 25 years.[35] Such collaboration is delivering similar benefits in other countries. Research in the United Kingdom found that public expenditure on biomedical and health research leveraged even greater private sector investment, delivering a total rate of return to public biomedical and health research of up to 28 percent.[36]

Patents and market-based pricing policies promote competition and greater treatment options. In exchange for the limited period of protection that patents provide,

[35] *See* Pressman L, Roessner D et al., "The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2020," Jun. 2022, available at https://autm.net/AUTM/media/About-Tech-Transfer/Documents/BIO-AUTM-Economic-Contributions-of-University-Nonprofit-Inventions_14JUN2022.pdf (last visited Jan. 26, 2025).

[36] Sussex J, Feng Y, et al., "Quantifying the economic impact of government and charity funding of medical research on private research and development funding in the United Kingdom," BMC Medicine, Feb. 2016, available at http://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-016-0564-z (last visited Jan. 26, 2025).

innovators must fully disclose their inventions to the world. That disclosure accelerates innovation and empowers potential competitors to build on those inventions. Competition means more medicines in the same therapeutic class, more options for patients and even lower prices.[37] For example, less than a year after market entry of the first in a new class of hepatitis C treatments, there were multiple suppliers that competed both on price and clinical benefits. Indeed, competition was so fierce that the largest U.S. pharmacy benefit manager claimed hepatitis C treatment is less expensive in America than in other western countries.[38] European countries have seen similar gains from competition.[39]

Today, biopharmaceutical innovators face competition faster – both from other innovators and from generic drug companies. In the 1970s, a new medicine might remain the only innovative treatment available in its therapeutic class for 10 years or more. By the 2000s, that period had declined to about two years.[40] Generic competitors now challenge patents earlier and more frequently, even as early as four years after the launch of a new medicine.[41] Today, over 94 percent of innovative medicines experience at least one patent challenge prior to generic entry, compared to 25 percent in 1995.[42] Increasing competition from biosimilars is driving down the cost of cutting-edge treatments.[43]

Patents promote faster access to new medicines. A major 2014 study found firms launch innovative medicines sooner in countries where there is effective patent protection and enforcement. The study looked at data from the launch of more than 600 drugs in almost 80 countries between 1983 and 2002. It showed that strong patent protection accelerates new product launches in higher and lower income countries alike.[44] Launching a medicine in a particular market also has important effects on the whole health care system. For instance, when a new medicine is introduced, biopharmaceutical companies invest in educating health care providers on the science and appropriate use

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[37] Int'l Fed'n Pharm. Mfrs. and Assocs., "The New Frontiers of Biopharmaceutical Innovation," 2012, available at https://www.ifpma.org/publications/the-new-frontiers-of-biopharmaceutical-innovation/ (last visited Jan. 26, 2025).

[38] LaMattina J, "For Hepatitis C Drugs, U.S. Prices are Cheaper Than in Europe," Forbes, Dec. 2015, available at http://www.forbes.com/sites/johnlamattina/2015/12/04/for-hepatitis-c-drugs-u-s-prices-are-cheaper-than-in-europe/#1483772d64bb (last visited Jan. 26, 2025).

[39] Berdud M et al., "R&D, Competition and Diffusion of Innovation in the EU: The Case of Hepatitis C," Office of Health Econ., July 2018, available at https://www.ohe.org/publications/rd-competition-and-diffusion-innovation-eu-case-hepatitis-c (last visited Jan. 26, 2025).

[40] Tufts Center for the Study of Drug Development, "First-in-class drugs in competitive development races with later entrants," Impact Report, Dec. 2015.

[41] Grabowski HG, Long G, et al., "Updated trends in US brand-name and generic drug competition," J. Med. Econ., Sept. 2016, available at https://www.ncbi.nlm.nih.gov/pubmed/27064194 (last visited Jan. 26, 2025).

[42] *Id.*

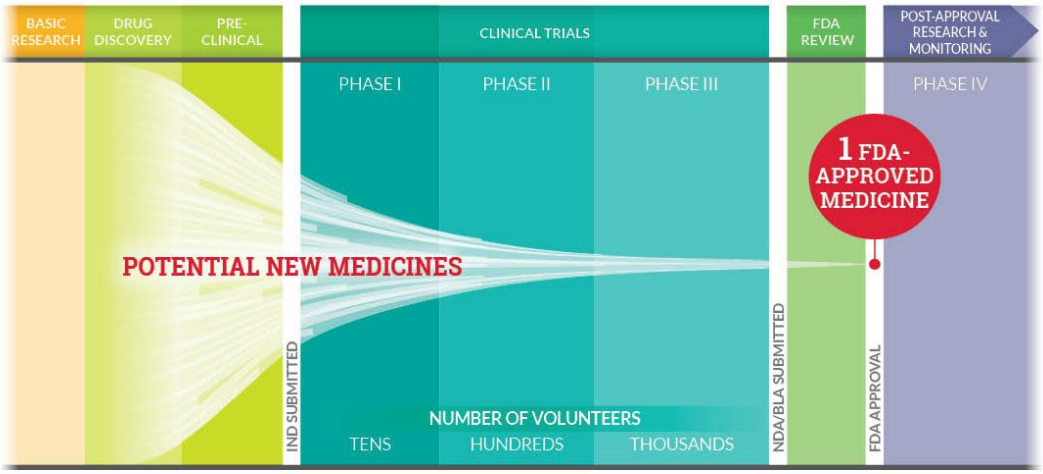
[43] *See*, *e.g.*, Sagonowsky E., "As competition heats up, U.S. prices for Remicade and biosims slip: analyst," FiercePharma, Dec. 2018, available at https://www.fiercepharma.com/pharma/amid-biosim-competition-remicade-prices-gradually-slipping-analyst (last visited Jan. 26, 2025).

[44] Cockburn IM et al., "Patents and the Global Diffusion of New Drugs," Nat'l Bureau Econ. Res., Sept. 2014, available at http://nber.org/papers/w20492 (last visited Jan. 26, 2025).

of that medicine.[45] This investment later enables accelerated acceptance of generic versions once relevant patents expire.

Strong intellectual property protection and enforcement at home and abroad, and the efficient market conditions necessary to enjoy those rights, provide essential incentives for investment in the biopharmaceutical sector and in all of the innovative industries that today account for more than 40 percent of U.S. gross domestic product.[46] For each of these industries, developing and bringing new products and processes to market is a risky endeavor; it requires time and substantial resources. In most cases, new products will fail to deliver returns that meet or exceed investment. Some three-quarters of all venture capital-backed internet startups fail.[47] And even those that succeed often fail to make a profit. Biopharmaceutical firms face similar challenges. Just two of every ten marketed medicines achieve returns that match or exceed average research and development costs.[48] Of the approximately 1,200 biopharmaceutical companies in the United States, more than 90 percent do not earn a profit.[49]

Figure 2: The biopharmaceutical research and development process



Key: IND=Investigational new drug application, NDA=New drug application, BLA=Biologics license application

*The average R&D cost required to bring a new FDA-approved medicine to patients is estimated to be $2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

[45] Wilsdon T and Chambers G, "The wider value delivered to patients, healthcare systems and competitors when innovators launch new products," Charles River Associates, Apr. 2013.

[46] U.S. Patent and Trademark Office, "Intellectual property and the U.S. economy: Third edition," Mar. 2022, available at https://www.uspto.gov/sites/default/files/documents/uspto-ip-us-economy-third-edition.pdf (last visited Jan. 26, 2025).

[47] Gage D, "The Venture Capital Secret: 3 Out of 4 Start-Ups Fail," Wall St. J., Sept. 2012, available at http://www.wsj.com/articles/SB10000872396390443720204578004980476429190 (last visited Jan. 26, 2025).

[48] Vernon JA, Golec JH, DiMasi JA, "Drug development costs when financial risk is measured using the fama-french three-factor model," Health Econ., Aug. 2010, available at http://onlinelibrary.wiley.com/doi/10.1002/hec.1538/abstract (last visited Jan. 26, 2025).

[49] Biotechnology Industry Organization, "Unleashing the Next Generation of Biotechnology Innovation."

The lengthy approval process for new products makes the research-based biopharmaceutical sector particularly reliant on the temporary protection intellectual property rights provide.[50] Unlike products made by other innovative industries, new medicines are not market-ready at the time they are developed. As highlighted in Figure 2 above, biopharmaceutical firms rigorously test and evaluate potential therapies through a series of clinical trials to demonstrate they are safe and effective for treatment of a particular disease or condition.[51] In 2017, biopharmaceutical companies sponsored more than 4,500 clinical trials in the United States alone, with trials in all 50 states, the District of Columbia and Puerto Rico. These trials involved close to one million participants and accounted for nearly $43 billion in economic activity.[52] Test data generated through those trials is then submitted to national regulatory agencies for marketing approval.

For these reasons and others, research and development is more capital intensive in the innovative biopharmaceutical sector than in other industries. Firms in this sector invest twelve times more in research and development per employee than the average of all other manufacturing industries.[53] In 2022, the U.S. biopharmaceutical companies invested approximately $141 billion in R&D in the United States, accounting for more than 80% of their global R&D.[54] Clinical trials can account for more than 60 percent of the total cost of bringing a new medicine to market and there is no guarantee promising molecules and proteins that enter clinical trials will result in a new treatment or cure.[55] The process of evaluating potential new therapies is so exacting that less than 12 percent of all potential new drugs entering clinical trials result in an approved medicine.[56]

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[50] Without patent protection, an estimated 65 percent of pharmaceutical products would not have been brought to market, compared with an average of eight percent across all other industries. *See* Mansfield E, "Patents and Innovation: An Empirical Study," Management Science, Feb. 1986, available at https://www.jstor.org/stable/2631551?seq=1#page_scan_tab_contents (last visited Jan. 26, 2025).

[51] PhRMA adaptation based on DiMasi JA, Grabowski HG, Hansen RW, "Innovation in the pharmaceutical industry: new estimates of R&D costs," J. Health Econ., 2016;47:20-33, available at https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub (last visited Jan. 26, 2025); U.S. Food and Drug Administration, "Development & Approval Process | Drugs," available at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ (last visited Jan. 26, 2025).

[52] TEConomy Partners, "Biopharmaceutical Industry-Sponsored Clinical Trials," Apr. 2019, available at https://www.phrma.org/-/media/TEConomy_PhRMA-Clinical-Trials-Impacts.pdf%EF%BB%BF (last visited Jan. 26, 2025).

[53] Pham N, "IP-Intensive Manufacturing Industries: Driving U.S. Economic Growth," NDP Analytics, Mar. 2015, available at https://ssrn.com/abstract=3045229 (last visited Jan. 26, 2025).

[54] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf (last visited Jan. 26, 2025).

[55] *Id.*

[56] PhRMA adaptation based on DiMasi JA, Grabowski HG, Hansen RW, "Innovation in the pharmaceutical industry: new estimates of R&D costs," J. Health Econ., 2016;47:20-33, available at https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub (last visited Jan. 26, 2025).

Advances in the treatment of diseases typically are not driven by large, dramatic developments, but more commonly build on a series of continuous improvements over time. The best clinical role and full value of a particular therapy typically emerges years after initial approval as further research is conducted and physicians and other health care providers gain real-world experience. These improvements and the further development of therapeutic classes of medicines often lead researchers to explore new treatments in related areas – restarting the research and development cycle. Indeed, nearly a quarter of existing therapeutic indications are treated by medicines initially developed to address a different concern.[57] In fact, most life-saving COVID-19 therapeutics were developed from existing therapeutic indications and more than 60 percent of therapies on the World Health Organization (WHO) Essential Medicines List relate to improvements on older treatments.[58] This step-by-step transformation in knowledge has led to increased survival, improved patient outcomes and enhanced quality of life for many patients.[59]

II. Practices that Undermine Innovation and Access to New Treatments

To research, develop and deliver new treatments and cures for patients who need them around the world, biopharmaceutical innovators must be able to secure and effectively enforce patents and protect regulatory test data. They must be able to obtain timely marketing approval for new medicines and make those therapies available to patients according to reimbursement rules and procedures that are fair, transparent, reasonable and non-discriminatory, and that appropriately value and reward patented pharmaceuticals. These conditions are also necessary to facilitate U.S. exports and ensure that the competitive biopharmaceutical industry can continue to provide jobs and advance the economic interests of the United States.

For well over a century, governments have recognized the need for global minimum standards that enable inventors to effectively and efficiently protect and share their inventions in a territorial system of intellectual property rights. Signed in 1883, the Paris Convention for the Protection of Industrial Property allowed inventors, regardless of nationality, to claim priority for their inventions and to take advantage of the intellectual property laws in each member country. To facilitate the process of filing patent applications around the world, many members of the Paris Convention established the

[57] Jin G, Wong S, "Toward better drug repositioning: prioritizing and integrating existing methods into efficient pipelines," Drug Discovery Today, Jan. 2014, available at http://www.sciencedirect.com/science/article/pii/S1359644613003991 (last visited Jan. 26, 2025).

[58] *See* Cohen J, Kaitin K, "Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice," Am. J. of Therapeutics, Jan.-Feb. 2008, available at http://journals.lww.com/americantherapeutics/Citation/2008/01000/Follow_On_Drugs_and_Indications__The_Importance_of.15.aspx (last visited Jan. 26, 2025).

[59] Sweeney N, Goss TF, "The Value of Innovation in Oncology: Recognizing Emerging Benefits Over Time," Boston Healthcare Associates, May 2015, available at https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/bha_value_of_cancer_innovation-whitepaper.pdf (last visited Jan. 26, 2025).

Patent Cooperation Treaty (PCT) in 1970. Today, more than 90 percent of all countries are members of the Paris Convention and the PCT.

The WTO TRIPS Agreement, which entered into force in 1994, was a major achievement in strengthening the worldwide protection and enforcement of intellectual property rights by creating an international minimum standard of protection for intellectual property rights. TRIPS was premised on the view that its obligations, if faithfully implemented by the diverse WTO Membership,[60] would create the policy and legal framework necessary for innovation-based economic development of WTO Members by rewarding innovation with reliable rights-based systems and permitting the flow of its attendant commercial benefits. Because it concerns both the definition and enforcement of rights, TRIPS is one of the single most important steps toward effective protection of intellectual property globally. WTO Members, including the United States, have an important role to play in fully and effectively implementing, reiterating and enforcing TRIPS minimum standards.

Decisions and efforts to waive or otherwise weaken TRIPS obligations, including the TRIPS waiver on COVID-19 vaccines supported by the previous Administration, by definition and design, undermine and devalue the intellectual property protections that the TRIPS Agreement provides to Americans. The TRIPS waiver marked a significant escalation in anti-intellectual property global activism and further polarized legitimate conversations on countries' engagement to combat the pandemic. Furthermore, such decisions and efforts embolden countries to take additional steps to weaken protection of intellectual property rights on American innovation. The waiver is a prominent example of how some countries used the COVID-19 pandemic opportunistically to advance longstanding industrial policies and to further erode intellectual property policies. These governments ignore the value of intellectual property, including enabling increased participation in the global economy and the availability of new technologies – not least the creation, production and delivery of innovative COVID-19 vaccines and therapeutics in record time.

Notwithstanding the prior Administration's support for the TRIPS waiver on COVID-19 vaccines, the United States and other countries historically have promoted, implemented and built on the global minimum standards of protection provided by the TRIPS Agreement through eligibility criteria for trade preference programs, WTO accessions and regional and bilateral trade agreements that establish strong intellectual property protections and require fair and equitable market access. However, certain U.S. trading partners maintain or are considering acts, policies or practices that are harming or would harm the ability of biopharmaceutical innovators to research, develop and deliver new treatments and cures for patients around the world. These acts, policies or practices deny or would deny adequate and effective intellectual property protection and/or fair and equitable market access for innovative medicines. In many cases, they appear to be inconsistent with global, regional and bilateral rules.

[60] 166 members as of August 30, 2024.

Since TRIPS took effect in 1994, economic growth has accelerated, billions have been lifted from poverty and global health has improved significantly.[61] Indeed, the innovations supported, incentivized and licensed as a consequence of intellectual property protections, including those championed by TRIPS, have saved millions of lives around the globe.[62] Moreover, evidence suggests that strong intellectual property protections, including those obligations established via TRIPS, are linked to increased technology transfer to developing countries and promote indigenous innovation by local companies.[63]

Emboldened by the TRIPS waiver[64] and the lack of U.S. leadership under the previous administration, some countries are working through multilateral organizations – including the WTO, the WHO, the United Nations Development Program (UNDP), the United Nations Conference on Trade and Development (UNCTAD), the World Intellectual Property Organization (WIPO), Unitaid and others – to undermine and even eliminate intellectual property protections that drive and sustain biopharmaceutical innovation in the United States and around the world. By reinterpreting international agreements and through meetings, reports, guidelines and training programs, these multilateral fora are straying from their mandates to promote acts, policies and practices globally and in specific countries to undermine intellectual property protections and thereby prevent biopharmaceutical innovators from securing and maintaining patents, protecting regulatory test data and enjoying fair and equitable market access.[65] Of particular concern are proposals related to "technology transfer" to establish mechanisms that would force technology transfers and the sharing of trade secrets and know-how, including in the ongoing negotiations at the WHO of the Pandemic Agreement, in calls from the UN Secretary General to remove intellectual property "constraints" to promote the sharing of know-how and technology for green technologies, and technology transfer proposals[66] by some WTO members. It is critically important to protect incentives for

[61] Geneva Network, "The WTO Trips Agreement and Global Health Progress," Nov. 2021, available at https://geneva-network.com/research/the-wto-trips-agreement-and-global-health-progress/ (last visited Jan. 26, 2025).

[62] Solovy E, "The Doha Declaration at Twenty: Interpretation, Implementation, and Lessons Learned on the Relationship Between the TRIPS Agreement and Global Health," Northwest. J. Int. Law Bus., Nov. 2021, available at https://ssrn.com/abstract=3965053 (last visited Jan. 26, 2025).

[63] Geneva Network, "The WTO Trips Agreement and Global Health Progress," Nov. 2021, available at https://geneva-network.com/research/the-wto-trips-agreement-and-global-health-progress/ (last visited Jan. 26, 2025).

[64] *See*, *e.g.*, Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from India and South Africa*: *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, IP/C/W/669 (Oct. 2, 2020), available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True (last visited Jan. 26, 2025).

[65] Hudson Inst., "The Patent Truth about Health, Innovation and Access," June 2016, available at https://s3.amazonaws.com/media.hudson.org/files/publications/20160706ThePatentTruthAboutHealthInnovationandAccess.pdf (last visited Jan. 26, 2025).

[66] *See*, *e.g.*, WTO, "Members discuss reinvigorating efforts of working group on trade and technology transfer," Oct. 13, 2023, available at https://www.wto.org/english/news_e/news23_e/devel_13oct23_e.htm (last visited Jan. 26, 2025).

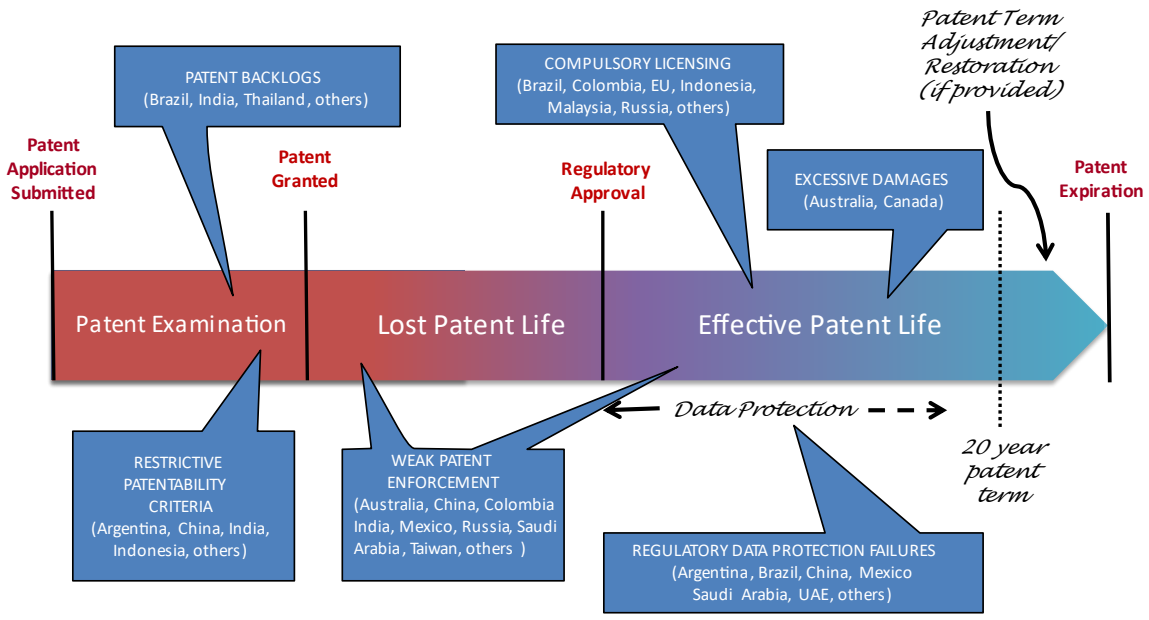
innovation and ensure that any technology transfer is voluntary and on mutually agreed terms (as reflected, for example, in Chapter two of the Phase One Trade Agreement between the United States and China). Such provisions guarantee that the decision to engage in technology transfer is not coerced and ensure that once a voluntary decision has been made to engage in technology transfer, the details on the arrangements for such transfers are agreed by both parties.

The following sections highlight the most serious challenges facing PhRMA members around the world. The acts, policies and practices of specific governments are described further below. PhRMA members urge USTR and other federal agencies to highlight these challenges, acts, policies and practices in the 2025 Special 301 Report and to use all available tools to address and resolve them.

A. Practices that undermine biopharmaceutical innovation

The six intellectual property challenges described below and highlighted in Figure 3 have serious and immediate impacts on the ability of PhRMA members to invest in discovering and transforming promising molecules and proteins into useful new medicines for patients around the world. These challenges hinder or prevent biopharmaceutical innovators from securing patents (restrictive patentability criteria and patent backlogs), maintaining and effectively enforcing patents (market-size damages, weak patent enforcement and compulsory licensing), and protecting regulatory test data (regulatory data protection failures).

Figure 3: Biopharmaceutical intellectual property challenges



Restrictive Patentability Criteria

To bring valuable new medicines to patients, biopharmaceutical innovators must be able to secure patents on all inventions that are new, involve an inventive step and are capable of industrial application.[67] National laws, regulations or judicial decisions that prohibit patents on certain types of biopharmaceutical inventions or impose additional or heightened patentability criteria restrict patient access to valuable new medicines and undermine investment in future treatments and cures. These restrictions prevent innovators from building on prior knowledge to develop valuable new and improved

[67] *See generally*, TRIPS Article 27.1.

treatments that can improve health outcomes[68] and reduce costs[69] by making it easier for patients to take medicines and by improving patient adherence to prescribed therapies. Some of the most serious examples of restrictive patentability criteria challenges facing PhRMA members in countries around the world include:

- *Patentability restrictions and additional patentability criteria.* A number of countries maintain laws and regulations that prevent the patenting of a wide range of specific improvements to existing medicines[70] – improvements that are valuable to patients and payers and that require significant investment and research to develop. For example, **Argentina** discriminatorily targets the biopharmaceutical industry by preventing innovators from securing patents on virtually all inventions – a practice that is only comparable to Venezuela. **India** severely limits the patenting of biopharmaceutical inventions by applying a unique "enhanced therapeutic efficacy" standard.

  In addition, multilateral organizations such as UNDP and Unitaid advocate actively for patentability restrictions and additional patentability requirements that are

[68] New improvements to existing treatments, such as new dosage forms and combinations, are of tremendous value to patients. They can make it easier for patients to take medicines and increase patient adherence. Specifically, they make it more likely patients will take their medicines consistently and as prescribed. Such improvements might allow patients to take an oral medication instead of an injection or reduce the number of doses required. Adherence is inversely proportional to the number of times a patient must take their medicine each day. The average adherence rate for treatments taken once daily is nearly 80 percent, compared to about 50 percent for medicines that must be taken four times a day. Patient adherence to prescribed courses of treatment leads to better health outcomes and is particularly important for the management of chronic, non-communicable diseases like diabetes, heart disease and cancer. According to the WHO, "[a]dherence to therapies is a primary determinant of treatment success." *See* Shrank WH et al., "A Blueprint for Pharmacy Benefit Managers to Increase Value," Am. J. Managed Care, Feb. 2009, available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2737824/ (last visited Jan. 26, 2025).

[69] Encouraging patients to take their medicines consistently and as prescribed can lower overall health care costs. The cost of non-adherence has been estimated at $100 billion to $300 billion annually, including the costs of avoidable hospitalizations, nursing home admissions and premature deaths. Making patents available for improvements and new indications can also drive price competition for medicines by encouraging the development of alternative treatments – leading to multiple drugs in a single therapeutic class and increasing the range of options for patients and health care providers. *See* Osterberg, Lars and Terrence Blaschke, "Adherence to Medication," New Eng. J. Med., Aug. 2005, available at http://www.nejm.org/doi/full/10.1056/NEJMra050100 (last visited Jan. 26, 2025); and DiMatteo MR, "Variations in Patients' Adherence to Medical Recommendations: A Quantitative Review of 50 Years of Research," Med. Care, Mar. 2004, available at http://journals.lww.com/lww-medicalcare/Abstract/2004/03000/Variations_in_Patients__Adherence_to_Medical.2.aspx (last visited Jan. 26, 2025); and DiMasi JA, Price Trends for Prescription Pharmaceuticals 1995-1999, background report prepared for the Dep't of Health and Human Services Conference on Pharmaceutical Pricing Practices, Utilization and Costs, Aug. 2000, available at https://aspe.hhs.gov/reports/price-trends-prescription-pharmaceuticals-1995-1999 (last visited Jan. 26, 2025).

[70] Examples of improvements include enantiomers and combination treatments. *See* Stevens P, Ellis J, "Enantiomer Patents," Geneva Network, June 2017, available at https://geneva-network.com/wp-content/uploads/2017/07/enantiomer-patents.pdf (last visited Jan. 26, 2025); and Stevens P, Ellis J, "The Power of Combination Drugs," Geneva Network, June 2017, available at https://geneva-network.com/wp-content/uploads/2017/07/Combination-drugs-patentability.pdf (last visited Jan. 26, 2025).

inconsistent with international practice. For example, UNDP issued patent examination guidelines in 2016 that, if followed, would prevent innovators from securing patents on many kinds of biopharmaceutical inventions.[71] Similarly, Unitaid partnered with various non-governmental organizations in 2018 to launch a campaign to erode intellectual property policies and laws globally.

- *Restrictions on post-filing submissions.* Unlike patent offices in the United States, Europe, Japan, Korea and other major markets, **China**'s National Intellectual Property Administration (CNIPA) does not consistently accept data generated after a patent is filed during patent prosecution to describe inventions or satisfy inventive step requirements. Consistent with its commitments in Article 1.10 of the Economic and Trade Agreement between the United States and China (U.S.-China Economic and Trade Agreement), China has issued a judicial interpretation providing that the Court will review post-filing experimental data and CNIPA has amended its Patent Examination Guidelines. PhRMA and its members welcome these positive steps and will be closely monitoring implementation of the revised Guidelines to ensure that they permit pharmaceutical patent applicants to rely on supplemental data to satisfy relevant requirements for patentability.

Restrictive patentability criteria in many of these countries and others are inconsistent with WTO rules and U.S. trade agreements, which require parties to make patents available for inventions that are new, involve an inventive step and are capable of industrial application.[72] These laws also appear to apply solely to pharmaceutical products, either expressly by law or in a *de facto* manner as applied. This is not consistent with the obligations of WTO Members and U.S. trade agreement partners to make patents available without discrimination as to the field of technology.

PhRMA members encourage USTR and other federal agencies to address restrictive patentability criteria issues with trading partners and look forward to working closely with these agencies to secure concrete progress and real results. Effective enforcement of U.S. trade agreements is needed to resolve these challenges in particular countries and to prevent others from adopting similar practices.

Patent Backlogs

Long patent examination and approval backlogs harm domestic and overseas inventors in every economic sector. Backlogs undermine incentives to innovate, prevent timely patient access to valuable new treatments and cures, and impose huge societal

[71] United Nations Development Program, "Guidelines for the Examination of Patent Applications relating to Pharmaceuticals," 2016, available at http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/guidelines-for-the-examination-of-patent-applications-relating-t.html (last visited Jan. 26, 2025).

[72] Hollman CM et al., "Patentability Standards for Follow-On Pharmaceutical Innovation," Biotechnology Law Report, June 2018, available at https://www.liebertpub.com/doi/pdf/10.1089/blr.2018.29073.cmh (last visited Jan. 26, 2025).

costs.[73] Because the term of a patent begins on the date an application is filed, unreasonable delays can directly reduce the value of granted patents and undermine investment in future research. For biopharmaceutical companies, patent backlogs can postpone the introduction of new medicines.[74] They create legal uncertainty for research-based and generic companies alike and can increase the time and cost associated with bringing a new treatment to market.

- Patent backlogs are a challenge around the world, but some countries stand out for persistently long delays. In **Brazil**, a 2024 analysis found that the average patent examination timeline for biopharmaceutical patents granted from January 2020 through November 2024 is 9.5 years.[75] The situation is only somewhat better in markets like **India**, where it takes an average of six years to secure a patent, and yet in 2015, India granted one patent based on an application filed 19 years earlier.[76]

Long patent examination delays cause significant damage. A London Economics study estimated the value of lost innovation due to increased patent pendency at £7.6 billion per year.[77] Patent backlogs are a particular challenge for small start-up firms that are playing an increasingly important role in biopharmaceutical innovation. According to a U.S. Patent and Trademark Office (PTO) Economic Working Paper, for every year an ultimately approved patent application is delayed, a start-up firm's employment growth decreases by 21 percent and its sales growth decreases by 28 percent on average over the following five years.[78] Each year a patent application is delayed, the average number of subsequent patents granted decreases by 14 percent and the probability that a startup will go public is cut in half.[79]

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[73] Schultz M, Madigan K, "The Long Wait for Innovation: The Global Patent Pendency Problem," Geo. Mason U., CPIP, 2016, available at https://sls.gmu.edu/cpip/wp-content/uploads/sites/31/2016/10/Schultz-Madigan-The-Long-Wait-for-Innovation-The-Global-Patent-Pendency-Problem.pdf (last visited Jan. 26, 2025).

[74] Business Standard, "Delay in Patents Can Slow Down Improvements in Medicines: Experts," Oct. 2016, available at http://www.business-standard.com/article/news-ians/delay-in-patents-can-slow-down-improvement-in-medicine-experts-116101600452_1.html (last visited Jan. 26, 2025).

[75] PhRMA, "Updated Analysis Underscores the Need for Brazil to Address Patent Backlogs," Jan. 24, 2025, available at https://phrma.org/Blog/the-time-is-now-to-address-brazils-notorious-patent-backlog (last visited Jan. 26, 2025).

[76] IndiaSpend, "Patent Delays Threaten 'Make In India'," Jan. 2016, available at https://www.newslaundry.com/2016/01/12/patent-delays-threaten-make-in-india (last visited Jan. 26, 2025).

[77] London Economics, "Patent Backlogs and Mutual Recognition report to the UK Intellectual Property Office," Jan. 2010, available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/328678/p-backlog-report.pdf (last visited Jan. 26, 2025).

[78] Farre-Mensa J, Hegde D, Ljungqvist A, "What Is a Patent Worth? Evidence from the U.S. Patent 'Lottery'," USPTO Economic Working paper No. 2015-5, Dec. 17, 2015, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2704028 (last visited Jan. 26, 2025).

[79] *Id.*

PhRMA members support patent term adjustment provisions in trade agreements and national laws to address unreasonable patent examination delays. In **Brazil**, the 2021 Supreme Court decision finding that the sole paragraph of Article 40 of the Patent Law, which ensured a minimum patent term of 10 years from the date of patent grant in Brazil, is unconstitutional leaves patent applicants no recourse for unreasonable delays during examination of patent applications. Further, damaging legislation in the **European Union** has weakened patent term restoration (PTR) mechanisms by reducing the patent protections restored through Supplementary Protection Certificates (SPCs). In addition, the European Commission is proposing to establish a new mechanism for third parties to oppose SPCs. Also, Singapore should adjust its PTR mechanism to compensate the patent holder for the time invested in conducting clinical trials either in Singapore or in any other market when such data is a condition of obtaining marketing approval in Singapore.

In addition, industry was disappointed to hear the sudden announcement on January 6, 2021, that the Gulf Cooperation Council (GCC) Patent Office was no longer accepting patent applications, thereby requiring innovators to file their patent applications in each of the GCC Member States rather than through the one office. This deprives innovators of the benefit of obtaining patent protection in all GCC Member States by filing one single regional application, which significantly reduced the financial and administrative burden on right holders. While we are glad to hear that the GCC Patent Office recently resumed handling patent applications, to date only Bahrain, Kuwait and Qatar have indicated that they will use this service, creating further uncertainty regarding how pending patent applications will be examined. Further work is needed to consolidate gains in patent protections and to extend effective models to other countries.

Compulsory Licensing

Biopharmaceutical innovators support strong national health systems and timely access to safe, effective and high-quality medicines for patients who need them. Patents drive and enable research and development that delivers new treatments and cures. These limited and temporary intellectual property rights are not a barrier to access to medicines[80] – particularly when governments and the private sector partner to improve health outcomes.

Compulsory licenses (CLs) have been issued recently in several countries, including **Colombia**, **Malaysia** and **Russia** that allow local companies to make, use, sell or import particular patented medicines without the consent of the patent holder. Other governments, including the **European Union**, have adopted or are considering resolutions, laws or regulations that promote or provide broad discretion to issue CLs,

[80] *See*, *e.g.*, Attaran A, Gillespie-White L, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatments in Africa?" J. Am. Med. Assoc., Oct. 2001, available at https://jamanetwork.com/journals/jama/fullarticle/194301 (last visited Jan. 26, 2025); Attaran A, "How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries," Health Aff., May 2004, available at https://www.healthaffairs.org/doi/full/10.1377/hlthaff.23.3.155 (last visited Jan. 26, 2025).

provide inadequate opportunity for patent holders to respond to CL petitions and appeal CL grants, and discriminate against pharmaceutical patents. PhRMA believes that governments should grant CLs in accordance with international rules and only in exceptional circumstances and as a last resort. Decisions should be made through fair and transparent processes that involve participation by all stakeholders and consider all relevant facts and options.

Experience and recent research demonstrate that compulsory licensing is not an effective way to improve access or achieve other public health objectives. It does not necessarily lower prices[81] or speed access[82] in the short-term or provide sustainable or comprehensive solutions to longer-term challenges. It does not address systemic barriers to access[83] – from weak health care delivery systems to low national health care funding and high taxes and tariffs on medicines. Compulsory licensing is particularly ineffective relative to the many alternatives available. Biopharmaceutical innovators support different tools and programs that make medicines available to patients who could not otherwise afford them, including drug donation and differential pricing programs, voluntary licensing and non-assert declarations.[84] In sub-Saharan Africa, for example, the majority of antiretrovirals are manufactured under voluntary licenses to local generic drug companies.[85] Indeed, the successful use of various mechanisms, such as voluntary licenses, explains why the compulsory licensing provisions in TRIPS have rarely been utilized. As several WTO Members have argued, the limited use is not surprising given that the vast majority of essential medicines are not patented and that developing countries acquire medicines through voluntary licenses for those medicines that are subject to intellectual property protections.[86]

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[81] Beall RF et al., "Compulsory Licensing Often Did Not Produce Lower Prices for Antiretrovirals Compared to International Procurement," Health Aff., Mar. 2015, available at https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2014.0658 (last visited Jan. 26, 2025).

[82] When Brazil issued a CL for an antiretroviral treatment in 2007, it took the local manufacturer two years to launch production of a generic version. *See* Bond E, Saggi K, "Compulsory licensing, price controls, and access to patented foreign products," Vand. U., Apr. 2012, available at http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_4_12/wipo_ip_econ_ge_4_12_ref_saggi.pdf (last visited Jan. 26, 2025).

[83] Vesper I, "Cheap drugs not enough to fight hepatitis C in Asia," SciDevNet, July 2018, available at https://www.scidev.net/global/news/drugs-fight-hepatitis-asia/ (last visited Jan. 26, 2025).

[84] IFPMA Policy Position, "Voluntary Licenses and Non-Assert Declarations," Feb. 18, 2015, available at https://www.ifpma.org/publications/ifpma-position-on-voluntary-licenses-and-non-assert-declarations/ (last visited Jan. 26, 2025).

[85] Chien C, "HIV/AIDS Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare?" *PLoS One*, Mar. 2007, available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1805689/ (last visited Jan. 26, 2025).

[86] Solovy E, "The Doha Declaration at Twenty: Interpretation, Implementation, and Lessons Learned on the Relationship Between the TRIPS Agreement and Global Health," Northwest. J. Int. Law Bus., Nov. 2021, available at https://ssrn.com/abstract=3965053 (last visited Jan. 26, 2025); *see also* Geneva Network, "The WTO Trips Agreement and Global Health Progress," Nov. 2021, available at https://geneva-network.com/research/the-wto-trips-agreement-and-global-health-progress/ (last visited Jan. 26, 2025).

Unfortunately, despite the evidence indicating that CLs are a deeply flawed means of facilitating access to medicines, some countries appear to be using CLs to promote the local production of medicines at the expense of manufacturers and jobs in the United States and elsewhere.[87] For example, **Colombia** issued a CL in 2024 on an antiretroviral medicine on ambiguous grounds to advance a political agenda. The need for engagement is critical in Colombia, with key government officials declaring that Colombia will "lead or support the position of abolishing patents."[88] **Russia**, which has made no secret of its intent to compel local manufacturing, has granted CLs for a COVID-19 therapeutic and other innovative medicines. **Malaysia** issued a CL in 2017 in a move that appears designed to facilitate the local development and marketing of a competing combination product. Since then, the Malaysian government appears to be inappropriately leveraging the CL to encourage medical tourism and travel to Malaysia.[89]

In its 2020 Special 301 Report, USTR rightly highlighted concerning actions by "trading partners to unfairly issue, threaten to issue, or encourage others to issue compulsory licenses" and committed to "engage, as appropriate, with trading partners."[90] PhRMA members welcomed these statements and urge USTR and other federal agencies to engage to address serious and growing compulsory licensing threats across Latin America, Southeast Asia and elsewhere.

Weak Patent Enforcement

To continue to invest in the research and development of new medicines, biopharmaceutical innovators must be able to effectively enforce patents. Mechanisms such as patent linkage that provide for the early resolution of patent disputes before potentially infringing follow-on products enter a market are essential for effective enforcement. The premature launch of a product that is later found to infringe a patent may disrupt patient treatment and require governments to adjust and re-adjust national formularies and reimbursement policies. For biopharmaceutical innovators, it may cause commercial damage that is impossible to repair later.

At a minimum, effective early resolution mechanisms (1) require governments to notify the holder of a patent on a biopharmaceutical product if another party applies for

[87] *See*, *e.g.*, Drugs for Neglected Diseases Initiative, "DNDi welcomes Malaysia's move to secure access to more affordable treatments for hepatitis C," Sept. 2017, available at https://dndi.org/press-releases/2017/dndi-welcomes-malaysia-move-access-affordable-treatments-hepc/ (last visited Jan. 26, 2025).

[88] La Silla Vacia, "Ifarma, the small NGO that took over pharmaceutical policy in Colombia," (Sept. 1, 2022), available in Spanish at https://www.lasillavacia.com/silla-nacional/ifarma-la-pequena-ong-que-se-tomo-la-politica-farmaceutica-en-colombia/ (last visited Jan. 26, 2025).

[89] *See*, *e.g.*, "Malaysia hopes to become Asia's treatment hub for hepatitis C; offering treatment at fraction of cost: Health minister," CNA (Nov. 16, 2021), available at https://www.channelnewsasia.com/asia/malaysia-hepatitis-c-medical-tourism-2316876 (last visited Jan. 26, 2025).

[90] USTR, 2020 Special 301 Report, at p. 14 (Apr. 2020), available at https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf (last visited Jan. 26, 2025).

marketing approval for a generic or biosimilar versions of that product; (2) enable the holder of a patent on a biopharmaceutical product to seek provisional enforcement measures, such as a stay, preliminary injunction or interlocutory injunction, to prevent the marketing of a potentially infringing generic or biosimilar version of that product; and (3) allow for the timely resolution of patent disputes before marketing approval is granted for a generic or biosimilar.

PhRMA members welcomed the inclusion of effective patent enforcement commitments in the U.S.-China Economic and Trade Agreement. Although **China** implemented a number of measures in 2021 to establish an early patent dispute resolution framework, we have concerns about the effectiveness of the resulting system. PhRMA and its member companies stand ready to work with the U.S. and Chinese governments on the implementation of an effective patent enforcement system in China, consistent with its commitments in Article 1.11 of the U.S.-China Economic and Trade Agreement and with a view to establishing an effective and commercially meaningful enforcement system for biopharmaceutical patents in China.

U.S. trade agreements generally require parties to notify patent holders, to act expeditiously on requests for provisional enforcement measures and to prevent the marketing of generic or biosimilar products during the patent term without the consent of the patent holder. However, some U.S. trade agreement partners do not comply with these obligations. For example, despite its USMCA commitments, **Mexico** has not implemented an effective patent enforcement system. Until recently, **Australia** did not require any notice of a third party's intention to obtain marketing approval, so as to enable final resolution of patent claims before marketing approval, but further measures are required to notify patent holders more reliably.

Saudi Arabia has knowingly facilitated the infringement of the patent on a medicine formulated and exported from the United States by giving a local company approval to produce a competing product during the patent term. Similarly, in 2017 the UAE approved the sale of patent infringing generics despite the government's pharmaceutical patent commitments in Ministerial Decree No. 404 and reciprocal patent recognition obligations under the Gulf Cooperation Council. Promisingly, Decree No. 321 (2020) suggests that the UAE may be poised to remedy this deficiency. In Bangladesh, local companies are taking advantage of the country's least developed country (LDC) status to undermine intellectual property protections in other countries. Under the terms of a grace period adopted in 2001 (and extended in 2021), LDCs are not obligated to comply with WTO intellectual property rules.[91] Local companies in Bangladesh are reverse engineering and making copies of biopharmaceutical products that are under patent in other parts of the world. These unlicensed biopharmaceutical products are entering markets abroad, e.g., India, where patent protection exists. The quality and safety of these products have not been reviewed and could pose significant risks.

[91] WTO, "WTO members agree to extend TRIPS transition period for LDCs until 1 July 2034," Jun. 29, 2021, available at https://www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm (last visited Jan. 26, 2025).

Furthermore, local companies are adopting product names for biopharmaceutical products that are nearly identical to well-known product names of U.S. biopharmaceutical companies creating confusion in the market as to their source and/or association. These actions are not consistent with the spirit, if not the letter, of the LDC grace period.[92]

Effective early resolution mechanisms are also needed in **India**, **Russia** and other countries, where innovators are not notified of marketing approval applications filed for potentially infringing products and generally are unable to secure provisional enforcement measures. In the Philippines, early resolution mechanisms were available before a 2005 Department of Health Administrative Order (A.O. No. 2005-0001) took effect that required pharmaceutical patent holders to monitor follow-on products seeking FDA registration and to pursue costly and time-consuming legal remedies to avoid potential patent infringement.

PhRMA urges USTR and other federal agencies to enforce intellectual property commitments in existing U.S. trade agreements and to continue to promote effective patent enforcement abroad, including through bilateral dialogues such as the U.S.-India Trade Policy Forum.

Excessive and Punitive Damages

Biopharmaceutical innovators must be able to rely on and enforce patents issued by competent government authorities. Laws or policies that allow governments or other non-parties to a patent dispute to collect excessive and punitive damage awards after the fact from innovators that pursue unsuccessful patent claims unfairly penalize and discourage the use of provisional enforcement measures as part of well-functioning early resolution mechanisms. These policies undermine legal certainty, predictability and the incentive provided by patents to invest in new treatments and cures.

The ability to enforce patents in **Canada** continues to weaken. Canada's current policies discourage and penalize innovators from seeking patent enforcement actions by enabling generic litigants to recover excessive and punitive damage awards simply because innovators unsuccessfully sought to protect patents granted by the Canadian Government. Pending court decisions could make that situation far worse – increasing the potential that innovators forfeit patents prematurely in Canada rather than defend them. Section 8 of the Patented Medicines (Notice of Compliance) Regulations (PM (NOC) Regulations) is intended to compensate generic drug companies that bring successful patent disputes against innovators for actual losses suffered during the stay period. But Canada's courts are granting generic litigants damages in excess of 100 percent of the total generic market.

Canada's implementing regulations of the Comprehensive Economic and Trade Agreement (CETA) further expose innovators to excessive liability under Section 8. These regulations enable competitors to claim indefinite future loses and to seek compensation

[92] *Id*.

for production "ramp-up" costs that they may have incurred before the stay was granted and after it was lifted. In addition, other proceedings have been allowed to proceed under various common law theories (Statute of Monopolies, Trademarks Act, unjust enrichment and others). These cases could result in damages or liability for PhRMA members which exceed the compensatory threshold.

Australia's Therapeutic Goods Act, passed as part of legislation implementing the U.S.-Australia Free Trade Agreement,[93] provided for "market-size damages" in certain instances. Since 2012, the Australian Government has stated its intent to seek – and has sought – market-size damages from biopharmaceutical innovators that have pursued unsuccessful patent claims. Those damages are designed to compensate Australia's pharmaceutical reimbursement scheme (PBS) for any higher price paid for a patented medicine during the period of a provisional enforcement measure. The PBS imposes automatic price cuts on medicines as soon as competing versions enter the market, but the policy entails no corresponding mechanism to compensate innovators for losses if an infringing product is launched prematurely.

By pursuing market-size damages, Australia is unfairly tipping the scales in commercial patent disputes – encouraging competitors to launch at risk and discouraging innovators from enforcing their patents. This action creates an inappropriate conflict of interest by permitting the same government that examined and granted a patent to seek damages if that patent is later ruled invalid or not infringed. It exposes innovators to significant additional compensation claims that are difficult to quantify and were not agreed to at the time provisional enforcement measures were granted. The size of these additional claims equates legitimate patent enforcement with patent abuse. Allowing governments or other non-parties to a patent dispute to collect market-size damages undermine legal certainty, predictability and the incentives patents provide for investment in new treatments and cures. Australia's practice appears to be inconsistent with the U.S.-Australia Free Trade Agreement and WTO intellectual property rules, including with respect to provisional measures.

In a 2004 letter[94] to Australia's trade minister, USTR raised concerns about the significant and negative impact that the Therapeutic Goods Act amendments permitting market-size damages could have on patent rights and the consistency of those amendments with Australia's international obligations. The letter stated that the "United States reserves its right to challenge the consistency of these amendments with such obligations." PhRMA members urge USTR and other federal agencies to prioritize actions to address Australia's pursuit of market-size damages.

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[93] *See* Schedule 7 of the U.S. Free Trade Agreement Implementation Act 2004, available at http://www.wipo.int/wipolex/en/text.jsp?file_id=206375 (last visited Jan. 26, 2025).

[94] Letter from U.S. Trade Representative Robert B. Zoellick to Australian Minister of Trade Mark Vaile, Nov. 17, 2004, available at https://ustr.gov/archive/assets/Trade_Agreements/Bilateral/Australia_FTA/Implementation/asset_upload_file393_6951.pdf (last visited Jan. 26, 2025).

Regulatory Data Protection Failures

Regulatory data protection (RDP) complements patents on innovative medicines. By providing temporary protection for the comprehensive package of information biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval, RDP provides critical incentives for investment in new treatments and cures.

RDP is a carefully balanced mechanism that improves access to medicines of all kinds. Prior to 1984, generic drug companies in the United States were required to generate their own test data for marketing approval. The Hatch-Waxman Act introduced abbreviated pathways that enabled generic drug companies to rely on test data developed by innovators.[95] In exchange, innovators received a period of protection for test data gained through substantial investments in clinical trials over many years. As a result of this and other provisions of Hatch-Waxman, the percentage of prescription drugs filled by generics soared from 19 percent in 1984 to approximately 90 percent of all prescriptions filled in the United States today.[96] Indeed, a new study shows just how important RDP is for improving patient access to medicines worldwide.[97] Comparing 53 markets with and without RDP, the report finds that those with RDP have, on average, access to three times more innovative medicines. Furthermore, the report concludes that for every new innovative medicine introduced, approximately 2.5 generic or biosimilar medicines would follow (the number is higher in countries with strong generic industries, like Brazil, where the report finds that almost 3.2 generic or biosimilar products would result from each innovative product). Also, the report highlights that RDP is associated with a 70 percent increase in clinical trial activity and that the rate of return associated with clinical trials, either through income or job creation, is estimated to be between 39 and 64 percent.

RDP is particularly critical for biologic medicines, which may not be adequately protected by patents alone. Made using living organisms, biologics are so complex that it is possible for others to produce a version – or "biosimilar" – of a medicine that may not be covered within the scope of the innovator's patent. For this reason and others, U.S. law provides twelve years of RDP for biologics. This was not an arbitrary number, but rather the result of careful consideration and considerable research on the incentives necessary to ensure biopharmaceutical innovators and the associated global scientific ecosystem are able to sustainably pursue groundbreaking biomedical research.[98]

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[95] Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271 and 282).

[96] PhRMA analysis based on IQVIA National Sales Perspective and Quintiles, IMS Institute MIDAS™ audited data, 2017.

[97] Copenhagen Economics, "Regulatory Data Protection – How Adopting Regulatory Data Protection Can Increase Medicine Availability, Innovation, and Investment," Aug, 2023, available at https://copenhageneconomics.com/wp-content/uploads/2023/09/Regulatory-Data-Protection-RDP-International-Report.pdf (last visited Jan. 26, 2025).

[98] *See*, *e.g.*, Grabowski H et al., "Data exclusivity for biologics," Nature Reviews – Drug Discovery, Jan. 2011, available at https://fds.duke.edu/db/attachment/1592 (last visited Jan. 26, 2025).

Unfortunately, many U.S. trading partners do not provide RDP. Examples, some of which are described further in the market profiles below, **Argentina**, **Brazil**, **China**, and **India**. Others, like **Saudi Arabia**, provide RDP but have allowed local companies to rely on data submitted by American innovators during the period of protection. This is contrary to WTO rules, which require parties to protect regulatory test data submitted as a condition of obtaining marketing approval against both disclosure and unfair commercial use. U.S. trade agreements generally require parties to provide RDP for a specified period of time, but some partner countries have not fully honored their commitments. For example, **Mexico** and Peru provide RDP for small-molecule treatments, but do not provide appropriate protection for biologics. Singapore does not provide RDP for new formulations, combinations, indications and dosage regimes. Alarmingly, proposals in the **European Union** would reduce the RDP term across the region and provide illusory opportunities to restore these lost years if certain conditionalities outside of the control of the innovator are met. Other countries have adopted mechanisms inconsistent with international rules that enable governments to circumvent RDP. In 2022, the UAE took steps to address discrepancies in its RDP regime. Specifically, the UAE clarified the relationship between Decree 321 and the new Industrial Property Rights Law (Law No. (11) of 2021), and confirmed the eight-year RDP term. We urge the UAE Government to codify this clarification and ensure that the Decree (and in particular the proposed exception in Article 5) is consistent with the UAE's international commitments and that it is implemented in a manner that provides effective and meaningful RDP for all innovative pharmaceuticals (including biologics). Meanwhile, **Canada** passed legislation in 2014 that gives the Health Minister broad discretion to share undisclosed test data without safeguards to protect against unfair commercial use. Other countries provide RDP in a manner that discriminates against foreign innovators.

PhRMA urges USTR and other federal agencies to enforce intellectual property commitments in existing U.S. trade agreements, to address RDP failures in bilateral forums and to seek and secure RDP commitments in trade agreement negotiations that reflect the high standards found in U.S. law.

B. Practices that deny fair and equitable market access

PhRMA members increasingly encounter acts, policies and practices abroad that deny fair and equitable market access. Through arbitrary and often discriminatory government price controls, unnecessary regulatory delays and high tariffs and taxes, markets across Europe, Asia, the Americas and beyond are limiting market competition, increasing costs and undermining the ability of biopharmaceutical innovators in the United States to bring new medicines to patients who need them.

In recent years, America's biopharmaceutical sector has witnessed a surge in the number and severity of arbitrary and discriminatory government price controls abroad that threaten U.S. exports and jobs. Such measures cause serious damage in the economies that maintain them by rationing patient access to health care. They also have significant ripple effects across other markets. For example, government price controls implemented in one market can spill over to many other markets through international reference pricing.

These policies can restrict competition and artificially depress prices below market value, ultimately delaying and denying patient access to new medicines.[99]

A 2004 Commerce Department study found that international reference pricing and other such measures that "rely heavily on government fiat to set prices rather than competition in the marketplace" put short-term government objectives ahead of long-term strategies that would ensure continued R&D into medicines that patients need most.[100] The report showed that moving to market-based systems would add billions to research and development for new medicines and lower overall health care costs around the world by promoting greater efficiencies in off-patent markets. A 2020 report from the Council of Economic Advisers found that foreign government price controls have worsened over the past 15 years, causing innovative products to be sold "below fair market value," leading to a "slower pace of innovation" and "fewer potential new life-saving therapies for patients in all countries."[101] Urgent action is needed to address and resolve the following government price control regulations, policies and practices that are limiting market access for medicines researched and developed in the United States:

- *Government price controls*. In many markets, governments are the primary payer of medicines and in effect dictate prices. This dominant position often results in U.S. trading partners failing to appropriately recognize the value of innovation in their pricing and reimbursement policies, instead engaging in actions that distort markets and artificially depress prices below what a competitive market would provide. Foreign governments are increasingly employing a range of regulatory measures, including international reference pricing, therapeutic reference pricing, mandatory price cuts, clawback payments and flawed health technology assessments. These measures are often layered to exert maximum pressure. Over the past several years, **Japan** has implemented over 50 changes to pricing policies that substantially undermine efforts to carry a fair share of the costs of global research and development. In particular, the eligibility criteria for the Price Maintenance Premium (PMP) program as well as other price-cutting measures such as annual price cuts to patented medicines and health technology assessments designed to erode premiums for innovation will mean that some of America's most innovative medicines will be significantly undervalued. **Korea** employs several price control measures – including health technology assessments that require unreasonable thresholds for "cost-effectiveness,"

[99] Danzon P, Wang Y, et al., "The Impact of Price Regulation on the Launch Delay of New Drugs – Evidence from Twenty-Five Major Markets in the 1990s," Health Econ., Mar. 2005, available at https://onlinelibrary.wiley.com/doi/abs/10.1002/hec.931 (lasted visited Jan. 26, 2025).

[100] U.S. Dep't of Commerce, Int'l Trade Admin., "Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation," Dec. 2004, available at https://web.archive.org/web/20190414170009/https://2016.trade.gov/td/health/DrugPricingStudy.pdf (last visited Jan. 26, 2025).

[101] The Council of Economic Advisers, "Funding the Global Benefits of Biopharmaceutical Innovation," Feb. 2020, available at https://trumpwhitehouse.archives.gov/wp-content/uploads/2020/02/Funding-the-Global-Benefits-to-Biopharmaceutical-Innovation.pdf (last visited Jan. 26, 2025).

international reference pricing of inappropriate off-patent and generic comparators, and *ad hoc* measures – to systematically cut prices. In **Canada**, the Patented Medicine Prices Review Board regulates the maximum allowable price that a manufacturer can charge for a patented medicine to public or private payers. The Board continues to consider draconian changes intended to set prices at levels paid by less wealthy countries. Examples of other highly developed markets that undervalue innovative medicines include **Australia**, countries in the **European Union** and the **United Kingdom**.

- *Discriminatory market access policies*. In some markets, governments have policies that further benefit domestic drug companies and wholesalers at the expense of innovators in the United States. For example, in 2018, **Japan** revised its PMP program based on company criteria that appear to be inherently biased towards domestic and larger companies (e.g., number of local clinical trials and whether the product was launched first in Japan). These new company criteria call into question Japan's commitment to fair and non-discriminatory policies, including that of national treatment. In **Korea**, the Ministry of Health and Welfare designates certain companies as Innovative Pharmaceutical Companies (IPCs), which receive tax credits, R&D support and more favorable drug pricing. As of September 2022, only three of 47 designated IPCs are non-Korean biopharmaceutical companies. PhRMA is concerned that this policy violates national treatment obligations and the spirit of KORUS Article 5.1. In **Thailand**, the Thai Innovation List and the Made in Thailand initiatives give only Thai majority-owned companies special government procurement privileges, including an earmark for at least 30 percent of orders by Thai Government agencies. Paradoxically, it appears that to qualify as a pharmaceutical innovator and be eligible for inclusion on the list, the Thai company needs only to demonstrate that their generic copy is bioequivalent to the originator product.

Other acts, policies and practices delay or limit market access for America's biopharmaceutical innovators and the benefits patients overseas could realize from faster access to medicines and greater competition between treatments in the same therapeutic class. These barriers include:

- *Import barriers.* High tariffs and taxes can limit U.S. biopharmaceutical exports and prevent access to new treatments in overseas markets.[102] Under the WTO Pharmaceutical Agreement, the United States and the 33 other countries do not impose any import duties on a wide range of medicines and other health products.[103] However, biopharmaceutical innovators in the United States do not

[102] Bate R et al., "Still Taxed to Death: An Analysis of Taxes and Tariffs on Medicines, Vaccines and Medical Devices," AEI-Brookings Joint Center for Regulatory Studies, Feb. 2006, available at https://www.researchgate.net/publication/46454258_Still_Taxed_to_Death_An_Analysis_of_Taxes_and_Tariffs_on_Medicines_Vaccines_and_Medical_Devices (last visited Jan. 26, 2025).

[103] General Agreement on Tariffs and Trade, Trade in Pharmaceutical Products, L/7430, Mar. 1994, available at

benefit from the same access to China, India and other emerging economies that, despite being major producers and exporters of drugs and active pharmaceutical ingredients, are not parties to the WTO Pharmaceutical Agreement. Between 2006 and 2018, the value of worldwide biopharmaceutical trade in countries that are not parties to that Agreement increased at a compound annual growth rate of more than 4 percent. This means that a larger proportion of medicines distributed around the world are potentially subject to tariffs.[104] For example, **India**'s basic import duties on biopharmaceutical products and active ingredients average about ten percent.[105] Additional duties and assessments can raise India's effective import duty to as high as 20 percent or more.[106] Combined federal and state taxes account for 31 percent of the cost of medicines in **Brazil**, one of the highest tax burdens on medicines in the world compared to the global average of 6 percent.[107] Examples of other countries that maintain high tariffs and taxes on imported medicines include **Argentina**, **Russia** and **Thailand**. To level the global playing field for the U.S. biopharmaceutical industry and its workers, USTR should engage meaningfully with trading partners to secure the elimination of tariffs on medicines, both on a bilateral basis and by engaging at the WTO to increase the membership and the product scope of the WTO Pharmaceutical Agreement.

- *Regulatory approval delays.* **China** remains an outlier in the drug approval process compared to other regulatory authorities, with new medicines typically taking longer to reach patients in China than in other large economies. Examples of other countries with complex and lengthy regulatory approval processes include **Mexico**, **Russia** and **Türkiye**. Accelerating regulatory approval in these countries and others will improve the efficiency of global drug development, facilitate U.S. exports and reduce the time it takes for new medicines to reach patients.

- *Government pricing, reimbursement and procurement delays.* Restrictive government pricing, reimbursement and procurement policies delay market access for biopharmaceutical innovators in the United States and prevent timely patient access to new treatments and cures that have received regulatory approval. These processes vary by market with the result that government reimbursement decisions can be almost immediate in some markets to several years in others. For example, in **Mexico**, delays can stretch as long as 1,500 days

https://ustr.gov/sites/default/files/WTO%20Pharmaceutical%20Agreement%20March%201994.pdf (last visited Jan. 26, 2025).

[104] Bauer M, Lamprecht P, "How Tariffs Impact Access to Medicines," Geneva Network, Oct. 12, 2021, available at https://geneva-network.com/research/how-tariffs-impact-access-to-medicines/ (last visited Jan. 26, 2025).

[105] *Id.*

[106] Olcay M, Laing R, "Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation," World Health Organization, May 2005, available at https://www.researchgate.net/publication/228389566_Pharmaceutical_Tariffs_What_is_their_effect_on_prices_protection_of_local_industry_and_revenue_generation (last visited Jan. 26, 2025).

[107] Brazilian Institute of Tax Planning, 2018.

or more.[108] In **Canada**, only 18 percent of new medicines launched globally since 2014 are reimbursed by public plans, with public plan patients waiting an average of 38 months from global first launch to reimbursement for the fewer medicines that become available.[109] In the **United Kingdom**, medicines are often not funded for their full market authorization, restricting patients from treatments proven to be effective. While **China** has undertaken efforts to accelerate updates to its national reimbursement list, patients would be better served by a model that allows all new drugs to be reviewed for reimbursement on a more regular, or rolling, basis with faster implementation at the hospital level.

- *Lack of transparency and due process.* Lack of transparency, due process and delayed reimbursement decisions are widespread across the world. **Canada**, **Japan** and **Korea** continue to make significant pricing policy reforms without adequate consultation with the industry. In **Mexico**, excessive regulatory approval delays are compounded by government procurement processes that lack transparency, are applied inconsistently and frequently change without warning or consultation. In **Taiwan**, the pricing and reimbursement process for innovative medicines lacks transparency, due process and meaningful opportunities for stakeholder input, as exemplified by the National Health Insurance Administration's mandatory renegotiation of Managed Entry Agreements and recent application of Health Technology Reassessments. In **Türkiye**, reimbursement decision criteria are not clearly defined, the process is non-transparent and unpredictable delays in decision-making significantly postpone patient access to innovative medicines. The United States has previously recognized the serious nature of these types of concerns and attempted to redress several of them through a variety of trade policy initiatives. For example, the United States-Mexico-Canada Agreement (USMCA) requires Canada and Mexico to adhere to detailed transparency and procedural fairness obligations, and the United States-Korea Free Trade Agreement (KORUS) requires Korea to comply with similar specific commitments. PhRMA and its member companies request continued U.S. Government attention to these issues and encourage the Administration to strengthen its enforcement of our trading partners' commitments in these areas.

More broadly, PhRMA members recognize the efforts historically undertaken by the U.S. Government to address these barriers, including eliminating tariffs and promoting fair, reasonable and non-discriminatory pricing, reimbursement and procurement policies in trade agreements and addressing regulatory approval delays and other market access

[108] Mexico data provided by the Asociación Mexicana de Industrias de Investigación Farmacéutica. *See also* Salieri G, Fuentes F, "Biopharmaceutical Innovation in Mexico: At the Crossroads," Fundacion IDEA, 2016, available at http://geneva-network.com/article/biopharmaceutical-innovation-mexico-crossroads/ (last visited Jan. 26, 2025).

[109] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023. In Canada, public reimbursement for medicines is determined at the province level. For this analysis, a medicine is counted as publicly reimbursed if at least half of the national population lives in a province that reimburses the medicine.

challenges in bilateral forums. As more markets enact price controls, the burden for financing medical advances will be borne increasingly by U.S. patients and biopharmaceutical innovators, while patients abroad will suffer decreased access to improved therapies over the long term. It remains critical that the U.S. Government engage on these issues with its trading partners, effectively enforce U.S. trade agreements and require immediate and meaningful steps by foreign governments to resolve existing barriers and to ensure that patients have faster access to new medicines.

C. Localization barriers – A cross-cutting challenge

Like businesses in many other sectors of the U.S. economy, PhRMA members are witnessing a proliferation of acts, policies and practices abroad that are designed to benefit local producers at the expense of manufacturers and their employees in the United States and elsewhere around the world. In several countries, including **Argentina**, **China**, **India**, **Indonesia**, **Russia**, **Saudi Arabia** and **Türkiye**, these localization barriers have become so pervasive that they are now a routine part of many transactions between businesses and governments – from securing patents, regulatory approval and market entry to the most minor administrative formalities.

These discriminatory measures put American jobs at risk and are inconsistent with the most basic principles of the global trading system found in the General Agreement on Tariffs and Trade, TRIPS and the WTO Agreements on Technical Barriers to Trade and Trade-Related Investment Measures. These measures deny adequate and effective intellectual property protection for biopharmaceutical innovators in the United States and fair and equitable market access for new medicines, vaccines and other health technologies. Some examples of the most serious localization barriers that undermine the ability of PhRMA members to develop and deliver new treatments and cures include:

- *Market entry or other benefits conditioned on local manufacturing.* While many economies provide positive incentives for businesses to conduct research and development and to manufacture in their markets,[110] an alarming number are seeking to grow their economies by discriminating against innovators in the United States and other countries. For example, **Türkiye** removed products from the reimbursement list that are not produced in Türkiye, only reversing course after a successful WTO challenge by the European Union. Algeria prohibits imports of virtually all biopharmaceutical products that compete with similar products manufactured domestically. **Russia**'s Law on the Federal Contract System allows government medicines procurement agencies to ban foreign goods in public procurement tenders. Moreover, Russia is implementing legislation that limits national medicine procurement to manufacturers in the Eurasian Economic Union if there are two or more manufacturers for a particular class of medicine.

[110] Pugatch Consilium, "Separating Fact From Fiction – How Localization Barriers Fail Where Positive Non-Discriminatory Incentives Succeed: A Global Assessment of Localization Policies and Incentivizing Life Science Investment and Innovation," 2016, available at http://www.pugatch-consilium.com/reports/Localization%20Paper_US_FINAL.pdf (last visited Jan. 26, 2025).

- *Mandatory technology transfer.* In **Indonesia** and other countries, local manufacturing requirements are coupled with other policies that directly expropriate sensitive intellectual property and know-how. For example, a foreign biopharmaceutical company may import medicines into Indonesia only if it partners with an Indonesian firm and transfers relevant technology so that those medicines can be domestically produced within five years. Requiring technology transfer to import medicines into Indonesia creates a windfall for domestic firms and artificially distorts the market.

- *De facto bans on imports.* Manufacturing licensing requirements generally are intended to ensure that companies meet globally recognized standards – such as good manufacturing practices (GMP). Some countries exploit these licensing requirements by adopting policies that virtually prevent market entry. For example, **Türkiye** does not recognize internationally accepted GMP certifications from other countries unless they have mutual recognition agreements (MRAs) on inspections with Türkiye. Given, however, the many steps that would need to be satisfied before an MRA could be pursued between the United States and Türkiye, this policy serves as a *de facto* restriction on imports from biopharmaceutical innovators in the United States. Türkiye has stated publicly that the purpose of this policy is to promote Turkish drug companies.

Recent research demonstrates the significant and widespread damage localization barriers can inflict on the global economy and on markets that put such barriers in place.[111] They cost businesses and their employees in the United States and other leading nations by cutting tens of billions of dollars in global trade and by reducing global income and innovation. They do not increase biopharmaceutical investment or knowledge-intensive employment in countries that adopt localization barriers. In fact, they can even reduce employment – particularly for the less skilled – by raising input costs and severing connections to global value chains.[112]

PhRMA members urge USTR to take action to remove these barriers and to discourage other countries from adopting similar acts, policies and practices. Biopharmaceutical innovators in the United States look forward to concrete progress and real results in 2024.

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[111] *See*, *e.g.*, Stone S, Messent J, Flaig D, "Emerging Policy Issues: Localisation Barriers to Trade," OECD Trade Policy Papers, No. 180, 2015, available at http://www.oecd-ilibrary.org/trade/emerging-policy-issues_5js1m6v5qd5j-en;jsessionid=ai5pr32hanqoq.x-oecd-live-03 (last visited Jan. 26, 2025); Ezell SJ, Atkinson RD, Wein MA, "Localization Barriers to Trade: Threat to the Global Innovation Economy," Information Technology and Innovation Foundation, Sept. 2013, available at http://www2.itif.org/2013-localization-barriers-to-trade.pdf?_ga=1.136058805.581989633.1484510758 (last visited Jan. 26, 2025); Hufbauer GC, Schott JJ et al., Local Content Requirements: A Global Problem, Peterson Inst. Int'l Econ., Sept. 2013, available at https://www.piie.com/bookstore/local-content-requirements-global-problem (last visited Jan. 26, 2025).

[112] Pugatch Consilium, "Separating Fact From Fiction – How Localization Barriers Fail Where Positive Non-Discriminatory Incentives Succeed: A Global Assessment of Localization Policies and Incentivizing Life Science Investment and Innovation," 2016, available at http://www.pugatch-consilium.com/reports/Localization%20Paper_US_FINAL.pdf (last visited Jan. 26, 2025).

III. Addressing Challenges and Securing the Benefits of Biopharmaceutical Innovation

To address these pressing challenges and ensure that biopharmaceutical innovators in the United States can continue R&D and deliver new medicines for patients who need them around the world, PhRMA members urge USTR and other federal agencies to take the following five actions. These actions can help ensure access to quality, safe and effective medicines at home and abroad by promoting high standards of protection for patents and regulatory test data, effective enforcement of these and other intellectual property rights and transparent and predictable legal and regulatory regimes.

A. Enforce and defend global, regional and bilateral rules

USTR and other federal agencies should use all available tools and leverage to ensure America's trading partners live up to their obligations in global, regional and bilateral trade and investment agreements. Negotiating new trade agreements, modernizing and building on existing trade agreements, resisting efforts by trading partners to eliminate or otherwise weaken provisions of existing trade agreements and strengthening enforcement activity will be critical to end discriminatory pricing policies and to address longstanding intellectual property challenges around the world – particularly in countries that are U.S. trade and investment agreement partners, that have made important unfulfilled WTO accession commitments and that benefit from U.S. trade preference programs.

The baseline global IP protections enshrined in the WTO TRIPS Agreement, play an essential role in enabling American workers to develop and manufacture innovative medicines and export them to health systems and patients around the world. The United States should pursue enforcement actions to address violations of the TRIPS Agreement and ensure that any reviews or discussions concerning the TRIPS Agreement focus on full compliance with its obligations.

U.S. regional and bilateral trade agreements affirm globally accepted standards for the patentability of biopharmaceutical and other inventions and require countries to protect regulatory test data, provide mechanisms that enable innovators to resolve patent disputes prior to the marketing of potentially infringing products and establish a stronger intellectual property framework. Some also include government pricing and reimbursement and transparency commitments. However, **Australia**, **Canada**, **Chile**, **Colombia**, **Korea, Mexico** and other U.S. trading partners fail to adequately comply with some or all of these obligations. USTR and other federal agencies should consider a process to systematically review compliance with trade and investment agreements and to take steps necessary to ensure that countries abide by rules to which they have agreed.

On joining the WTO in 2001, **China** committed to provide six years of protection for clinical test and other data submitted for regulatory approval of biopharmaceutical

products containing a new chemical ingredient.[113] China has never implemented this obligation, despite agreement to do so during the 2012 U.S.-China Joint Commission on Commerce and Trade meeting.[114] In light of these deficiencies, we strongly welcomed the CFDA draft Circular 55 (Relevant Policies on Protecting Innovators' Rights to Encourage New Drug and Medical Device Innovation) and draft "Implementing Provisions on Protection of Drug Trial Data" (April 2018), which propose up to twelve years of RDP for therapeutic biologics, orphan and pediatric medicines and six years of RDP for new small molecule drugs. These proposals represent a strong first step toward reform in this area, but it is now imperative that these proposed policy revisions are transparently and expeditiously implemented in a manner that provides for effective protection for U.S. biopharmaceutical companies and is consistent with international best practices and China's renewed commitment to provide RDP as affirmed in the chapeau to Section C of Chapter One of the U.S.-China Economic and Trade Agreement.

In the United States-Taiwan Initiative on 21st-Century Trade First Agreement, **Taiwan** made commitments to adhere to a variety of good regulatory practices, including transparent development of regulations. However, Taiwan continues to administer certain pricing and reimbursement processes concerning medicines in manners that conflict with these commitments. PhRMA member companies are concerned about the lack of transparency and due process in Taiwan's pricing and reimbursement processes, including the use of heath technology reassessments and managed entry agreements. The United States should ensure that Taiwan promptly implements these commitments to remedy these deficiencies to promote certainty for U.S. businesses operating in Taiwan and to improve patient access to innovative medicines.

Although not currently authorized, the Generalized System of Preferences (GSP) program generally provides unilateral duty-free access to the U.S. market for approximately 3,500 products.[115] Before granting GSP benefits to an eligible country, the President must take into account a number of factors, including the extent to which the country is willing to "provide equitable and reasonable access to its markets" and is "providing adequate and effective protection of intellectual property rights."[116] However, multiple traditional GSP beneficiaries, including **Argentina**, **Brazil** and **Indonesia**, do not provide adequate and effective protection of intellectual property rights or fair and equitable market access.

The Special 301 Report is an important tool to address intellectual property and market access barriers abroad. Action plans required by the Trade Facilitation and Trade

[113] WTO, *Report of the Working Party on the Accession of China* (WT/ACC/CHN/49), Oct. 2001, available at https://www.wto.org/english/thewto_e/acc_e/completeacc_e.htm (last visited Jan. 26, 2025).

[114] Office of the U.S. Trade Representative, "Fact Sheet: 23rd U.S.-China Joint Commission on Commerce and Trade," Dec. 2012, available at https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2012/december/23rd-JCCT (last visited Jan. 26, 2025).

[115] Office of the United States Trade Representative, "U.S. Generalized System of Preferences Guidebook," Nov. 2020, available at https://ustr.gov/sites/default/files/gsp/GSPGuidebook_0.pdf (last visited Jan. 26, 2025).

[116] *See* Title V of the Trade Act of 1974 (19 U.S.C. § 2461 et seq.), as amended.

Enforcement Act of 2015 should be developed for countries listed on the Priority Watch List with input from relevant stakeholders. Out-of-cycle reviews announced in the Special 301 Report should be conducted and involve the participation of relevant stakeholders.

The National Trade Estimate Report likewise is an important tool to identify and prioritize acts, policies and practices in these and other overseas markets that are harming America's creative and innovative industries by denying adequate and effective intellectual property protection and fair and equitable market access. PhRMA members urge USTR and other federal agencies to ensure that this tool is used effectively.

USTR should pursue a variety of enforcement initiatives, including – but not limited to – the filing of dispute settlement cases to secure compliance with trade and investment agreement commitments. In addition, USTR should create and fill key positions. To that end, PhRMA and its member companies encourage the President to nominate a Chief Innovation and Intellectual Property Negotiator, as required by the Trade Facilitation and Trade Enforcement Act of 2015 (TFTEA).[117] According to TFTEA, the "principal functions of the Chief Innovation and Intellectual Property Negotiator shall be to conduct trade negotiations and to enforce trade agreements relating to United States intellectual property and to take appropriate actions to address acts, policies and practices of foreign governments that have a significant adverse impact on the value of United States Innovation."[118] TFTEA states further that the "Chief Innovation and Intellectual Property Negotiator shall be a vigorous advocate on behalf of United States innovation and intellectual property interests."[119] PhRMA encourages USTR to pursue and accomplish these statutory objectives.

B. Secure strong commitments in global, regional and bilateral negotiations

Global, plurilateral and bilateral trade and investment negotiations provide critical opportunities to build on the existing foundation of international rules and to secure commitments necessary to drive and sustain 21st century biopharmaceutical innovation. Ending discriminatory pricing policies, eliminating restrictive patentability criteria, addressing unreasonable patent examination and approval delays, providing for the early and effective resolution of patent disputes, ensuring robust protection of regulatory test data and reducing unnecessary regulatory barriers can promote biopharmaceutical innovation and improve market access.

PhRMA supports the negotiation of new trade agreements that include strong protections for intellectual property, ensure fair and equitable market access and enable biopharmaceutical innovators in the United States to export lifesaving medicines to patients around the world. Free and fair trade agreements, if commercially meaningful

[117] Public Law 114–125 (Feb. 24, 2016), available at https://www.congress.gov/114/plaws/publ125/PLAW-114publ125.pdf (last visited Jan. 26, 2025).

[118] *Id*.

[119] *Id.*

and properly enforced, open new markets, create better and higher-paying jobs and safeguard the United States' global competitiveness.

Unfortunately, the United States recently has fallen far behind its peers in the pursuit of new trade agreements that reflect national interests. Under the Biden Administration, the United States did not implement a single commercially meaningful trade agreement with a new or existing partner. This lack of engagement placed America's biopharmaceutical workers at a competitive disadvantage relative to global competitors, missed critical opportunities to increase economic growth and allowed foreign governments to shape global economic rules at the expense of the United States.

To expand economic opportunities for the U.S. workforce engaged in biopharmaceutical research, invention and manufacturing, the U.S. Government should engage more ambitiously with trading partners to negotiate commercially meaningful trade agreements. Immediate opportunities include resuming negotiations on a precedent-setting bilateral trade agreement with the United Kingdom, initiating targeted negotiations with the European Union, Japan and Switzerland, and exploring opportunities to further strengthen the USMCA and thereby incentivize additional North American manufacturing and stronger supply chains. PhRMA members desire to work more closely with USTR and other federal agencies to modernize, build on and enforce existing trade agreements and to consider opportunities to further improve public health and grow American manufacturing exports and jobs through additional trade agreements, including with leading U.S. biopharmaceutical export markets.[120]

C. End discrimination in pricing and reimbursement

PhRMA members are, and seek to be, partners in solutions to health care challenges facing patients and their communities around the world. However, some governments have proposed or implemented pricing and reimbursement policies that discriminate against medicines made in America, do not appropriately value innovation and lack predictable, transparent and consultative processes. As stated above, such measures can undermine the ability of biopharmaceutical innovators to bring new medicines to patients who need them and to invest in future treatments and cures.

The biopharmaceutical industry is unique in that most foreign governments, as sole or primary health care providers, impose burdensome and often discriminatory price controls and regulations on the sector. Others have resorted to improperly using national compulsory licensing provisions to threaten or coerce manufacturers to accept pricing agreements on unreasonable commercial terms and conditions. As a result, market access for pharmaceuticals is dependent not only on innovators meeting strict regulatory approval standards and obtaining necessary intellectual property protections, but also on obtaining positive government pricing and reimbursement determinations. It is imperative,

[120] U.S. Dep't of Commerce, Int'l Trade Admin., "2016 Top Markets Report: Pharmaceuticals," May 2016, available at https://legacy.trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf (last visited Jan. 26, 2025).

therefore, that regulatory procedures and decisions regarding the approval and reimbursement of medicines are governed by fair, transparent and verifiable rules guided by science-based decision making. There should be meaningful opportunities for input and consultation from manufacturers and other stakeholders to health authorities and other regulatory agencies and a right to appeal government pricing and reimbursement decisions to an independent, objective court or administrative body.

The U.S. Government can play a critical role in ensuring transparency and due process of pricing and reimbursement policies, as well as in highlighting the global benefits to patients that result from a reduction in trade barriers. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 called for the Administration to develop a strategy to address foreign price controls on pharmaceuticals and related practices through bilateral and multilateral trade negotiations. PhRMA believes that the cornerstone of any such strategy must be a proactive U.S. trade policy focused on: (i) addressing discriminatory government price controls and related practices and (ii) highlighting the global benefits for patients from the potential groundbreaking research that could result from a reduction in key trade barriers. Unfortunately, governmental policies around the globe over the last year have continued to harm patient access to innovative medicines.

PhRMA members appreciate steps USTR and other federal agencies have taken to ensure fair and equitable market access for innovative medicines in overseas markets, including seeking and securing commitments in trade agreements that ensure pricing and reimbursement policies abroad are fair, reasonable and non-discriminatory, and appropriately value patented pharmaceuticals. PhRMA urges USTR and other federal agencies to promote the full implementation of these commitments and to build on them in future trade negotiations by insisting that future trade agreements ensure that government regulatory reimbursement regimes are transparent and non-discriminatory and provide procedural fairness and full market access for United States products.[121]

In particular, proposed laws, regulations and procedures concerning how medicines are approved, priced and reimbursed should be:

- Promptly published or otherwise made available to enable interested parties to become acquainted with them.
- Published prior to adoption in a single official journal of national circulation, with an explanation of the underlying purpose of the regulation. In addition, interested parties (including trading partners) should be provided a reasonable opportunity to comment on the proposed measures. Those comments and any revisions to the proposed regulation should be addressed in writing at the time that the agency adopts its final regulations. Finally, there should be reasonable time between publication of the final measures and their effective date so that the affected parties can adjust their systems to reflect the new regulatory environment.

[121] *See*, *e.g.,* Section 102(b)(7)(G) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2016 (P.L. 114-26).

In turn, specific regulatory determinations or pricing and reimbursement decisions should be:

- Based on fair, reasonable, consistent and non-discriminatory procedures, rules and criteria that are fully disclosed to applicants.
- Completed within a reasonable, specified timeframe. In some countries, there are no deadlines for making decisions on whether to approve new medicines. In others, deadlines exist, but are regularly not met. These delays impede market access, deplete the patent term and are detrimental to patients waiting for life-saving medicines.
- Conducted so that they afford applicants timely and meaningful opportunities to provide comments at relevant points in the decision-making process.
- Supported by written reports which explain the rationale for the decision and include citations to any expert opinions or academic studies relied upon in making the determination.
- Subject to an independent review process.

D. Combat the worldwide proliferation of counterfeit medicines

PhRMA members view counterfeit medicines as a critical public health and safety concern threatening patients around the world. Counterfeit medicines may deprive patients of the medicines they need and contribute to drug-resistant forms of tuberculosis and other serious diseases and contain impurities or toxins that can cause harm or even death.[122] This challenge is exacerbated by the ease with which counterfeiters can offer fake medicines over the Internet[123] and ship them by mail[124] to patients and consumers

[122] Testing reported in *The Lancet* found one-third of anti-malarial medicines in sub-Saharan Africa and South East Asia lacked active ingredients. Guarvika MLN et al., "Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa," The Lancet, June 2012, available at https://doi.org/10.1016/S1473-3099(12)70064-6 (last visited Jan. 26, 2025). *See also* Testimony of Howard Sklamberg, U.S. Food and Drug Administration Deputy Commissioner for Global Regulatory Operations and Policy, before the House Energy and Commerce Subcommittee on Oversight and Investigations, "Counterfeit Drugs: Fighting Illegal Supply Chains," Feb. 2014, available at https://www.gpo.gov/fdsys/pkg/CHRG-113hhrg88828/pdf/CHRG-113hhrg88828.pdf (last visited Jan. 26, 2025).

[123] Of more than 11,000 web sites selling prescription medicines to patients in the United States, the National Association of Boards of Pharmacy® has found approximately 96 percent of them are operating illegally. *See* National Association of Boards of Pharmacy, "Internet Drug Outlet Identification Program: Progress Report for State and Federal Regulators," Aug. 2017, available at https://nabp.pharmacy/wp-content/uploads/2016/08/Internet-Drug-Outlet-Report-August-2017.pdf (last visited Jan. 26, 2025).

[124] An OECD study found that more than 60 percent of counterfeit goods seized around the world between 2011 and 2013 were shipped by mail or express carrier. OECD, "Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact," 2016, available at https://read.oecd-ilibrary.org/governance/trade-in-counterfeit-and-pirated-goods_9789264252653-en#page1 (last visited Jan. 26, 2025).

worldwide.[125] Unfortunately, the pandemic provided yet another arena in which counterfeiters sought to profit from unsuspecting consumers.[126]

Counterfeit medicines are a potential danger to patients everywhere, including in the United States. During 2022, the Pharmaceutical Security Institute documented almost 6,900 incidents of pharmaceutical crime in the United States.[127] Across all sectors, the Organization for Economic Cooperation and Development (OECD) found that global counterfeiting and piracy accounts for 2.5 percent of world trade and disproportionately harms innovators in the United States.[128] PhRMA and its members welcomed the proactive launch and implementation of "Operation Stolen Promise 2.0" by the U.S. Department of Homeland Security in April 2020 to address COVID-19-related fraud and criminal activity, including the illicit sale and distribution of counterfeit or unauthorized vaccines and treatments.

China is the leading source of fake products (including medicines) seized at ports of entry in the United States[129] and elsewhere,[130] though many other jurisdictions are involved – particularly in online sales.[131] According to the WHO, regions where protection and enforcement systems are weakest also see the highest incidence of counterfeit medicines. In these jurisdictions and others, customs and other law enforcement officials often are not able to seize counterfeit medicines, particularly goods in transit, goods in free trade zones and goods offered for sale on the Internet. Violations of limited laws on the books often are not effectively enforced or do not come with sufficient penalties to deter counterfeiting.[132]

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[125] Institute of Medicine (IOM), "Countering the Problem of Falsified and Substandard Drugs," Feb. 2013, available at https://www.ncbi.nlm.nih.gov/books/NBK202530/ (last visited Jan. 26, 2025). The IOM notes that "because the internet facilitates easy international sales, online drug stores have spread the problem of falsified and substandard drugs ...." *Id.*

[126] *See* Homeland Security, "Intellectual Property Rights Seizure Statistics: Fiscal Year 2021," available at https://www.cbp.gov/document/annual-report/fy-2021-ipr-seizure-statistics (last visited Jan. 26, 2025), (highlighting seizures of counterfeit COVID-19 countermeasures).

[127] Pharmaceutical Security Institute, "Incident Trends," available at https://www.psi-inc.org/incident-trends (last visited Jan. 26, 2025).

[128] OECD, "Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact," 2016, available at https://read.oecd-ilibrary.org/governance/trade-in-counterfeit-and-pirated-goods_9789264252653-en#page1 (last visited Jan. 26, 2025).

[129] Homeland Security, "Intellectual Property Rights Seizure Statistics: Fiscal Year 2023," available at https://www.cbp.gov/sites/default/files/2024-06/ipr-seizure-stats-fy23-508.pdf (last visited Jan. 26, 2025).

[130] *See*, *e.g.*, "Report on EU customs enforcement of intellectual property rights: Results at the EU border and in the EU internal market 2021," available at https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/2022_EU_enforcement_of_IPRs_2021/2022_EU_enforcement_of_IPRs_results_2021_FullR_en.pdf (last visited Jan. 26, 2025).

[131] United States Government Accountability Office, "Internet Pharmacies: Federal Agencies and States Face Challenges Combatting Rogue Sites, Particularly Those Abroad," (GAO-13-560), July 2013, available at http://www.gao.gov/assets/660/655751.pdf (last visited Jan. 26, 2025).

[132] Office of the U.S. Intellectual Property Enforcement Coordinator, "Supporting Innovation, Creativity & Enterprise: Charting a Path Ahead," U.S. Joint Strategic Plan on Intellectual Property Enforcement,

PhRMA members companies work to maintain the safety of their manufacturing facilities and the security of their global supply chains. They currently employ and routinely enhance a variety of anti-counterfeiting technologies, including covert and overt features on the packaging of high-risk prescription medicines. They have adopted a range of business processes to better secure prescription drug supply chains and facilitate the early detection of criminal counterfeiting activity. They partner with law enforcement officials around the world.

To combat the global proliferation of counterfeit medicines and active pharmaceutical ingredients, PhRMA supports strengthening training and collaboration with U.S. trading partners to adopt and implement a comprehensive regulatory and enforcement framework that: (i) subjects drug counterfeiting activity to effective administrative and criminal remedies and deterrent penalties; (ii) adequately regulates and controls each link in the legitimate supply chain; (iii) trains, empowers and directs drug regulators, law enforcement authorities and customs to take effective and coordinated action, including against exports and online activity; and (iv) educates all stakeholders about the inherent dangers of counterfeit medicines.

E. Build and strengthen global cooperation

Finally, PhRMA members urge USTR and other federal agencies to further build and strengthen partnerships with countries around the world that also have a critical stake in a strong and effective intellectual property system that values and protects innovation. Federal agencies should promote full implementation and ensure effective enforcement of global, regional and bilateral commitments and support training of regulators, law enforcement officials, judges and other court personnel overseas to enforce those commitments.

PhRMA members appreciate the steps that USTR and other federal agencies have taken to strengthen cooperation with other governments. Bilateral forums like the Transatlantic IPR Working Group have helped to build understanding and to identify and advance common priorities. They can be a model for similar engagement with other countries, particularly those which are parties to Trade and Investment Framework Agreements. The network of PTO intellectual property attachés around the world is a vital resource for American inventors and should be expanded. Cooperation between PTO and other leading patent offices through the PCT, the IP5 and Patent Prosecution Highway programs is cutting costs, improving the efficiency of patent examination in overseas markets and helping to reduce stubbornly high patent examination backlogs.

All this provides a valuable foundation on which to build in the coming year and beyond. PhRMA members believe that strengthening such coalitions will be particularly critical in multilateral organizations that advise countries and provide assistance on policies related to global trade, intellectual property and pharmaceutical markets.

FY2017-2019, available at https://obamawhitehouse.archives.gov/blog/2016/12/12/supporting-innovation-creativity-and-enterprise-charting-path-ahead (last visited Jan. 26, 2025).

Organizations such as Unitaid, UNCTAD, UNDP, the WHO, WTO and WIPO often focus their work inappropriately on limitations and exceptions to intellectual property rights, as well as promote a range of harmful policies that would undermine vital incentives for innovation. For example, WHO's 2019-2023 Roadmap on Access to Medicines envisions providing "technical support" to countries that intend to engage in compulsory licensing,[133] with one regional WHO office openly asserting that compulsory licensing is "important and to be encouraged."[134] As the WHO prepares the new Roadmap, this should be urgently corrected. Unitaid has directed millions of dollars to programs that seek to weaken intellectual property laws and lobby governments to reject provisions in international trade agreements that would strengthen innovation incentives.[135]

Similarly, despite being a member-driven organization in which policy proposals are supposed to be advanced by Member States, the WTO inappropriately submitted an "outcome document" concerning "an intellectual property response to COVID-19" to the WTO Membership for consideration;[136] most of the provisions of this "outcome document" were later adopted by the WTO Membership and incorporated into the TRIPS waiver. Meanwhile, the WHO Director-General publicly supported the even more extreme original proposal at the WTO TRIPS Council to waive entirely certain international obligations with respect to COVID-19 technologies, even as Member States were debating that proposal at the WTO – a separate multilateral forum.[137]

Federal agencies should ensure that intellectual property matters are addressed in organizations with the appropriate mandate and expertise, and with full visibility of the organization's Member States. The U.S. Government should strengthen interagency coordination and ensure that officials with intellectual property expertise are part of U.S. delegations to relevant global meetings. U.S. leadership can help to ensure that all stakeholders, including those in the private sector, are able to contribute to discussions in multilateral organizations on relevant topics.

[133] WHO, "Road Map for Access to Medicines, Vaccines, and Other Health Products, 2019–2023," p. 18, available at https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_17-en.pdf (last visited Jan. 26, 2025).

[134] WHO South-East Asia Regional Office (SEARO), "Access to medical products in the South-East Asia Region 2019," available at https://iris.who.int/handle/10665/326829 (last visited Jan. 26, 2025).

[135] Unitaid, "Unitaid expands its work on access to medicines," Sept. 8, 2018, available at: https://unitaid.org/news-blog/unitaid-expands-its-work-on-access-to-medicines/#en (last visited Jan. 26, 2025).

[136] WTO, "Quad's outcome document on IP COVID-19 response made public," May 3, 2022, available at https://www.wto.org/english/news_e/news22_e/trip_03may22_e.htm (last visited Jan. 26, 2025).

[137] WHO, "WHO Director-General's opening remarks at the COVID-19 media briefing," June 14, 2022, available at https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-covid-19-media-briefing--14-june-2022 (last visited Jan. 26, 2025).

IV. Market Designation Index

A. Priority Watch List

PhRMA recommends that **15** markets be included on the Priority Watch List. We further recommend that **China** continue under Section 306 Monitoring. The detailed information presented in the market-specific sections below demonstrates that the acts, policies and practices of these markets are denying adequate and effective intellectual property protection or fair and equitable market access. They are harming biopharmaceutical innovators and their employees in the United States and limiting their ability to bring new treatments to patients around the world. In many cases, they appear to be inconsistent with relevant global, regional and bilateral trade and investment agreement rules.

B. Watch List

PhRMA recommends that **five** markets be included on the Watch List. We urge USTR and other federal agencies to include all these markets in the *2025 Special 301 Report* – particularly those markets that are current or potential U.S. bilateral trade agreement partners. USTR and other federal agencies should monitor developments in these markets and address specific intellectual property and market access concerns through bilateral and multilateral engagement.

C. Out-of-Cycle Reviews

PhRMA's Out-of-Cycle Review recommendations for **Colombia** and the **European Union** reflect clear opportunities for heightened engagement and cooperation with trading partners to address specific issues of concern. Specifically, the European Commission's pending legislation present opportunities throughout 2025 for heightened U.S. government engagement outside of the routine Special 301 cycle to reverse negative trends and/or encourage continued progress. In Colombia, increased engagement is necessary given the Colombian authorities' declarations of using compulsory licensing repeatedly in the near term to lead and support "the position of abolishing patents."

SECTION 306 MONITORING

THE PEOPLE'S REPUBLIC OF CHINA

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in China:

Key Issues of Concern:

- **New drug definition that excludes products previously approved outside of China**: China maintains that a "new drug" is one not yet approved anywhere in the world when the new drug application is filed in China, even though this definition is not codified in law or regulation.[138] This new-to-the-world definition is inconsistent with international standards, under which new drugs are those that are new to a specific country, and has paved the way for China to treat drugs manufactured and approved abroad differently in various policies. For example, only new-to-the-world drugs qualify for the expedited approval pathway for breakthrough drugs,[139] the full benefit of former proposals to provide regulatory data protection (RDP), certain determinations of innovativeness in the National Reimbursement Drug List (NRDL) price negotiations, as well as the NRDL price renegotiation pathway. It has also been applied in the recently established patent term extension (PTE) mechanism, contrary to Article 1.12 of the U.S.-China Economic and Trade Agreement (Trade Agreement), under which China agreed to provide PTE to new approved pharmaceutical products in China, and China's commitment under Article 2.4 of the Agreement to treat all parties, both foreign and domestic, equally. PhRMA and its member companies urge China to clarify "new" to mean newly approved for marketing in China, as opposed to new to the world.

- **Weak patent enforcement**: Transparent mechanisms and legal standing to bring suit are needed in China to ensure parties are afforded a meaningful opportunity to resolve patent disputes before potentially infringing pharmaceutical products are launched in the market. While we are encouraged by the issuance of the revised Patent Law and final measures[1] to establish an early patent dispute resolution mechanism, we have concerns about the effectiveness of the resulting system. Moreover, requests for preliminary injunctions for patent infringement lawsuits are rarely, if ever, granted. PhRMA and its member companies stand ready to work with the U.S. and Chinese Governments on the implementation of an effective patent enforcement system in China, consistent with its commitments in Article 1.11 of the Trade Agreement and with a view to establishing an effective and commercially meaningful enforcement system for medicines patents in China.

- **Patent term adjustment (PTA) and Patent Term Extension (PTE)**: Industry welcomed the language in the revised Patent Law to provide PTA and PTE. After

[138] Chemical Drug Registration Categorization and Application Requirements (NMPA No. 44 2020); Biological Product Registration Categorization and Application Requirements (NMPA No. 43 2020).

[139] Drug Registration Regulation, Article 59 (NMPA 2020).

more than two years of delay, on December 21, 2023, CNIPA released the revised Patent Law Implementing Rules (PLIR) and the revised Patent Examination Guidelines to implement these provisions. Unfortunately, the revised PLIR and Patent Examination Guidelines appear to limit PTE to products that are new-to-the world, thereby denying this critical IP incentive to innovative medicines first approved outside of China (which account for the vast majority of innovative medicines approved in China). PTE should be afforded to all drugs or improved drugs that are new to China (see comments below on New Drug Definition). These revisions are essential for effectuating the patent term compensation provisions in Article 42 of the revised Patent Law and satisfying China's commitments under the Trade Agreement.

- **Lack of RDP**: China committed as part of its accession to the World Trade Organization (WTO) to provide a six-year period of RDP against unfair commercial use for clinical test and other data submitted to secure approval of products containing a new chemical ingredient. However, China does not have a mechanism to apply for or grant RDP and numerous follow-on products approved by NMPA appear to rely on originator clinical data to secure that approval. We urge implementation of an RDP system that is consistent with international best practice and China's commitment to provide RDP as affirmed in the chapeau to Section C of Chapter One of the Trade Agreement.

- **Restrictive patentability criteria**: Despite revisions to the Patent Examination Guidelines and judicial interpretations clarifying the ability to consider post-filing experimental data, further reforms are needed to ensure that there are clear, consistent and coherent standards regarding acceptance of post-filing data in China for biopharmaceutical patents, as stipulated in Article 1.10 of the Trade Agreement. In addition, China should provide patent protection for "specific therapeutic methods," consistent with other major drug markets.

- **Burdensome and nontransparent human genetic resource (HGR) requirements**: China's HGR regulations prohibit collection of certain human samples with human cells by foreign parties and restrict the use, analysis and transfer of samples and related data except in the context of an approved collaboration with Chinese parties, such as medical institutions or enterprises with no foreign investment.[140] This process has added significantly to the timeline for completion of clinical trials (at times over a year) and carries heavy penalties for non-compliance. By definition, the HGR regulations disproportionately burden U.S. and other foreign companies who may need to export samples and data to complete their clinical trials to avoid delays in approving innovative medicines. While the HGR process has improved in recent years, the regulations remain a challenge for our members. Further, the regulations also contain provisions regarding mandatory IP sharing that are inconsistent with Chapter 2 of the Trade

[140] Human Genetic Resource Regulations, Articles 21-22 (State Council No. 717, 2019) ("HGR Regulations").

Agreement, which provides that any transfer of technology as part of securing marketing approval for innovative medicines occurs on voluntary, market-based terms.

- **Government pricing and reimbursement**: While PhRMA supports the increased frequency of NRDL updates (now annual), the negotiation process continues to diverge from best practices and faces major implementation challenges, such as low reimbursement percentages, hospital listing restrictions and other cost containment regulations. We encourage the Chinese Government to shift toward a more timely, transparent and evidence-based reimbursement system, in which manufacturers may apply for reimbursement at any time, product value assessment is informed by evidence-based methodologies that consider holistic value and is completed within a pre-defined period following the application (e.g., within 90 days), and negotiations between manufacturers and the responsible government agency occur more frequently. Such a comprehensive and sustainable policy framework should also include an enhanced role for commercial health insurance (CHI). Finally, China should continue to ensure free-market pricing for newly launched medicines with reimbursement determined in the context of insurance coverage.

- **Regulatory approval process**: NMPA has undertaken significant reform efforts to accelerate the drug review and approval process in China and align its regulatory framework with international standards. PhRMA is encouraged by the development of expedited review pathways (breakthrough, conditional approval, priority review and special review) that will facilitate accelerated development and approval of new drugs. However, the qualifying criteria, process and timelines for these pathways need to be more clearly defined and transparent. It is also critical for NMPA to issue and implement regulatory guidance and other policies that leverage the best science and innovation to improve the efficiency and predictability of the regulatory approval process.

- **Data requirements for NMPA clinical trial applications (CTAs)**: NMPA has in recent years required an unusually detailed review of the manufacturing and control process at the CTA stage, which can include asking questions that require companies to reveal proprietary information about manufacturing steps and requesting additional data beyond what is required on the face of the application materials. This is not consistent with international practice and is particularly concerning for innovative products including cell and gene therapies. The detailed analysis delays the clinical trials and raises concerns about potential disclosure of manufacturing confidential commercial information (CCI) to third parties.

- **Counterfeit medicines**: We commend the United States and China on the commitments in Section G of Chapter One of the Trade Agreement to combat counterfeiting. Over the last several years, China has implemented national plans to improve drug safety and crack down on the production and sale of counterfeit medicines, resulting in several positive and tangible actions on the enforcement

front. However, the production, distribution and sale of counterfeit medicines and unregulated APIs continue to pose a problem in China and continue to pose a threat to China's trading partners. The 2019 Drug Administration Law (DAL) expressly subjects APIs to applicable good manufacturing practice regulations, but also removes APIs from the scope of the definition of drug, which leaves the application of other drug regulations to APIs unclear. Also, the DAL removes the prohibited act of manufacturing or importing unapproved drugs from the definition of counterfeit drug. The DAL now further states that individuals who import small quantities of unapproved drugs that are approved abroad may receive lesser or no penalties. That provision is not limited to drugs that are not for resale. Subsequent amendments to the Criminal Law in 2021 penalize importation of unapproved drugs that causes or could cause serious human harm. This combination of legislation still gives local officials substantial discretion to allow companies that import unapproved drugs to escape liability altogether or offer lighter penalties if there is no evident harm and the unapproved drugs are in small quantities.

For these reasons, PhRMA requests that China remain on the **Priority Watch List** and be subject to **Section 306 Monitoring** for the 2025 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

PhRMA and its members companies strongly support the IP commitments in the U.S.-China Trade Agreement and look forward to securing implementation of these commitments in a manner fully grounded in international best practices. Further work is required to ensure that the final mechanisms are implemented in a manner that advances innovation and patient access, consistent with China's international commitments, provide meaningful market access and allow U.S. biopharmaceutical companies to compete on a level playing field.

<u>Weak Patent Enforcement</u>

PhRMA is encouraged by the issuance of China's amended Patent Law, the NMPA-CNIPA Implementation Measures and the SPC JI to establish an early patent dispute resolution framework but has concerns about the regime that has been put into place. In addition, although China's laws and regulations provide for injunctive relief, in practice preliminary injunctions are rarely, if ever, granted in the context of preventing premature follow-on product market entry.

Consistent with Article 1.11 of the Trade Agreement, transparent mechanisms and a legal standing to sue are needed in China to ensure that parties are afforded the opportunity to resolve patent disputes before potentially infringing pharmaceutical products are launched on the market. If a follow-on company begins to market a drug that infringes the innovator's patents, the damage to the innovator may be irreparable even if

the innovator later wins its patent litigation. This could undermine the goal of encouraging innovation in China.

Over the course of 2020-21, responsible agencies released a number of final measures to implement a mechanism for early resolution of biopharmaceutical patent disputes, including amendments to the Patent Law, the NMPA-CNIPA Implementation Measures and the SPC JI. While aspects of an effective early dispute resolution system are reflected in these measures, the resulting system does not appear to be fit for purpose. Key deficiencies include (i) the scope of patents for which notice would be provided is severely limited, particularly for biologics; (ii) the stay period of nine months (with no stay provided for biologics) is inadequate; (iii) the availability of injunctive relief to allow for the resolution of patent disputes outside of or beyond the proposed patent linkage mechanism is unclear; (iv) which declarations by generic or biosimilar companies trigger the ability to initiate an Article 76 dispute is unclear, as is the remedy if a generic or biosimilar manufacturer submits an erroneous declaration; (v) lack of a mechanism for a generic or biosimilar company to change or correct an erroneous declaration (other than refiling the entire ANDA); and (vi) an approval of a generic or biosimilar product is not conditioned on the expiry of the listed patents when a Category 3 declaration is filed (i.e., the generic or biosimilar company promises not to launch its product before the expiry of the listed patents).

In addition, while the revised Patent Law creates a cause of action (Article 76), the SPC JI limits the scope of that action to listed patents. This, combined with the fact Article 76 creates a different type of action than a traditional infringement or validity proceeding, means that it is highly unlikely that an Article 76 case alone will resolve the patent dispute (particularly given that the NMPA-CNIPA Implementation Measures offer a 12-month "marketing exclusivity" period to the first generic applicant to successfully challenge the validity of the innovator's patent).

The lack of efficiency of the Chinese IP court system and the near impossibility of securing preliminary injunctions to keep infringing products off the market have made it very difficult for innovative drug makers to stop patent violations. In addition, parallel patent dispute resolution proceedings through China's judiciary and CNIPA's Patent Reexamination and Invalidation Department (PRID) further frustrate biopharmaceutical innovator's ability to effectively and efficiently resolve patent disputes. Patent owners are often faced with unnecessary and burdensome procedural hurdles to seek the timely resolution of patent disputes because invalidity decisions issued by CNIPA's PRID during an ongoing infringement proceeding are grounds for automatic dismissal of such an infringement proceeding, even if the invalidity decision is under appeal. In that situation, patent owners are required to appeal the PRID decision through the judiciary and, if successful, seek a court to compel PRID to confirm the judgment. Due to PRID's extremely strict inventive step and supplemental data requirements and fast docket times, patent infringement defendants can use the PRID proceedings as a tactic to circumvent the judicial process.

We look forward to continuing to work with the Chinese and U.S. Governments to ensure that China implements an effective patent enforcement system consistent with its commitments in Article 1.11 of the Trade Agreement.

Patent Term Adjustment (PTA) and Restoration/Extension (PTE)

The U.S. and Chinese Governments committed in Article 1.12 of the Trade Agreement to provide effective patent term extension mechanisms to compensate for unreasonable delays that occur in granting patents (PTA) and unreasonable curtailment of the effective patent term due to the lengthy marketing approval process (PTE) for innovative medicines.

Article 42 of China's Patent Law generally anticipates the provision of PTE in China. However, the recently released amendments to the PLIR and the Patent Examination Guidelines suggest that these IP incentives are limited to "innovative drugs" and "improved new drugs," i.e., a drug that has not been approved elsewhere in the world at the time that the new drug application is filed in China. Such an approach would deny PTE to those innovative medicines first approved outside of China, contrary to the way any other economy provides PTE (including the United States).

It is critical in these measures that terms such as "new drugs," "innovative drugs" and "improved new drugs" are defined as drugs or improved drugs that are new to China. Any interpretation that these terms apply a new-to-the-world standard would deny PTE to innovative medicines first approved outside of China at the time that the new drug application is filed in China, which account for the vast majority of innovative medicines approved in China. These revisions and clarifications are essential for effectuating the patent term compensation provisions in Article 42 of the revised Patent Law and satisfying China's commitments under the Trade Agreement.

Lack of Regulatory Data Protection

We urge China to adopt measures that are consistent with international best practices and China's WTO commitments to provide RDP,[141] as affirmed in the chapeau to Section C of Chapter One of the Trade Agreement, in order to prevent the unfair commercial use of safety and efficacy data generated by innovative pharmaceutical companies. While we note RDP's inclusion in the draft May 2022 Drug Administration Law Implementing Regulations (DALIR) and in prior regulations and proposals, as it stands, China provides no period of protection during which a non-originator (or follow-on) applicant is prevented from relying on the data submitted to NMPA or a foreign regulatory agency to secure approval of the originator product. This practice gives an

[141] As part of its accession to the WTO in 2001, China committed to provide a six-year period of RDP for undisclosed test or other data submitted to obtain marketing approval for pharmaceuticals in accordance with Article 39.3 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). *See* WTO, *Report of the Working Party on the Accession of China to the World Trade Organization*, WT/MIN(01)/3 (Nov. 10, 2001), at para. 284. Article 39.3 provides that a country must protect data submitted in the context of a drug registration application from unfair commercial use.

unfair commercial advantage to the follow-on manufacturer by permitting it to rely on the full clinical data submitted by an innovator – which the follow-on manufacturer did not incur the costs to produce – while having to submit only a small amount of China-specific supplemental data to NMPA.

Furthermore, RDP should be granted in full to any product that is "new" to China, i.e., has not been approved by NMPA. Prior proposals, however, suggest that China would only grant full RDP to pharmaceutical products that are "new" to the world – in other words, products that have not been approved in any other market at the time that the new drug application is filed in China.[142] That is at odds with the approach of other regulatory systems and even at odds with the approach taken in China with respect to RDP for agricultural chemicals. PhRMA is concerned that this definition of "new drug" or similar concepts may continue to create risk that a drug approved first outside of China may receive weaker or no protection in China. This approach would also be discriminatory in that it would favor domestic industry, contrary to China's international obligations.

Restrictive Patentability Criteria

While PhRMA appreciates revisions to the Patent Examination Guidelines and judicial interpretations clarifying the ability to consider post-filing experimental data, further reforms are needed to ensure that there are clear, consistent and coherent standards regarding acceptance of post-filing data in China for biopharmaceutical patents, consistent with other major drug markets. Such standards must reflect the realities of the drug development lifecycle.

For example, unlike patent offices in the United States, Europe, Japan, Korea and other major markets, CNIPA does not consistently accept data submitted after a patent is filed to satisfy sufficiency and inventive step requirements, pursuant to Articles 26.3 and 22.3 of China's Patent Law, respectively, and as stipulated in Article 1.10 of the Trade Agreement. This practice has caused uncertainty about the ability to obtain and maintain biopharmaceutical patents in China, and has caused denials of patents on new medicines in China that received patents in other jurisdictions.

In addition, "specific therapeutic methods" cannot be protected by patents in China. New specific therapeutic methods are new methods of treatment of a known indication with a known product (such as new dosage regimens, treatment of new subgroups of

[142] NMPA continues to draw distinctions between drug applications in China relative to approvals in other countries. The February 2016 NMPA "Chemical Drug Registration Category Work Plan," defined a "new drug" as a chemical entity that is "new to the world." Although this definition is contrary to international practice and the definition in the earlier DAL Implementing Regulation itself, NMPA continues to utilize this concept to grant priority to certain applications. NMPA is also proposing that only products "new to the world" would qualify for full RDP terms (in an April 2018 draft of NMPA measures on the Implementation of Drug Clinical Trial Data Protection). Applicants that submit marketing applications in China before the product has secured first global approval receive benefits; those who submit later in China receive less. The 2020 DRR contains a separate application category for drugs approved abroad but not in China, which could be used to perpetuate this disparate treatment of drugs approved abroad.

patients or new routes of administration). They are distinguished from new product forms (such as dosage forms and formulations), manufacturing processes and treatment of new indications, which can be protected by patents in China either directly or through use of the Swiss-type claim format. Most countries with strong IP laws provide patent protection for specific therapeutic methods either directly (by permitting methods of treatment to be patented) or indirectly (by permitting alternative claim formats, e.g., Swiss-type claims). Incentives to develop such new specific therapeutic methods should be provided by the patent system because such new uses of existing medicines can bring important patient benefits, including methods of treatment specific to the Chinese population that may not be developed in the absence of a local incentive to do so. We urge CNIPA to revisit this gap in China's patent system and conform China's practice to that of many other countries.

Mandatory IP Sharing Related to HGR Requirements

Any research conducted by foreign companies using certain Chinese human biological samples with human cells must be undertaken in collaboration with Chinese partners (e.g., Chinese state hospitals) under the HGR regime and their "international collaboration" approved by the Ministry of Science and Technology (MOST), and since May 2024, the National Health Commission (NHC).[143] Both the original 1998 HGR Regulation and the 2019 amended version require that (1) the foreign and Chinese party jointly submit and own any patent applications in China arising from the results of any exploratory research; and (2) the two parties agree on an arrangement for rights to other intellectual property (e.g., know-how or data) or, in the event that there is no arrangement, jointly share the rights and benefits to this IP, including obtaining the consent of the other party to transfer those rights and sharing benefits according to their respective contributions.

In practice, these rules mean that the responsible ministry, NHC, requires the parties to agree to jointly own the patents to the results of exploratory research, sometimes even if the China party does not have any inventorship contributions and in some cases also the underlying data. While not necessarily impacting rights over the investigational product, in cases of exploratory research applicants are required to submit their clinical trial agreements (including the IP-related provisions) and insert or summarize those IP provisions in the application to NHC for international collaboration approval, sometimes requiring a negotiation with NHC that creates uncertainty as to the rights over certain aspects of pre-market research (e.g., exploratory endpoints) and post-marketing studies. The Revised Patent Examination Guidelines (December 2023) also include

[143] NHC took over HGR management responsibilities from MOST, effective May 1, 2024. See MOST's announcement, available at https://www.most.gov.cn/tztg/202404/t20240425_190494.html (last visited Jan. 26, 2025).

concerning provisions that may limit the ability for companies to patent inventions if CNIPA deems that the applicant has not complied with HGR requirements.

The IP sharing requirement and the HGR application process together can be a significant hurdle and create uncertainty for foreign companies conducting clinical research in China. The mandatory IP sharing requirement should be eliminated to ensure, consistent with Chapter 2 of the Trade Agreement, that any transfer of technology as part of securing marketing approval for innovative medicines occurs on voluntary, market-based terms.

Lack of Transparency in Patent Prosecution

According to Article 54 of the newly revised PLIR (formerly Article 48), any party may, from the date of publication of a patent application until the date of issuance, submit observations as to why the application does not satisfy the patentability criteria. In turn, section 4.9 of Part II Chapter 8 of the Patent Examination Guidelines provides:

> *The observations submitted by any party* to the Patent Office on an invention application not in conformity with the provisions of the Patent Law shall be included in the application file, for consideration by the examiner during the substantive examination. … The Patent Office's handling of the observation submitted by the public does not need to be notified to the public, who submitted the observation. (Emphasis added.)

Regarding third-party observations, it is critical that China provide basic transparency and due process as part of its patent prosecution process. In particular, patent applicants should be notified of the submission of third-party observations and offered the opportunity to rebut any allegations that they contain.

Market Access

Government Pricing and Reimbursement

To improve patient access and affordability, PhRMA urges China to establish a more timely, transparent and evidence-based reimbursement system, in which manufacturers may apply for reimbursement at any time, product value assessment is informed by evidence-based methodologies that consider holistic value and is completed within a pre-defined period following the application (e.g., within 90 days), and negotiations between manufacturers and the responsible government agency occur more frequently (e.g., semi-annually vs. annually). Such a comprehensive and sustainable policy framework should also include an enhanced role for commercial health insurance (CHI), including by ensuring that the relationship between Basic Medical Insurance (BMI) and CHI is clearly defined and coordinated such that CHI can cover pre-existing conditions and innovative medicines that are not listed on the NRDL. PhRMA welcomes the NHSA 2025 priorities announcement to further support CHI development, including

by enabling BMI data sharing with CHI companies, allowing BMI personal deposit accounts to pay for CHI premiums and piloting more seamless patient expense settlement mechanisms. However, PhRMA is concerned that creating a "Category C" Reimbursable Drug List for CHI as included in the priorities would limit patient access to certain innovative medicines.[144] Moreover, China should continue to ensure free-market pricing for newly launched medicines with reimbursement determined in the context of insurance coverage (whether BMI or CHI). Restrictions on launch price could result in reduced R&D investment and patient access to new medicines in China. PhRMA and its member companies are committed to working with the appropriate government authorities in China to support the timely and transparent development of this policy framework.

National Reimbursement Drug List

PhRMA welcomes recent annual updates to the NRDL, which have improved access and affordability of innovative medicines for patients in China. Despite this progress, the negotiation process continues to lack sufficient transparency and diverges from global best practices. The product selection and assessment criteria appear to be based on narrowly defined dimensions of value and budget impact, without clarity on how these criteria are determined and applied. In addition, the process unfairly favors "new-to-the-world" medicines when determining a medicine's level of innovation, resulting in price premiums and disproportionately more "new-to-the-world" domestic medicines added to the NRDL in 2024. Major implementation challenges remain even after reimbursed prices for NRDL products are established, such as delayed hospital listing and additional hospital-level cost containment regulations that restrict patient access. Only 18 percent of new medicines launched globally since 2014 are available in China's public national health insurance and patients wait an average of 56 months from global first launch for new medicines to be reimbursed in the public national health insurance.[145]

Contract renewal and in certain cases full price renegotiation are required two years after NRDL listing, which can result in irreversible reductions in the payment standard (i.e., the reimbursed price) without any mechanism for positive adjustment based on the demonstrated benefits of the product. PhRMA acknowledges that the NHSA's 2023 NRDL rules have somewhat lessened reductions in the payment standards for medicines that have been on the NRDL for several years. However, the 2024 NRDL negotiation rules only allow companies to request renegotiations of payment standards during the contract renewal if the medicines are "new-to-the-world"; medicines first approved outside of China at the time that the new drug application is filed in China do not qualify. This is yet another example of how China is defining "new drug" to impermissibly favor domestic industry.

[144] NHSA summary of the National Medical Security Conference held in December 2024, available at https://www.gov.cn/lianbo/bumen/202412/content_6993301.htm (last visited Jan. 26, 2025).

[145] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

PhRMA recommends that the Chinese Government continue to take steps to improve the clinical assessment, economic assessment, negotiation process and BMI fund allocation for including innovative medicines in the NRDL. The clinical assessment should be a transparent, evidence-based and comprehensive analysis of scientifically proven clinical benefits that is independent of economic considerations. Following the clinical assessment, a transparent and evidence-based framework that holistically reflects the clinical, economic and societal benefits and costs – as opposed to the current focus on lowest international reference prices and cost-effectiveness thresholds – should be established before conducting individual product negotiations. Greater clarity and engagement with industry and other stakeholders is needed regarding these issues, including assessment and budget impact analysis criteria, standards for appropriate comparator selection, flexibility to address challenges for particular therapy areas and rare diseases (which remain disadvantaged by per-patient ceiling prices), and new pathways for companies to pursue innovative payment arrangements. Selection standards for individual expert groups that support these assessments should also be more scientific and transparent. Negotiations between the national reimbursement authority and the manufacturer should be based on clear conditions and standardized documentation, with sufficient time for companies to prepare submissions and open communication channels before, during and after negotiations to resolve any issues.

PhRMA and its member companies seek to work with the Chinese Government to improve NRDL policies. Needed reforms would increase the transparency and predictability, more appropriately recognize the value of innovative medicines and provide PhRMA member companies increased market access that leads to improved patient access.

Volume-Based Procurement (VBP)

In late 2018, NHSA initiated a VBP pilot program to centrally procure off-patent and generic products that passed a generic quality consistency evaluation (GQCE) for all public hospitals in 11 cities, which collectively represented around a third of the Chinese biopharmaceutical market. Twenty-five of the 31 molecules proposed for procurement were selected based on the lowest bidders, with an average price cut of 52 percent. In September 2019, the Chinese Government expanded the program to most of China but modified the procurement methodology to allow three suppliers with the lowest bids. Subsequent procurements organized by the National Drug Joint Procurement Office (the procurement agency authorized by the NHSA) have increased the number of allowed suppliers for individual medicines. For example, the most recent 10th national VBP in 2024 allowed seven suppliers with the lowest bids. While allowing multiple winning bidders is a positive development, PhRMA urges the Chinese Government to ensure that the national VBP program does not reduce the number of quality suppliers in the market, increase the risk of drug shortages or hinder patient and physician choice in selecting the clinically most appropriate medicines. PhRMA encourages the Chinese Government to provide additional sales channels to ensure that patients have the full range of treatment options available.

As articulated in China's Health Security 14th Five Year Plan, by the end of 2025, the national and provincial VBP programs will include as many as 500 medicines that have GQCE-certified generics. The NHSA is also expanding the national VBP program to biologic products, beginning with insulins in November 2021 and then other types of biologic products, including biosimilars. To ensure patient safety, PhRMA recommends that biosimilars demonstrate strong and specific scientific, clinical and quality standards. To this end, the Chinese Government should improve the regulatory framework for biologic products before expanding the national VBP program to biologic products, including through clear, science-based policies on naming, pharmacovigilance, interchangeability, extrapolation of approved indications of reference biologics and production capability. With the appropriate regulatory framework in place, PhRMA encourages the Chinese Government to develop a tailored biologic VBP model that recognizes value, ensures patient safety and therapeutic continuity, allows for shared decision-making between physicians and patients and incentivizes innovation.

New concerns with the national and local VBP programs and tendering platforms have emerged with respect to the protection of IP rights. In 2021, the announced procurement methodology for the sixth national VBP grouped patented and off-patent products in the same class for competitive lowest price bidding. PhRMA urges the Chinese Government to abandon the practice of including patented medicines (including, but not limited to, patents on compounds and medical use patents) in the national and local VBP and tendering platforms, which abrogates innovator's IP rights and, in the case of therapeutic class tendering, treats as interchangeable products with very different clinical characteristics and performance.

PhRMA is committed to working collaboratively and expeditiously with the appropriate government authorities to resolve these concerns and to implement transparent government pricing and procurement policies that recognize quality, innovation and the value that our member companies' products bring to China.

Regulatory Approval Process

China has made significant strides in reforming and strengthening its regulatory framework, including shorter review times for CTAs (notwithstanding unique manufacturing documentation requests) and expedited programs. Although there have been a number of examples where NMPA granted expedited regulatory approval consistent with timelines in the United States and European Union (or even faster), further improvements are needed to consistently match the review times for other regulatory authorities. We encourage China to address these issues rapidly, given the promise that a significant number of medicines currently in development have shown and the importance of predictable and timely review processes to encourage innovators to bring these new medicines to China for regulatory approval.

PhRMA is encouraged that the 2019 DAL and certain aspects of the 2020 Drug Registration Regulation (DRR) have implemented reforms to speed up the approval process for some drugs. This supports greater flexibility in the drug development process,

including a shortened notification process to initiate clinical trials and strengthened channels for stakeholder-NMPA communications. We also support the issuance of guidance in July 2018 on the acceptance of overseas clinical trial data followed by the new clinical technical requirements for drugs approved overseas but not yet in China in October 2020. Furthermore, we support NMPA's implementation of various conditional approval programs and a recent draft announcement to expedite review and approval of overseas marketed drugs that are urgently needed in clinical practice.

NMPA's involvement in ICH since its May 2017 accession to the ICH and successful election to the ICH Management Committee in 2018 further exemplifies China's reform efforts. In 2021 and 2024, NMPA was re-elected to the ICH Management Committee. Being an active ICH member will further encourage NMPA's harmonization with international regulatory standards, including the forthcoming China Pharmacopeia 2025, implementation of harmonized global regulatory practices (including good manufacturing and clinical practices) and further implementation of standardized electronic submission for new drug applications (eCTD) and safety reporting, which will enable companies to pursue global simultaneous drug development and accelerate Chinese patient access to innovative medicines. Industry and other ICH stakeholders have high expectations for NMPA to implement fully ICH's technical guidelines through the support of relevant training programs.

Clinical Trial Applications

To help China further integrate into the global innovation network and reduce the time it takes for innovative medicines to reach patients, it is critical for China to address critical factors that delay initiation of clinical trials. As discussed above, China now permits a new drug clinical trial to move forward if NMPA has not raised objections within 60 business days.[146] PhRMA recognizes these important steps NMPA has taken to make the development process more efficient; however, remaining barriers that delay study start time include HGR and rigid and extensive CMC requirements, and difficulties in sample export.

But there is still more that could be done. Based on PhRMA member company experience in other major markets, NMPA should maintain consistent and specific timelines for reviewing and approving applications. In addition, applications should be evaluated based on a clear set of standardized criteria coupled with science-based and risk-based decision making (principles embedded in ICH guidelines) that applies equally to both local and foreign manufacturers and matches the stage of development.

Specifically, we are encouraged that the 2019 DAL and 2020 DRR create a more uniform system that does not draw distinctions between local trials and international Multi-

[146] In July 2024, NMPA announced a one-year pilot program to shorten clinical trial review time to 30 working days in selected institutions in Beijing and Shanghai. The effect of this pilot is yet to be seen. See NMPA's announcement, available at www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20240731184417109.html?type=pc&m= (last visited Jan. 26, 2025).

Regional Clinical Trials (MRCT). To enable simultaneous global development and facilitate access to innovative treatments, we are encouraged by the progress seen to fully implement ICH E-17 (MRCT) guidelines and accept a pooled region approach as well as sample size allotments for Chinese patients. PhRMA members further welcome reviews by the NMPA's Center for Drug Evaluation to apply E17 principles more consistently across all therapeutic areas. In addition, it is critical that laws seeking to protect data and patient privacy in China do not unduly hinder China's ability to participate in MRCTs efficiently and effectively.

i. Human Genetic Resources Requirements

One of the more significant impediments to development has been an additional approval or notification now applicable to all trials conducted in China by foreign companies or their affiliates that collect *any* samples that contain Chinese human genetic resources, regardless of whether those samples are for genetic testing. Pursuant to the HGR Regulations issued in 2019, foreign applicants must apply to the HGRAO before they can collect and transfer these samples and associated data. The trial may not commence until this process is complete. The final HGR Implementing Rule issued in 2023 appears to have loosened some restrictions to be able to submit a filing process (rather than an approval application) for trials that are intended to support a marketing application in China and subsequent guidelines have clarified that certain bio samples (e.g., urine, plasma) are not considered "HGR materials." However, the effects of these changes remain to be seen and members have reported that additional administrative hurdles, as well as greater scrutiny by customs authorities of exports of bio samples that are not considered HGR materials, have since arisen. As before, trials with the need to export samples of HGR materials and data still require full approval.

The HGR application process can add months to the development timeline. Under the 2019 amendment, applicants must file any data that they intend to transfer outside of China with the HGRAO. Inter-agency coordination remains a challenge with overlapping legal requirements related to export controls, data privacy and data security regulations, among others. This situation presents a hurdle for China to participate in global development, particularly for early-stage trials, and contradicts various reform policies to encourage innovation. The additional conditions for HGR research by foreign companies, limitations on data transfer and storage, and IP sharing requirements described above in the section on Mandatory IP Sharing Related to HGR Requirements raise serious questions about China's compliance with its international commitments, including Article 3(1) of the TRIPS Agreement, which prohibits the granting of less favorable treatment to foreign intellectual property right holders compared to national intellectual property right holders and Article 2 of the Trade Agreement. The HGR requirements – which are unique to China – disproportionately burden foreign companies. If not eliminated entirely, they should be reduced to a simple notification procedure without restrictions on export of samples and data.

ii. Chemistry, Manufacturing and Control Data Requirements

An additional concerning impediment to development is NMPA's unusually detailed information requests for the manufacturing process at the CTA stage, which can include asking questions that require revealing proprietary information about manufacturing steps and requesting additional data beyond what is required on the face of the application materials. This is not in line with international best practice. The detailed information required not only delays the clinical trials but also raises concerns about potential disclosure of manufacturing CCI to third parties, such as during copy or transport of the information. NMPA has been hesitant to permit redactions of these records or accept less sensitive substitutes when making such requests. The NMPA requests for detailed information continue throughout the product life cycle, including for NDA and post-approval submissions.

Drug Approvals Process

PhRMA welcomes a number of other key regulatory reforms described above because they represent positive movement in China's progress toward supporting a simultaneous global development and registration framework in China. These reforms are consistent with industry's primary recommendations, including full implementation of the ICH E17 guideline, strengthened expedited programs, acceptance of foreign clinical data to satisfy registration in China and structured agency consultation.

Although the establishment of a rare disease list in 2018 was an encouraging step to better serve patients with rare diseases, the first list only contains 121 rare diseases of the about 8,000 rare diseases in total known today. In September 2023, China included an additional 86 rare diseases in the list. As it is impossible to create a complete list, PhRMA suggests replacing this list with a definition of prevalence, which is the approach taken in the United States and by other ICH regulatory agencies. The rare diseases community in China has already developed and published a report for a definition based on prevalence of the disease that could be considered. In addition, PhRMA encourages China to pair the establishment of a rare disease definition with an orphan drug regulatory framework that provides for the expedited development and review of orphan drugs, as well as regulatory incentives. We note that the 2022 draft DALIR contains incentives for orphan drugs and recommend clarification that the references to "new" in these provisions mean the orphan drug is new to China, as opposed to new to the world.

The 2019 DAL adopted a marketing authorization holder (MAH) system nationwide and applies it to ex-China applicants. This system unifies the previously separate imported and domestically made drug pathways in certain ways. Applicants can now receive a marketing authorization tied to a product and have the freedom to contract out manufacturing and distribution to multiple partners. However, for biologics there are still restrictions on China cross-border segmented manufacturing and use of CMO within China for domestically produced biologics. While NMPA recently announced a pilot program to allow segmented manufacturing for certain eligible biological products in selected provinces in China, it is unclear whether this would apply in cross-border

settings, and when the program can be extended to all biologics. Also, the 2019 DAL unifies what were previously separate applications for the drug product, the active ingredient, excipients and primary packaging materials. If the material is for self-use or exclusive use by a drug marketing authorization applicant, it can either file information related to these aspects of the products with the drug application, or in this or certain other cases, reference an "active" drug master file (DMF) covering the small molecule API, excipient or packaging material, unless the ingredient is a common, low risk excipient that is exempted from masterfile coverage. The DMF system also does not apply to APIs for biologics.

Although the bundled system streamlines the review process, some of the required administrative and technical information for ingredients and packaging materials is burdensome for suppliers and it is unnecessary to ensure product quality and safety. PhRMA recommends that the DMF system should be broadly available and entirely voluntary as is the case in the United States and the European Union and should include biologics API. We are also concerned about the dual standards for API produced in China. API produced in China to be exported is not approved by the NMPA, unless there is an import GMP certification requirement in the recipient country. This approach is contradictory to the very strict and regulated standard applied to API used in products for the Chinese market.

We also recommend China eliminate rules that tie the location of the MAH and the clinical trial applicant to the location of manufacturing, and that essentially prohibit manufacturing and supply steps from taking place across borders. These rigid silos and distinctions between imported and domestic drugs are not productive and result in unnecessary costs and challenges to segmented and cross-border supply chains. This approach appears to be maintained in the 2022 draft DALIR revision, even though it is not called for in the Drug Administration Law. We urge China to expressly state that an MAH can be located in China or abroad, regardless of where some or all of the manufacturing takes place or the type of product (e.g., small molecule drug or biologic).

To ensure Chinese patients receive timely access to new therapies, PhRMA recommends that NMPA continue to align its regulatory framework with accepted international standards and adopt science-based, transparent, consistent and predictable policies for evaluating and approving drugs and biologics. For example, on January 12, 2021, NMPA issued a Regulation on Post-Marketing Changes of Drugs, which speaks to the requirements that must be met for any post-approval variation to an approved medicine. Whereas international standards typically allow for the drug product to be manufactured but not released until approval of the change is obtained, this Regulation could be read to restrict the manufacture of the drug product until after the regulatory approval (or notification) of the change has been issued. Such an approach could negatively impact the supply of medicines – particularly biologics and vaccines with long manufacturing lead times – to the detriment of patients. PhRMA recommends that the NMPA expressly align its approach for post-marketing approval changes with international practice. While we are encouraged by the draft DALIR revision provisions that would permit drugs manufactured prior to NMPA approval to be marketed, provided

they meet requirements in their applicable good manufacturing practice, and as reinforced by Circular No. 53, we recommend this approach be expressly stated to apply to post-approval changes as well.

China's Vaccine Administration Law and biologic lot release rules require that vaccine lot release occur at a lot release institution designated by NMPA in China. In practice, this means that vaccines must be released at laboratories designated by NMPA's National Institute for Food and Drug Control, which can result in delays in the importation and market release process.

PhRMA commends NMPA on its continued leadership at ICH and encourages its timely and robust implementation of all ICH guidelines. PhRMA recommends continued reforms to accelerate and simplify the drug regulatory approval process, unify requirements and practices for locally manufactured and imported products and clearly outline and streamline the criteria and timeline for reviewing and approving clinical trial and marketing application processes. PhRMA and its members stand ready and look forward to working closely with the U.S. and Chinese Governments to support China's regulatory reform efforts.

Foreign Investment Restrictions

China has removed a number of restrictions on foreign investment in recent years. Most recently, the Chinese Government announced that it would lift bans on foreign companies engaging in the development and application of human stem cell and genetic diagnosis and treatment in selected free trade zones in Beijing, Shanghai, Guangzhou and Hainan.[147] While the industry is encouraged by the positive move, full elimination of restrictions across the country is needed to ensure foreign companies can develop and provide life-saving cell and gene therapies to China's patients.

The Chinese Government also recently announced that it would allow the establishment of wholly foreign-owned private hospitals in selected cities, with specific implementation measures pending.[148] The industry strongly recommends expanding the number of cities that can host wholly foreign-owned private hospitals to enable improved patient access to innovative medicines.

Counterfeit Medicines

Pharmaceutical counterfeiting poses global public health risks, exacerbated by rapid growth of online sales of counterfeit medicines and the production and sale of unregulated APIs used to manufacture counterfeit products. China has increased

[147] Announcement from the Ministry of Commerce, NHC and NMPA on the pilot work of expanding openness in the healthcare sector, available at https://www.mofcom.gov.cn/zwgk/zcfb/art/2024/art_f0a5d342d5054b9bb48ad778df866f83.html (last visited Jan. 26, 2025).

[148] *Id*.

enforcement efforts against counterfeited drugs in recent years, both through legislative reforms and increased police activity, and we commend the two governments on the commitments in Section G of Chapter One of the Trade Agreement to combat counterfeiting. In implementing these commitments, it will be particularly important to address online distribution of counterfeit medicines and unregulated API. Stories involving counterfeit medicines continue to make headlines, such as an arrest in 2021 of a manufacturer of fake COVID-19 vaccines in China.[149]

Under current pharmaceutical regulations, there is no effective regulatory control over the manufacture and distribution of API, which creates a major regulatory loophole that exerts a negative impact on the security of China's upstream drug supply chain and creates the possibility for API produced in China that is not NMPA approved to be exported globally. The 2019 DAL states that APIs used in drug production must comply with good manufacturing practice regulations and that drug producers must verify the compliance of APIs they purchase. But the DAL is not clear on the applicability of other regulations to APIs as it has removed API from the definition of "drug."

The DAL also contains provisions on a system for drug traceability. This includes building upon existing efforts to establish an online platform for collecting and publishing traceability records and a requirement for a unique identifier according to uniform coding rules on each drug package. In addition, the DAL also contains increased fines and longer debarment penalties for counterfeiting.[150] These provisions are helpful, but further measures are still needed to adequately address the problem, including:

- amending the Criminal Code to ease the burden of proof to prosecute brokers or API suppliers who knowingly deal with illegal APIs;
- empowering NMPA or another authority to regulate any party that manufactures API even if that party has not declared an intent to do so;
- empowering NMPA (through implementation of the revised DAL) to penalize API manufacturers based on *prima facie* evidence of a product having medicinal use or being an "API" or a "chemical drug substance" without cGMP certification; and
- deepening cooperation with major Internet Service Providers, portal sites and search engines for earlier identification and tracking of illegitimate API suppliers through business-to-business websites.

While the State Administration for Market Regulation plays a critical role in developing future solutions, any significant reform plan will require coordination and consultation among all relevant ministries within the central government. These efforts to

[149] China arrests leader of fake vaccine scam, BBC News, Feb. 16, 2021, available at https://www.bbc.com/news/world-asia-china-56080092 (last visited Jan. 26, 2025).

[150] *See* DAL Chapter 11. The potential fines for manufacturing or distributing counterfeit drugs increased from two to five times the value of the goods to 15 to 30 times the value of the goods with a minimum fine of RMB 1,500,000 (about USD 208,000). These entities can be debarred for 10 years. The maximum penalty for a responsible person increased from ten years' debarment to lifetime debarment from the pharmaceutical industry. For severe violations, the police department may detain the responsible person for five to 15 days.

crack down on unregulated API must go hand-in-hand with China's efforts against counterfeit drugs in order to enhance the effectiveness of China's national drug safety plan objectives.

PhRMA hopes that the U.S. Government will work with China to increase transparency of its anti-counterfeiting efforts, including enhancing information sharing with drug manufacturers to help evaluate the effectiveness of online actions and supporting enforcement efforts, given the importance of protecting patients. China's actions in this area could serve as a model for other countries facing similar challenges online.

PhRMA encourages the Chinese and U.S. Governments to continue and increase further their cooperation related to counterfeit medicines sold on the Internet, given the role of the Internet in the global counterfeit drug trade. This notably requires a holistic approach since not only finished counterfeit medicines are sold on the major online platforms in China but also separate materials (i.e., API, secondary packaging, primary packaging, labels) especially on business-to-business platforms for these to be assembled in and outside China.

Finally, while we commend China for improvements in customs regulations, which include monitoring and seizure of imports and exports, Chinese Customs authorities rarely exercise their authority to monitor pharmaceutical exports. PhRMA believes that Customs authorities need clear guidance, more and better trained resources and support should be targeted to monitoring pharmaceutical and chemical exports to ramp up efforts against counterfeiting and unregulated API producers. This could include, for example, encouraging greater cooperation between Chinese Customs and the Public Security Bureau to ensure the identification and prosecution of those manufacturing and exporting counterfeit medicines. In addition, Chinese Customs should consider working with the World Customs Organization to exchange information and potentially align activities, as well as customs authorities in recipient countries to jointly combat pharmaceutical crime. Close cooperation and intense risk analysis with key intermediaries such as online e-commerce platforms and postal courier companies is critical to effectively monitor and detect small parcels with counterfeit medicines. Legal mechanisms should be established that incentivize e-commerce platforms and postal courier companies to monitor, analyze and share intelligence on transactions that may involve counterfeit medicines.

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PRIORITY WATCH LIST

ARGENTINA

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in Argentina:

Key Issues of Concern:

- **Restrictive patentability criteria**: For over a decade, Argentina has maintained a policy that restricts virtually all patenting of biopharmaceutical inventions. A 2012 joint resolution, issued by the Ministries of Health and Industry and the Argentina Patent Office (INPI) targeting only biopharmaceutical technologies, created guidelines requiring INPI examiners to deny the patenting of important and valuable biopharmaceutical inventions in Argentina. This practice creates significant obstacles to introduce new medicines to patients and provides a windfall to non-originators. The guidelines are contrary to Argentina's obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), norms and standards of the Organization for Economic Cooperation and Development (OECD), and the laws, policies and practices of other jurisdictions around the world, including the United States.

- **Regulatory data protection failures**: Argentina does not provide protection for regulatory test data, as required under TRIPS. Specifically, Law 24,766 and Decree 150/92 permit Argentine officials to rely on data submitted by originators to approve requests by competitors to market similar products.

- **Compulsory licensing**: On December 21, 2019, the Argentine Congress passed economic emergency legislation that empowered the Ministry of Health (MoH) to establish a mechanism to monitor the prices of medicines and to utilize measures such as compulsory licensing against "problems of availability or unjustified or irrational price increases." While it appears that the authority granted to the MoH expired in December 2023, the Argentine Congress passed legislation in 2022 that raises concerns of compulsory licensing being leveraged inappropriately in Argentina.

- **Flawed cost containment measures and discriminatory reimbursement policies**: The Argentine Government adopted several policies regarding price controls for "high-cost" medicines through preferential reimbursement systems for locally manufactured products, harming patient access to innovative medicines. The government further made several statements regarding their plans to establish international reference pricing (IRP), which limits the flexibility and adaptation of prices to local market conditions. PhRMA and its members are hopeful that the new Argentine Government will not pursue these plans.

For these reasons, PhRMA requests that Argentina remain on the **Priority Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Restrictive Patentability Criteria

In May 2012, through a ministerial level resolution, the Argentine Government issued "Guidelines for Patentability Examination of Patent Applications on Chemical and Pharmaceutical Inventions," making it virtually impossible to secure patents on key pharmaceutical inventions. It expressly states that pharmaceutical patents are not available for compositions, dosages, salts, esters and ethers, polymorphs, analogous processes, active metabolites and pro-drugs, enantiomers and selection patents. Further, the guidelines prohibit the use of certain claim constructions widely recognized in other jurisdictions.

The guidelines are impermissible and discriminatory under international rules and contravene provisions of Argentina's Patent Law. International IP rules require that patents be made available for all inventions that are novel, involve an inventive step and are capable of industrial application. By establishing that certain biopharmaceutical inventions are *per se* unpatentable, the guidelines are arbitrary and inconsistent with Articles 1 and 27.1 of TRIPS, as well as Argentina's obligations under its bilateral investment treaty with the United States.[151] Indeed, the guidelines and resolution continue to be challenged in federal court.[152]

Notwithstanding the inconsistency with international rules, the guidelines create an unfair competitive environment that harms American innovators. Argentine entities are filing patent applications for innovative medicines that include claims that they would not be able to secure in Argentina in IP5 jurisdictions (i.e., the United States, China, Europe, Japan and South Korea). Specifically, from 2000 to 2020, Argentine entities submitted 279 patent applications in IP5 jurisdictions and it was found that all of them included claims that would not be eligible for patenting in Argentina under the guidelines. This imbalance in patenting standards penalizes U.S. innovators seeking to access the Argentine market and provides an unfair windfall to the local industry. One American innovator faced immediate generic competition, and unfair pricing pressures, right after launching its product. In less than one year, the innovator found it difficult to maintain the investment necessary to keep the product on the market. Moreover, after the innovator started to scale back, one of the generic companies started charging 20 percent more for

[151] *See* United States of America-Argentina Bilateral Investment Treaty, 103rd Congress 1st Session 103-2, Nov. 14, 1991, available at https://2009-2017.state.gov/e/eb/ifd/43232.htm (last visited Jan. 26, 2025).

[152] On June 6, 2012, CAEMe, joined by over 40 innovative biopharmaceutical companies, filed an administrative petition seeking to invalidate the Joint Resolution. That administrative review petition was dismissed in 2013. Following that dismissal, CAEMe filed a civil complaint in federal court challenging the Joint Resolution, the dismissal of the administrative petition and the application of the Patent Examination Guidelines. That complaint is still pending.

its product when compared to the innovator's original price. Indeed, experiences with cancer medicines and treatments for inflammatory diseases reveal that prices for innovative medicines are frequently less than the generic or biosimilar versions of the medicines in Argentina.

Also, because the guidelines set patentability standards only for biopharmaceutical inventions, Argentina's patent system discriminates based on the field of technology in which the invention lies, which is contrary to international law. Specifically, the guidelines have resulted in only 11 percent of biopharmaceutical patent applications being granted, while other sectors enjoy a 46 percent grant rate. While a prior Argentine administration recognized that the guidelines and resolution are problematic, it did not take action to reform them.

In 2015, Argentina furthered its patentability restrictions for biopharmaceutical inventions. INPI passed Resolution 283/2015 which narrows the patentability of certain biotechnological inventions, including inventions based on nucleotide or amino acid sequences. The resolution also expands the scope of subject matter that is not patentable to include genetically modified organelles. These and other restrictions in Resolution 283/2015 potentially create an unprecedented class of inventions that are excluded from patentability.

Regulatory Data Protection Failures

Biopharmaceutical innovators work with hospitals, universities and other partners to rigorously test potential new medicines and demonstrate they are safe and effective for patients who need them. Less than 12 percent of medicines that enter clinical trials ever result in approved treatments.[153]

To support the significant investment of time and resources needed to develop test data showing a potential new medicine is safe and effective, governments around the world protect that data submitted for regulatory approval from unfair commercial use for a period of time. WTO members considered such protection so important to incentivize biopharmaceutical innovation that they established a TRIPS provision (Article 39.3) requiring each country to safeguard regulatory test data for a period after the approval of a new medicine in that country.

Argentina was among the countries that crafted that provision but has so far failed to provide protection of test and other data in a manner consistent with its international obligations. Indeed, Law No. 24,766 and Decree 150/92 allow Argentine officials to rely on data submitted by innovators in other markets to approve requests by competitors to

[153] DiMasi JA, Grabowski HG, Hansen RW, "Innovation in the pharmaceutical industry: new estimates of R&D costs," J. Health Econ., 2016;47:20-33, available at https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub (last visited Jan. 26, 2025).

market similar products in Argentina. The Law provides no period of protection against reliance and does not define key terms including “dishonest” use.

Weak Patent Enforcement

A critical tool to protect against irreparable harm from the loss of IP is the ability to seek a preliminary injunction to prevent the sale of an infringing product during litigation. Preliminary injunctions become even more important when there are no other effective mechanisms to facilitate early resolution of patent disputes.

Section 83 of Law No. 24,481 on Patents and Utility Models provides for the grant of preliminary injunctions. These Articles were amended in 2003 by Law 25,859 to fulfill the terms in the agreement to settle a dispute between the United States and Argentina (WT/DS171/13). The agreed-upon terms were intended to provide, under certain conditions, effective and expeditious means for patent owners in Argentina to obtain relief from infringement before the conclusion of an infringement trial. Unfortunately, these terms, as implemented in the Argentine legal system, have not had the intended effect. Member companies have reported that the process of obtaining injunctive relief has become very lengthy and burdensome, thereby denying the relief that they were intended to provide.

A more transparent regulatory process whereby not only the receipt of regulatory submissions is published on an official website but also a mechanism where the INPI and MoH exchange information related to the patent that protect a pharmaceutical product would help patent holders to anticipate and mitigate potential patent infringements. Currently, regulatory approvals are only made public at the end of the process, but they are mostly published after delays and sometimes even after the marketing authorization is granted.

Further, the procedures for enforcing patents and seeking damages are ineffective due to the lengthy judicial process and inadequate damages awards that do not make the patent holder whole. These impediments eviscerate the value of patents in Argentina.

Compulsory Licensing

Among other things, the economic emergency law passed by the Argentine Congress in December 2019 (Law No. 27,541 on Social Solidarity and Productive Reactivation) empowered the MoH to establish a compulsory or mandatory licensing mechanism, or to directly import certain medicines, to address potential problems caused by unjustified or unreasonable price increases that affect the population’s access to medicines in a way that could put their health at risk. While the authority granted to the MoH appears to have expired, in July 2022, Argentina’s Congress passed Law 27,675 on a comprehensive national response to HIV, viral hepatitis, tuberculosis and other sexually transmitted diseases. That law reaffirms the use of compulsory licensing and the use of “safeguards available in the TRIPS Agreement in accordance with the provisions of Law

24,481, its regulations and complementary norms, which allow guaranteeing the sustainability of the treatments."

As a general matter, CLs should only be used in extraordinary circumstances as a last resort rather than standard government practice. CLs are not a sustainable or effective way to address health care needs. Voluntary arrangements independently undertaken by member companies better ensure that current and future patients have access to innovative medicines.

Patent Backlogs

The ability to secure a patent in a reasonable period is critical to attracting investment in the research and development needed to create new medicines and bring them to patients who need them. Patent backlogs hinder innovation by creating uncertainty and significantly raising investment risk.

Patent application delays can be lengthy in Argentina, where life science innovators wait an average of 6.6 years for patents to be granted.[154] According to some estimates, the overall patent backlog is approximately 21,000 applications. Argentina's patent law does not provide for patent term adjustments to compensate for unwarranted delays in the examination of patent applications. Although the Argentine Patent Office implemented a Patent Prosecution Highway (PPH) mechanism under Regulation P-56/2016 in order to accelerate the examination process, the restrictions on the application of this mechanism, due to the restrictive patentability guidelines, make it inapplicable for patent applications covering key pharmaceutical innovations.

In addition, Argentina should accede to the Patent Cooperation Treaty (PCT), a step that would facilitate the filing and examination of patent applications in Argentina as it does now in 157 Contracting Parties. While Argentina's Congress has long-considered accession to the PCT, no action has been taken. Accession to the PCT could allow Argentina to reduce its current patent application backlog and use the PCT system to lower filing costs and reduce the review period for future patent applications. Indeed, it is noteworthy that there are concrete examples where Argentine national institutions, such as the National Scientific and Research Council (Consejo Nacional de Investigaciones Científicas y Técnicas, or CONICET), have established a mechanism to access PCT in order to pursue the recognition of Argentine inventions in other countries. It is time, therefore, that Argentina extends the benefit of acceding to the PCT to innovators in other countries.

[154] Schultz M, Madigan K, "The Long Wait for Innovation: The Global Patent Pendency Problem," CPIP, 2016, available at https://sls.gmu.edu/cpip/wp-content/uploads/sites/31/2016/10/Schultz-Madigan-The-Long-Wait-for-Innovation-The-Global-Patent-Pendency-Problem.pdf (last visited Jan. 26, 2025).

Market Access

Flawed Cost Containment Measures

Prior to recent elections, the Argentine Government made several statements regarding their plans to establish price controls for "high-cost" medicines through international reference pricing (IRP). As a general matter, IRP suffers from serious flaws as a mechanism for biopharmaceutical pricing. It assumes similarity across all countries in the reference basket and implicitly imports the pricing policies of those countries without accounting for circumstances that justify price differentiation. Importantly, IRP ignores the local value of the product by ignoring the local standard of care, patterns of disease burden and socioeconomic factors. IRP also imports circumstances unrelated to a product's value, such as budget overruns in reference countries that lead to price cuts. For these reasons, the biopharmaceutical industry does not consider IRP appropriate for achieving competitive prices and improving patient access to innovative medicines in Argentina. Only 31 percent of new medicines launched globally since 2014 have launched in Argentina, with patients waiting an average of 32 months after global first launch for new medicines to become available. Only 16 percent of these new medicines are reimbursed in Argentina's public national health insurance.[155] PhRMA and its members are hopeful that the new Argentine Government will not pursue these plans.

Discriminatory Reimbursement Policies

In October 2015, the MoH and the Secretary of Commerce issued Joint Resolutions 1710 and 406, which establish a preferential reimbursement system for locally manufactured versions of "high-cost" medicines. These resolutions require that public and private health insurers prioritize reimbursement for lower cost products manufactured in Argentina that have the same active ingredient as products manufactured abroad. Further, Argentina is facing a significant backlog in both inclusion of new medicines on the reimbursement list and processing reimbursement payments to manufacturers. Public and social security organizations face financial challenges due in part to Argentina's economy and inflation, which resulted in a focus on paying off older debts rather than expanding coverage. As a result, patients in Argentina are increasingly turning to the legal system to gain access to medicines that are not covered by public health insurance.

[155] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

BRAZIL

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in Brazil:

Key Issues of Concern:

- **Patent backlogs**: Historically, patent applicants in Brazil have experienced some of the longest patent pendency times in the world. A 2024 analysis concluded that the average patent examination timelines for biopharmaceutical patents exceeded nine years, and the lack of a mechanism to restore a portion of the patent term lost due to unreasonable examination delays further hinders innovation and significantly raises investment risk. PhRMA is encouraged by the National Institute of Industrial Property's (INPI) efforts to tackle the patent backlog and improve the efficiency of patent prosecution in Brazil, including expansion of the Patent Prosecution Highway pilot program to all sectors.

- **Lack of regulatory data protection (RDP)**: Brazil does not provide RDP for biopharmaceutical products (despite applying RDP for veterinary, fertilizer and agrochemical products).

- **Regressive taxes on medicines**: Combined federal, state and municipal taxes account for 31 percent of the cost of medicines in Brazil, one of the highest tax burdens on medicines in the world compared to the global average of 6 percent.[156] On December 15, 2023, the National Congress approved a consumption tax reform to simplify the Brazilian tax system. This reform will replace five separate consumption taxes with a dual value-added tax (VAT) system – one charged by federal authorities and the other, at a regional level. Promisingly, tax rates on certain medicines could be reduced by 60 to 100 percent, but reform and implementation will be phased in over an eight-year period beginning in 2026.

- **Restrictive government pricing, reimbursement and access policies**: ANVISA's Drug Market Regulation Chamber (CMED) regulates the pricing and reimbursement of medicines in Brazil, which often creates market access barriers for PhRMA member companies and prevents timely patient access to new treatments and cures. Key challenges include delayed and provisional pricing decisions, government price ceilings on innovative medicines sold to private and public purchasers as a condition of market entry, delays in new medicine price definitions, price increases capped below inflation despite rising production costs and rigid health technology assessment (HTA) requirements by the National Committee for Technology Incorporation (CONITEC) that prevent more flexible and value-based approaches to evaluating and paying for health care. Only 40 percent of new medicines launched globally since 2014 have launched in Brazil,

[156] IQVIA (2023). Market Prognosis Country Report: Brazil.

with patients waiting an average of 29 months from global first launch for the new medicines that become available. Further, only five percent of these new medicines are publicly reimbursed by the *Sistema Unico de Saude* (SUS), with patients waiting an average of 52 months from global first launch to public reimbursement by the SUS.[157]

- **Government purchasing and Product Development Partnerships**: Brazil has developed a regulatory framework for the establishment of Product Development Partnerships (PDPs) to encourage public and private investment in manufacturing by facilitating technology transfer. While this framework aims to improve transparency, Brazil still lacks clear rules regarding the purchasing preferences offered to PDPs. The Federal Audit Court (TCU) recently issued a decision instructing the Ministry of Health to suspend the initiation of new PDPs until certain issues identified within the program are addressed.[158] Despite changes to the legal framework to address TCU concerns, the PDP policy still lacks transparency and predictability, disincentivizing pharmaceutical investment in Brazil. PhRMA and its member companies encourage the Brazilian Government to engage with industry while developing legislation for this policy to ensure transparent and streamlined rules and regulations that allow for equal opportunities for both national and multinational companies.

For these reasons, PhRMA requests that Brazil be placed on the **Priority Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Patent Backlogs

Patent backlogs hinder innovation and compromise the certainty and predictability necessary for the proper functioning of IP regimes. Brazil's patent examination backlog is particularly egregious. According to a recent study, the average patent examination timeline for biopharmaceutical patents granted from January 2020 through November 2024 was 9.5 years. Patent offices in OECD countries (e.g., United States and Korea), China, Europe and other economies have an average patent pendency period of two to four years. The time is ripe for Brazil to establish a patent term adjustment (PTA)

[157] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[158] Tribunal de Contas da União. Process No. 034.653/2018-0, Judgement No. 2015;2023, available at https://pesquisa.apps.tcu.gov.br/documento/processo/*/NUMEROSOMENTENUMEROS%253A34653201 (last visited Jan. 26, 2025).

mechanism to ensure that innovators are not harmed by undue delays in the patent examination process, consistent with OECD best practices and international standards.

Indeed, the need for PTA is even more acute given the Brazilian Supreme Court's 2021 decision eliminating the sole paragraph of Article 40 of the Patent Law, which ensured a minimum patent term of 10 years from the date of patent grant in Brazil, leaving patent applicants across all technology sectors without a recognized mechanism to be compensated for unreasonable patent office examination delays. Even worse for pharmaceutical and other health-sector innovators, the Supreme Court held that the decision should be applied retroactively to their patents – eliminating overnight thousands of patents and raising discrimination concerns under Brazil's international commitments, including the WTO TRIPS Agreement.

Countries have long recognized that patent office delays diminish the incentive that patents are designed to provide and stunt critical investment to small and medium enterprises. It is noteworthy that several OECD countries – such as Chile, South Korea and the United States – have implemented PTA mechanisms to restore a portion of the patent term for unreasonable delays during examination of a patent application. Brazil should seize the opportunity, including through the work of the Inter-ministerial Group on Intellectual Property (GIPI), to provide PTA and align its IP regime with OECD best practices.

Lack of Regulatory Data Protection

Brazilian law (Law 10.603/02) provides data protection for veterinary, fertilizer and agrochemical products, but still does not provide similar protection for pharmaceutical products for human use, resulting in discriminatory treatment. Contrary to TRIPS Article 39.3, Brazil continues to allow government officials to grant marketing approval for pharmaceuticals to competitors relying on test and other data submitted by innovators to prove the safety and efficacy of their products. Additional efforts are needed to provide certainty that test and other data will be fully protected against unauthorized use to secure marketing approval for a fixed period of time. Although there have been lawsuits seeking to secure a period of data protection for specific products, those cases are still pending in the Brazilian courts, leaving innovators without reliable RDP.

Compulsory Licensing

The compulsory licensing mechanisms being championed by some in the National Congress undermine Brazil's efforts to empower innovative and creative industries and to establish a robust and reliable IP framework. These mechanisms incorrectly assume that IP is a barrier to access, expand compulsory licensing on vague and ambiguous grounds, and subject all sectors to the threat of unfettered compulsory licensing. Compulsory licenses should only be considered in exceptional circumstances and as a last resort. Indeed, compulsory licenses are not an effective or sustainable way to improve

access to medicines or achieve other critical public health goals. Compulsory licensing is particularly ineffective relative to the many alternatives available.

National Intellectual Property Strategy

On December 11, 2020, Brazil published its National Intellectual Property Strategy. The Strategy has the potential to be a powerful framework to address longstanding IP concerns and to proactively drive an IP policy agenda that provides innovators the necessary certainty they need to collaborate with partners, support necessary research and development investments, and accelerate the launch of new medicines.

The strategy identifies essential policies related to life sciences innovation, including patent examination and backlog procedures, RDP and others. Further initiatives such as the strengthening of the Brazilian PTO and enforcement actors are also provided for in the strategy. We urge GIPI to coordinate with stakeholders, including the innovative biopharmaceutical industry, as it works to implement its national IP strategy and to clearly define a strategy and actions to eliminate the patent examination backlog (i.e., provide for PTA) and address RDP failures. A successfully implemented IP strategy should align biopharmaceutical patentability and IP enforcement criteria and procedures with international rules and best practices.

Market Access

Regressive Taxes on Medicines

Combined federal, state and municipal sales taxes account for approximately 31 percent of the cost of medicines in Brazil, one of the highest tax burdens on medicines in the world compared to the global average of six percent.[159] On December 15, 2023, the National Congress approved a consumption tax reform that simplifies Brazil's tax system by merging federal, state and municipal taxes into a single "dual" VAT system. The new tax reform will begin implementation in 2026 over an eight-year period. Specific tax rates and exceptions under the new system are still to be determined, however practical details of the new system will be discussed by Congress in 2024. It is likely that certain industries and sectors will be affected differently. The biopharmaceutical industry could see a 60 to 100 percent discounted tax rate for some medicines. PhRMA and its member companies continue to support reform proposals to reduce or eliminate taxes on medicines. While the approved tax reform is promising, proposals to eliminate taxes on certain products including medicines have previously lapsed.

High tariffs and taxes can prevent access to new treatments for patients that need them. Under the WTO Pharmaceutical Agreement, 34 countries agreed to eliminate import duties on a wide range of medicines and other health products. However, the majority of Latin American economies, including Brazil, are not parties to the WTO Pharmaceutical Agreement. Between 2006 and 2013, the value of worldwide

[159] IQVIA (2023). Market Prognosis Country Report: Brazil.

biopharmaceutical trade in countries that are not parties to that Agreement increased at a compound annual growth rate of more than 20 percent. This means that a larger proportion of medicines distributed around the world are potentially subject to tariffs.[160] To help remedy this trend, Brazil should accede to the WTO Pharmaceutical Agreement.

Restrictive Government Pricing, Reimbursement and Access Policies

CMED is the inter-ministerial body responsible for the economic regulation of medicines in Brazil, mainly pricing and annual price adjustment, among other duties. CMED's decisions often create market access barriers for PhRMA member companies and prevent timely patient access to new treatments and cures. Key challenges include government price ceilings on innovative medicines sold to both private and public purchasers as a condition of market entry, delays in new medicine price definitions, use of "provisional" prices for uncertain periods of time and price increases capped below inflation despite rising production costs.

CMED is currently undergoing a review process to update its regulations, specifically focusing on pharmaceutical pricing. Key areas for review encompass pricing criteria for innovative medicines, including gene therapies and biosimilars. CMED is further updating the internal regulations, including Resolution No. 3, and revising the criteria for the Price Adequacy Coefficient, a mandatory discount on public medicines. PhRMA and its member companies welcome the opportunity to engage with CMED and provide feedback in the review process.

Rigid HTA requirements, including new cost-effectiveness thresholds, by CONITEC prevent more flexible and value-based approaches to evaluating and paying for health care, specifically for orphan drugs. Although new medicines are supposed to be available for patients within 180 days from the filing of a successful application, CONITEC assessments may take up to nine months for a final decision and the overall pricing and reimbursement process typically takes significantly longer. In addition, the government has imposed new access limitations on advanced therapies (including CAR-T) that also affect patients with private insurance. Only 37 percent of new medicines launched globally since 2012 have launched in Brazil, with Brazilian patients waiting an average of 29 months from global first launch for the medicines that become available.[161] Further, only 12 percent of these new medicines are publicly reimbursed by the SUS, with patients waiting an average of 59 months from global first launch to public reimbursement by the SUS.[162]

Finally, a recent ruling by the Brazilian Supreme Federal Court (STF) raises significant concerns. The Court held that while the federal government was responsible for providing access to medications incorporated into the SUS, the issue of patient access

[160] *Id*.

[161] PhRMA, "Global Access to New Medicines Report," 2023, available at https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report (last visited Jan. 26, 2025).

[162] *Id*.

to medicines not included on the SUS is nonjusticiable. In addition to delaying treatments for patients waiting for judicial intervention, this is problematic given CONITEC's lack of transparency, limited representation and challenges in evaluating technologies, especially for rare diseases. The SUS remains underfunded, impacting cost-effectiveness analyses and making it harder to incorporate new technologies, resulting in further delays to innovative medicine for Brazilian patients.

To enable access to innovative medicines, PhRMA and its member companies recommend streamlining CONITEC processes with clear guidelines to ensure greater transparency and fairness in decision-making to harmonize judicial decisions with patient needs and public resource management.

Government Purchasing and PDPs

The Brazilian Government issued Federal Law No. 12,349/10 in 2010, granting preferences for locally manufactured products and services in public tenders. A price preference of up to 25 percent is automatically applied to locally produced medicines in government tenders. An amendment to Portaria MDIC No. 279/11 provided a list of pharmaceutical products eligible for preference margins and defined the parameters for its application in public purchases. While the issuance of Portaria MDIC No. 279/11 brought more transparency to the purchase process, it still does not adequately define the compensation to be offered by those companies that benefit from this mechanism.

Meanwhile, a new PDP regulation (Portaria No. 2,531/14, subsequently referenced in Consolidation Ordinance No. 5 in 2017) was issued in 2014 with participation of the private sector, which was intended to provide greater transparency and predictability. Since then, the Brazilian Government has announced several PDPs under the new regulation. It remains unclear what criteria were evaluated in assessing and approving these PDPs and the purchasing preferences that will be extended to an approved PDP.

Recognizing these shortcomings, Brazil conducted a public consultation in 2018 toward revising PDP requirements. In 2019, the MoH held a public consultation with industry to discuss updates to the PDP framework that seek to redefine eligibility criteria and update submission procedures and protocols for governance and monitoring. Further, in July 2019, 19 PDP agreements were unexpectedly put into various phases of suspension for a wide range of reasons. Products included medicines to treat hepatitis C, autoimmune conditions and vaccines.

In September 2023, the Federal Government launched the National Strategy for the Development of the Health Economic-Industrial Complex, updating the PDP legal framework with the goal of increasing the stability of the policy. In December, the MoH

published the Public Consultation MS No. 54/2023[163] to establish new regulatory frameworks for PDPs. In August 2024, the MoH expressed aspirations to increase local production of strategic health inputs to 50 percent by 2026 and 70 percent by 2033 of national needs, suggesting that more PDPs will be developed in the coming years. However, the Federal Court of Accounts (TCU) instructed the MoH to suspend the initiation of new PDPs until certain issues identified with the program are addressed.[164]

The new framework was published in June 2024 (Portaria GM/MS Nº 4.472), seeking to address the inconsistencies and streamline processes of the previous regulations. In particular, it clarifies selection criteria, definitions of development phases, timelines and sanctions. While the release of the framework is a positive development, it is based on Ministerial decrees and ordinances, rather than Congressionally approved Acts, bringing its legal certainty into question. A stakeholder consultation was announced by the MoH and submissions closed September 30, 2024. PhRMA's member companies welcome the opportunity to participate and provide feedback as the framework advances.

Furthermore, at the end of 2024, through Decree 12.218/2024, the government updated the price preference margins for locally manufactured products in procurement. For medicines and vaccines purchased centrally by the SUS, the preference is set at 5 percent with an additional 10 percent if the active pharmaceutical ingredient is also produced locally. A 10 percent preference is applied for medical and surgical devices that can demonstrate domestic development and innovation.

[163] Brazil's Ministry of Health. Public Consultation MS No. 54/2023 DECEIIS/SECTICS/MS - Partnership Program for Productive Development – PDP, available at https://www.soutocorrea.com.br/wp-content/uploads/2023/12/CP-MS-54-2023-PDP-_eng_-1782552.1.pdf (last visited Jan. 26, 2025).

[164] Tribunal de Contas da União. Process No. 034.653/2018-0, Judgement No. 2015;2023, available in Portuguese at https://pesquisa.apps.tcu.gov.br/documento/processo/*/NUMEROSOMENTENUMEROS%253A3465320180/DTAUTUACAOORDENACAO%2520desc%252C%2520NUMEROCOMZEROS%2520desc/0 (last visited Jan. 26, 2025).

CANADA

PhRMA members have identified the following market access barriers and intellectual property (IP) challenges in Canada:

Key Issues of Concern:

- **Patient access delays due to protracted health technology assessments (HTAs) and public reimbursement processes**: Canada has many bureaucratic barriers that extend the time between submission to the federal government of newly discovered medicines and vaccines for regulatory approval and their availability to patients through public reimbursement plans. The time between regulatory approval and when new drugs were first listed on public provincial formularies averaged 736 days (25 months) in 2022. This is double the average time reported in other OECD countries.[165] Only 18 percent of new medicines launched globally since 2014 are reimbursed on Canada's public plans, compared to 84 percent in the United States.[166] These barriers significantly delay the benefits of new medicines and vaccines for Canadian citizens and erode the time that companies have to commercialize their innovations.

- **Lack of a policy and adequate incentives for drugs for rare diseases**: Unlike the United States and Europe, Canada has no established definition, dedicated regulatory pathway or specific IP incentives for drugs treating rare diseases. Current HTA processes in Canada significantly undervalue these medicines, often calling for unrealistic price reductions in excess of 90 percent. In March 2023, the federal government announced an investment of 1.5 billion over three years as part of the National Strategy for Drugs for Rare Diseases, designed to increase access to rare disease medications through agreements with the provinces and territories. Uptake amongst provinces varies, and only half of provinces have successfully negotiated agreements with the federal government. Canada should elevate its regulatory standards and incentives to be more consistent with international best practices.

- **The Patented Medicine Prices Review Board (PMPRB)**: On July 1, 2022, amendments to the Patented Medicines Regulations ("Amended PMR") governing the PMPRB came into force. The amendments included arbitrary changes to the PMPRB's basket of reference countries to cut the prices of patented biopharmaceutical products. In September 2023, the PMPRB finalized

[165] PhRMA, "Global Access to New Medicines Report," 2023, available at https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report (last visited Jan. 26, 2025).

[166] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023. In Canada, public reimbursement for medicines is determined at the province level. For this analysis, a medicine is counted as publicly reimbursed if at least half of the national population lives in a province that reimburses the medicine.

its interim Guidance which was adopted without modification following stakeholder consultation.[167] The PMPRB has taken a multi-phased approach to developing the Guideline. The first phase of consultations took the form of a policy roundtable in December 2023, and the second phase invited stakeholders to respond to a Discussion Guide that set out the PMPRB's proposed approach. In December 2024, the Board published draft final guidelines for public consultation until March 19, 2025. It is anticipated final guidelines will be released in 2025. PhRMA and its member companies remain very concerned that the PMPRB Guideline could significantly undermine the marketplace for innovative pharmaceutical products. The changes may have the effect of undervaluing and discouraging medical advances, delaying or preventing the introduction of new medicines in Canada due to a suboptimal pricing environment, and reducing investments in Canada's life sciences sector where free-market pricing is not upheld.

- **Non-compliant patent term adjustment (PTA) system**: The U.S.-Mexico-Canada Agreement (USMCA) requires Canada to provide PTA for unreasonable delays during the prosecution and issuance of any patent, which Canada has not yet enacted. New PTA regulations adopted on December 18, 2024, and implemented on January 1, 2025, are riddled with significant deficiencies, including running the PTA term concurrently with Canada's equivalent of patent term restoration rather than as independent adjustments. As passed, Canada's PTA system does not comply with its international commitments, since it imposes significant and inequitable barriers that will prevent innovators from receiving the intended meaningful remedy for patent office delays.

- **Weak patent enforcement**: The Canadian Patented Medicines (Notice of Compliance) Regulations (the "PM(NOC) Regulations")[168] include several key deficiencies that weaken Canada's enforcement of patents, including excessive and windfall damage awards to generic litigants, and limitations and inequitable eligibility requirements on the listing of patents in the Patent Register. Jurisprudence under the PM(NOC) Regulations has also resulted in a heightened level of liability for patent owners akin to punitive damages. PhRMA and its member companies continue to be troubled that Canada has used implementation of the Canada-EU Comprehensive Economic and Trade Agreement (CETA)[169] to implement reforms not required by that Agreement, which expose innovators to even greater potential liability under Section 8 of the PM(NOC) Regulations.

[167] PMPRB, "Notice and Comment – Amendment to the Interim Guidance re: New Medicines", 2023, available at https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-new-medicines.html (last visited Jan. 26, 2025).

[168] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133.

[169] *See* CETA, Final Text, as published by the Government of Canada, available at http://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/toc-tdm.aspx?lang=eng (last visited Jan. 26, 2025).

- **Inadequate patent term restoration (PTR)**: Under CETA, Canada is required to provide innovators with some compensation for the lengthy period required to obtain marketing approval for pharmaceuticals. However, in its CETA implementing regulations, Canada has chosen to implement an "export" exception that is inconsistent with the fundamental purpose of restoring a portion of the patent term lost due to the marketing approval process and has only adopted the minimum term of PTR negotiated under CETA further deviating from global standards. Furthermore, Canada's adoption of restrictive time limits and eligibility criteria will unduly and unreasonably limit patent term restoration eligibility in Canada in a manner that is contrary to the intent of the negotiation and the CETA text itself. Finally, Canada interpreted the PTR regulations required by CETA in a narrow manner that is inconsistent with the spirit, if not the text, of the treaty. PhRMA's member companies believe Canada should support innovation by ensuring that its PTR system effectively ameliorates the effects of lengthy regulatory processes, which can significantly erode the duration of the IP rights of innovators.

- **Standard for the disclosure of confidential business information (CBI)**: In November 2014, Canada enacted legislation to update its Food and Drugs Act (Bill C-17).[170] Provisions in that law granted the Health Minister discretion to disclose a company's CBI without notice to the owner of the CBI and in accordance with a standard that is both inconsistent with other similar Canadian legislation and Canada's treaty obligations. On March 20, 2019, regulations were put in place respecting these authorities to release information about therapeutic products.[171] Further, on July 9, 2018, the Federal Court of Canada issued a decision ordering Health Canada to release vast amounts of pharmaceutical clinical trial data on five medications to a researcher, undercutting the federal government's attempts to keep the information confidential. The decision, which was not appealed by Health Canada, has the potential to exacerbate the negative impacts of the regulations and guidelines on biopharmaceutical innovators.[172]

For these reasons, PhRMA requests that Canada be placed on the **Priority Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

[170] *See* https://www.parl.ca/DocumentViewer/en/41-2/bill/C-17/royal-assent (last visited Jan. 26, 2025).

[171] Canada Gazette, Part II, Volume 153, Number 6 Regulations Amending the Food and Drug Regulations (Public Release of Clinical Information) SOR/2019-62, available at http://canadagazette.gc.ca/rp-pr/p2/2019/2019-03-20/html/sor-dors62-eng.html (last visited Jan. 26, 2025).

[172] *Doshi v. Canada (Attorney General)*, 2018 FC 710.

Market Access

Patient Access Delays Due to Protracted Health Technology Assessments and Public Reimbursement Processes

Obtaining market authorization is only the first hurdle in launching a pharmaceutical product in the Canadian market. Once the regulator determines that a product is safe and effective, it is subsequently reviewed by an HTA body (of which there are two in Canada, INESSS (Quebec), CDA (rest of Canada), which informs the negotiations led by the pan-Canadian Pharmaceutical Alliance (pCPA). Following pCPA negotiations, interested public payers enter into a common agreement known as a Letter of Intent (LOI) with manufacturers detailing the preliminary terms and conditions for public reimbursement. Following the LOI, manufacturers must then negotiate with each individual jurisdiction to finalize PLAs to ultimately list a drug on a public formulary. These processes have become increasingly time-consuming and complex in nature, and on average they take 25 months to complete, which is double the amount of time it takes in most other OECD countries.[173] During that time period, patients are unable to access these medicines except when supported by a manufacturer's patient support bridging program. This puts additional cost burden on manufacturers entering the Canadian market. As a result, patentees are unable to fully benefit from market exclusivity and the rights and benefits associated with their patents are eroded as a result.

Recognizing the lengthy delays, the CDA and pCPA have recently introduced time-limited reimbursement recommendations (TLR) and negotiations, which allow earlier recommendations and negotiations to be made when less evidence is available. Given the narrow scope of the TLR it will have limited impact on improving market access unless the new accelerated process is expanded to other product profiles. Further, at a meeting of Canada's Premiers in December 2024, a joint statement was issued commending the pCPA on the launch of their new Temporary Access Program and noted their continued interest in driving work to accelerate patient access to medicines.[174]

Eighty-four percent of new medicines launched globally since 2014 have launched and are publicly reimbursed in the United States compared to just 18 percent available on Canadian public drug plans, with Canadian public plan patients waiting an average of 38 months from global first launch to reimbursement for the new medicines that do become reimbursed in public drug plans.[175]

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[173] *See* The Conference Board of Canada, "Access and Time to Patient: Prescription Drugs in Canada," Jan. 4, 2024, available at https://www.conferenceboard.ca/product/access-and-time-to-patient-jan2024 (last visited Jan. 26, 2025).

[174] Canada's Premiers, "Premiers Discuss Important Issues for Canadians," Dec. 16, 2024, available at https://canadaspremiers.ca/premiers-discuss-important-issues-for-canadians/ (last visited Jan. 26, 2025).

[175] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023. In Canada, public reimbursement for medicines is determined at the province level. For this analysis, a medicine is counted as publicly reimbursed if at least half of the national population lives in a province that reimburses the medicine.

Overall, these barriers, coupled by a complex multijurisdictional approach, significantly delay the benefits of new medicines and vaccines for Canadian citizens and erode the already limited time for innovative companies to commercialize their significant investments in R&D, clinical trials and regulatory approval processes. Fewer clinical trials also result in less access for patients to potentially innovative treatments.

PhRMA and its member companies urge the U.S. Government to engage with the Canadian Government on these growing delays that are hindering patient access to new medicines.

Lack of a Policy and Adequate Incentives for Drugs for Rare Diseases

Unlike the United States and Europe, Canada has no established definition, dedicated regulatory pathway or specific IP incentives for drugs for rare diseases. Without a dedicated rare disease regulatory pathway, delays in access are common for patients living with rare disease, with disparities in access between provinces and territories. Existing clinical trial and HTA processes are ill-equipped to assess value and manage uncertainty at the time of rare disease product launch. Current HTA processes significantly undervalue these medicines, often calling for unrealistic price reductions in excess of 90 percent. In March 2023, the federal government announced a total investment of up to $1.5 billion over three years in support of the first-ever National Strategy for Drugs for Rare Diseases to help increase access to, and affordability of, promising and effective drugs for rare diseases. Of this funding, $1.4 billion will be available to provinces and territories to cover a small set of new and emerging drugs that will be covered in a consistent way across the provinces and territories.

To date, only five agreements have been reached with the governments of Alberta, British Columbia, New Brunswick, Newfoundland and Labrador, and Saskatchewan. The agreements provide funding in line with each province's share of Canada's total population. Fifty percent of the funding is provided for drugs on a common list that were negotiated between the federal and provincial/territorial governments; to date there is variability amongst provinces over which drugs are covered. Furthermore, only a few of the drugs from the common list have been listed and the remaining drugs will be announced once negotiations with the pCPA are completed. The drugs on the list were selected based on their ability to help build capacity for real-world evidence collection and assessment. Forty percent is available to help increase access for current rare disease drugs, or other new rare disease drugs. Finally, 10 percent will be available to improve screening and diagnostics, with details of specific plans and actions to be developed in consultation with the federal government and provinces and territories. The federal government has indicated that all future bilateral agreements will have the same structure.

While the signing of these agreements is a positive step, there is still work remaining to reduce disparities in access to medications across the provinces and territories. Further, the bilateral agreements provide no assistance in elevating IP and regulatory standards and incentives to ensure that Canada becomes more consistent with international best practices.

The Patented Medicine Prices Review Board (PMPRB)

The PMPRB is a quasi-judicial body created under the Canadian Patent Act with a legislative mandate to ensure that prices of patented medicines are not "excessive."[176] The PMPRB regulates the maximum allowable price that a manufacturer can charge for all patented medicines in Canada regardless of payer. The PMPRB does not make decisions about the amount of reimbursement for a product, which is appropriately the responsibility of separate federal and provincial/territorial drug plans, or private insurers.

On August 21, 2019, Health Canada published the Amended PMR[177] as part of the PMPRB's professed role as a "counterweight to the patent rights of pharmaceutical manufacturers."[178] The Amended PMR constituted an impermissibly broad exception to IP rights in contrast to Canada's obligation under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The implementation of the Amended PMR[179] was delayed on four occasions to account for the COVID-19 pandemic and the need for further stakeholder consultation in the context of other initiatives.[180] On July 1, 2022, the only element of the Amended PMR upheld by the courts to date, namely, the changes to the basket of reference countries, came into force.[181]

This change remains of great concern to U.S. biopharmaceutical innovators due to the potential impact on the availability of new medicines and the competitiveness of Canada for research-based pharmaceutical investment. Canada amended the PMPRB's basket of reference countries with the goal of setting ceiling prices of patented medicines at the OECD median. Through this amendment, the PMPRB removed the United States and Switzerland – two countries that take a more holistic view of the value of medicines – and added six jurisdictions with lower drug prices and more onerous price controls to the reference basket of countries. The reference countries now consist of Australia, Belgium, France, Germany, Italy Japan, Netherlands, Norway, Spain, Sweden and the United Kingdom, collectively referred to as PMPRB11. The United States is Canada's

[176] Patent Act, R.S.C. 1985, c.P-4, ss.79-103.

[177] Canada Gazette, Part II, Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), Vol. 153, No. 17, Aug. 21, 2019, available at http://www.gazette.gc.ca/rp-pr/p2/2019/2019-08-21/html/sor-dors298-eng.html (last visited Jan. 26, 2025).

[178] PMPRB 2015-16 Report on Plans and Priorities, available at http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1163 (last visited Jan. 26, 2025).

[179] Canada Gazette, Part II, Regulations amending the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), Vol. 155, No. 14 , July 7, 2021, available at https://canadagazette.gc.ca/rp-pr/p2/2021/2021-07-07/html/sor-dors162-eng.html (last visited Jan. 26, 2025).

[180] Government of Canada, Order in Council, available at https://orders-in-council.canada.ca/attachment.php?attach=41417&lang=en (last visited Jan. 26, 2025).

[181] While the Federal Court of Appeal upheld the collection of international pricing information, it has clearly stated that if the Board later uses the comparative information to set or control prices then it has exceeded its jurisdiction. *See Innovative Meds Can. v. Can. (Attorney General,* 2022 FCA 210, available at https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/521063/index.do (last visited Jan. 26, 2025).

largest trading partner and the pharmaceutical markets in both countries share many common features, including important supply chains for the pharmaceutical industry. While PhRMA and its member companies believe that international reference pricing is a deeply flawed methodology that undermines continued R&D in medicines that patients need most, it is particularly egregious for Canada not to reference the United States and other countries with pro-innovation biopharmaceutical policies. The change will continue to see patented drug prices come under stronger downward pressure.

In addition to the regulatory change, the PMPRB must implement new pricing guidelines. In September 2023, the PMPRB finalized an interim Guidance which was adopted without modification following stakeholder consultation.[182] The PMPRB has taken a multi-phased approach to developing the Guidelines. The first phase of consultations took the form of a policy roundtable in December 2023, and the second phase of the consultations invited stakeholders to respond to a Discussion Guide that set out the PMPRB's proposed approach.[183] Stakeholders were invited to participate in a series of virtual consultation meetings to discuss the Discussion Guide in September and October 2024. In December 2024, the Board published draft Guidelines for stakeholder feedback and it is anticipated that final Guidelines will be issued later this year.

The draft Guidelines create two different price review standards, depending on whether a product's price exceeds an initial threshold, the Highest International Price, or if it is the subject of a complaint, creating opportunities for complaints by those with competing commercial interests. The draft Guidelines also propose annual price reviews that take into consideration factors that are outside the PMPRB's scope. Further, they do not distinguish between new and existing medicines. As a result, medicines launched before the Amended PMR came into force will be required to adjust their prices according to the new threshold one year after the Guidelines come into force. For these reasons, industry remains concerned about the impact that the draft guidelines would have on existing products and future innovation.

In the thirty years since the PMPRB was established, a variety of mechanisms have emerged in Canada for the government and industry to work together to ensure the affordability of medicines.[184] Any expansion of the PMPRB's mandate is therefore

[182] *See* PMPRB, "Notice and Comment – Amendment to the Interim Guidance re: New Medicines", 2023, available at https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-new-medicines.html (last visited Jan. 26, 2025).

[183] PMPRB Decision on the Amended Interim Guidance Consultation, Sept. 27, 2023, available at https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-new-medicines/decision-amended-interim-guidance.html (last visited Jan. 26, 2025).

[184] For example, these mechanisms include the Canadian Drug Agency (CDA), formerly the Canadian Agency for Drugs and Technologies in Health (CADTH) Reimbursement Reviews, the Institut national d'excellence en santé et services sociaux (INESSS) in Quebec, the pan-Canadian Pharmaceutical Alliance (pCPA) and confidential Product Listing Agreements (PLAs) directly with public and private payors, among others.

unnecessary and would harm U.S. innovative biopharmaceutical companies and the patients they serve.[185]

From 2004 to 2023, general price inflation, as measured by the CPI, has exceeded the average increase in the prices of patented medicines almost every year.[186] Additionally, patented medicines accounted for only 6.5 percent of Canadian health care spending in 2019[187] and have not grown in real terms over the last decade.[188] This data suggests that patented medicines are not the primary cost driver of health care spending, which calls into question whether the regulatory changes will generate benefits that outweigh the potential risks to access and innovation. Low prices should not be the only goal of pharmaceutical policy and we urge the government to carefully consider the impact of pricing policies on access to new medicines, clinical studies, launch of new treatments, investment, jobs and the research ecosystem as a whole.

PhRMA requests that the U.S. Government urge the Canadian Government to reconsider any changes to the PMPRB's mandate that would harm U.S. innovative biopharmaceutical companies and undermine its own initiatives to strengthen Canada's life sciences sector, including Canada's Biomanufacturing and Life Sciences Strategy. The PMPRB's role must be placed in its proper context with the many other agencies already active in the Canadian pharmaceutical marketplace and should not be a means to unreasonably prejudice the legitimate interests of a patent owner, consistent with Canada's international obligations to protect patents.

The PMPRB is also required to report to the Federal Minister of Health on pharmaceutical trends and on R&D spending by pharmaceutical patentees. Due to the antiquated 1987 tax law formula used to measure R&D spending, which is referenced in its governing regulations, PMPRB has consistently and systematically under-reported the R&D levels of innovative pharmaceutical companies operating in Canada for many years, underestimating the industry's contribution to private sector R&D spending and lessening the government's willingness to address the myriad issues described above. To the extent

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[185] As it is, PMPRB is already taking decisions that exceed its statutory mandate. On July 29, 2021, the Federal Court of Appeal ruled against a decision of the PMPRB requiring that the price of Alexion's Soliris® be lower than that in the Board's seven comparator countries. *See Alexion Pharms Inc. v. Can. (Attorney General)*, 2021 FCA 157, available at https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do?q=alexion (last visited Jan. 26, 2025). The Federal Court of Appeal held forcefully that the Board's decision went beyond its statutory mandate, engaging in the regulation of what it viewed to be reasonable prices for medicines, rather than its proper mandate of determining whether a medicine's price is "excessive", i.e., an abuse of the innovator's patent rights. While the federal government sought leave to appeal to the Supreme Court of Canada, that application was dismissed.

[186] PMPRB Annual Report 2023, available at https://www.canada.ca/en/patented-medicine-prices-review/services/annual-reports/annual-report-2023.html (last visited Jan. 26, 2025)

[187] Based on analysis of information from the Canadian Institute for Health Information, available at https://www.cihi.ca/sites/default/files/document/nhex-trends-2020-narrative-report-en.pdf (last visited Jan. 26, 2025) and the PMPRB Annual Report 2019, available at https://www.canada.ca/en/patented-medicine-prices-review/services/annual-reports/annual-report-2019.html (last visited Jan. 26, 2025).

[188] *Id.*

that the PMPRB should have a mandate to report on R&D spending in Canada, PhRMA members urge the U.S. Government to encourage Innovation, Science and Economic Development Canada to engage with industry as it assesses how to update the regulatory R&D definition so that the PMPRB can more accurately calculate the significant R&D contributions made by pharmaceutical patentees to the Canadian knowledge-based economy.

Intellectual Property Protection

Non-Compliant Patent Term Adjustment (PTA) System

Under USMCA, Canada is required to implement a PTA system to compensate patentees for "unreasonable" delays in the patent examination process by January 1, 2025. On June 22, 2023, the Canadian Government passed a budget bill which included amendments to the Patent Act to implement a PTA system,[189] and related regulatory amendments were published on December 18, 2024.[190] Before finalizing the regulatory framework, the Canadian Intellectual Property Office had launched consultations for stakeholder feedback.[191,192] Despite consultations, Canada proceeded to implement a PTA system on January 1, 2025 that does not comply with its international commitments, since it imposes significant and inequitable barriers that will prevent innovators from receiving the intended meaningful remedy for patent office delays.

Under Canada's system, PTA terms run concurrently with Certificate of Supplementary Protection (CSP) terms, which is a separate and distinct benefit provided to pharmaceutical patentees due to the lengthy development and regulatory approval process. In practice, running PTA and CSP terms concurrently will result in the term of one vitiating the other term, and patentees will not receive the full benefit to which they are entitled. By taking this approach, Canada fails to fulfill two independent trade obligations, which each serve important purposes and compensate for distinct delays.

The process of obtaining PTA is also rife with barriers that render PTA unattainable for most patents and prevent patentees from receiving the intended meaningful remedy. The Canadian Government will not commit to deadlines for critical milestones but suggests that it may take years for the government to consider a patentee's application

[189] An Act to implement certain provisions of the budget tabled in Parliament on Mar. 28, 2023, available at http://www.parl.ca/DocumentViewer/en/44-1/bill/C-47/royal-assent#ID0E01G0BA (last visited Jan. 26, 2025).

[190] Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act, Canada Gazette, Nov. 29, 2024, available at https://www.gazette.gc.ca/rp-pr/p2/2024/2024-12-18/html/sor-dors241-eng.html (last visited Jan. 26, 2025).

[191] Canadian Intellectual Property Office, "Consultation on amendments to the Patent Rules," Aug. 7, 2023, available at https://ised-isde.canada.ca/site/canadian-intellectual-property-office/en/consultation-amendments-patent-rules (last visited Jan. 26, 2025).

[192] Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act, Part 1, Volume 158, Number 20 (May 18, 2024), available at https://www.gazette.gc.ca/rp-pr/p1/2024/2024-05-18/html/reg1-eng.html (last visited Jan. 26, 2025).

for PTA and determine whether any PTA is owed and make a final determination. This projected timeframe is inconsistent with comparable service standards, such as for the CSP system. The Canadian government has also imposed significant PTA fees, both to apply for PTA consideration, and by way of maintenance fees. Such fees are inconsistent with comparable patent office fees and are contrary to the remedial nature of the PTA system.

The Canadian Government has also set out a number of "example" actions and periods of time that may lead to days being subtracted in the determination of additional term, including delays which are not attributable to, and in many circumstances cannot be avoided by the innovator applicant.[193] For example, the system will not provide a reasonable period of time for an applicant to respond to communications and requisitions from the patent office. This means that days will be deducted during a period when even a diligent applicant could not respond. Deducting such time period will particularly prejudice larger or American companies, who must relay notices through multiple parties, global head offices and external counsel.

In addition to the deductions, the Commissioner of Patents (the Commissioner) also has residual discretion to further subtract unspecified days from the PTA calculation. Enabling the Commissioner to consider ambiguous and unknown factors makes it extremely challenging for patentees to determine whether it is feasible to obtain additional term and therefore assess whether it is worth undertaking the administrative burden to apply and pay the prescribed fee. This discretion undermines the obligation to compensate for unreasonable delays.

If PTA is granted, Canada has implemented a redetermination process that is wholly inequitable. Concerningly, there is no opportunity for patentees to seek redetermination if they believe additional PTA is owed, unless they initiate costly judicial review litigation. Calculation issues may occur, particularly in light of the proposed periods of time that may be deducted from any additional term, as noted above. As currently legislated, the Commissioner can only shorten the duration of the PTA provided or dismiss the application for redetermination. The Commissioner may reconsider the PTA term at any time and third parties may challenge the PTA term through the Commissioner or Federal Court.

[193] *See* CIPO, "Consultation Scene Setter – Additional Term and Miscellaneous Amendments to the Patent Rules", 2023, available at https://ised-isde.canada.ca/site/canadian-intellectual-property-office/en/consultation-amendments-patent-rules/consultation-scene-setter-additional-term-and-miscellaneous-amendments-patent-rules (last visited Jan. 26, 2025). For example, the proposed rules do not provide a reasonable period of time for an applicant to respond to CIPO communications and requisitions. As written, the deduction of days will begin immediately once a notice requiring applicant action is issued. Deducting this time period may particularly prejudice foreign or larger applicants where CIPO notices must be relayed through multiple parties, such as global head offices, and local or international counsel. Other concerning subtractions include delays caused by error on the part of the Commissioner, the period of time following a Request for Continued Examination (a regulatory requirement), and days taken to respond (or not) to communications from the Canadian Intellectual Property Office precipitated by communications from unauthorized persons.

PhRMA and its member companies are highly concerned with Canada's approach to implementing a PTA system. For the reasons set out above, Canada's framework would not provide a meaningful remedy to patentees who are impacted by unreasonable patent office delays. We urge the U.S. government to work with the Canadian Government to align its approach with that of the U.S. in order to ensure that Canada complies with its trade treaty obligations.

Weak Patent Enforcement

In 1993, the PM(NOC) Regulations were promulgated to prevent the infringement of patents by the premature market entry of generic drugs as a result of the "early working" exception. In 2015, the Canadian Government helped resolve significant difficulties related to inappropriate court decisions that prevented the listing of patents relevant to combination inventions, which seriously undermined patent enforcement actions relevant to those inventions. However, serious and systemic deficiencies remain with the PM(NOC) Regulations. The regulations do not reliably provide "expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements," as required under USMCA and the TRIPS Agreement. For example:

1. Proceedings under the PM(NOC) Regulations and appeal rights

The negotiated CETA text stipulates that "patent linkage" systems must provide all litigants with "equivalent and effective rights of appeal." The intention behind this negotiated outcome was to address the asymmetric legal rights afforded to generic litigants under Canada's previous restrictive PM(NOC) Regulations regime. Under that system, patent owners did not have an equal return on assets (ROA) as that afforded to a generic drug producer. CETA simply required Canada to correct this imbalance. The Government of Canada however exacerbated that imbalance by amending the PM(NOC) Regulations[194] in a manner that prejudices existing innovator rights.

For example, despite adopting significantly more procedural complexity under the new regime, which require full pleadings, discovery and trials in order to make final patent determinations in a single proceeding, Canada has maintained the same 24-month statutory stay that governed the old summary system. As a result, the innovative industry is concerned that patentees are now forced to choose between the surrender of procedural rights and obtaining meaningful injunctive relief under the new regime, contrary to Canada's many other related international obligations to protect intellectual property rights.

[194] Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, 2017, available at http://www.gazette.gc.ca/rp-pr/p2/2017/2017-09-07-x1/html/sor-dors166-eng.php (last visited Jan. 26, 2025).

2. Limitation on Listing of Valid Patents and Inequitable Listing Requirements

Patent owners continue to be prevented from listing their patents on the Patent Register established under the PM(NOC) Regulations if the patents do not meet certain arbitrary timing requirements that are not present in the United States under the Hatch-Waxman Act. The effect of these rules is to deny innovative pharmaceutical companies access to enforcement procedures in the context of early working for any patent not meeting these arbitrary listing requirements.

In addition, the PM(NOC) Regulations may only apply to patented products that are marketed in Canada, despite being approved by the health authority and having an assigned drug identification number.[195] This is contrary to Canada's obligations under USMCA, which require effective patent enforcement for all "approved" drugs.

3. Excessive Level of Liability for Lost Generic Profits

The PM(NOC) Regulations allow an innovator to seek an order preventing a generic manufacturer from obtaining a Notice of Compliance, on the basis that the innovator's patent covers the product and is valid. When the innovator seeks such an order, but is ultimately unsuccessful, Section 8 provides the generic manufacturer the right to claim damages in the form of lost profits for the period of time they could have been selling the product, but for the innovator's action. As such, Section 8 unreasonably prejudices the legitimate interests of the patent owner. One legitimate right of a patent owner is to petition the government to enforce a patent which that government granted in the first place. Unless the patent owner has obtained its patent by fraud or otherwise knows that the patent is invalid or uninfringed, any grievance or damages claim by a generic manufacturer in connection with a patent that is later found invalid or uninfringed should not result in punishment of a patent owner for relying in good faith on a patent duly issued by the Canadian Intellectual Property Office (CIPO).

PhRMA members are also concerned that Canadian courts have taken an approach to Section 8 damages that allows for excessive damages. Subsection 8(1) compensates for all losses actually suffered in the period during which the second person/company was held off the market – a provision that, as currently interpreted by the courts, has led to instances of overcompensation. The Courts have granted damages in excess of 100 percent of the total generic market, despite holdings that the provision is meant to be compensatory and not punitive in nature. Such overcompensation is

[195] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s 5(1), available at https://laws-lois.justice.gc.ca/eng/regulations/sor-93-133/index.html (last visited Jan. 26, 2025). In turn, on August 17, 2022, Canada's Federal Court upheld Health Canada's position that a generic is not required to serve a notice of allegation under Canada's patent linkage system where the reference product – in this case certain dosage strengths of the medicine – were not "marketed in Canada." *See Abbvie Corp, et al. v. Jamp Pharma Corp.*, 2022 FC 1209, available at https://decisions.fct-cf.gc.ca/fc-cf/decisions/en/522054/1/document.do (last visited Jan. 26, 2025). That decision has been appealed to Canada's Federal Court of Appeal and the hearing is due to take place this year.

contrary to the law of damages and reflects a punitive as opposed to a compensatory theory of damages.[196, 197]

The amended PM(NOC) Regulations established new rules that further expose innovators to excessive liability under Section 8. The Regulations eliminate previous language specifying that the period during which the innovator is liable to the competitor for any losses suffered ends on the date the stay is withdrawn or discontinued by the innovator or is dismissed or reversed by the court. This unwarranted change is likely to result in excessive damages awards by enabling competitors to claim indefinite future losses and to seek compensation for production "ramp-up" costs they may have incurred before the stay was granted and after it was lifted. In addition, innovators are now "jointly and severally" liable for any damages. Expanding the scope of liability in this manner will enable competitors to claim damages from local subsidiaries or licensees, as well as their licensors or corporate partners in the United States.

Therefore, PhRMA members request that the U.S. Government urge Canada to implement amendments to the PM(NOC) Regulations to address this issue.

Inadequate Patent Term Restoration

PTR seeks to compensate for a portion of the crucial effective patent life lost due to clinical trials and the regulatory approval process. Most of Canada's major trading partners, including the United States, the European Union and Japan, offer forms of PTR which generally allow patent holders to recoup a valuable portion of a patent term where time spent in clinical development and the regulatory approval process has kept the patentee off the market. In these countries, up to five years of lost time can be recouped.

By way of implementing CETA, Canada had an opportunity to make a significant step to provide innovators with some compensation for delays in obtaining marketing approval for pharmaceuticals. Under CETA, Canada agreed to implement a "*sui generis* protection" period of between 2 to 5 years for pharmaceuticals to compensate for delays in drug marketing approval, subject to certain specified conditions.

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[196] The Supreme Court of Canada granted leave with respect to a Section 8 damages case, but in April 2015 dismissed this case from the bench, stating that it did so substantially for the reasons of the majority in the Federal Court of Appeal. *Sanofi-Aventis, et al. v. Apotex Inc., et al.*, SCC. 35886, available at http://www.scc-csc.gc.ca/case-dossier/info/dock-regi-eng.aspx?cas=35886 (last visited Jan. 26, 2025). The dismissal of the appeal provided parties to Section 8 damages litigation with no meaningful higher court guidance with respect to how these damages are to be calculated in future lower court decisions, which means any clarity must come from regulatory amendments by the Government of Canada.

[197] On April 23, 2018, Eli Lilly Canada (Lilly) applied to the Supreme Court of Canada for leave to appeal in respect of a March 2018 decision of the Federal Court of Appeal. The Federal Court of Appeal had dismissed Lilly's appeal of a trial decision awarding more than $70 million to Teva Canada (Teva) under Section 8. The Federal Court of Appeal granted Teva's cross-appeal seeking to add to its recovery lost sales and an adjustment to account for an under-reporting of sales in the data relied on by both parties' experts. *Eli Lilly Can. Inc. v Teva Can. Ltd.*, 2018 FCA 53, available at https://decisions.fct-cf.gc.ca/fca-caf/decisions/en/307557/1/document.do (last visited Jan. 26, 2025). Lilly was denied leave by the Supreme Court of Canada on November 8, 2018.

However, PhRMA has concerns with Canada's implementation of this commitment under the Certificate of Supplemental Protection (CSP) Regulations.[198] At a fundamental level, the *sui generis* protection provided by the CSP does not appear to grant the full patent protections that PTR is intended to provide and instead appears to be implemented subject to an exception for "manufacture for export." While this is permitted by the CETA text, this is not consistent with Article 20.46 of the USMCA, or with PTR in most other jurisdictions.[199] Implementing PTR so that it does not confer full patent rights, e.g., providing an exception for "manufacturing for export" or other infringing activities, is not consistent with the fundamental purpose of restoring patent term lost due to the lengthy marketing approval process.

Moreover, having only adopted the minimum term of PTR negotiated under CETA (i.e., Canada's term is capped at two years of a possible five), Canada's further adoption of restrictive time limits and eligibility criteria will unduly and unreasonably limit CSP eligibility in Canada in a manner that is contrary to the intent of the negotiation and the CETA text itself.

In particular, the CSP Regulations introduce a new and complex CSP application requirement whereby only those Canadian new drug submissions (NDSs) filed within 1 year of any first international drug submission filed for the same drug (in any of the EU, UK, U.S., Australia, Switzerland or Japan) will be CSP eligible (the "Timely Submission Requirement"). The Timely Submission Requirement is a novel requirement in Canada that is unprecedented amongst the PTR regimes of Canada's major trading partners, including the United States. PhRMA is concerned that the 1-year time limit being enforced under the Timely Submission Requirement will inappropriately bar otherwise deserving and eligible innovative medicines from benefiting from the period of *sui generis* protection.

Moreover, unlike other jurisdictions, Canada has further implemented a list of "variations" of medicinal ingredients and other prior drug approvals that will automatically exclude new drug submissions from possible CSP eligibility. Neither the U.S. nor EU PTR regimes provide enumerated lists of excluded variations ineligible for restoration.

Finally, Canada is interpreting the CSP Regulations in a manner that is inconsistent with the intent of CETA. In the first judicial review decision under the CSP Regulations, the Federal Court reinforced Canada's requirement to comply with the rationale, purview and specific constraints of the statutory scheme and any relevant

[198] Available at http://www.gazette.gc.ca/rp-pr/p2/2017/2017-09-07-x1/html/sor-dors165-eng.php (last visited Jan. 26, 2025).

[199] *See* Solovy E, "A Manufacturing-for-Export Exception to Patent Protection: A Proposal for Exporting Violations of the TRIPS Agreement and Beyond," J. Intell. Prop. and Practice (Sept. 2017), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3004845 (last visited Jan. 26, 2025).

international law, including CETA.[200] However, the Federal Court's decision was overturned on appeal.[201]

We urge the U.S. Government to engage with the Canadian Government on this issue in all available fora and encourage Canada to join the ranks of other industrialized countries who are champions of IP protection internationally and to provide for effective and competitive PTR measures in Canada. CSP eligibility should not be circumscribed by overly restrictive enumerated exclusions on medicinal ingredients and patents.

Standard for the Disclosure of Confidential Business Information

PhRMA members are concerned with provisions in the *Food and Drugs Act*,[202] (the Act) which could allow for an unprecedented disclosure of CBI contained in clinical trial and other data submitted by pharmaceutical companies in the course of seeking regulatory approval for medicines. These provisions could significantly impact incentives for drug innovation and are inconsistent with Canada's international treaty obligations.

There is particular concern surrounding issues of confidentiality, the broad definition of CBI (broad enough to also cover trade secrets) and the threshold for the disclosure of CBI by Health Canada to governments and officials, as well as to the public. These provisions are inconsistent with the standards set out in other Canadian federal health and safety legislation, including similar provisions in other federal legislation,[203] are inconsistent with Canada's treaty obligations under USMCA and TRIPS, as well as the standards and practices of other national health regulators, including the U.S. Food and Drug Administration.

[200] On April 7, 2020, the Federal Court issued its first judicial review decision under the CSP Regulations. The Court held that the Minister's decision to deny a CSP for the drug Shingrix® was unreasonable. While the Minister was ordered to redetermine the matter on the merits, the Minister is appealing the court's decision. The parties disagree on whether a particular vaccine adjuvant is a medicinal ingredient for the purpose of applying the CSP Regulations. Protecting vaccine adjuvants as "medicinal ingredients" promotes innovation and is consistent with the object of CETA. In determining that the Minister's decision was unreasonable, the Federal Court held that Minister's rationale demonstrated "administrative tunnel vision" and failed to address "highly relevant considerations." *GlaxoSmithKline Biologicals S.A. v. The Minister of Health*, 2020 FC 397, available at https://decisions.fct-cf.gc.ca/fc-cf/decisions/en/item/468729/index.do?q=shingrix (last visited Jan. 26, 2025).

[201] On April 14, 2021, the Federal Court of Appeal issued its decision allowing the appeal in favor of the Minister of Health. The Court held that, while there was more than one reasonable interpretation of the legislation, the Minister's reading was a reasonable one. With respect to CETA, the Court found that Canada had only agreed to provide protection in a "very specific and limited way of doing so". *The Minister of Health v GlaxoSmithKline Biologicals S.A.,* 2021 FCA 71, available at https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/495570/index.do (last visited Jan. 26, 2025).

[202] Available at https://laws-lois.justice.gc.ca/eng/acts/f-27/ (last visited Jan. 26, 2025).

[203] Hazardous Materials Information Review Act, Amendments to the Act, 2019, Subdivision H, Disclosure of Confidential Business Information, available at https://www.parl.ca/DocumentViewer/en/42-1/bill/C-97/royal-assent (last visited Jan. 26, 2025).

Both the USMCA and the TRIPS Agreement require that CBI be protected against disclosure except where necessary to protect the public. For disclosure to the public, the provisions require a "serious risk," but it does not reach the standard set out in the treaty language since subjective and discretionary language has been included: the Minister may disclose CBI "if the Minister believes that the product may present a serious risk of injury to human health." (Emphasis added.) In other words, it is not necessary that there be a serious risk of injury to justify the disclosure; rather the provisions merely require that the Minister believes the disclosure to be necessary.

The Act also states that the Minister may disclose CBI to a person who "carries out functions relating to the protection or promotion of human health or safety of the public" and this can be done "if the purpose of the disclosure is related to the protection or promotion of health or safety of the public." There is no necessity requirement for the disclosure to occur, only that it be related to protecting or promoting health. USMCA and TRIPS do not refer to disclosure for the promotion of health, but rather to disclosure needed to protect the health of the public.

Finally, the Act provides inadequate protections to ensure that there is no unfair commercial use of the disclosed CBI as required by TRIPS Article 39.3. The potential recipients of the disclosed CBI are very broad and there is no mechanism, such as a confidentiality agreement, to ensure that those recipients (or anyone else to whom they disclose that data) are not able to use the divulged CBI to secure an unfair commercial advantage.

In July 2015, a final guidance document was issued by Health Canada with respect to the administration of its powers to require and disclose CBI.[204] This guidance document was later updated and more recently in June 2021 to include the medical devices regulations.[205] PhRMA and its member companies were pleased that the document provides some reassurances with respect to the administration of Health Canada's powers under the Act. However, the document is a non-binding guidance as opposed to binding law or regulations.

In September 2015, a pharmaceutical company was subjected to a disclosure by Health Canada of CBI related to its pharmaceutical product, representing the first known usage of the new legislative disclosure powers. Following a request made under the new mechanisms in the Act, approximately 35,000 pages of raw trial data were released, demonstrating the potential prejudice to U.S. innovative biopharmaceutical companies that could result from future CBI disclosures.[206]

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[204] *See* Archived Amendments to the *Food and Drugs Act*: Guide to New Authorities (power to require and disclose information, power to order a label change and power to order a recall), available at http://www.hc-sc.gc.ca/dhp-mps/legislation/unsafedrugs-droguesdangereuses-amendments-modifications-eng.php (last visited Jan. 26, 2025).

[205] *Id*.

[206] *See* selected media reports on the CBI disclosure: Toronto Star, "Health Canada Hands Over Documents But Muzzles Doctor," Oct. 14, 2016, available at

In December 2017, Health Canada released a draft regulatory package that would amend the *Food and Drug Regulations* (Regulations) and facilitate automatic public access to manufacturer submitted clinical information following the issuance of a final Health Canada regulatory decision.[207] As previously noted, those Regulations were published on March 20, 2019.

The Regulations specify the scope of clinical information in drug submissions that cease to be CBI following the issuance of a final regulatory decision (Notice of Compliance, Notices of Non-Compliance – Withdrawal, or Notice of Deficiency – Withdrawal). The Regulations authorize the Minister to release information that has ceased to be CBI to the public without notifying or receiving consent from the originator. Clinical information provided in drug submissions would continue to be treated as confidential during the regulatory review process. In addition, the Regulations apply to drugs for human use and medical devices and apply to clinical information in drug submissions filed with Health Canada both before and after the coming into force of the Regulations. The Regulations establish a mechanism to release previously submitted information, even from years or decades prior, within the scope of public disclosure.

Further complicating matters, on July 9, 2018, the Federal Court of Canada issued a decision ordering Health Canada to release vast amounts of pharmaceutical clinical trial data on five medications, undercutting the federal government's attempts to keep the information confidential.[208] The effect of this decision, which Health Canada chose not to appeal, on the Regulations and/or the guidelines document is unknown at present, but it presents the risk that the scope of clinical information susceptible to public release will be made even broader than under the current regulatory and guidance document proposals.

PhRMA members therefore urge the U.S. Government to press the Canadian Government to ensure that the regulations and guideline documents to implement the Act are consistent with Canada's international treaty obligations.

https://www.thestar.com/news/canada/2015/10/14/health-canada-hands-over-documents-but-muzzles-doctor.html (last visited Jan. 26, 2025); Macleans, "Health Canada OKs research into popular morning-sickness drug," Nov. 23, 2015, available at http://www.macleans.ca/society/health/health-canada-oks-research-into-popular-morning-sickness-drug/ (last visited Jan. 26, 2025).

[207] Canada Gazette, Part II, Regulations Amending the Food and Drug Regulations (Public Release of Clinical Information), Vol. 151, No. 49, Dec. 9, 2017, available at https://canadagazette.gc.ca/rp-pr/p1/2017/2017-12-09/html/reg3-eng.html (last visited Jan. 26, 2025).

[208] *Doshi v Canada* (Attorney General), 2018 FC 710.

CHILE

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in Chile:

Key Issues of Concern:

- **Compulsory licensing**: In 2020, Chilean legislators supported resolutions which, while nonbinding, called for or implicated compulsory licensing mechanisms related to COVID-19 technologies. Further, public pressure is building to compel the Ministry of Health to consider compulsory licensing of innovative COVID-19 treatments. Moreover, some provisions of the "Medicines II" bill have already been negotiated by legislators and approved by the Conference Committee, including articles on compulsory licensing. These Articles establish extremely vague and ambiguous grounds for the government and third parties to seek compulsory licenses in Chile, and could be used as undue leverage in pricing negotiations between the Chilean Government and U.S. innovators.

- **Weak patent enforcement**: PhRMA member companies believe that the Chilean Government's draft legislative and regulatory proposals would, if approved by the Chilean National Congress and implemented, represent a step toward compliance with Chile's treaty obligations to prevent patent infringement in the marketing approval process. Unfortunately, this legislation, introduced in 2012, continues to be unlikely to move forward in the near term. Meanwhile, PhRMA members report that third parties, through the public tender process, have attempted to supply patent infringing products to the Chilean health system.

- **Inadequate patent term adjustment and extension**: Despite having a patent term adjustment (PTA) mechanism in place, patent applicants are not being adequately compensated for INAPI delays, due to arbitrary interpretations by the TDPI (Industrial Property Court) of what constitutes an unjustified delay during the patent prosecution process. Similarly, TDPI has adopted a very high standard for patent term extension (PTE), finding that many delays incurred by the Institute of National Health are not "unjustified administrative delays."

- **Proposed trademark limitations**: As part of the "Medicines II" bill, Chile's Congress is currently considering provisions to significantly limit the use of trademarks in all pharmaceutical products packaging. That bill also makes the use of the International Non-Proprietary Name (INN) mandatory in drug prescriptions and restricts the ability of doctors to prescribe a medicine using its corresponding trademark.

- **Regulatory data protection**: The Chilean Government's enactment in December 2010 of Supreme Decree 107 corrected some deficiencies in Chile's existing system for protecting proprietary pharmaceutical test data. However, significant

practical and legal hurdles continue to deny innovators appropriate regulatory data protection (RDP).

- **Government price controls**: With the pending finalization of the Medicines II bill, the Conference Committee in the Chilean National Congress is reviewing price regulation proposals that would grant new powers to the Chilean Government to use international reference pricing to regulate the price of patented medicines in the market. Unfortunately, these proposals do not address the underlying reasons why patients in Chile face high out-of-pocket costs for medicines, including insufficient health care coverage and markups in the supply chain. Industry stakeholders largely have been excluded from consultations regarding these proposals.

For these reasons, PhRMA requests that Chile remain on the **Priority Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Compulsory Licensing

The Medicines II bill, introduced in the Chilean Congress in 2015, is still pending. The Conference Committee has approved an article which enables the issuance of compulsory licenses on vague and ambiguous grounds, such as elevating essentially all medicines to the status of a “public interest”, and broadening the criteria for compulsory licenses to include “economic inaccessibility.” PhRMA and its member companies are concerned about possible adoption, interpretation and implementation of that article in a manner which would be inconsistent with international best practices and key provisions of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Specifically, if the Medicines II bill is finalized, relevant agencies will need to adopt corresponding implementing regulations reflecting the new law. We urge Chile to implement provisions of any finalized Medicines II bill in a manner consistent with its international obligations.

Moreover, a number of Congressional resolutions were passed in 2020 implicating compulsory licensing of different products related to COVID-19. While the resolutions are non-binding, they incorrectly assume that IP is a barrier to access and underscore the challenges faced by innovators in Chile.

The 2020 resolutions follow several Congressional resolutions that have passed in the last few years calling for the compulsory licensing of innovative hepatitis C and other medicines. Starting in 2017, the Chilean Chamber of the National Congress passed a resolution calling on the Minister of Health “to incorporate and use existing compulsory

licensing mechanisms to facilitate [medicines] acquisition at *competitive prices*."[209] In addition, the Chamber approved Resolution No. 1014 in January 2018, seeking to establish that access to certain hepatitis C medicines is not consistent with the constitutional right to health, thus warranting, they assert, a CL. Further, on March 9, 2018, the former Minister of Health issued Resolution No. 399 declaring that the compulsory licensing of hepatitis C treatments would be justified on public health grounds. In June 2018, the Chamber approved Resolution No. 68 asking the Minister of Health to directly request a CL for hepatitis C medicines. On August 28, 2018, the new Minister of Health issued Resolution No. 1165 rejecting the patentee's challenge to Resolution No. 399/2018.

While the Chilean Government is not currently reviewing any CL requests, the research-based biopharmaceutical industry is very concerned with Congressional actions that inappropriately seek to expand the scope of the government's compulsory licensing authority to pursue objectives that are not clearly related to legitimate health emergencies.

Weak Patent Enforcement

Notwithstanding the requirement contained in Article 17.10.2 of the U.S.-Chile FTA, Chile has thus far failed to establish a satisfactory mechanism to enable effective patent enforcement before marketing approval decisions are made and implemented. Article 17.10.2 requires Chile to "make available to the patent owner the identity of any third-party requesting marketing approval effective during the term of the patent" and "not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner."

During 2011, the Chilean Government acknowledged to USTR and the innovative pharmaceutical industry that it needed to enact new legislation aimed at establishing an effective patent enforcement mechanism that would bring Chile closer to compliance with its FTA obligations. Recently, in 2023, the Chilean Government acknowledged significant shortcomings in its current patent enforcement system. Specifically, it confirmed that there is no (1) system for the registration and management of drug patents; (2) mechanism to notify the innovator that an application for marketing approval for a follow-on product has been filed; and (3) authority within the executive to prevent marketing approval of a follow-on product based on a request submitted by the innovator.[210] PhRMA supports a policy framework that: (1) provides sufficient time prior to the grant of sanitary registration of a follow-on product to obtain a final decision regarding the validity of relevant patents; (2) enables patent holders to seek provisional enforcement measures, such as a stay or preliminary injunction, prior to the grant of sanitary registration for a

[209] Resolution No. 798, Chamber of Deputies, available in Spanish (unofficial translation) at https://www.camara.cl/verDoc.aspx?prmId=4692&prmTipo=RESOLUCION (last visited Jan. 26, 2025).

[210] *See* Patent Linkage System for Intellectual Property Rights and Public Health Harmonisation, APEC Intellectual Property Rights Experts Group (July 2023), available at https://www.apec.org/docs/default-source/publications/2023/7/223_ipeg_patent-linkage-system-for-intellectual-property-rights-and-public-health-harmonisation.pdf?sfvrsn=bc4d2712_2 (last visited Jan. 26, 2025).

potentially patent-infringing medicine; and (3) excludes the imposition of additional requirements or conditions that might prove unreasonable or unduly burdensome, and that might discourage reasonable patent enforcement efforts (e.g., excessive bond requirements and disproportionately high fines for declarations subsequently judged to be inaccurate).

PhRMA welcomed the government's work to introduce relevant draft legislation in January 2012. Unfortunately, that legislation has not received any attention since its introduction and, as a result, Chile is still not complying with its international obligations and the impact of a lack of effective patent enforcement continues to worsen. In 2023 and 2024, there have been several attempts by third parties, through the public procurement process, to commercialize products during the underlying product's patent term. Although relevant stakeholders have expressed their concern, until effective action is taken, these oversights have the potential of weakening the IP ecosystem.

Inadequate Patent Term Adjustment and Extension

Over the last several years, INAPI has implemented several administrative and procedural reforms to decrease patent prosecution times, such that most patent applications now receive a definitive decision within three to four years. PhRMA commends Chile's participation in the Global Patent Prosecution Highway program and implementation of a Patent Prosecution Highway partnership with USPTO to further improve prosecution time of patent applications.

To the extent that patent reviews can still be delayed, Chilean Patent Law provides all patent applicants the right to request PTA to offset unjustified delays during the patent prosecution process. However, applicants are being denied adequate PTA due to arbitrary interpretations by the TDPI of what constitutes "unjustified administrative delay" during prosecution and narrowly interpreting PTA requests. The TDPI has determined that many types of delays that are outside of the applicants' control are in fact justified, resulting in inadequate PTA in Chile. Additionally, the TDPI has adopted a very high standard regarding PTE requests in Chile, ruling on several occasions that considerable delays incurred by the Institute of National Health are not to be considered "unjustified administrative delays."

Trademarks

During 2020, the Conference Committee of Congress reconciling the Medicines II bill approved articles that would significantly limit the use of trademarks or other "fanciful" designations for any prescribed medicine. A trademark for a medicine designates its source and helps doctors and patients identify the quality, safety and intrinsic effectiveness of a given product – reputational capital and goodwill that manufacturers strive to build over time. Restricting the use of trademarks for medicines would significantly deviate from the current trademark protection guaranteed in Article 19 N° 24 and N° 25 of Chile's Constitution and from Chile's multilateral (e.g., WTO TRIPS) and bilateral (e.g., U.S.-Chile FTA) obligations.

In addition, the Conference Committee approved measures that would severely limit the prescription of medicines based on their trademarked names, by requiring that, absent exceptional circumstances, prescribers use the INNs instead.

Regulatory Data Protection

Final enactment in December 2010 of Supreme Decree 107 resolved some longstanding concerns of the U.S. Government and PhRMA regarding deficiencies in Chile's RDP system. Nevertheless, Chile's RDP system contains significant weaknesses, ranging from inappropriate procedural barriers to seek and receive RDP to ambiguous carveouts precluding RDP for certain pharmaceutical innovations (e.g., new uses, formulations, compositions, dosage forms, etc.). Specifically, Chilean regulators inappropriately require innovators to request RDP for specifically identified data and deny RDP in the event subsets of clinical trial data were voluntarily disclosed publicly. Further, regulators are not obligated to protect clinical trial and other data against disclosure after the five-year RDP term has expired.

While Supreme Decree 107 made progress to advance implementation of Chile's RDP under the U.S.-Chile FTA, WTO TRIPS Agreement and other multilateral agreements, compliance with these commitments requires further action by the Chilean Government to correct these deficiencies.

Market Access

Government Price Controls

Only 18 percent of new medicines launched globally since 2014 have launched in Chile, with patients waiting an average of 38 months after global first launch for new medicines to become available. Only six percent of these new medicines are publicly reimbursed in Chile's public national health insurance.[211]

Even with the Medicines II bill still pending, the Conference Committee in the Chilean National Congress has approved price regulation proposals that would grant new powers to the Chilean Government to directly set the price of patented medicines in the market. Unfortunately, these proposals threaten to reverse Chile's progress in access to medicines and do not address the underlying reasons why patients in Chile face high out-of-pocket costs for medicines, including insufficient health care coverage and markups in the supply chain.

Industry stakeholders largely have been excluded from consultations regarding these proposals. However, it is widely speculated that the government price controls would be applied to patented medicines and involve international reference pricing of other countries in Latin America, nearly all of which have lower GDP per capita.

[211] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

Compounded by heavily devalued currencies throughout the region, these proposals would significantly reduce prices in Chile without creating the policy environment needed to increase patient access and affordability. PhRMA and its member companies stand ready to work with the Chilean Government on more practical solutions.

COLOMBIA

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in Colombia:

Key Issues of Concern:

- **Compulsory licensing**: The threat of unmitigated compulsory licensing in Colombia is a continued risk for the innovative biopharmaceutical industry. In April 2024, the Colombian Government issued a compulsory license (CL) on an antiretroviral medicine on vague and ambiguous grounds. Since that action, the Ministry of Health (MoH) has publicly signaled its desire to use the threat of CLs as a price "negotiation" tool despite other and more effective options that would not compromise incentives for innovation.

- **Regulatory data protection failures**: Colombia fails to respect existing legislation that would otherwise provide RDP upon approval of novel pharmaceutical products.

- **Restrictive patentability criteria**: Contrary to its obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Colombia does not grant patents for second uses.

- **Effective patent enforcement**: Despite having a specialized court under the auspices of the Superintendence of Industry and Commerce (SIC) designed to address IP infringement matters, Colombia needs to implement effective early resolution mechanisms that provide for the timely resolution of patent disputes before marketing approval is granted to infringing follow-on products during the patent term through increased collaboration between INVIMA and SIC.

- **Substandard biologics regulation**: On September 18, 2014, Colombia issued Decree 1782, which establishes marketing approval evaluation requirements for all biologic medicines. As part of the Decree, Colombia created an unprecedented "abbreviated" pathway for the registration of non-comparable products, which is inconsistent with WHO guidelines and accepted standards in the United States and other countries, and which could result in the approval of medicines that are not safe and/or effective. Industry urged the Colombian Government to remove this third pathway from the Decree but was unsuccessful.

- **Cost containment measures focused solely on the biopharmaceutical industry**: Government measures to improve the sustainability of the Colombian health system have focused solely on the biopharmaceutical industry and have not addressed broader issues within the pharmaceutical supply chain or other health care sectors. For example, in 2020, the Colombian Government issued regulations to limit expenditures on medicines not included in the publicly funded Health

Benefit Plan (HBP) based on historical levels that would effectively restrict new innovative medicines from entering the country. These measures have been criticized for their technical shortcomings by virtually all sectors of the health system and academia.

- **The National Food and Drug Surveillance Institute (INVIMA) delays**: In recent years, the pharmaceutical industry has experienced worsening delays in regulatory approval times, resulting in significant market access barriers. In November 2023, the Administrative Court of Cundinamarca issued an emergency measure in response to the growing shortage of drugs in Colombia due to the delays in regulatory approvals. The Court mandated a contingency plan, developed jointly by INVIMA and the Ministry of Health, detailing necessary actions to reduce the shortage of drugs in Colombia, including accelerating regulatory approvals. In June 2024, INVIMA updated industry associations on the progress of the planned procedures in the contingency plan agreed to by the Cundinamarca court. This order was revoked by the Consejo de Estado, eliminating the obligation for INVIMA and the Ministry to proceed with these plans. As of November 1, 2023, there were 26,000 drug evaluations pending. By August 2024, shortly before the Consejo de Estado's ruling was overturned, 64 percent of this backlog (17,000 evaluations) had been cleared, yet 70 percent of licenses for innovative medicines remained unresolved. In December 2024, the Administrative Court of Cundinamarca again mandated the continuation of an urgent response plan to address ongoing medicine and supply shortages, however, INVIMA's capacity to reduce these backlogs.

- **New drug price regulation methodology**: A draft circular was published by MOH in September 2023, outlining a new method for pricing new medicines. In addition to international reference pricing (IRP), it established a value-based pricing model based on clinical value assessments undertaken by the *Instituto de Evaluación Tecnológica en Salud* (IETS). In March 2024, the National Drug Pricing Commission (NDPC) issued Circular 18 of 2024 adjusting the methodology for regulations in place since 2013. This Circular allows for more restrictive IRP by expanding the number of reference countries from 17 to 19 and cherry-picking countries to include those that are less supportive of innovation. In addition, if a drug is declared by the government to be of public interest, then the price will be set to the lowest price in the reference basket of countries.

For these reasons, PhRMA requests that Colombia be placed on the **Priority Watch List** in the 2025 Special 301 Report. Further, we urge USTR to provide an opportunity for an assessment of Colombia's IP and market access environment through an **Out-of-Cycle Review**, so that the U.S. Government can evaluate progress on these important issues and dedicate the required bilateral attention necessary to make progress on the barriers confronted by U.S. businesses in Colombia.

Intellectual Property Protection

Compulsory Licensing

In April 2024, the MoH, through Resolution 20049, issued its first-ever compulsory license (CL) for an antiretroviral medication. Subsequently, the MoH issued another resolution regarding implementation of the CL through the Pan American Health Organization. According to the technical body created by Decree 2699 of 2007 to study the burden of particular diseases in Colombia, in 2023, more than 83 percent of people who have been diagnosed with HIV in Colombia have access to antiretroviral treatments.[212] It appears MoH is seeking to leverage compulsory licensing simply to achieve further price cuts, even though the price in Colombia for this product is the lowest compared to peer countries in the region and is the lowest compared to other medicines in the same class in Colombia. U.S. administrations have specifically called out such practices and made clear that compulsory licensing should not be used as undue leverage in pricing negotiations.[213]

Resolution 20049 follows repeated CL threats in Colombia, including in 2017 and 2016. PhRMA urges USTR and other federal agencies to address this serious threat to American innovation through discussions under the U.S.-Colombia Trade Promotion Agreement. Industry is concerned about the increasing interest within the MoH to consider the use of compulsory licensing improperly, particularly when other options exist which would not compromise incentives for innovation. Experience and research demonstrates that compulsory licensing is not an effective way to improve access to medicines or achieve other public health objectives. It does not necessarily lower prices or speed access in the short-term, or provide sustainable and comprehensive solutions to longer-term challenges.

Regulatory Data Protection Failures

Existing Colombian legislation, Decree 2085 of 2002 (and its subsequent interpretation through a March 2003 joint act signed by the Ministers of Trade and Health), requires that new chemical entities receive a five-year period of regulatory data protection upon approval. Nevertheless, INVIMA is denying regulatory data protection upon approval of some new chemical entities, simply because they share a minor portion of their chemical structure with previously approved products.

This sudden and drastic change in procedure is inconsistent with the requirements of Decree 2085 of 2002 and contrary to the practice in other countries that provide regulatory data protection for such products. Such disregard of existing legislation

[212] Colombian Fund for High-Cost Diseases, "2023 HIV Situation in Colombia," Feb. 2023, available at https://cuentadealtocosto.org/publicaciones/situacion-de-vih-en-colombia-2023/ (last visited Jan. 26, 2025).

[213] *See*, *e.g.*, 2020 Special 301 Report, at p. 14 (Apr. 2020), available at https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf (last visited Jan. 26, 2025).

undermines incentives to conduct clinical trials and develop new biopharmaceutical products in Colombia.

Restrictive Patentability Criteria

The Andean Court of Justice (ACJ) has issued several legal opinions (89-AI-2000, 01-AI-2001 and 34-AI-2001) holding that Andean Community members should not recognize patents for second uses. These decisions are contrary to long-standing precedents and inconsistent with TRIPS Article 27.1. Andean member countries, including Colombia, have chosen to honor their Andean Community obligations, while ignoring their TRIPS obligations.

The failure to provide patents for second uses harms patients by undermining incentives for biopharmaceutical innovators to invest in evaluating additional therapeutic benefits of known molecules (second uses) and provide more effective solutions for unsatisfied medical needs. The ACJ position is dispositive on the issue and no further domestic appeals or remedies are possible.

Effective Patent Enforcement

Despite having a specialized court under the auspices of the SIC designed to address IP infringement matters, Colombia needs to implement effective early resolution mechanisms that provide for the timely resolution of patent disputes before marketing approval is granted to infringing follow-on products during the patent term through increased collaboration between INVIMA and SIC.

Market Access

Numerous market access barriers have had a detrimental effect on patient access to innovative medicines in Colombia. Overall, only 17 percent of new medicines launched globally since 2014 have launched in Colombia, with Colombian patients waiting an average of 34 months from global first launch for new medicines to become available. Only 10 percent of these new medicines are reimbursed in Colombia's public national health insurance.[214]

Substandard Biologics Regulation

On September 18, 2014, Colombia issued Decree 1782, which establishes marketing approval evaluation requirements for all biologic medicines. As part of the Decree, Colombia established an unprecedented "abbreviated" pathway for the registration of non-comparable products, which is inconsistent with WHO standards and practices in the United States and other countries, and which could result in the approval of medicines that are not adequately evaluated in terms of safety and efficacy in

[214] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

accordance with harmonized international guidelines and standards. Strict regulatory processes required for marketing approval ensure safe and effective medicines for Colombian patients.

PhRMA members participated actively in the public consultations and engaged extensively with MoH and their technical experts, specifically highlighting that the abbreviated "third pathway" created by the Decree is not in line with the WHO guidelines for approval of biologics. In contrast to the Full Dossier Route (for originators) and the Comparability Pathway (pathway for Biosimilars) found in WHO guidelines, the "Abbreviated Comparability Pathway" as described in the Decree allows for summary approval of non-comparable products and does not provide adequate controls or any clarity regarding how the safety or efficacy of a product approved via this pathway will be evaluated and assured.

Furthermore, per the Decree, a product approved via the "Abbreviated Comparability Pathway" will use the same non-proprietary name as the innovator, even though any similar biologic product would be a distinct biologic product from that of the originator or other biosimilar products. Assigning identical non-proprietary names to products that are not the same could result in inadvertent substitution of the products, generate a false sense of equivalence or substitutability and would make it difficult to quickly trace and attribute adverse events to the correct product. In addition, a product approved via the "Abbreviated Comparability Pathway" will receive approval of the same indications as the innovative product without demonstrating safety or efficacy.

Relatedly, in May 2023, the Government issued the National Development Plan 2022-2026. Article 161 focuses on streamlining marketing authorizations for medicines, health devices and technologies, including expediting market entry of competing medicines (branded or generic). If the competing medicine requires bioequivalence and/or bioavailability studies as part of the pharmaceutical evaluation, they will be evaluated by an internal technical unit at INVIMA within three months. PhRMA and its member companies are concerned that this could result in unfair competition and approval of certain medicines that fail to meet international quality standards and international safety and efficacy requirements.

Cost-containment Measures Focused Exclusively on the Biopharmaceutical Industry

Government measures to improve the sustainability of the Colombian health system have focused solely on the biopharmaceutical industry and have not addressed broader issues within the pharmaceutical supply chain or other health care sectors. These measures have been developed in an arbitrary, hasty manner that leaves industry unable to plan for transitions. For example, in 2020, the Colombian Government issued Resolutions 205 and 206 to cap the expenditure of medicines not included in the publicly funded HBP. Most of these are innovative medicines, including products developed by PhRMA member companies. The budget caps set by the resolutions and the implementing regulations are based on historical spending, which by definition does not

include more recent innovative medicines and are inadequate to ensure that Colombian patients have access to new treatments and cures.

The calculation of these budget caps has been strongly criticized by virtually all sectors of the health system and academia for technical limitations. These problems were aggravated by the methodology published for 2021, which set caps based on the historical minimum prices paid and atypical utilization volumes observed during 2020 because of the COVID-19 pandemic. As part of this calculation, the government publishes the estimated prices for each product according to the information reported by the government-sponsored HMO system (EPS), which may contain errors and does not provide opportunity for relevant stakeholders to verify the quality of the information. Recently, the Colombian Government has stated repeatedly that a special budget for orphan diseases will not be created and that those diseases will not be covered anymore with budget caps, delaying payments to HMOs. In December 2024, the Colombian government passed Legislation 2717, allowing the MoH to set the value for the Unit Capitation Payment (UPC) premium for 2025, announcing a subsequent 5.36 percent increase. The UPC determines the amount of money allocated per person in the HBP. The 5.36 percent adjustment to the UPC is not sufficient to ensure access to health for Colombian patients in 2025. In October 2024, the Colombian Association of Pharmaceutical Research and Development Laboratories (AFIDRO) and the National Association of Financial Institutions (ANIF) presented a study indicating that by 2025 a 16.4 percent increase would be required for the UPC to provide Colombians with their necessary health needs. Unfortunately, the MoH announcement leaves the 2025 health budget with a deficit of more than 19 billion COP. Given the lack of devoted resources and the health system's serious financial problems, it remains uncertain how new health technologies and medicines both included and not included in the publicly funded HBP will be covered.

PhRMA and its member companies request that any cost containment measures consider the entire health care system, be developed and implemented through a participatory process with relevant stakeholders and include appropriate transition periods. In addition, MoH should consider alternative approaches to addressing uncertainty over spending, such as managed entry agreements and innovative financing mechanisms for health.

INVIMA delays

In recent years, the pharmaceutical industry has experienced worsening delays in regulatory approval times, resulting in significant market access barriers. In November 2023, the Administrative Court of Cundinamarca issued an emergency measure in response to the growing shortage of drugs in Colombia due to the delays in regulatory approvals. The Court mandated contingency plan, developed jointly by INVIMA and the Ministry of Health, detailed necessary actions to reduce the shortage of drugs in Colombia, including accelerating regulatory approvals. In June 2024, INVIMA updated industry associations on its progress in implementing the contingency plan. Whereas the plan indicated that the backlog would be cleared by June 2024, only 8,000 of the 27,000

pending regulatory approval requests had been cleared. PhRMA and its member companies remain concerned that barriers to market access in Colombia remain a significant challenge and request expedited action on the contingency plan to ensure Colombian patients can access innovative and life-saving medicines.

New Drug Price Regulation Methodology

In March 2024, the National Drug Pricing Commission (NDPC) issued Circular 18 of 2024 adjusting the methodology for regulations in place since 2013. This Circular allows for more restrictive IRP by expanding the number of reference countries from 17 to 19 and cherry-picking countries to include those that are less supportive of innovation. In addition, if a drug is declared by the government to be of the public interest, then the price will be set to the lowest price in the reference basket of countries. Further, Circular 19 of 2024 updated the maximum selling price of medicines subject to the direct price control regime.

Additionally, Circular 16 of 2023 established the use of a value-based pricing model for new drugs, based on clinical value assessment undertaken by the IETS, a process that lacks transparency and could bias the value assessment, including the exclusion and strict limitation of stakeholder engagement.

PhRMA and its member companies remain concerned about these new price regulation methodologies, including the frequency of price adjustments and the new cost containment mechanism allowing for the adoption of the lowest unit price observed domestically or internationally among groups of products that differ in strength, formulation, delivery system and quality. This approach fundamentally penalizes continued innovation that better meets diverse patient needs. Industry submitted technical comments to the NDPC highlighting these concerns.

Regulatory Decisions Inconsistent with Global Best Practices

Products approved by reference authorities such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) are frequently either denied approval in Colombia or approved with deviations from their approvals in reference countries (e.g., approximately 80 percent of new medicines denied by INVIMA have been approved by the FDA and/or EMA). The data provided for these drugs is pharmacologically the same as provided to reference country authorities and no explanation is provided for why Colombia has reached a different outcome. These inconsistent outcomes underscore the need for ongoing collaboration between the MoH and INVIMA to ensure that the MoH adopts and applies regulatory assessment procedures and guidelines that are consistent with international best practices.

Moreover, Decree 677 of 1995 allows that, when a product has been approved in at least two reference countries and has not been rejected in any other reference country, the pharmacological evaluation will only consider a summary of the product's clinical information. Despite this regulation, INVIMA in practice denies without justification the

approval of innovative medicines that comply with these requirements, which blocks the entry of innovative medicines and ultimately increases trade barriers.

The Colombian American Chamber of Commerce engaged in stakeholder consultations with the Directorate General of INVIMA to address these concerns. During these consultations, INVIMA justified its practices citing insufficient understanding of abbreviated mechanisms and the FDA's/EMA's accelerated procedures for evaluating new molecules and a lack of confidence in the design of clinical trials, as well as new criteria of 'socio-economic convenience' citing the high costs of innovative drugs. Industry remains concerned that INVIMA's regulatory approach is inconsistent with global best practices and remains focused on cost-containment rather than health investment.

In October 2023, the Administrative Court of Cundinamarca issued an order to the Ministry of Health and INVIMA requesting two work plans aimed at addressing drug shortages and drug evaluation backlogs. However, this order was overruled by the Consejo de Estado, no longer requiring INVIMA and the Ministry of Health to continue these plans. As of November 1, 2023, there are officially 26,000 backlogged drug evaluations. As of August 2024, just before the overturned ruling by the Consejo de Estado, 64 percent of the total backlog has been resolved (17,000 procedures), with 70 percent of the licenses for innovative medicines still pending. AFIDRO requested the inclusion of urgent short-term actions to resolve long delayed evaluations for new molecules and the resulting denial of registration for new products by the Review Committee.

In December 2024, the Administrative Court of Cundinamarca again ordered the continuation of the urgent response plan to address these backlogs and supply shortages; however, uncertainty remains regarding INVIMA's capacity to resolve these concerns.

INDIA

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in India:

Key Issues of Concern:

- **Unpredictable patent environment**: While the Patent (Amendment) Rules, 2024, should help address some long-standing IP obstacles with respect to pre-grant opposition proceedings and working statements, systemic barriers remain. India's legal and regulatory systems pose longstanding substantive and procedural barriers for innovators, including impermissible hurdles to patentability per Section 3(d) of India's Patents Act, 1970. Also, in December 2024, India deployed a new framework concerning inventions based on digital sequence information on biological resources accessed from India which could significantly compromise the grant of intellectual property rights not just in India but globally.

- **Lack of patent enforcement**: A significant challenge facing biopharmaceutical innovators seeking marketing approval in India is that marketing and manufacturing approvals are not transparent or coordinated between the Central Drugs Standard Control Organization (CDSCO) and state agencies. After four years of the medicine's first approval in India, any of the state/union territory (UT) drug regulators may grant a license to manufacture and market the product in India. The State/UT drug regulators are not required to inquire or assess whether the drug approval is being granted to a patent-protected product, resulting in irreparable harm to patients, innovators and follow-on producers.

- **Regulatory data protection failures**: Contrary to India's obligations under Article 39.3 of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), regulatory authorities in India rely on test data submitted by originators to seek approval in India and/or another country when granting marketing approval to follow-on pharmaceutical products to third parties. This reliance results in unfair commercial use prohibited by the TRIPS Agreement and discourages the development and introduction into India of new medicines for unmet medical needs.

- **Discriminatory and non-transparent government pricing policies**: PhRMA's members understand the need for making medicines available and affordable in a market where most patients have to pay for their medicines out-of-pocket. At the same time however, there must be recognition of the research and development that goes into innovative medicines and for new cures for unmet medical needs. The National List of Essential Medicines (NLEM) 2022 released September 2022 includes four patented medicines that will be included in Schedule I of the Drug Price Control Order 2013 (DPCO) and subject to price controls like generic medicines. PhRMA also remains concerned about the application of Trade Margin

Rationalization (TMR) on high value non-scheduled medicines where trade margin is arrived at by a formula that does not exclude free medicines provided under Patient Assistance Programs (PAP), which results in deep price cuts on patented and proprietary medicines. Further, the 2019 amendment to Paragraph 32 of the DPCO that allows manufacturers of patented medicines to apply for exemption from price controls for five years from the commencement of marketing in India (as well as a permanent exemption for orphan drugs) has not been implemented for importers of patented medicines and orphan drugs. The overall lack of transparency, predictability and reasonableness in implementing policies that impact pricing of medicines creates an unviable business environment.

- **Discriminatory government procurement policies**: The Make in India regulations have increasingly excluded or disadvantaged suppliers that do not manufacture in India from participating in tenders run by public organizations. In fact, suppliers of imported drugs are not eligible to bid in government procurement except in permitted Global Tender Enquiry (GTE). The General Financial Rules were amended in 2020 to exclude the participation of non-local suppliers (i.e., suppliers that do not meet the 20 percent minimum local content requirement) from government procurement where the value of the goods to be procured is less than INR 2 billion. The Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry has consequently amended the 2017 Public Procurement Order (PPO) to disqualify non-local bidders in all government tenders of such value (except in permitted GTEs). The December 2020 notification issued by the DoP for procurement of medicines requires a minimum 80 percent local content to qualify as a favored Class 1 local supplier and more than 50 percent local content to qualify as a Class 2 local supplier. Further, in April 2022, DoP shared the details of local manufacturers of 67 medicines (subsequently revised to 60) to various central procurement agencies to assist them in procurement from a local supplier without regard to the patent status. The list included 19 potentially patent-infringing products manufactured in India, which resulted in several innovator companies filing infringement cases and obtaining interim injunctions against these local manufacturers. Since November 2022, the government has provided exemptions from GTE requirements and PPO for specified patented drugs; however, industry is requesting exemption for additional patented drugs because public entities are facing challenges in procuring them and it's having an adverse impact on patients who depend on government programs for their medicines.

- **High tariffs and taxes on medicines**: Taxes, duties and other levies contribute substantially to pharmaceutical prices in India. Import duties for active ingredients and finished products with the basic import duties average around 10 percent. When combined with the Integrated Goods and Service Tax, the effective tax can be as high as 28 percent with surcharges on these taxes included.

- **Unpredictable environment for clinical research and new drug approval**: While the government is keen to reinvigorate clinical research in India, ambiguities

and discriminatory practices in the Indian regulatory space continue to hinder that effort. Promisingly, on August 7, 2024, CDSCO announced that local clinical trials may be waived for certain categories of drugs if those drugs have been approved in Australia, Canada, the European Union, Japan, United States or United Kingdom. Nonetheless, the process for seeking waivers remains ill-defined and related provisions in the New Drugs and Clinical Trials Rules, 2019 (NDCT) allowing for deemed approval of clinical trials applications appears to be discriminatory in that it does not apply to drugs whose research and development was conducted outside of India. Furthermore, the Subject Expert Committees (SECs) that review and examine clinical trials and new drug applications do not have standard operating procedures (SOPs) or guidelines and, therefore, the recommendations made by them are often subjective and arbitrary. Hence a large part of the process of new drug approval and clinical trial waiver is characterized by absence of time bound decisions and subjective application of waiver criteria leading to unpredictability and uncertainty. These issues perpetuate a burdensome environment for clinical research and new drug approvals that undermine the availability of new treatments and vaccines for Indian patients.

- **Counterfeit medicines**: Counterfeit medicines pose serious and pervasive health and safety threats, and according to recent reports, more than half of the counterfeit medicines seized originated in India. Moreover, illicit trade in counterfeit medicines is growing and the need to stem the flow of these counterfeit medications is even more pronounced given the global efforts to combat the COVID-19 pandemic.

For these reasons, PhRMA requests that India remain on the **Priority Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

India announced its National IPR Policy in May 2016.[215] The Policy recognizes the tremendous economic and socio-cultural benefits that a strong IP regime could bring to India through economic growth, employment and a vibrant R&D environment. The Policy also puts forward important administrative and procedural improvements. However, it has been more than eight years since the National IPR Policy was introduced and a revision and update of the Policy, along with appropriate consultation with stakeholders, is necessary. A comprehensive overview of the applicable legislation and policies, in line with the recommendations outlined in the 161st Department related Parliamentary Standing Committee on Commerce Report and the August 2022 Economic Advisory

[215] Dep't of Industrial Policy and Promotion, "National Intellectual Property Rights Policy," May 12, 2016, available at https://ipindia.gov.in/writereaddata/Portal/Images/pdf/2016-_National_IPR_Policy-2016__English_and_Hindi.pdf (last visited Jan. 26, 2025).

Council to the PM report on India's patent ecosystem, is necessary to reassure India's commitment to a strong IP framework.[216]

Restrictive Patentability Criteria

PhRMA members continue to face considerable barriers at every step of the patent application process, including restrictive patentability criteria posed by Section 3(d) of India's Patents Act, 1970, narrow patentability standards applied during pre- and post-grant opposition proceedings, conditioning patent grant on unclear and subjective access and benefit sharing requirements, and outdated patent application disclosure requirements.

TRIPS Article 27 requires that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that an invention is new, involves an inventive step and is capable of industrial application. Section 3(d) of the Indian Patents Act, 1970, as amended by the Patents (Amendment) Act 2005, adds an impermissible hurdle to patentability by adding a fourth substantive criterion of "enhanced efficacy" to the TRIPS requirements. Moreover, this additional hurdle appears to be applied only to pharmaceuticals. Under this provision, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances are presumed to be the same substance as the original chemical entity and thus not patentable, unless it can be shown that they differ significantly in properties with regard to therapeutic efficacy. Further, indiscriminate and routine use of Section 3(d) by the Indian Patent Office during prosecution of patent applications even for a novel compound or a derivative, with the onus of proof on the applicant to prove otherwise, poses an unreasonable and unnecessary burden on innovators.

Additional substantive requirements for patentability beyond those enumerated in the TRIPS Agreement are inconsistent with India's international obligations. For example, Article 27 of the TRIPS Agreement provides an exclusive list of the types of subject matter that can be precluded from patent coverage and this list does not include "new forms of known substances lacking enhanced therapeutic efficacy," as excluded by Section 3(d) of the Indian law. Therefore, Section 3(d) is inconsistent with the TRIPS Agreement. Moreover, Section 3(d) represents an additional hurdle for patents on inventions specifically relating to chemical compounds and, therefore, the Indian law is in conflict with the non-discrimination principles provided by TRIPS Article 27 and WTO rules.[217]

[216] Dep't Related Parliamentary Standing Committee on Commerce, "Review of the Intellectual Property Rights Regime in India," July 2021, available at https://files.lbr.cloud/public/2021-07/161_2021_7_15.pdf?VersionId=S01fCQEC5DzDqKNymsGgxal6YXmJbUwM (last visited Jan. 26, 2025).

[217] The additional patentability hurdle imposed by section 3(d) was recently reinforced by the Pharmaceutical Patent Examination Guidelines issued in October 2014.

From a policy perspective, Section 3(d) undermines incentives for biopharmaceutical innovation by preventing patentability for improvements that do not relate to efficacy, for example an invention relating to the improved safety or toxicity of a product. Further, Section 3(i) of the Indian Patents Act, 1970, excludes method of treatment claims, discouraging U.S. biotechnology companies with needed treatment methods from entering the Indian market and providing life-saving products.

India's pre- and post-grant patent opposition system is another source of unreasonable restrictive standards for patentability. Patent revocations using "hindsight" analyses made during pre- and post-grant oppositions have cited a lack of inventiveness concluding that inventions were based on "old science" or failed to demonstrate an inventive step. In addition, the lack of clear rules guiding pleading and evidentiary standards during pre-grant opposition proceedings create further uncertainty relating to the patentability of inventions. Further, pre-grant opposition procedures under Section 25 of India's Patents Act, 1970, have created significant uncertainty and delayed the introduction of new medicines by undermining patent office efficiency and delaying patent prosecution. "A Study of Patent Opposition System,"[218] a recent publication by the Center for Intellectual Property, Innovation, and Technology at Hidayatullah National Law University, illustrates how India's pre-grant opposition system compromises its IP regime and negatively impacts the certainty and predictability necessary for innovators. The report highlights the significant backlog of pre-grant oppositions, which doubled between 2018 and 2019, and finds that it takes almost nine years to resolve pre-grant opposition disputes. Moreover, the report concludes that serial oppositions and oppositions filed by persons with no discernible interest or connection to the subject matter have delays of around 10 years. Indeed, these two situations are responsible for the longest delays and are consistent with a system that allows practically no time limit for filing an opposition, nor a requirement to show direct interest in the matter. Further, the existing patent backlog and the absence of mechanisms such as patent term adjustment further complicate this process and contribute to the loss of patent life.

While PhRMA continues to believe that eliminating the pre-grant opposition process is in India's best interest because it would ensure the timely granting of patents and provide inventors with the ability to enjoy and enforce their legitimate patent rights, the recently finalized Patent (Amendment) Rules, 2024, will help improve India's pre-grant opposition regime. Specifically, requiring that the Controller consider the "maintainability" of the pre-grant petition is a positive development which will help provide some certainty and predictability to innovators.

PhRMA recommends that DPIIT develop criteria that will be used to assess "maintainability" so that the Controller, as part of the assessment associated with maintaining opposition petitions, ensures that only real parties in interest can proceed

[218] Vivekanandan VC et al., "A Study of Patent Opposition System," Centre for Intellectual Property, Innovation and Technology, Hidayatullah National Law University, Jan. 2023, available at https://hnlu.ac.in/wp-content/uploads/2023/01/Patent-Opposition-System-Report-1-3.pdf (last visited Jan. 26, 2025).

with pre-grant opposition proceedings (which would be consistent with the law in place for post-grant oppositions). The criteria should include a timeline for making the maintainability determination and such findings should be timely notified to the relevant parties through a reasoned order that clearly provides the rationale for the decision. Moreover, India should establish a deadline after which no oppositions can be filed (e.g., six months from the date of issuance of the First Examination Report). This requirement should be implemented in a manner that ensures only real parties in interest can file pre-grant opposition proceedings.

Finally, in December 2024, India deployed a new, and problematic, framework concerning inventions based on digital sequence information (DSI). The new rules apply to any invention implicating Indian biological resources, including DSI, which are accessed from India or repositories outside of India. Under the new rules, foreign entities need permission from the Ministry of Environment, Forest and Climate Change's National Biodiversity Authority to secure patents implicating DSI not just in India, but any jurisdiction worldwide. Indian entities do not need permission from the NBA to secure patent protection. These discriminatory new rules seriously call into question India's commitment to its international obligations.

Weak Patent Enforcement

Indian law permits CDSCO to approve third-party manufacturers to commercialize copies of innovator chemically synthesized products, regardless of whether those products potentially infringe on an innovator's patent(s). After four years of the medicine's first approval in India, a medicine is deemed to no longer be a new drug.[219] As such, approval from CDSCO is not required and a mere license from any of the state/UT drug regulators to manufacture and market the product in India suffices. Neither the Central nor State/UT regulatory authorities are required to verify or consider the remaining term of the patent protection on the original product. Therefore, an infringer can obtain marketing authorization from the CDSCO and manufacturing authorization from the state/UT drug regulator for a generic version of an on-patent drug, forcing the patent holder to seek redress in India's court system, which often results in irreparable harm to the patent holder.

India's National IPR Policy, 2016 calls for identification of important areas of potential policy development related to ambiguities between IP laws and other laws or authorities whose jurisdictions impact administration or enforcement of patents.[220] At a minimum, through the draft Drugs, Medical Devices, and Cosmetics Bill, 2023, India should amend its rules for "new drugs" in the NDCT, by increasing the period a drug is

[219] As per Rule 2(1)(w) of the New Drugs Clinical Trials Rules, 2019 a drug (apart from a modified or sustained release form of a drug or novel drug delivery system of any drug or a vaccine, r-DNA derived product, living modified organism, monoclonal anti-body, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug) "*shall continue to be new drugs for a period of four years from the date of their permission granted by the Central Licensing Authority ….*"

[220] *See* Secs. 3.8 and 3.8.3 of the National IPR Policy.

considered "new" from four years to 10 years (thereby extending the period before which a manufacturer can seek approval for a follow-on product).[221]

India also does not provide mechanisms for notification or resolution of patent disputes prior to marketing approval of generic products. Such mechanisms are needed to prevent the marketing of potentially patent infringing products and resolve disputes in a timely manner. CDSCO's SUGAM initiative launched in November 2015 and DPIIT's National Single Window System, deployed in January 2024, lack the transparency necessary to facilitate timely notification to a patentee of a possible infringement. In April 2017, India amended Form 44 of the Drugs and Cosmetics Rules[222] to omit Item 8 which previously required new drug applicants to disclose the "patent status of the drug."[223] This action further eroded the ability of patent owners to effectively and timely notify generic manufacturers and state drug regulatory authorities of existing patents related to medicines approved by CDSCO or get timely and adequately notified of filing of applications for marketing or manufacturing approval by any subsequent applicant. CDSCO's Notification GSR 19(E) dated January 10, 2019, falls short in providing an opportunity to facilitate notification of manufacturing applications between government agencies and patent holders under the SUGAM initiative. The industry has submitted many formal representations urging the Ministry of Health and Family Welfare (MoHFW) to take immediate steps to increase transparency and cooperation between central and state medicines regulatory authorities. At a minimum, MoHFW should ensure all biopharmaceutical manufacturers, the relevant Indian authorities and the broader public have timely notice of marketing and manufacturing applications filed with central and state regulators. Further, while the draft Drugs, Medical Devices and Cosmetics Bill, 2023 reflects on the relationship between the Central Licensing Authority and State Licensing Authorities, it falls short of ensuring that innovators have timely notice of manufacturing approval applications and are able to seek injunctive relief before potential patent infringing drugs enter the market.

With regard to patent enforcement, in at least one specific case, the patent holder was forced to wait seven years before receiving a court decision upholding its patent. In that case, the court ultimately did not grant an injunction because by the time the decision was issued the patent was close to expiration. In another case, a company waited two years for a Court to grant an injunction. During that time the infringing product was marketed and sold. In some cases, defendants have started to obtain market authorizations and manufacturing licenses without the knowledge of the innovator and pre-emptively filing declaratory suits as to the non-infringement of the patents in a civil court so as to delay grant of any injunction orders. Moreover, while some innovators have been successful in obtaining interim injunctions, that relief is often very limited because infringers are only enjoined from future infringing acts, i.e., it does not prohibit the marketing of products already manufactured and/or launched.

[221] For clarity, the effective date of the approval of any follow-on product should not be before the relevant patents on the underlying innovative product have expired.

[222] Form 44, Schedule A, Drugs and Cosmetics Rules, 1945.

[223] *Id.*

The Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015 (as amended in 2018) provides for the creation of commercial and commercial appellate divisions in High Courts and commercial courts at the district level to assist in addressing disputes in a timely manner. Moreover, the Delhi High Court, the Calcutta High Court, and the Madras High Court have established Intellectual Property Divisions to facilitate adjudication of IP cases. Designation of specialized tribunals with the appropriate knowledge and resources is critical for accurately adjudicating patent issues involving complex technologies. PhRMA and its members strongly encourage the Indian Government to establish an IP Division in the Bombay High Courts.

Compulsory Licensing

The grounds for issuing a CL in India under the Patents Act, 1970 are broad, vague and appear to include criteria that are not clearly related to legitimate health emergencies. While the Indian Government continues to take a more measured and cautious approach in responding to recent CL cases, the MoHFW continues to entertain potential recommendations to impose CLs on certain anti-cancer and rare disease medicines under the special provisions of Section 92 of India's Patents Act, 1970, which would cause further difficulty for patent owners to defend their patents. Moreover, some Indian pharmaceutical companies routinely initiate requests for voluntary licenses under Section 84(6)(iv) of the Patents Act as a precursor to seeking a CL, reducing CLs to a commercial tool rather than a measure of last resort. Internationally, in various multilateral forums, India has advocated for the broad adoption and implementation of measures to facilitate the routine use of CLs, contrary to the spirit of the TRIPS Agreement. A market with ongoing threats of CLs perpetuates an unreliable environment for patent protection and investment.

In addition, rules promulgated under Section 146 of the India Patents Act, 1970, required all patent holders to file an annual statement (i.e., Form 27) summarizing the extent to which the patented invention has been worked on a commercial scale in India. Also, Form 27 required the disclosure of commercially sensitive financial information and licensing particulars, and was the basis for local companies to seek CLs, which occurred in 2012.

The Patent (Amendment) Rules, 2024, significantly improve India's working statement practice by: (1) not requiring the disclosure of commercially sensitive information (e.g., prices, volume, etc.); (2) reducing annual Form 27 filing frequency to once every three years; and (3) explicitly providing that importation satisfies India's patent working requirement. However, concerns remain about how the licensing information disclosed in Form 27 filings will be utilized by Indian authorities and third parties.

We believe that resorting to CLs is not a sustainable or effective way to address health care needs. Voluntary arrangements independently undertaken by our member companies can better ensure that current and future patients have access to innovative medicines. Statements from the government incorrectly imply that CLs are widely used

by other governments, both developed and developing.[224] These are misunderstandings and do not justify widespread use of CLs. At a minimum, India should ensure that CLs are exercised with extreme caution and as a measure of last resort.

Administrative Burdens

PhRMA welcomes the Indian Government's ongoing work to address India's patent examination backlog including the commitment to reduce examination periods from up to seven years to 18 months from initial submission. Backlogs undermine incentives to innovate and hinder timely patient access to valuable new treatments and cures. Because the term of a patent begins on the date an application is first filed, unreasonable delays can directly reduce the value of granted patents and undermine investment in future research activity. For biopharmaceutical companies, patent examination backlogs can delay the introduction of new medicines in India. Generic manufacturers are also affected by patent examination backlogs. So long as a patent application is unreasonably delayed, generic manufacturers cannot assess whether they will have freedom to operate. That lack of certainty could discourage the launch of generic medicines or expose generic companies to damages once the patent is granted. In addition to increasing the number of patent examiners, it is equally important to assess administrative procedures that unduly extend patent examination timelines.

Section 8 of the Indian Patents Act sets forth requirements that have been interpreted in a manner that creates heightened and unduly burdensome procedures that mainly impact foreign patent applicants – those most likely to have patent applications pending in other jurisdictions. Section 8(1) requires patent applicants to notify the Controller and "keep the Controller informed in writing" of the "detailed particulars" of patent applications for the "same or substantially the same invention" filed outside of India. Section 8(2) requires a patent applicant in India to furnish details to the Indian Controller about the processing of those corresponding foreign patent applications if that information is requested. These additional patent application processing requirements have been interpreted in a manner that creates heightened and unduly burdensome patent application procedures that mainly impact foreign patent applicants – those most likely to have patent applications pending in other jurisdictions.

PhRMA welcomes the changes outlined in the Patents (Amendment) Rules, 2024, which mitigate some of the harmful impacts of the Section 8 filing requirements. For example, the changes make clear that patent examiners may leverage public databases to satisfy foreign application disclosure requirements, helping shift the burden from patent applicants. PhRMA recommends that the information being considered via the public databases be limited to information that is material to patentability and that penalties

[224] *See*, *e.g.*, Rao N, The Hill (op-ed), "India honors – not dishonors – patent laws," Aug. 14, 2013, available at http://thehill.com/blogs/congress-blog/campaign/316883-india-honors--not-dishonors--patent-laws (last visited Jan. 26, 2025). These misstatements of wide-spread use of CLs in the U.S. and the premise that CLs can resolve access problems in India have been refuted by OPPI and PhRMA.

under Section 8 be limited to deliberate failures to disclose information (which is consistent with current jurisprudence in India).

Regulatory Data Protection Failures

Contrary to its TRIPS Article 39.3 obligation, India fails to prevent unfair commercial use of the regulatory data submitted by an innovator in securing marketing approval in India or in a third country. Rather, when a pharmaceutical product has been previously approved by a Regulatory Authority in India or in another country, India requires only limited clinical data *in lieu* of requiring submission of the entire dossier by the applicant for review by India's regulatory authority. Moreover, in some instances when an applicant seeks approval for a generic or biosimilar product that has already been approved in other countries, Indian authorities waive the requirement to submit even this data.[225] In those circumstances, any subsequent approval of the drug granted to an entity who is not an innovator in India is based entirely on the prior approval granted to the innovator in a third country.

By linking approval in other countries that require the submission of confidential test and other data to its own drug approval process, India, in effect, uses those countries as its agents. Approval by the Indian regulatory authorities to third parties based on other-country approvals amounts to indirect and unfair reliance on the clinical trial and other test data generated and submitted by the innovators for such other-country approvals. This indirect reliance results in unfair commercial use, which is prohibited by TRIPS Article 39.3.

PhRMA and its member companies are committed to engaging with the Indian Government for the latter's consideration to provide for RDP in the Drugs, Medical Devices and Cosmetics Bill 2023, consistent with India's international commitments.

Market Access

Discriminatory and Nontransparent Government Pricing Policies

Despite decades of government price controls ostensibly seeking to improve patient access to medicines, just 16 percent of new medicines launched globally since 2014 have launched in India, with patients in India waiting an average of 40 months from global first launch for new medicines to become available.[226] Even basic medicines are not easily accessible. This is despite having thousands of biopharmaceutical manufacturers which operate in a very competitive environment with some of the lowest

[225] *See* Rules 75 and 80 of the MoHFW, "The New Drugs and Clinical Trials Rules, 2019," available at https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf (last visited Jan. 26, 2025).

[226] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

prices of medicines in the world.[227] Instead of resorting to these failed policies, India should focus on removing key barriers to patient access, including insufficient health care financing and infrastructure.

In 2014, an Inter-Ministerial Committee was constituted to suggest a methodology to be applied to the pricing of patented medicines in India.[228] Earlier, a DoP Committee Report on Price Negotiation for Patented Drugs (February 2013) recommended an international reference pricing scheme with a purchasing power parity adjustment for government procured patented medicines, with those patented medicines to be provided through health insurance. A final decision on the 2014 Inter-Ministerial Committee recommendations has yet to be made. However, PhRMA and its member companies are concerned that the 2013 proposals could be adopted, which would significantly reduce the benefits of patent protection, *de facto* discriminate against importers in order to pacify the domestic generic industry and create an unworkable government pricing framework and business environment for innovative pharmaceutical companies.

PhRMA and its member companies supported the DoP decision to amend Paragraph 32(i) of the DPCO allowing manufacturers and importers of patented medicines exemption from price controls for a period of five years from the commencement of marketing in India. PhRMA and its member companies have additionally requested that patented drugs be exempt from price controls until the expiry of the patent term. Further, Paragraph 32(iv), which was inserted to exempt medicines for treating orphan diseases, has not been implemented yet because the list of medicines for orphan diseases has not been released.

More broadly, PhRMA and its member companies are concerned about an evolving price control regime that is discriminatory, unpredictable and opaque. The DoP is considering several amendments to the DPCO that would expand price controls in India to all strengths and doses of a scheduled medicine, and introduce TMR to all non-scheduled medicines, which will operate in practice as another form of price controls.

PhRMA and its member companies generally supported the 2019 introduction of TMR as a more sensible approach to monitoring the price build-up by actors in the retail supply chain for non-scheduled products. Specifically, the government proposed regulating a retail ceiling price based on the price-to-stockist (PTS) plus a 30 percent margin. However, the PTS used by the government since 2021 was not the actual PTS (which is verifiable from government data sources), but rather a derived figure that includes products that do not have retail trade channels, including government supplies, free products and discounted products supplied through patient assistance programs.

[227] Analysis based on IMS MIDAS Data.

[228] Government of India Speed Post No. 31011/5/2009/PI-II(pt), Ministry of Chemicals & Fertilizers, DoP, Subject: Inter-Ministerial Committee on Prices of Patented Drugs, New Delhi, Feb. 17, 2014, available at https://pharmaceuticals.gov.in/sites/default/files/Inter-Ministerial%20Committee%20on%20Prices%20of%20Pateneted%20Drugs.pdf (last visited Jan. 26, 2025).

Inclusion of these non-retail products serves to bias downward the regulated retail ceiling price, penalizing PhRMA member companies for providing discounted products to improve patient affordability. In short, the current application of TMR is less about regulating excessive retail trade margins and more about imposing arbitrary price controls on non-scheduled innovative medicines. As a result, the retail ceiling prices set by the government under TMR are as much as 70 percent lower than the company's Maximum Retail Price and therefore significantly exceed the existing trade margins added by other actors in the supply chain. This is inconsistent with the mandate of DPCO and NPPP 2012, which envisaged only a price monitoring mechanism for non-scheduled products. These developments underscore how the broad authority granted to the NPPA (the drug pricing regulator) and the continued lack of transparency and predictability in NPPA decisions further inhibit investment in India.

The expansion of price controls to a broader scope of medicines will not substantially improve access to medicines in India, as the real barriers are insufficient health care financing, poor access to physicians and inadequate health care facilities.[229] For example, even therapies and vaccines offered free of charge often do not reach the patients who need these medicines.[230] A 2015 study by IMS titled "Analyzing the Impact of Price Controls on Access to Medicines" found that price controls are neither an effective nor a sustainable strategy for improving patient access. The study found that the primary beneficiaries of price controls have been high-income patients, rather than the intended low-income population.[231] A considerable body of evidence demonstrates that price controls contribute to lower investment in pharmaceutical research and development, ultimately harming patients who need improved therapies.[232] The Annual Economic Survey also clearly highlighted that price control of medicines has not improved access.

PhRMA and its member companies remain concerned that patented medicines are being included in the NLEM. Once medicines are included in the NLEM, they are subjected to direct price controls under the DPCO. NLEM 2022 includes four patented products. The Parliamentary Standing Committee on Health and Family Welfare recognized that patented products should be excluded from the NLEM and specifically recommended that: "There needs to be a predictable and transparent pricing regime in

[229] "A Study of Healthcare Accessibility," Dr. DY Patil Medical College, Pune, India, prepared for India Health Progress, Mar. 2011; Wagstaff, A, "Health System Innovation in India Part I: India's health system challenges," available at http://blogs.worldbank.org/developmenttalk/health-system-innovation-in-india-part-i-india-s-health-system-challenges (last visited Jan. 26, 2025).

[230] *See*, *e.g.*, Patra N, "'When Will They Ever Learn?': The Great Indian Experience of Universal Immunisation Programme," Dec. 2009, available at http://www.isid.ac.in/~pu/conference/dec_09_conf/Papers/NilanjanPatra.pdf (last visited Jan. 26, 2025).

[231] IMS, "Assessing the Impact of Price Control Measures on Access to Medicines in India," June 2015.

[232] U.S. Dep't of Commerce, Int'l Trade Admin., "Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation," Dec. 2004, available at https://web.archive.org/web/20190414170009/https://2016.trade.gov/td/health/DrugPricingStudy.pdf (last visited Jan. 26, 2025); Vernon J, "Drug Research and Price Controls," Regulation, Winter 2002-2003, available at https://www.cato.org/sites/cato.org/files/serials/files/regulation/2002/12/v25n4-7.pdf (last visited Jan. 26, 2025).

the country. Patented drugs should not be included under the NLEM as their price fixation will nullify the IPR so granted."[233] However there have been recent instances of price fixation for combination drugs, where one drug is near the end of its patent term. In May 2023 and August 2024, the NPPA applied a fixed price to combination drugs prior to the expiration of each drug's patents, encouraging patent infringement.

PhRMA and its member companies are committed to engaging with the Indian Government to discuss more pragmatic public policy approaches, including the development of government pricing and reimbursement mechanisms that provide patients with greater access to medicines, recognize innovation and encourage continued investment into unmet medical needs.

Discriminatory Government Procurement Policies

The Indian Government's Make in India policy has increasingly excluded or disadvantaged suppliers that do not manufacture in India from participating in tenders. On May 15, 2020, the General Financial Rules 161(iv) were amended to prohibit international tenders where the value of the goods to be procured is less than INR 2 billion. In September 2020, the Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry issued a revised Public Procurement Order that discriminates against non-local bidders (i.e., products with less than 20 percent local content) in all government tenders (except in permitted international tenders), although there are some exemptions to ensure operational continuity. The revised PPO also excludes bidders from countries that do not allow Indian bidders in their government procurements. Further, in December 2020, the DoP issued yet another restrictive order requiring a minimum 80 percent local content to qualify as a favored Class 1 local supplier and more than 50 percent local content to qualify as a Class 2 local supplier.[234] The revised PPO was partially modified in July 2024 to further tighten its scope and implementation. This current framework creates challenges for PhRMA member companies to continue supplying patented and proprietary medicines that are manufactured outside India to government procurers. Since November 2022, the government has provided exemptions from GTE requirements and PPO for specified patented drugs. Currently, this list includes 127 drugs, but there is no mechanism for innovative pharmaceutical companies to apply for new products to be included in the exemption list and to be eligible to participate in central government procurements. PhRMA and its member companies encourage the Indian Government to add patented therapies to this list on an automated biannual basis, along with reviews of the GTE exemption list.

[233] Para 5.17.2 of Parliamentary Standing Committee on Health & Family Welfare's 139th Report on "Cancer Care Plan & Management: Prevention, Diagnosis, Research & Affordability of Cancer Treatment" tabled before the Rajya Sabha on Sept. 12, 2022.

[234] Guidelines for implementing the provisions of Public Procurement (Preference to Make in India) Order (PPO), 2017 - revision, related to procurement of Goods & Services in Pharmaceutical Formulations Dec. 30, 2020, available at https://pharmaceuticals.gov.in/sites/default/files/PPO%20SIGNED%20DRUGS.pdf (last visited Jan. 26, 2025).

The Make in India Policy of the government has increasingly excluded suppliers that do not manufacture in India from participating in tenders and has facilitated the potential government purchase of patent-infringing products. This raises significant concerns about discrimination against imported products and patent holders, and that Indian patients will not have access to needed treatments.

High Tariffs and Taxes on Medicines

PhRMA member companies operating in India face high import duties for active ingredients and finished products. Though the basic import duties for pharmaceutical products average about 10 percent, due to the integrated GST imposed on imports, the effective taxes on imported medicines can exceed 20 percent and almost be as high as 28 percent with surcharges on these taxes included. Moreover, excessive duties on the reagents and equipment imported for use in research and development and manufacture of biotech products make biotech and pharmaceutical operations difficult to sustain. Compared to other Asian countries in similar stages of development, import duties in India are very high. And while certain essential and life-saving medicines may be granted exemptions from some of the taxes, even these are affected by the government's policy objective to promote domestic manufacturing. The Indian Government has phased out custom duty exemptions on more than 70 life-savings medicines, a trend that is likely to continue. For those medicines that get the benefit of exemptions, the eligibility criteria are vague and subject to constant revision and debate.

GST was implemented in July 2017 and, while it is expected to significantly reduce layers and complexity in the indirect tax system, it levies a 0 to 18 percent tax on medicines. Measures to exempt life-saving drugs from GST and customs duties should be expanded to all medicines.[235] In March 2021, the Indian Government launched the National Policy for Treatment of Rare Diseases (NPTRD). The policy highlights the need to increase the affordability of medicines for rare diseases. The Indian Government has already given exemption from Basic Customs Duty to such drugs when they are imported by the Centres of Excellence (CoEs) set up under the NPTRD. In addition, the Indian Government has also exempted rare disease medicines imported by an individual for personal use from customs duty.

However, there remain a large number of patients receiving treatments not covered under CoEs and whose drugs are subject to a customs duty of 10 percent, which creates a huge burden and adversely impacts access. Given the spirit of the NPTRD and the significant impact of rare diseases on child health, customs duty exemptions applicable to CoEs should be extended to all medical institutions and importers, including those in the private sector.

[235] Hindu Business Line, "GST: The right prescription," Aug. 5, 2016 (updated Jan. 17, 2018), available at http://www.thehindubusinessline.com/specials/pulse/gst-the-right-prescription/article8949378.ece (last visited Jan. 26, 2025).

Insufficient Financing and Low Access to Care

PhRMA's members are concerned about the general lack of access to health care in India. The Indian Government released the National Health Policy in March 2017,[236] which calls for greater access to health care for low-income patients, and progressively achieve Universal Health Coverage which eventually led to the launch of Ayushman Bharat (AB-PMJAY) scheme in February 2018. In September 2024, the government also extended health coverage under AB-PMJAY to all senior citizens aged 70 years and above irrespective of income. The National Health Policy denotes expanding comprehensive primary health care through health and wellness centers, including care for major non-communicable diseases (NCDs), mental health, geriatric health care, palliative care and rehabilitative care services. The policy also calls for increasing public health expenditure to 2.5 percent of GDP by 2025.

While these calls to action are laudable, India nevertheless has insufficient numbers of qualified health care personnel, inadequate and poorly equipped health care facilities, and most importantly lacks a comprehensive system of health care financing that would pool financial risk through insurance and help to share the cost burdens. The doctor-population ratio is 1:836 in the country assuming 80 percent availability of registered allopathic doctors.[237] This is significantly lower than the norms set by the World Health Organization (WHO).[238] This shortfall is exacerbated by limited government investment and low allocation for health care in the national budget.

In addition to the above, many lifesaving oncology drugs and treatments (including innovative medicines) are not included under Ayushman Bharat PMJAY despite being priced within the annual cover of Rs. 5 lakh (~$6k). India should look at global examples of higher threshold for HTA and modifiers being applied to oncology and severe diseases, such that the treatments are made available as widely as possible.

Despite the encouraging and ambitious goals in the new National Health Policy and the MoHFW's goal of increasing health spending as a percentage of GDP to 2.5 percent by 2025, government spending on health care was 2.1 percent of GDP in FY23.[239] However, this figure includes spending in water, sanitation and hygiene, and disaster management.[240] Without continued increased resources (both in terms of government spending and through reducing barriers for commercial health insurance)

[236] *See* National Health Policy, available at https://mohfw.gov.in/sites/default/files/9147562941489753121.pdf (last visited Jan. 26, 2025).

[237] MoHFW, "Enhancement of Healthcare Workforce," Mar. 25, 2022, available at https://pib.gov.in/PressReleasePage.aspx?PRID=1809812 (last visited Jan. 26, 2025).

[238] Report of the 15th Finance Commission for 2021-2016 (Oct. 2020).

[239] India Ministry of Finance, "Economic Survey 2022-2023," at p. 148, available at https://www.indiabudget.gov.in/economicsurvey/ (last visited Jan. 26, 2025).

[240] The Wire, "What Modi Govt's Shift in Health Spending – From Infrastructure to Insurance – Shows," Apr. 18, 2024 available at https://thewire.in/health/modi-health-insurance-infrastructure (last visited Jan. 26, 2025).

and a full implementation of the reform, high out-of-pocket spending on health care and pressure on the cost of medicines will persist.

Unpredictable Environment for Clinical Research and Drug Approval

India has many of the components of an effective regulatory system, such as institutional capacity across central and state regulators and a robust technical framework. India also has several components to support a broader ecosystem for clinical research and drug development, such as the presence of a highly skilled workforce of qualified scientists, hundreds of medical colleges and a large and diverse patient pool.

We welcome the fact that the MoHFW and CDSCO have undertaken regulatory reforms, including adoption of the NDCT, with the goal of strengthening the regulatory regime and reinvigorating clinical research. Strong, transparent and predictable regulatory frameworks that are aligned to international best practices are essential for protecting patients as well as for promoting globally competitive innovative and generic pharmaceutical industries. We also welcome the Government of India's decision to overhaul the drug regulations with a new draft Drugs, Medical Devices and Cosmetics Bill, 2023 (draft DMDC Bill) and we look forward to its adoption. Promisingly, on August 7, 2024, CDSCO announced that local clinical trials may be waived for certain categories of drugs if those drugs have been approved in Australia, Canada, the European Union, Japan, United States or United Kingdom. That said, the process for seeking waivers remains ill-defined and related provisions in the NDCT allowing for deemed approval of clinical trials applications appears to be discriminatory, as it does not apply to drugs whose research and development was conducted outside of India.

However, as noted above, the NDCT includes significant ambiguities, which creates uncertainty in the regulatory process for clinical trials and threaten the overall clinical research environment in India. These issues must be addressed in order to increase the availability of new treatments and vaccines for Indian patients.

Further, certain challenges that existed in the Drugs Rules 1945, continue to exist in the NDCT. Rule 41 of the NDCT, which describes attributable causes of injury for clinical trials participants, is overly broad and lacks a legally or scientifically sound process for determining causality of injury. Definitions for "trial related injury" and "standard of care," remain uncertain. Furthermore, many provisions in the NDCT are ambiguous and highly subjective. For example, the NDCT do not designate an appellate authority for hearing appeals arising from SEC recommendations. Further, with no guidelines/SOPs for the SECs, reviewing the applications for clinical trials and new drug approval heightens the existing subjectivity. Furthermore, requests for review of SEC decisions tend to be reviewed by the same SEC panel against the principles of *nemo judex in causa sua* and therefore in breach of principles of natural justice. In addition, the provision allowing for approval of clinical trial applications is discriminatory in nature due to significant differences in approval timelines for molecules discovered in India (30 days) compared to drugs for which research and development were conducted outside of India (90 days).

Further, timelines for individual steps within the approval process are arbitrary and undefined, leading to delays and unpredictability.

As a result, adoption of the NDCT leaves great uncertainty relating to future costs and liabilities associated with conducting clinical trials in India, resulting in many sponsors not launching clinical trials in India until these uncertainties have been resolved. Research shows that if India were to address outstanding concerns, India could see an increase in the number of new clinical trials per year to above 800, adding over $600 million in economic gains.[241] Greater clarity and predictability are needed for administrative procedures and regulations *qua* drug registration applications, drug labelling standards and drug review standards and procedures in order to make the latest research products available in India. The draft DMDC Bill and the proposed Rules to be made thereunder, must provide for streamlined, predictable and transparent regulatory processes aligned with global standards.

Further, PhRMA members are concerned that the MoHFW has notified draft amendments to the NDCT vide GSR 354(E) dated June 5, 2020, proposing to permit import and manufacture of unapproved candidates that are under Phase-III clinical trial in the country, or in any other country, for compassionate use for diagnosis, treatment, mitigation or prevention of any life-threatening disease or disease causing serious permanent disability or disease requiring therapy for an unmet medical need. Critically, these proposed amendments would allow for such import and manufacture not only by the sponsor of the unapproved drug under the treatment protocol, but also by third parties. PhRMA members believe that such a proposal will not only discourage research and development that is critical for addressing unmet medical needs but would also put patient safety at risk and compromise clinical trial data.

Furthermore, the SECs that review and examine clinical trials and new drug applications do not have SOPs or guidelines and, therefore, the recommendations made by them are often subjective and arbitrary. These issues perpetuate a burdensome environment for clinical research and new drug approvals that undermine the availability of new treatments and vaccines for Indian patients.

Counterfeit Medicines

Illicit trade in counterfeit pharmaceutical products, poses significant global public health risks. Counterfeit medicines are not inspected by relevant regulatory authorities and are subject to production under unsafe manufacturing practices. Further, counterfeit medicines have not undergone the rigorous protocols used to ensure quality, efficacy and safety, and contribute to drug and multi-drug resistance, intensifying the challenge of effectively fighting disease. Exacerbated by the rapid growth of online sales of counterfeit

[241] Pugatch Consilium, "Quantifying the Economic Gains of Strengthening India's Clinical Research Policy Environment," Sept. 2015, available at http://www.pugatch-consilium.com/reports/Quantifying%20the%20Economic%20Gains%20from%20Strengthening%20the%20Clinical%20Research%20Policy%20Environment%20in%20India.pdf (last visited Jan. 26, 2025).

medicines, studies indicate that more than half the counterfeit medicines seized in recent years originated in India.[242] Moreover, Indian authorities have seized large quantities of counterfeit COVID-19 related medical products ranging from oxygen to antivirals.[243] Indeed, in August 2021, the WHO issued an alert related to counterfeit COVID-19 vaccines present in multiple countries including India.[244] The Indian Government should work with relevant stakeholders to address the growing illicit trade in counterfeit and unregulated medicines which is putting lives at risk.

[242] *See*, *e.g.*, OECD, "Covid-19 crisis underscores need to address trade in fake pharmaceuticals, say OECD & EUIPO" (Apr. 21, 2020), available at https://web-archive.oecd.org/2020-04-21/551275-covid-19-crisis-underscores-need-to-address-trade-in-fake-pharmaceuticals-say-oecd-and-euipo.htm (last visited Jan. 26, 2025).

[243] *See*, *e.g.*, Aljazeera, "Fake medicines, recycled PPE: Scammers worsen India COVID misery", June 4, 2021, available at https://www.aljazeera.com/news/2021/6/4/fake-medicines-recycled-ppe-scammers-worsen-india-covid-misery (last visited Jan. 26, 2025).

[244] WHO, "Medical Product Alert N°5/2021: Falsified COVISHIELD vaccine (Update)," Aug. 31, 2021, available at https://www.who.int/news/item/31-08-2021-medical-product-alert-n-5-2021-falsified-covishield-vaccine (last visited Jan. 26, 2025).

INDONESIA

PhRMA members have identified the following market access barriers and intellectual property (IP) challenges in Indonesia:

Key Issues of Concern:

- **Forced localization requirements**: The 2023 Omnibus Health Law emphasized prioritization for use of locally-made products, reinforcing forced localization requirements in Decree 1010 and further restricting access to new medicines for Indonesian patients. The Indonesian government also demonstrates preferential treatment for medicines with higher local content for purposes of public procurement.

- **Cost-focused formulary decisions**: While Indonesia is to be commended for developing guidelines and an online portal for listing new medicines on the Indonesian National Formulary, actual listing decisions appear to be primarily based on price and the overall National Health Insurance (JKN) budget. Only two percent of new medicines launched globally since 2014 are reimbursed by the JKN, with patients in Indonesia waiting an average of 71 months after global first launch for JKN reimbursement.[245] Consistent with Indonesian Government guidelines, listing decisions should better reflect all evidence submitted, including scientific data demonstrating the product's safety and efficacy. To this end, PhRMA member companies encourage the Indonesian Government to take a more holistic approach to health technology assessment (HTA) for procuring medicines, including during the much-welcomed initiative from the Ministry of Health (MoH) to revise the HTA guidelines.

- **Mandatory halal certification**: In November 2020, the Indonesian Parliament partly revised the 2014 Halal Products Law through the Omnibus Job Creation Law and in February 2021 implemented the Omnibus provisions through Regulation No 39/2021. The revisions streamline the certification process; however, they do not address key concerns regarding the Halal labelling policy. The Halal Law has broad application to all consumables, including biopharmaceuticals, and requires that producers label their products as "halal" if certified, or otherwise cite non-halal substances. PhRMA's member companies recognize and support religious and cultural sensitivities but are concerned that this mandatory labeling requirement, including audits and certification for COVID-19 vaccines and therapeutics, could have unexpected negative implications on patient health and broader public health priorities.

- **Compulsory licensing**: In 2021, Indonesia issued CLs for antiviral COVID-19 therapeutics. Moreover, Indonesia issued a CL for one of these antiviral

[245] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

therapeutics despite the rights holder entering into a voluntary licensing agreement with generic manufacturers to supply the Indonesian market. Also, in 2020, Indonesia issued Presidential Regulation No. 77/2020 on government use of CLs. The regulation was published in final form without meaningful stakeholder consultation. The regulation broadly enables government agencies to request CLs for pharmaceutical products to address emergency needs in the public interest. If a CL is granted and the government is unable to implement the patent, it may appoint a third party to do so. Despite efforts in 2019 to address and revise existing CL regulations to align more appropriately with global norms and best practices, this new regulation and the process by which it was developed and issued, along with the CLs for the antiviral COVID-19 therapeutics, send a troubling signal to innovators.

- **Restrictive patentability criteria**: 2016 amendments to the Patent Law preclude patents on new uses (indications) and establish an additional patentability criterion of "increased meaningful benefit" for certain forms of innovation, such as new salts or new dosage forms. These restrictions are overly broad and will undermine support for important innovations and appear to conflict with existing international obligations by imposing additional or heightened patentability criteria that discriminate against particular classes of technology. The Patent Office has been implementing technical guidelines that remove this impermissible restriction, but the underlying provisions in the 2016 Patent Law remain unchanged. In addition, the 2016 Patent Law still imposes new patent disclosure requirements regarding the source and origin of genetic resources. Such requirements introduce uncertainties into the patent system that inhibit innovation in relevant technologies and undermine the potential of benefit-sharing.

For these reasons, PhRMA requests that Indonesia remain on the **Priority Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access

Forced Localization Requirements

Decree 1010/MENKES/PER/XI/2008 ("Decree 1010") prevents multinational research-based biopharmaceutical companies from obtaining marketing authorization for their products if not meeting certain localization criteria. Under Decree 1010, only companies registered as "local pharmaceutical industry" are granted marketing approval. Products of multinational research-based pharmaceutical companies and other foreign companies, except for on-patent products, are barred from the Indonesian market unless: (1) a local manufacturing facility is established; or (2) sensitive registration dossier containing IP is transferred to another pharmaceutical firm with local manufacturing facilities in Indonesia after five years in the market. The first condition is not possible for many PhRMA member companies, given the structure of their global pharmaceutical supply chains. The second condition poses a serious threat to IP protection and patient

safety. In a recent development, we understand that the Indonesian Government plans to revoke Decree 1010 and replace it with a new “Omnibus Ministerial Regulation”, but these provisions will remain unchanged.

PhRMA member companies are also concerned with escalating local content requirements, first established as a result of Presidential Instruction No. 16/2016, as a means to accelerate the development of the biopharmaceutical and medical device industry in Indonesia. Under the regulation, a local content requirement calculation was created to be used as a criterion for government procurement of biopharmaceutical and medical device products. Finally, this trend was further bolstered by Presidential Decree 2/2022, which prioritizes for government procurement products with domestically produced raw materials, specifically those with a local content threshold of at least 25 percent. It is critical that these requirements are not applied in a manner that restricts patient access to innovative medicines in Indonesia and that greater recognition is given to biopharmaceutical innovators for their contribution in bringing innovative therapies to Indonesia. Prioritization to use locally-made products was also emphasized in the recently promulgated 2023 Omnibus Health Law. The Ministry has been working on a draft revision for the calculation of local content requirements and industry has started engagements, however the revision draft has not yet been circulated.

Within the 2023 Omnibus Health Law, Articles 327 and 328 explicitly dictate that the government and healthcare facilities – both public and private – must prioritize the procurement and utilization of domestically produced and sourced pharmaceuticals and medical devices, if the raw materials can be produced locally. Recently, draft regulations to implement the Omnibus Health Law stipulate that hospitals and government procurement must prioritize locally produced products with at least 52 percent of local content for therapeutics and at least 70 percent of local content for vaccines. This further escalates the aggressive import substitution policy pursued in recent years, which has centered around the imposition of local content requirements as well as the “freezing” of imported products from the public procurement catalogue. Further, key changes in the e-catalogue, which guides the national drug formulary, aim to replace imported products with domestically produced alternatives to meet localization requirements.

Finally, Indonesia demonstrates preferential treatment toward locally manufactured or packaged pharmaceutical products, including vaccines. The Indonesian government issued ministerial regulations for the procurement of vaccines that only allow locally produced vaccines for government immunization programs, unless a local alternative is not available.

PhRMA member companies are concerned about Indonesia’s localization requirements and the lasting harm to market access, IP protection and patient health if left unresolved. PhRMA members encourage the Indonesian government to institute policies that enable a pro-innovation environment and increase access to new medicines for Indonesian patients.

Cost Focused Formulary Decisions

Indonesia's national formulary (FORNAS) serves as a basis for pharmaceutical reimbursement and public-sector procurement. While Indonesia should be commended for developing guidelines and an online portal (eFORNAS) for listing new medicines on FORNAS, actual listing decisions appear to be primarily based on price and the overall JKN budget. Patients in Indonesia have very limited access to innovative medicines compared to other countries: only nine percent of new medicines launched globally since 2012 have launched in Indonesia compared to an average of 38 percent across all G20 countries.[246] Further, only two percent of new medicines launched globally since 2012 are publicly reimbursed by the National Health Insurance (JKN), with patients waiting an average of 71 months for JKN reimbursement.[247]

PhRMA encourages FORNAS to consider broader health and global economic evidence for listing decisions that improve health outcomes for Indonesian patients, rather than budget impact analysis. Although products in FORNAS, can be added or removed annually, formal updates to the FORNAS only take place every two years. Recent moves to delist and freeze products based on arbitrary standards for cost-effectiveness and localization requirements have raised additional concerns. In addition, the newly issued 2023 Omnibus Health Law gives the government authority to regulate and control the price of drugs and medical devices in the context of securing their accessibility for public health efforts.

During the most recent FORNAS meeting, only three out of 117 new drugs were approved to be included on the national formulary, 56 new drugs were rejected and the remaining 58 were recommended for a HTA before a decision on their inclusion in the formulary was determined.

PhRMA encourages FORNAS to be transparent in its HTA assessment and processes, allowing for more robust dialogue with the innovative pharmaceutical industry and encourage the Indonesian Government to take a more holistic approach for procuring medicines and establish a transparent and credible decision-making process.

Presidential Regulation No. 12/2021 and its implementing regulations simplify the listing process of pharmaceutical products in the government procurement catalogue, allowing for the inclusion of any FORNAS-listed drug priced below the ceilings set by the MoH. On the recent update, the government procurement catalogue adopted multi provider and single price system. Previously, the system was single provider with single price. However, the single provider system did not run as expected due to some cases where the supplier was not able to produce as committed in the contract. Therefore, the Ministry of Health changed the mechanism to avoid shortages and reduced patient access.

[246] PhRMA, "Global Access to New Medicines Report," 2023, available at https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report (last visited Jan. 26, 2025).
[247] *Id*.

PhRMA and its member companies remain concerned about government price controls on drugs and medical devices through the implementation of the Omnibus Health Law and its implementing regulations. Adequate valuation of medical products and drugs must account for treatment outcomes, patient experience, quality, safety and efficacy, rather than solely budget impacts. Finally, PhRMA encourages the government to issue technical guidelines to ensure catalogue-listed products meet certain standards (i.e., product quality and supplier capacity) and await further clarity on the pricing of medicines.

Mandatory Halal Certification

The 2020 Omnibus Job Creation Law partly amended Indonesia's 2014 Halal Product Assurance Law, which mandates Halal certification and labeling for food and beverages, medicines, cosmetics, chemical products, biological products and genetically-engineered products. The Law establishes a new Halal certification authority called the Halal Product Assurance Organizing Agency (BPJPH) and requires pharmaceutical firms to hire a Halal specialist and disclose sensitive product formulas to the new Halal authority. The revisions to the Halal Law also streamline the process of halal certification, simplify the certification renewal process and provide clearer timelines.

In February 2021, the government issued Regulation No 39/2021 to implement Halal-related provisions of the Omnibus Job Creation Law, replacing Regulation No 31/2019, which implemented the 2014 Halal Law. The 2021 Regulation stipulates a phased implementation of the law. Manufacturers will be required to provide halal certification for over-the-counter drugs by October 2029 and for prescription drugs by October 2034. The Presidential Regulation on Halal Certification for Biological Products and Medical Devices was issued in 2023, mandating Halal certification for biological products and vaccines by 2039.

The new regulation better aligns labeling requirements for non-Halal drugs and biological products through packaging differentiation. BPOM is currently in the process of adjusting its existing labeling requirements to reflect this change and PhRMA welcomes clear guidance to the pharmaceutical industry for compliance. Furthermore, BPJPH acknowledged the possibility of a mutual recognition agreement with foreign Halal agencies giving the possibility that imported products that already have Halal certification be registered as Halal in Indonesia. Challenges in assessment standard harmonization remain between Indonesia and many other countries.

PhRMA member companies urge the Indonesian Government to ensure that the stipulations and requirements for Halal certification take into consideration and align with the biopharmaceutical industry's rigorous standards and practices already in place that ensure safety, efficacy and good manufacturing processes. Further, while PhRMA's member companies recognize and support the religious and cultural sensitivities of all Indonesians, it is critical that these regulations do not hinder patient access to the medicines they need.

Counterfeit Medicines

Although PhRMA's member companies welcome Indonesia's ongoing efforts to promote the use of safe medicines, there is an urgent need to expand national enforcement efforts. Increasing and enforcing the penalties for criminals caught manufacturing, supplying, or selling counterfeit pharmaceuticals as well as unsafe medicines will greatly assist Indonesia's efforts to reduce the harmful impact of counterfeit medicines. Greater collaboration and government initiatives, such as a nationwide campaign and devoted budget to combat counterfeit products, should be intensified to ensure the health and safety of Indonesian patients.

As such, PhRMA's member companies support Indonesia's ongoing legislative agenda to create a stronger drug administrator and drug supervision process to combat offline and online channels of counterfeits product.

Intellectual Property Protection

Compulsory Licensing

The 2024 Amended Patent Law does not address significant compulsory licensing concerns. For example, Indonesia maintains vague and ambiguous compulsory licensing authorities enabling the government to consider the "public interest" or if a patented product is deemed "expensive" to advance CL decisions. In addition, the Amended Patent Law does not provide necessary due process and maintains provisions that discourage voluntary licensing, including requirements to disclose private licensing agreements.

Presidential Regulation No. 77/2020, issued in 2021 facilitating government use of CLs to address emergency needs in the public interest, further compromises Indonesia's patent regime. The regulation was published without meaningful stakeholder consultation. In addition, while the government must notify the patent holder when a CL request is accepted for review, there is no formal procedure allowing patent holders to dispute claims in a request or recommend alternatives. PhRMA and its members are concerned that the regulation could be used by the Indonesian government without due process or engagement with the patent holder.

The issue with CLs in Indonesia is not theoretical. In 2021, Indonesia issued CLs for antiviral COVID-19 therapeutics. For one of these antivirals, Indonesia issued a CL despite existing voluntary licensing agreements in place with generic manufacturers supplying the drugs to Indonesia. Before resorting to compulsory or government-use licenses, Indonesia should first consider the unprecedented industry collaboration and access strategies, including voluntary licensing, deployed by pharmaceutical companies to address emergencies like the COVID-19 pandemic. CLs will not necessarily speed access to complex set of treatments and vaccines that are currently being tested and developed and should only be used in accordance with international rules and as a measure of last resort. Further, such actions are likely to undercut Indonesia's effort to attract foreign investment and align public policy reforms with global best practices.

Indonesia should make clear that CLs will be used only in exceptional circumstances and assessed on a patent-by-patent basis with full consideration of the particular circumstances in each case. CLs should only be used in extraordinary circumstances as a last resort rather than standard government practice. As a general matter, CLs are not a sustainable or effective way to address health care needs. Voluntary arrangements independently undertaken by member companies better ensure that current and future patients have access to innovative medicines.

Restrictive Patentability Criteria

In a positive development, the Amended Patent Law appears to eliminate provisions in the prior law that precluded patents on new uses (indications) and established an additional patentability criterion of "increased meaningful benefit" for certain forms of innovation, such as new salts or new dosage forms. These types of restrictions undermine support for important innovations and are contrary to existing international obligations by imposing additional or heightened patentability criteria in a manner that discriminates against particular classes of technology.

To bring valuable new medicines to patients, biopharmaceutical innovators must be able to secure patents on *all* inventions that are new, involve an inventive step and are capable of industrial application. Restrictions that narrow patentability prevent innovators from building on prior knowledge to develop valuable new and improved treatments that can improve health outcomes and/or reduce costs by making it easier for patients to take medicines and improving patient adherence to prescribed therapies. Industry will be closely monitoring implementation of the Amended Patent Law to ensure that patents are now available in Indonesia for these important innovations.

Burdensome and Vague Disclosure Obligations

Members of the World Intellectual Property Organization (WIPO) recently adopted the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (Treaty). In those economies that accede to the Treaty, patent applicants will be required to disclose if their inventions are based on genetic resources and/or associated traditional knowledge.

Indonesia's Patent Law requires the disclosure of the origin of genetic resources or traditional knowledge related to inventions and provides that a patent may be revoked for failure to disclose that origin if the patent holder has demonstrated "bad faith." PhRMA and its members believe that mandatory disclosure requirements introduce uncertainties into the patent system that inhibit innovation in relevant technologies and undermine the potential of benefit-sharing. As Indonesia implements the Amended Patent Law, it will be critical for Indonesia to ensure that, absent fraudulent intent, patents may not be denied, revoked, rendered unenforceable or otherwise limited for failure to satisfy the disclosure requirement.

JAPAN

PhRMA members have identified the following market access barriers and intellectual property (IP) challenges in Japan:

Key Issues of Concern:

- **Annual price cuts to patented medicines**: In December 2020, the Japanese Government announced that it would move from the prevailing system of biennial price revisions to an annual system in which prices are cut in both full price revision years and in off-years. Effective FY2021, all medicines with more than a certain percentage difference (*yakka-sa*) between the National Health Insurance (NHI) reimbursement price and the surveyed wholesaler price to providers received annual price cuts. While this threshold has varied over time, the scope of products subject to annual price cuts has exceeded any policy option put forward by the Ministry of Health, Labor and Welfare (MHLW) for discussion at the Central Social Insurance Medical Council (Chuikyo) in 2020 and was never shared with the industry prior to its formal announcement. For 2025, the Japanese Government will apply price cuts to 43 percent of patented medicines and break precedent by implementing rules, such as deferred price cuts when products lose Price Maintenance Premium (PMP) eligibility, that are not based on actual market prices and that have never been applied in an off-year drug price revision. The reduction in biopharmaceutical expenditure generated by price cuts in FY2025 is estimated to be 247 billion yen. Both the increased frequency of price cuts to patented medicines and the negative impacts from the other pricing measures noted below severely undervalues U.S. innovation and makes Japan an outlier among leading economies. PhRMA requests that annual price revisions be reconsidered and proposes transitioning to a new system that allows prices to be maintained during the patent period.

- **Degradation of the Price Maintenance Premium (PMP)**: The PMP was introduced in 2010 as a supportive measure for innovation that protected patented medicines from automatic, biennial price cuts by deferring those price cuts until the product no longer qualified for the PMP. PhRMA remains concerned by the dramatic reduction in the number of patented medicines that are now recognized as “innovative” for the purpose of qualifying for the PMP. In 2018, Japan introduced product eligibility criteria that are non-science based and unique in the world, as well as new company eligibility criteria that discriminate against smaller companies and foreign companies. In December 2023, Japan announced that it would abolish the company eligibility criteria and expand the product eligibility criteria to cover products with pediatric indications or dosages, as well as products eligible for a new early introduction premium. However, PMP eligibility will be restricted to products with a smaller-than-average percentage difference (*yakka-sa*) between the NHI reimbursement price and the surveyed wholesaler price to providers. While some of these changes may increase the number of products that can maintain their prices during the patent period, significant further revisions to the

PMP and a structural reform of the market-price-based revision method are urgently needed.

- **Overuse of re-pricing rules for patented medicines:** Over the past few years, the Japanese Government has applied new or more draconian re-pricing rules. In 2016, the huge seller re-pricing rule was introduced; since 2018, some re-pricing rules have been applied on a quarterly basis instead of a biennial basis; and in 2020, a special rule for indication change re-pricing was introduced. Such frequent application and tightening of the re-pricing rules significantly undervalues innovation, reduces the predictability of drug prices and disincentivizes investment in R&D for additional indications. PhRMA believes that these complex re-pricing rules need to be restructured (or abolished, in the case of the spillover rule) by examining their requirements and impacts.

- **Use of health technology assessment (HTA) to devalue innovation**: MHLW implemented a new HTA system in April 2019 that remains severely inconsistent with international norms, focusing solely on cost-effectiveness thresholds to cut prices of innovative medicines and ignoring many product benefits to patients and the health care system. By August 2024, 27 of 36 innovative medicines that completed assessments have had their prices cut. The HTA system has been developed with few meaningful opportunities for the innovative biopharmaceutical industry and other stakeholders to provide input. PhRMA and other industry associations subsequently provided views on operational challenges during Chuikyo hearings, but most challenges have not been adequately addressed. PhRMA remains concerned about possible expansion of a special price adjustment scheme for a single product (Leqembi®) to other products such that the resulting price of a new product would be set paradoxically lower than the price of a clinically inferior comparator. PhRMA also remains concerned about current proposals to expand the HTA system to reimbursement listing decisions, which would delay market access contrary to previous U.S.-Japan trade understandings and significantly undervalue U.S. innovation. There remains a strong need to enhance the transparency and scientific basis of how the HTA system operates and makes decisions.

- **Lack of transparency and predictability in government decision-making**: As the Japanese Government developed detailed plans to carry out the drug pricing reforms over the past several years, there have been few formal attempts by the decision-making bodies to seek input from stakeholders, including the innovative biopharmaceutical industry. For example, despite the key policy issues being debated by the government since 2017 (including the FY2025 drug price revision), the Japanese Government has not once released the proposed new rules for public comment. In addition, the industry has been invited to testify before the Chuikyo on limited occasions and the time allotted for testimony has typically been rigidly limited to a matter of minutes. Frequently, no government proposal is put forward in advance of the Chuikyo meeting on which the industry could comment. Except for the formal hearings at which industry is invited to testify,

industry representatives are only able to attend Chuikyo meetings as observers. Even after rules are announced, PhRMA member companies are often uncertain about how they will be applied or experience their capricious application. Moving forward, PhRMA and its member companies request more regular and meaningful opportunities to provide input regarding the development of further reforms to Japan's pricing and reimbursement rules.

- **Regulatory policies**: To ensure that Japanese patients have prompt access to the latest medicines, more flexible approaches are needed in approval and regulatory process that allow for simultaneous global development. This includes (1) acceptance of a pooled region approach for clinical data as well as Japanese sample size allotments for multi-regional clinical trials as described in the ICH E17 (MRCT) guideline, (2) increase in the number of drugs designated and approved early under the *Sakigake* designation, the conditional early approval systems and the orphan designation, and (3) the development of a new innovative expedited approval system that focuses on the clinical benefit-risk assessment of a new drug itself. PhRMA encourages the harmonization of compendials, Chemistry, Manufacturing and Controls (CMC) data requirements, and the Risk Management System with the United States and European Union.

- **Vaccines and prophylaxis measures**: In order to ensure that Japanese citizens have access to the world's most innovative preventive technologies, Japan needs to execute the National Vaccine Plan and to develop a system that provides for permanent and full funding of all recommended vaccines and other preventive medicines such as pre-and post-exposure prophylaxis for infectious diseases, predictability in the evaluation and adoption of new vaccines and other preventive medicines into the recommended (i.e., funded) schedule, and a data-driven science-based process to determine the benefits of vaccines and other preventive medicines and to manage adverse events.

- **Patent term restoration (PTR)**: PhRMA members appreciate Japan's PTR laws, as they provide term extensions for subsequent marketing approvals for additional indications or medical uses, or modifications of previously approved products. The Japanese law acknowledges the value that additional approvals can provide to patients. However, the laws as currently interpreted by the Japanese Patent Office (JPO) often result in extensions for subsequent marketing approvals which are shorter in term than the extensions for the original approval and can thus act as a disincentive to conduct research on additional medical uses and indications, including new formulations for an approved product.

- **Effective patent enforcement**: Actions by the MHLW to approve generic versions of an innovative product during ongoing litigation raises concerns for industry as to Japan's commitment to effectively enforce patents. While injunctive relief is typically available in Japan, such relief can take at least several months to secure, thereby frustrating the ability of the innovator to seek an injunction before potentially infringing products are allowed to enter the market. MHLW

commissioned a study group in 2024 to identify reforms to Japan's early patent dispute resolution practice. PhRMA encourages MHLW to provide industry meaningful engagement opportunities as possible reform activities take shape.

For these reasons, PhRMA requests that Japan be placed on the **Priority Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access

Drug pricing policies strongly influence biopharmaceutical R&D investment in Japan and patient access to innovative medicines. PhRMA supports a system in which new innovative medicines receive a reimbursed price at launch that appropriately recognizes value, maintain prices during the patent period and significantly reduce prices at loss of exclusivity. However, when policies disincentivize investment and undermine early access – as Japan has pursued in recent years – it leads to fewer clinical trials, fewer drugs being brought to the market and fewer patients able to access life-saving medicines. Overall, while 84 percent of new medicines launched globally since 2014 are available in the United States, just 47 percent are available in Japan's public national health insurance, with Japanese patients waiting an average of 15 months from global first launch for the fewer medicines that become available.[248]

Annual Price Cuts to Patented Medicines

In December 2020, the Japanese Government announced that it would move from the prevailing system of biennial price revisions to an annual system in which prices are cut in both full price revision years and in off-years. Effective FY2021, all medicines with more than a certain percentage difference (yakka-sa) between the National Health Insurance (NHI) reimbursement price and the surveyed wholesaler price to providers received annual price cuts. For 2025, the Japanese Government will apply price cuts to 43 percent of patented medicines and break precedent by implementing rules, such as deferred price cuts when products lose Price Maintenance Premium (PMP) eligibility, that are not based on actual market prices and that have never been applied in an off-year drug price revision. The reduction in biopharmaceutical expenditure generated by price cuts in FY2025 is estimated to be 247 billion yen. Both the increased frequency of price cuts to patented medicines and the negative impacts from the other pricing measures noted below severely undervalues U.S. innovation and makes Japan an outlier among leading economies. PhRMA requests that annual price revisions be reconsidered and proposes transitioning to a new system that allows prices to be maintained during the patent period.

The scope of products subject to annual price cuts has exceeded any policy option put forward by MHLW for discussion at the Chuikyo in 2020 and was never shared with

[248] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

the industry or other stakeholders prior to its formal announcement. The scope of the revision also marked a major departure from previous Japanese Government policy decisions that have been publicly announced and codified in various documents, including the 2016 four-ministers agreement which stated that only products with a "large" *yakka-sa* would be subject to the off-year price revision as opposed to a *yakka-sa* threshold capturing most products, including about half of patented medicines in recent years. Finally, the decision ignored prior discussions at the Chuikyo, during which several health care stakeholder groups (e.g., physicians and pharmacists) opposed implementing the price revision on a broad range of products. PhRMA requests that annual price revisions be reconsidered during future policy reforms. Moreover, the current market-price-based revision system, which is unique to Japan, results in a delay or a loss in launching innovative medicines in Japan. To address this, PhRMA proposes transitioning to a new system that allows prices to be maintained during the patent term.

Degradation of the Price Maintenance Premium

The introduction of the PMP in 2010 as a two-year pilot project (followed by its renewal in 2012, 2014 and 2016), has been a critical factor in promoting innovation in Japan, eliminating the drug lag, ensuring that Japanese patients have timely access to innovative medicines and more appropriately valuing innovative products. This system has demonstrably led to increased R&D and applications and approvals for new drugs and indications, even though the net benefit of the price maintenance premium has been somewhat reduced by the 80 percent ceiling on the premium under certain circumstances and the continued use of the market expansion and other re-pricing rules. Investment in biopharmaceutical innovation is a long-term endeavor, such that any unpredictability in the PMP could lead to slower development or launch of new medicines.

However, under the government pricing reforms implemented in April 2018, products eligible to receive the PMP were restricted to those that meet the product eligibility criteria that MHLW newly established. PhRMA believes the product criteria are too restrictive as a definition of innovation and, as a result, several globally leading U.S. products have been deemed non-innovative and stripped of their PMP eligibility, clearly demonstrating that the system fails to appropriately value U.S. innovation. Due to these policy changes, approximately 50 percent of patented medicines no longer qualify for the PMP. In addition to the product eligibility changes, companies with PMP-eligible products were ranked and sorted into three tiers based on multiple indicators of R&D activity in Japan. The number of companies eligible for Tier 1 status was limited to 25 percent but not exceeding 30 percent, even if companies have the same rank. All PMP-eligible products marketed by Tier 1 companies were awarded the full amount of the PMP. Eligible products marketed by Tier 2 or Tier 3 companies were awarded 90 percent or 80 percent of the PMP, respectively. PhRMA has opposed the ranking of companies as the criteria inappropriately favor large companies and specific elements are inherently biased toward domestic companies.

While the Japanese Government undertook a review of the new PMP rules during the 2020 and 2022 drug pricing reform, only minor changes were made despite industry

proposals to address concerns. During this period, the drug lag and loss reemerged in Japan. The MHLW Expert Panel underscored the need to reform the pricing system for patented products to solve this problem. The 2023 *Honebuto* also stated that the government should promote further drug pricing measures to appropriately recognize innovation.

In response, the Japanese Government decided to change the PMP rules in December 2023 for the FY2024 drug pricing reform. Company tiers were abolished, allowing all companies that undertook domestic development in the past five years to maintain prices of their PMP-eligible products. In addition, the product criteria were expanded to cover products with pediatric indications or dosages, as well as products eligible for a new early introduction premium. However, PMP eligibility will be restricted to products with a smaller-than-average percentage difference (*yakka-sa*) between the NHI reimbursement price and the surveyed wholesaler price to providers. While some of these changes represent an important first step to eliminate drug lag and loss, it remains unclear how these changes will impact the number of products that can maintain their prices during the patent period. PhRMA believes that significant further revisions to the PMP and a structural reform of the market-price-based revision method are urgently needed to allow innovative products to maintain their prices during the patent term.

Overuse of Re-pricing Rules for Patented Medicines

Over the past several years, the Japanese Government has applied new or strengthened re-pricing rules for patented medicines. In 2016, the huge seller re-pricing rule was introduced; since 2018, some re-pricing rules have been applied on a quarterly basis instead of a biennial basis; and in 2020, a special rule for indication change re-pricing was introduced. Such frequent application and tightening of the re-pricing rules significantly undervalues innovation, reduces the predictability of drug prices and disincentivizes investment in R&D for additional indications. PhRMA believes that these complex re-pricing rules need to be restructured by examining their requirements and impacts. In particular, PhRMA has requested that the spillover rule be abolished, which applies price cuts to pharmacologically similar products of other products that have undergone significant market expansion. In response to the MHLW Expert Panel proposal to review the rule, MHLW decided to exclude two therapeutic areas from the spillover rule from quarterly repricing in FY2024. PhRMA requests that further improvements in the repricing rules be made to increase the predictability of investments in Japan.

Use of Health Technology Assessment to Devalue Innovation

PhRMA supports the use of sound evidence to guide decisions about allocating health care resources. However, deficient HTA processes can run counter to their key objectives and risk denying or delaying patients' appropriate access to medical technologies, inefficiently allocating resources, constraining clinical freedom and harming innovation through unreasonable cost-containment methods.

In April 2019, the Japanese Government implemented a new HTA system after cutting the prices of several leading innovative medicines that were subject to an ongoing cost-effectiveness assessment pilot program in 2018. The HTA system is severely inconsistent with international norms in both methods and process. With respect to methods, the system is solely focused on cutting prices based on a poorly justified incremental cost-effectiveness threshold that ignores the benefits that innovative medicines bring to Japanese patients and the health care system. Moreover, the process does not include input from multiple stakeholders, including patients. By primarily serving to reduce the price premiums granted at launch for innovativeness and clinical benefit, the adopted approach perversely acts to remove the incentives for medicines that deliver better patient outcomes. By August 2024, 27 of 36 innovative medicines that completed assessments have had their prices cut. There remains a strong need to enhance the transparency of the process, foster science-based discussions on product value and develop sound guidelines that can serve as a basis for analysis.

Furthermore, the system was developed without meaningful opportunities for interested stakeholders, including the innovative industry, to provide input. PhRMA has provided views on the operational challenges of the HTA system during Chuikyo hearings, but most challenges have not yet been adequately addressed by the Japanese Government. More recently, in considering the cost-effectiveness analysis of Leqembi®, MHLW suddenly issued a detailed proposal and conducted discussions over a short period without any meaningful opportunity for industry associations to express their opinions. PhRMA testified that expanding the price adjustment range beyond the premium would result in a price cut to the main part of the NHI price and would be contrary to how the NHI drug pricing system values innovation. Based on the cost-effectiveness analysis, the resulting price of a new drug would be set paradoxically lower than the price of a clinically inferior comparator drug. Nonetheless, the Japanese Government introduced a special price adjustment scheme for Leqembi®, which may go beyond the scope of the usefulness premium. Although the case of Leqembi® may be exceptional, PhRMA remains concerned that this decision may establish a precedent for more general application in the future and requests that it remain limited to this special case.

PhRMA also remains concerned about current proposals to expand the HTA system to reimbursement listing decisions. Such a broader policy would create further market access barriers for U.S. biopharmaceutical products and almost certainly delay patient access to innovative medicines and worsen the drug lag and drug loss, contrary to previous U.S.-Japan trade understandings. There remains a strong need to enhance the transparency and scientific basis of how the HTA system operates and makes decisions to ensure continued patient access to innovations.

Lack of Transparency and Predictability in Government Decision-Making

As the Japanese Government developed detailed plans to carry out the drug pricing reform initiative over the past several years, there have been few formal attempts by the decision-making bodies to seek input from stakeholders, including the innovative biopharmaceutical industry. For example, despite the key policy issues being debated by

the government since 2017, the Japanese Government has not once released the proposed new rules for public comment. In addition, the industry has been invited to testify before the Chuikyo on limited occasions, the time allotted for testimony has typically been rigidly limited to a matter of minutes and there has frequently been no government policy proposal put forward in advance on which the industry could comment. Except for the formal hearings at which industry is invited to testify, industry representatives are only able to attend Chuikyo meetings as observers.

In addition to the failure to provide adequate meaningful opportunities for interested stakeholders, including PhRMA member companies, to provide input into the development of these policies, the Japanese Government has also failed to publish clear guidelines on how some of the new policies will be interpreted and implemented. Even after rules are announced, PhRMA member companies experience sudden, *ad-hoc* and non-transparent application of rules to their products and increasingly in a way that is contrary to their stated intent. This lack of transparency and frequent changes to the rules for setting prices at reimbursement listing, re-pricing of existing products and other key policies have made the Japanese market highly unpredictable and lacking in procedural fairness.

Moving forward, PhRMA and its member companies request that Japan implement more transparent decision-making processes that include regular and meaningful opportunities to provide input regarding the development of further reforms to Japan's pricing and reimbursement rules. It is necessary to create an environment that enables industry to be involved in the drug pricing policy process, such as Chuikyo, as one of the decision makers on an equal footing with other stakeholders. We urge the U.S. Government to engage with their counterparts in the Japanese Government in an early timeframe to ensure that Japan provides the appropriate transparency and due process – including the opportunity for meaningful consultations with industry and other interested stakeholders – before Japan finalizes proposed laws, regulations and procedures concerning how medicines are priced and reimbursed.

Other Government Pricing Policies of Concern

The industry also recommends that other unfair or unreasonable price-setting rules in Japan's drug pricing and reimbursement system be corrected as follows:

1. *Reward Additional Innovative Indications*: MHLW should consider not only improving the re-pricing rules but also the mechanism by which the reward for additional innovative indications can be reflected in the drug price. Under current rules, when pediatric or orphan indications are added, a corrective premium can be granted at the time of re-pricing. A similar approach should be adopted when adding other highly innovative indications. Although this issue was raised during the FY2024 drug pricing system reform, MHLW decided to postpone a decision until the FY2026 system reform, noting the need to examine the scope of additional indications subject to this scheme. PhRMA encourages MHLW to reach a decision on this issue during the FY2026 drug pricing reform.

2. *Grant Price Premiums in Line with Product Value*: Under the existing pricing method for new drugs, certain price premiums may be granted when a drug shows greater innovation or usefulness than its comparator or existing treatments. Unfortunately, most new drugs eligible for a price premium receive no, or relatively low, premiums. Under the FY2024 drug pricing system reform, five new criteria for innovation and usefulness premiums were added, and MHLW stated that it had begun making more flexible judgements when calculating premiums, allowing for a higher percentage within the existing range. However, it remains unclear how long such flexibility will continue. Further reforms to secure appropriate premiums are needed, such as setting the magnitude of the premium in line with the degree of improvement in product effectiveness. In addition, for the FY2026 drug pricing system reform, new pricing methods to appropriately recognize the value of new modalities (e.g., regenerative medicines) should be discussed and implemented.

3. *Expand Scope of Admissible Evidence for Innovation and Usefulness Premiums:* Another challenge is that even if evidence of usefulness is available, a premium is often not awarded when the supporting evidence is not evaluated in the Pharmaceuticals and Medical Devices Agency (PMDA) review report. PhRMA believes that even if such evidence is not included in the PMDA review report, it should be accepted for determining whether a premium is applied as long as the evidence can withstand scientific and objective evaluation. MHLW has claimed that it lacks capacity to reference evidence other than the PMDA review report within the 60-90-day timeframe for price-listing after regulatory approval. MHLW should continue discussions with industry on what evidence can be referenced and how product value can be reflected in NHI prices.

<u>Pharmaceutical Regulatory Reform and Related Issues</u>

1. Simultaneous Global Development of Drugs

PhRMA welcomes the government's continued support of simultaneous global development and efforts to promote multiregional clinical trials (MRCT), which will expedite the availability of lifesaving and life-enhancing drugs to patients. PhRMA also welcomes discussions by the Study Group on Pharmaceutical Regulations to Strengthen Drug Discovery and Development Capabilities and Ensure Stable Supplies in 2023, which resulted in notifications to realize recommendations, including a rule change to not mandate an additional Phase 1 study in Japanese patients before Japan participates in an MRCT, unless it is deemed necessary. PhRMA also welcomes the enactment of the revised Pharmaceuticals and Medical Devices Law in May 2022 to facilitate regulatory approval requirements for therapeutic drugs and vaccines in certain emergency situations. Other efforts such as pediatric development and orphan drug designations are expected to expedite access to innovative medicines in Japan. PhRMA recommends further progress in this area, including:

- Increase global and regional regulatory harmonization efforts, particularly more flexible regulatory requirements and processes to allow for simultaneous global

development. These efforts include the acceptance of a pooled region approach for clinical data and sample size allotments as described in the ICH E17 (MRCT) guideline, and working collaboratively with academia, patient advocacy groups and industry.

- Harmonization of the following CMC data requirements: (1) globally aligned science- and risk-based approach for developing commercial products; (2) flexibility of requirements for CMC data; and (3) harmonization of compendial.

2. Improved Efficiencies at PMDA

PhRMA appreciates the significant efforts made by PMDA to meet its review performance goals for standard and priority files, as well as its efforts to meet the demands for consultations in an expeditious manner. PhRMA values its participation in PMDA Working Groups on consultations and review practices. PhRMA looks forward to continuing its active participation in these groups and hopes that its participation will lead to the development and implementation of concrete process improvements that will aid PMDA in continuing to meet its performance goals.

3. Revision of Post-Approval Change Process and Reduction in Review Times

PhRMA appreciates the opportunity to discuss Japan's post-approval changes to manufacturing and control processes and will continue to provide constructive recommendations based on global best practices to align the Japanese system with those used by other major regulatory agencies. PhRMA further appreciates the efforts to reduce the review times of partial change applications and encourages PMDA to include biologic and new modality products, especially those arising from recombinant technology, in those review targets.

4. Risk Management System

Reform of the pharmacovigilance system (which has many Japan-specific requirements), including risk management assessments, is an important undertaking. PhRMA has supported the government's preparation and implementation of its Risk Management System (i.e., Risk Management Plan (RMP)), which went into effect in April 2013. Global standardization of a pharmacovigilance system and maintenance of benefit-risk balance based on the RMP in an effective and efficient manner are critical. PhRMA looks forward to continuing to engage collaboratively with academia and regulatory authorities on the implementation of this concept and process to collect and provide better post-marketing information for use in medical settings.

5. AMED – the Japan Agency for Medical Research and Development

PhRMA continues to support AMED, created in April 2015, to enhance translational research, support drug development from discovery through clinical development to launch and coordinate the government's budget on health care research

and development from different ministries. PhRMA emphasizes the need to ensure that AMED programs are open to all biopharmaceutical companies, whether Japan- or foreign-based, and more efforts are needed to enhance drug discovery and translational research capabilities in Japan.

6. Expedited Approval Systems

PhRMA welcomes the implementation of the *Sakigake* program and the conditional early approval system to encourage the early evaluation and approval of important new medicines. To avoid worsening drug lag and drug loss in Japan, PhRMA encourages the government to adopt a flexible approach to the application acceptance requirements to increase the number of medicines designated and approved early under the *Sakigake* designation, the conditional early approval systems and the orphan designation. Currently, the number of medicines qualifying for the *Sakigake* designation and the conditional early approval system remains very low. For example, in 2023, 44 products in the United States received Breakthrough Therapy designation, 18 products in the European Union received PRIME designations, while only four products in Japan received *Sakigake* designations. Therefore, PhRMA encourages the government to amend the *Sakigake* program or to develop a new expedited approval system focusing solely on the safety and efficacy of a new medicine rather than other factors such as the order of development and launch in the world. The new system should also allow flexibility in regulatory submission documents. This will ensure Japan's expedited approval pathways enable earlier access similar to systems in the United States and the European Union. The number, timing and granting of priority review of the orphan designation also remain concerns, although improvements are expected based on recent discussions by the Study Group. Finally, PhRMA appreciates the enactment of the new emergency approval system that is not contingent on prior approvals in other countries as such a system will help improved pandemic preparedness.

Preventive Health Care and Vaccines

Prevention plays a critical role in protecting a population's health and well-being. However, more effective and efficient awareness initiatives aimed at the public should be undertaken. Vaccines are particularly important in reducing disease burden and medical expenses, as well as improving the quality of life. The past several years have seen some important changes, including a revision in 2013 of the Immunization Act, implementation of a National Vaccine Plan and adoption of six vaccines into the National Immunization Program (NIP). Although the Japanese Government intended to revise the Act in 2021, the COVID-19 pandemic has delayed this timeline, which remains unclear. In addition, other preventive medicines for pre-exposure prophylaxis and post-exposure prophylaxis for infectious diseases have not been fully licensed and reimbursed in Japan despite solid evidence of clinical and health system benefits.

The following issues require attention:

1. Increasing priority given to support investments in “Made in Japan” products

COVID-19 has revealed weaknesses in the Japanese system and the government’s *Strategy for the Strengthening of Vaccine Development and Manufacturing* adopted in June 2021 as well as recent government discussions point to a growing trend by the Japanese Government to support investments in “Made in Japan” products. The rapid development and deployment of COVID-19 vaccines was made possible because of global partnerships and consistent investments in research and development, manufacturing, and marketing. For Japan to promptly develop vaccines that can be used widely, it must participate in international networks for vaccine development and manufacturing through an open global ecosystem instead of relying solely on the research and development and manufacturing of domestic companies and academia.

2. Lack of predictability and timeliness in the NIP decision-making process at MHLW

The current recommendation process is significantly nontransparent as it relates to the evaluation and adoption of new vaccines into the NIP. As a result, vaccine manufacturers lack crucial information as to what data are necessary to receive a national recommendation and when the data should be presented. Furthermore, the vaccination decision-making process is unclear. While a Vaccination Policy Committee under MHLW exists, the timeline of a new vaccine’s evaluation, the criteria by which it is evaluated and the committee’s ability to change vaccination policy, as well as how the necessary funding is secured, are not transparent and lack predictability. For example, in October 2019, MHLW’s Vaccination Policy Committee made the decision to include rotavirus vaccines into the NIP from October 2020. This decision came eight years after regulatory approval in Japan. It is essential that decisions related to vaccine access and equity are timely and based on science. This is especially important for inclusion in the NIP and in any evaluation of adverse events.

3. Lack of international regulatory harmonization

Japan used to have a “vaccine gap” with fewer nationally recommended vaccines due to the lack of harmonization between domestic and international regulations. In March 2024, the *Guideline for Clinical Trials of Preventive Vaccines* and *Guideline for Nonclinical Trials of Preventive Vaccines* were amended to reflect the latest international regulations and scientific knowledge. In particular, the *Guideline for Nonclinical Trials of Preventive Vaccines* is nearly harmonized with World Health Organization guidance. Also, in 2018, the government created a forum for regulatory authorities and industry to discuss challenges in vaccine development and national vaccine inspection. This forum led to the removal of the abnormal toxicity denial test and the harmonization of quality standards, helping to close the development gap for single component vaccines. However, harmonization of regulatory and quality standards for combination vaccines remains a significant problem, raising continued challenges for the introduction of combination vaccines widely used in NIP overseas but not in Japan.

4. Lack of broad recognition from Japanese citizens of the value of vaccines

Although the revision of the Preventive Vaccination Law provided for full national funding for most recommended vaccines, the changes did not apply to several approved vaccines. The value of vaccines should be recognized by a funding system and NIP process that incentivize manufacturers to develop and bring new vaccines to Japan as quickly as possible, together with a nationwide program to educate citizens about the importance of vaccinations and address vaccine hesitancy. While the COVID-19 pandemic has raised public interest in vaccines and disease prevention, definitive action by the Japanese Government is needed to educate citizens about the importance of life-course immunization, including "voluntary vaccines" that are not in the scope of the NIP.

Intellectual Property

Patent Term Restoration

Japan's PTR system permits term extensions for subsequent approvals for a product, such as for a new use of a previously approved product. PhRMA members appreciate Japan's PTR laws, as they acknowledge the value that additional approvals can provide to patients. However, PhRMA urges the JPO to review its practices in granting PTR for subsequent approvals, to take into account the full regulatory review period in determining the length of any extensions. In particular, the current JPO practice, which provides an extension period based only on what is considered "necessary testing" for the subsequent approval, often results in extension periods for subsequent approvals that are shorter than the extension period of the first approval. As a result, the current practice can act as a disincentive to conduct research on additional medical uses and indications, including new formulations for an approved product.

Effective Patent Enforcement

PhRMA's members value the highly predictable and reliable IP protections provided in Japan. Predictable and reliable IP protections are particularly important to our sector given the significant resources required to develop innovative medicines, as well as the inherently risky nature of developing new medicines which must not only be developed but also must be shown to be safe and effective for treatment of a particular disease or condition. Less than 12 percent of all potential new drugs entering clinical trials result in an approved medicine and, in most cases, new products in our sector fail to deliver returns that meet or exceed investment.[249]

However, actions by the MHLW have undermined the predictability of Japanese IP protections. Specifically, while MHLW appropriately takes the position that it should not arbitrate patent disputes, it essentially did so in 2020 when unilaterally determining that it

[249] Research!America, "U.S. Investments in Medical and Health Research and Development, 2016-2020," 2022, available at https://www.researchamerica.org/wp-content/uploads/2022/09/ResearchAmerica-Investment-Report.Final_.January-2022-1.pdf (last visited Jan. 26, 2025).

was appropriate to approve multiple generic versions of an innovative product even though the JPO had upheld some claims of a patent directed to the innovative product. In other words, MHLW took it upon itself to interpret whether the upheld patent claims covered the innovative product, without involving the market authorization holder of the innovative product in the process. In 2023, MHLW has both approved a generic version for an indication even though that indication in the innovative product was still subject to patent protection and approved another generic drug even during the restored patent term of the reference product. Further, once the MHLW has approved these generic versions, those products are eligible to be added to the National Health Insurance price list, thereby enabling potentially infringing products to enter the market and potentially terminating the Price Maintenance Premium for the originator product, resulting in price cuts. While injunctive relief is typically available in Japan, such relief can take at least several months to secure, thereby frustrating the ability of the innovator to seek an injunction before potentially infringing products were allowed to enter the market, and the removal of a generic product already on the market can cause significant confusion and disruptions among wholesalers, providers and patients.

As a result, the manufacturers of each of the approved generics have been put in the position of having to decide whether to launch at risk despite the ongoing litigation. Indeed, in at least one recent case, the manufacturer of a prematurely approved generic version had to withdraw and discontinue supply of their drug as a result of injunctive relief granted to the innovator, resulting in confusion among healthcare professionals and patients. In short, this situation creates significant uncertainty for innovators and generic manufacturers alike, and ultimately disrupts patient access to a steady drug supply. It is exactly this uncertainty that well-functioning and effective patent enforcement systems are designed to avoid.

In 2024, MHLW commissioned a study group to review the scope of patents subject to the patent enforcement system and identify reforms which would facilitate accurate and expeditious resolution of patent infringement disputes.[250] PhRMA encourages further industry engagement to discuss potential reforms to Japan's patent enforcement system – including reforms which would encourage early judicial resolution of patent disputes for small molecule and biologic products identified by innovative manufacturers and follow-on companies.

Finally, PhRMA strongly requests that MHLW respect its 2009 guidance, *Nikacho-tsuchi,* regarding enforcement of innovators' patents, including compound and use patents, for their full term, including all granted PTR. The economic and political impact of potentially losing up to five years of patent life on many or most pharmaceutical products would be enormous. Not only would this represent a severe financial loss for PhRMA members in Japan but could radically change the financial outlook for future investment in Japan.

[250] PHARMA JAPAN, "MHLW Mulls System to Seek Expert Input for Patent Linkage," 2024, available at https://pj.jiho.jp/article/251400 (last visited Jan. 26, 2025).

KOREA

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in Korea:

Key Issues of Concern:

- **Impermissible government pricing and reimbursement policies**: On multiple levels, Korea's pricing policies contravene its KORUS commitments and negatively impact the rights of U.S. innovators. Korea's Health Insurance Review and Assessment Service (HIRA) often disregards evidence of clinical benefit and values innovative medicines using an unreasonably low and outdated cost-effectiveness threshold that has declined in real terms over time. Rather than updating this threshold and adopting more appropriate assessment methods, HIRA announced in September 2021 that it would instead use "past assessment results," thereby continuing the use of outdated thresholds and limiting transparency and predictability in the assessment process. For medicines not subject to the cost-effectiveness threshold, HIRA expanded the number of countries from seven to eight that it could use to recommend the lowest international price. Following HIRA's review and recommendations, the National Health Insurance Service (NHIS) can also require additional concessions (e.g., risk-sharing agreements) as a condition of NHIS reimbursement and impose excessive and repeated price cuts even if HIRA has already deemed these medicines to be cost-effective. As a result, Korea's government-set prices are among the lowest in the OECD. Combined, these price controls constitute a failure to "appropriately recognize the value of the patented pharmaceutical product," in violation of KORUS Article 5.2(b) and deprive Korean patients of access to innovative pharmaceutical treatments.

- **Lack of transparency, predictability and due process**: Compounding these challenges, Korea also does not provide meaningful transparency and due process for companies that apply for reimbursement, contrary to Korea's commitments under KORUS Article 5.3. Applicants are often not provided with a satisfactorily informative written basis for evaluations and decisions by HIRA subcommittees and Korea has never honored its commitment in KORUS Article 5.3(5)(e) and the side letter thereto, to make available an effective independent review mechanism relating to medicine reimbursement.

- **Discriminatory Innovative Pharmaceutical Company (IPC) accreditation**: The Ministry of Health and Welfare (MoHW) designates certain companies as IPCs, which receive tax credits, R&D support and more favorable drug pricing. However, the current accreditation criteria lack transparency and discriminate against U.S. and other foreign innovators by requiring domestic investments to prove "innovativeness." As of January 2025, only four of 49 designated IPCs are non-Korean biopharmaceutical companies. Recently, MoHW indicated plans to revamp

certification standards of IPC in 2025. PhRMA is concerned that this policy violates national treatment obligations and the spirit of KORUS Article 5.1.

- **Issues with patent term extension (PTE)**: While Korea has implemented PTE, there are three significant issues. First, the PTE calculation should include all relevant essential clinical trials used for the approval of the Korean product, including international clinical trials that are submitted as a part of the Korean dossier for approval of the product. Failure to do so has a discriminatory effect on companies outside Korea that conduct necessary trials, on which the Korean MoHW relies in approving the drug, outside of Korea. Second, there is a lack of due process in the PTE procedures. If the Patent Office determines a certain duration of PTE that is less than the full amount originally requested by the patentee and the patentee challenges that determination and subsequently loses the challenge, no PTE is granted; even the duration previously determined by the Patent Office is lost. This all-or-nothing approach significantly undermines a patentee's right to appeal, effectively deterring appeals of erroneous calculations, and undermines the patentee's rights. Third, the scope of PTE in Korea is unduly narrow and inconsistent with the legislative intent and international practice it was modeled on. The effective patent scope during PTE in Korea is restricted to claims necessary to "working of the patented invention of a product whose approval was the basis for PTE," and its "specific use." The recently passed amendments to Korea's PTE mechanism fail to address these longstanding, fundamental issues with Korea's approach to PTE, and instead appear to exacerbate existing challenges, tipping the balance further against innovators.

- **Inadequate damages for patent infringement**: A Supreme Court decision has undermined patent enforcement in Korea and the ability of innovators to be awarded appropriate damages in the event that a patent-infringing generic launches on the market. When a generic product enters the Korean market, the price of the innovator product is automatically reduced. In November 2020, the Korean Supreme Court held that generic companies were not liable for damages caused by a mandatory price reduction to a patented product even if the patent was upheld and the generic company entered the market illegally, forcing the price cut in question. As a result, damages for infringement of biopharmaceutical patents in Korea are neither adequate to serve as a deterrent to further infringements, nor sufficient to cover the innovators losses, contrary to Korea's international commitments. Further, amendments to the NHIA went into effect on November 20, 2023, that allow MoHW to seek damages if an innovator is ultimately unsuccessful in defending its patents, or, conversely, for the innovator to seek compensation if the generic prematurely launches on the market, thereby triggering automatic drug price cuts. Industry is concerned that these revisions to the NHIA could make it harder to secure stays from the courts during the patent litigation and that damages will still be insufficient to compensate the patent holder for its losses.

- **Patent enforcement concerns**: While Korea has implemented a patent linkage mechanism pursuant to its KORUS commitment, certain key issues of concern

remain. These issues include the discretion afforded to the Ministry of Food and Drug Safety (MFDS) as to whether to list a patent in the Green List or to permit a change to the patent listing and the limited period of only nine months for a sales stay. In addition, if an innovator elects not to seek a stay of a second (or subsequent) generic/biosimilar, any stay granted against the first generic/ biosimilar application is cancelled. Moreover, preliminary injunctions take several months to be granted, thereby frustrating the ability of innovators to prevent irreparable damages in the event potentially infringing products enter the market.

For these reasons, PhRMA requests that Korea remain on the **Priority Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access

Impermissible Government Pricing and Reimbursement Policies

Since the implementation of a positive reimbursement list system in 2007, new prices of innovative medicines are determined based primarily on cost reduction rather than a holistic assessment of value. Multiple pricing regulations and volume caps are layered to set artificially low prices for innovative medicines, which is inconsistent with Korea's international obligations and results in reduced access to innovative medicines for Korean patients and doctors. Eighty-four percent of new medicines launched globally since 2014 are available in the United States compared to just 19 percent in Korea's National Health Insurance Service (NHIS), with Korean patients waiting an average of 40 months from global first launch for the fewer medicines that eventually are reimbursed by the NHIS.[251] Moreover, only 8.5 percent of total pharmaceutical expenditures by the NHIS, which covers 97 percent of the population, is for new medicines.[252]

Korea's Drug Reimbursement Evaluation Committee (DREC) operating under HIRA assesses the cost-effectiveness of innovative medicines using an unreasonably low and outdated threshold on how much can be paid for health gains, with few products exempted. This incremental cost per QALY threshold was set based on Korean GDP per capita in 2007 and has not been increased for most innovative medicines even though Korean GDP per capita is now (as of 2023) more than 90 percent higher.[253]

The challenges that this cost-effectiveness threshold present to biopharmaceutical innovators and Korean patients were raised during the 2020 National Assembly Audit, which resulted in a request to HIRA to review the threshold. Unfortunately, HIRA rejected the National Assembly request and further announced in September 2021 that it had removed references to Korean GDP per capita in the relevant regulations and instead

[251] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[252] *Id*. Korea National Assembly Forum Report, "NHI Expenditure Status on Medication" Oct. 4, 2023.

[253] The World Bank, GDP per capita local currency units data series. Sept. 2024.

would rely on “past assessment results.” Apparently, HIRA would prefer to avoid tying the threshold to current Korean GDP per capita, but it will continue to use very low and outdated thresholds and limit transparency and predictability in the assessment process. In addition, for medicines not subject to the cost-effectiveness threshold, HIRA expanded the number of countries from seven to eight that it can use to recommend the lowest international price. However, PhRMA is encouraged by progress made by HIRA following industry-wide engagement efforts on predictability, specifically on disclosed incremental cost-effectiveness ratio (ICER) values used from the 2007-2021 cost-effectiveness evaluations. However, HIRA’s continued use of very low and outdated ICER thresholds fails to appropriately recognize the value of innovative medicines.

Manufacturers are often required to make repeated price concessions as they move through the many DREC subcommittees before the final reimbursement recommendation, despite the ostensibly different roles and responsibilities of each subcommittee. For example, the oncology subcommittee tends to review materials that should be reviewed instead by the pharmacoeconomic subcommittee or the budget assessment subcommittee and rejects reimbursement despite proven clinical benefit. Other price concessions may be required that further disincentivize innovation, such as a dose-pricing formula that requires price cuts when a medicine developed for a pediatric indication uses a lower dose than that for adults. Even when a price is recommended following the cost-effectiveness evaluation, the Korean Government tends to impose additional risk sharing agreements in the form of expenditure caps or excessive rebates as a condition of reimbursement.

Following DREC review and recommendation of a maximum reimbursement price, the NHIS conducts a price negotiation with the manufacturer. During negotiations, the price for a new innovative medicine recommended by the cost-effectiveness evaluation tends to be lowered based on the prices of off-patent and generic comparators, as well as the prices in other countries. The MoHW has the ultimate authority for approving all pricing and reimbursement decisions.

Over the last decade, the Korean Government has used excessive and repetitive measures to further reduce prices of innovative medicines, such as Actual Transaction Pricing (ATP) investigations and price cuts associated with volume and new indication expansions. If the reimbursement scope is expanded or claim amounts increased, then prices can be significantly reduced through various mechanisms during the period of patent protection. For example, NHIS implements mandatory volume-based price cuts whenever an innovative medicine exceeds by 30 percent the sales volume originally negotiated for the introductory year. As a result, there is a very high likelihood of subsequent price cuts. Greater flexibility is needed to establish reasonable volume targets beyond the introductory year. In addition, starting in 2026, MoHW plans to incrementally increase the cap on price cuts from 10 to 15 percent in price volume-based agreements.

NHIS can also require risk-sharing agreements (RSAs) as a condition of reimbursement that are designed to force additional concessions from manufacturers of innovative medicines. Recently, there has been a tendency to require additional patient

level clinical performance based RSAs or conditional real-world data generation RSA schemes for medicines that the government deems to be priced too high. RSAs are renewed every five years based on a cost-effectiveness re-evaluation that creates additional administrative burdens and price erosion of reimbursed products. While industry supports some forms of voluntary RSAs, these payment mechanisms will only be helpful if they facilitate greater flexibility on pricing and patient access and are coupled with broader reforms that allow for appropriate recognition of the value of patented medicines. Additionally, HIRA has proposed implementing a new system of international reference pricing for medicines that is applied after loss of exclusivity; this will lead not only to lower price for older medicines, but also lower prices for new medicines because HIRA often uses generic prices when calculating reference prices for new medicines.

Combined, Korea's pricing policies negatively impact the rights of U.S. innovators and constitute a failure to "appropriately recognize the value of the patented pharmaceutical product," in violation of KORUS Article 5.2(b).

Moreover, Korea's pricing and reimbursement regime goes far beyond a "limited exception" to the patentee's exclusive rights and thus is inconsistent with KORUS Article 18.8(3) and Korea's broader obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS Article 28 provides that a patent "shall confer" on its owner the exclusive rights to prevent third parties without the owner's consent from "the acts of: making, using, offering for sale, selling, or importing for these purposes that product."[254] In turn, TRIPS Article 30 permits WTO members to grant only "limited" exceptions to these exclusive rights, provided that such exceptions do not conflict with the "normal exploitation" of the patent and do not prejudice the legitimate interests of the patent owner.[255] The *Canada – Pharmaceutical Patents* panel appropriately recognized that the "normal exploitation" of a patent includes the realization of anticipated "economic returns" during a defined period of exclusivity "as an inducement to innovation."[256] This TRIPS jurisprudence supports a parallel reading of KORUS Article 18.8(3).

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[254] TRIPS Article 28.

[255] *Id.* Article 30.

[256] WTO, Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS/114/R, ¶¶ 7.54-55 (adopted Mar. 17, 2000), available at https://www.wto.org/english/tratop_e/dispu_e/7428d.pdf (last visited Jan. 26, 2025). Similarly, the TRIPS Agreement negotiating history indicates that the "rights conferred" by a patent within the meaning of TRIPS Article 28 include the right to sell pharmaceutical products at prices that would permit recoupment of investments and provide an incentive to develop innovative products. In a 1987 statement, the United States set forth this view, stating that "price control" was not a legitimate reason to deny intellectual property protection or to "impose conditions that preclude reasonable compensation for use of an invention or creation." Statement by the United States at Meeting of 25 March 1987, MTN.GNG/NG11/W/2 (Apr. 3, 1987), at 3. As the United States expressed at that time, "[s]uch policies interfere with obtaining and maintaining intellectual property rights and thus reinforce the direct distortion of trade that results from such policies." *Id.* Others involved in the TRIPS negotiations made similar statements. At a September 1989 meeting, a participant discussed providing patentees "the right to exclude others from making, using or selling the patent or invention for a specified time" and asserted that "[t]hese rights were necessary to provide patentees with the necessary economic incentive

Under terms of a premium pricing policy for global innovative drugs approved in June 2017, Korea impermissibly provided reimbursement price preferences and other advantages to products developed by local companies. These policies discriminated against U.S. and other foreign-based innovative biopharmaceutical companies and were the subject of renegotiated KORUS commitments agreed to in 2018. Following this agreement, HIRA revised the premium pricing policy for global innovative drugs effective from January 2019. However, the new criteria are so strict and unworkable that it is highly unlikely that any innovative medicine would be eligible for premium prices. While it was hoped that Korea would use this opportunity to demonstrate its broader pledge to apply fair and reasonable rules and appropriately value innovative medicines, Korea has implemented this commitment in a manner that eviscerates the ability of companies to qualify for premium pricing and is contrary to the spirit of the commitment it made to the U.S. Government.

Lack of Transparency, Predictability and Due Process

Since 2010, MoHW has repeatedly changed its pharmaceutical pricing and reimbursement policies without considering the long-term implications for innovation and market predictability, resulting in an uncertain business environment for innovative pharmaceutical companies in a manner that is inconsistent with Korea's transparency and due process obligations under KORUS Article 5.3. This was exemplified by HIRA's recent proposal to expand the reference basket of countries. That proposal, which was issued on November 21, 2022, provided a mere 20 days for comments (far shorter than the 60-day period provided for in Article 5.3.3(b) of KORUS).[257]

Korea also does not provide meaningful transparency and due process for companies that apply for reimbursement. The evaluation criteria lack precision and the various subcommittees involved in the reimbursement process do not share the outputs of their deliberations and applicants are often not provided with a satisfactorily informative written basis for evaluations and decisions, as well as reasonable opportunities for appeal. In addition, following the HIRA review, there is a separate and onerous review by the NHIS on price and volume determinations, resulting in additional price concessions below the prices already set by HIRA.

Finally, under Article 5.3(5)(e) of KORUS and the side letter thereto, Korea agreed to "make available an independent review process that may be invoked at the request of

to justify investment in innovation." Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Meeting of the Negotiating Group of 12-14 July 1989: Note by the Secretariat, MTN.GNG/NG11/14 (Sept. 12, 1989), ¶ 75. In a previous meeting, another TRIPS negotiator noted that "the recovery of an investment [of a patented product] depended not only on the duration of patent[] rights[s] but also on a number of other factors, for example whether there was price control." Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Meeting of Negotiating Group of 16-19 May 1988: Note by the Secretariat, MTN/GNG/NG11/7 (June 21, 1988), ¶ 11.

[257] Further, the proposal provided little to no explanation for the proposed change, contrary to Articles 5.3.3(a) and 21.1.3(c) of KORUS, and did not provide a reasonable period between the finalization of the regulation and its implementation on January 1, 2023, contrary to Article 5.3.4 of KORUS.

an applicant directly affected by a [pricing/reimbursement] recommendation or determination." Korea has taken the position, however, that reimbursed prices negotiated with pharmaceutical companies should not be subject to the independent review mechanism because the NHIS does not make "determinations" and merely negotiates the final price at which a company will be reimbursed. Moreover, for many innovative medicines, prices are decided by HIRA based on WAP without subsequent price negotiations with NHIS. However, this interpretation negates the original purpose of the independent review mechanism, which should apply to the process for setting prices of all reimbursed medicines, particularly patented medicines. While an independent review process is actively used for medical devices, there is not an effective independent review mechanism relating to medicine reimbursement, in part because regulations permit HIRA to conduct re-evaluations even after an independent review has taken place.

Discriminatory Innovative Pharmaceutical Company Accreditation

The MoHW designates certain companies as IPCs, which receive tax credits, R&D support and more favorable drug pricing. However, the current accreditation criteria discriminate against U.S. and other foreign innovators by requiring domestic investments to prove "innovativeness." As of January 2025, only four of 49 designated IPCs are non-Korean biopharmaceutical companies. PhRMA is concerned that this policy violates national treatment obligations and the spirit of KORUS Article 5.1. The MoHW announced that it would establish new selection criteria in 2024, reflecting the current pharmaceutical market and R&D trends (such as open innovation collaborations), however new criteria have not been published as of January 2025. Moreover, the accreditation process lacks transparency and predictability. For example, companies are denied inclusion on the accreditation list without any explanations. To fulfill the IPC objectives to foster biopharmaceutical innovation, the criteria and process should be revised as soon as possible so that it is transparent, provides due process and is equally available to domestic and foreign innovators in how it defines investment.

Intellectual Property Protection

Patent Term Extension Reform Bill

The Patent Term Extension (PTE) amendments, introduced in September 2024, further restrict the patent rights of original pharmaceutical products, which are already subject to considerable limitations under the current system. These amendments were passed by the National Assembly at the end of 2024 and raise significant concerns for innovative pharmaceutical companies. The amendments, rather than addressing longstanding, fundamental issues with Korea's approach to PTE, appear to exacerbate existing challenges, tipping the balance further against innovators.

While Korea has implemented a system for PTE, three major issues remain unresolved: (1) exclusion of foreign clinical trials in PTE calculations; (2) lack of due process in PTE procedures, and (3) excessively narrow scope of PTE protections.

First, the PTE calculation should include all relevant clinical trials used for the approval of the Korean product, including foreign clinical trials that are submitted as a part of the Korean dossier for approval of the product. Under the current system, foreign clinical trials are excluded from the PTE calculation, even though these trials are submitted as part of the Korean dossier and relied upon by the MoHW for product approval. This exclusion disproportionately disadvantages pharmaceutical companies conducting trials abroad. In 2020, the Korean Patent Court held that foreign clinical trials should be considered in PTE calculations. Korea has taken no steps to reflect that holding in its policies or in pending legislation seeking to amendment PTE practice.

Second, Korea's PTE practice denies patent owners due process. The current PTE system imposes a high-stakes, all-or-nothing approach to appeals. Patent owners risk losing any PTE term by challenging the accuracy of a PTE term calculated by the Korean Intellectual Property Office (KIPO). In the event an unsuccessful challenge, the previously determined PTE term is nullified. This all-or-nothing approach significantly undermines a patentee's right to appeal, effectively deterring appeals of erroneous calculations, and undermines the patentee's rights.

Finally, the scope of PTE protections under Article 95 of the Korean Patent Act is excessively narrow and limited to the "working of the patented invention of a product whose approval was the basis for PTE," and the "specific use." This approach diverges from that adopted by other developed economies that provide for PTE. In the United States and Europe, for example, PTE protections apply broadly to products with the same therapeutic effect and medicinal use (including salt or ester forms), while PTE in Japan similarly covers not only the particular medicinal product approved, but also other medicinal products substantially identical to it.

Despite the above issues, the amendments are a missed opportunity to address these fundamental deficiencies. Instead, the PTE amendments selectively incorporate aspects of other national jurisdictions in ways that further restrict the rights of innovators. This piecemeal approach fails to comprehensively address the existing structural deficiencies in Korea's PTE system.

A balanced approach that includes comprehensive stakeholder input and resolves the fundamental issues in the current system is critical to ensuring that Korea's PTE framework supports, rather than undermines, pharmaceutical innovation. We urge the U.S. government to engage in a thorough dialogue with the KIPO in collaboration with the National Assembly to exchange information on best practices that support innovation and U.S. rightsholders.

Inadequate Damages for Patent Infringement

A decision by the Korean Supreme Court has undermined patent enforcement in Korea and the ability of innovators to be awarded appropriate damages if a patent-infringing generic launches on the market. When a generic product enters the Korean market, the price of the innovator product is automatically reduced. In November 2020,

the Korean Supreme Court held that generic companies were not liable for damages caused by a mandatory price reduction to a patented product even if the patent was upheld and the generic entered the market illegally, forcing the price cut in question.

This jurisprudence is inconsistent with Korea's international commitments. Specifically, Article 41(1) of the TRIPS Agreement requires WTO members to provide "remedies which constitute a deterrent to further infringements". The Supreme Court decision essentially eliminates any deterrent for a generic company to launch their product during ongoing patent litigation. Further, it contravenes Korea's commitment in Article 18.10(5)(b) of KORUS that "in determining damages for infringement of intellectual property rights, its judicial authorities shall consider … the value of the infringed good or service measured by the market price …." That market value cannot reasonably be the reduced price triggered by the launch of a patent infringing generic.

Further, amendments to the NHIA went into effect on November 20, 2023, that allow MoHW to seek damages if an innovator is ultimately unsuccessful in defending its patents, or, conversely, for the innovator to seek compensation if the generic prematurely launches on the market, thereby triggering automatic drug price cuts. Industry is concerned that these revisions to the NHIA could make it harder to secure stays from the courts during the patent litigation. Further, while the proposed procedure (captured in proposed amendments to the NHIA Enforcement Decree and NHIA Enforcement Regulation) asserts that innovators will be able to seek 100 percent of the difference between the original price and the automatically reduced price due to the patent-infringing generic drug entry, the proposed methodology for calculating those damages excludes patient co-payments (typically 30 percent of the drug price) or out-of-pocket payments. As such, it is expected that innovative pharmaceutical companies will continue to suffer irreparable harm from automatic drug price cuts as a result of premature generic entry.

Strong patent protection is necessary for innovative companies to continue to invest in R&D for innovative medicines. The Korean Supreme Court ruling undermines that foundation and will inevitably have an adverse impact on future R&D and public health in Korea. A patent right should be protected during the entire patent term. Where a final decision to invalidate a patent is not yet rendered, a generic company willing to take the risk of infringing the patent should bear full responsibility for its choice. However, the Supreme Court's decision and current legal system in Korea make it difficult to substantively protect patents for innovative medicines, considerably undermine the value of drug patents and will discourage future investments and innovations.

Patent Enforcement

Consistent with its IP obligations under KORUS,[258] effective March 15, 2015, Korea implemented the framework of an effective patent enforcement system. PhRMA continues to monitor a number of key issues concerning this system. First, the system provides overly broad discretion to MFDS to determine whether to list a patent in the

[258] *See* U.S.-Korea Free Trade Agreement, Art. 18.9, para. 5.

Green List or to permit a change to the patent listing. Second, the system only provides for a nine-month sales stay. In the ordinary course, this is not an adequate period of time to resolve a patent dispute (consistent with Article 18.9(5)(b) of KORUS) before an infringing product is allowed to enter a market. Third, the sales stay system mechanism is problematic in that it requires the patentee to seek a sales stay against all generic/biosimilar applications, regardless of whether those products may infringe the innovator's patent(s), as long as they are the same in terms of (i) active ingredient and amount thereof, (ii) formulation, (iii) dosage and administration, and (iv) efficacy and effectiveness. If the patentee fails to do so, the sales stay against the first generic/ biosimilar is canceled. Moreover, while preliminary injunctions are available in Korea, in practice it takes several months for them to be granted, thereby frustrating the ability of the innovator to seek an injunction before potentially infringing products are allowed to enter the market.

MALAYSIA

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in Malaysia:

Key Issues of Concern:

- **Halal pharmaceutical requirements**: PhRMA's member companies, while strongly supportive of religious and cultural sensitivities, do not believe that the government should provide preferential treatment to such products in government procurement, but instead adhere firmly to the tenets of safety, quality and efficacy of medicines. Furthermore, it is important to ensure that patients, in partnership with their health care providers, are prescribed the appropriate medicine for their conditions.

- **Listing medicines on the national formulary**: As of 2016, Malaysia adopted a new process for listing medicines on the MoH Medicines Formulary. While this was a welcome development, PhRMA and its members are concerned that the final guidelines require six to 12 months of post-marketing surveillance data prior to listing and that there is no mechanism to ensure that patients who benefited from the medicines during local clinical trials can maintain access during this period. In addition, if a product is not approved for listing on the formulary, the applicant should be provided a detailed explanation for that decision so that it can better understand the criteria for listing and to determine if it may negotiate an alternative access scheme with the government. MoH listing decisions continue to lack transparency and are based on ambiguous criteria.

- **Preferential treatment of local manufacturers**: The Malaysian Government indirectly discourages a fair, open and competitive marketplace for international pharmaceutical compounds through procurement preferences for locally manufactured products. For example, the Malaysian Government has announced that it will grant three-year procurement contracts to companies that move production of imported products to Malaysia, with the potential for a two-year extension if those locally produced products are exported.

- **Forced localization requirements**: In recent years, the Malaysian Government introduced the Industry Collaboration Programme (ICP), an initiative that aligns with the New Industrial Master Plan 2030 (NIMP 2030). The ICP mandates technology transfer, human resource development and/or offsets for any procurement surpassing RM50 million (equivalent to USD 10.5 million). Initially designed for sectors like engineering, military and large-scale infrastructure projects, it has now been expanded to include the pharmaceutical industry, specifically for vaccines. This expansion is inappropriate for the pharmaceutical sector and should be reconsidered.

- **Market access delays and long regulatory processes**: The National Pharmaceutical Regulatory Agency (NPRA)'s current registration system (QUEST 3+) is not fit for purpose, delaying companies' ability to secure marketing approvals for multiple indications. Industry welcomes recent decisions to upgrade the registration system (QUEST 5), which is expected to go live by 2028.

- **Compulsory licensing**: Through a flawed and non-transparent process, the Malaysian Government issued a compulsory license (CL) for a breakthrough innovative medicine developed in America that provides a cure for patients suffering from hepatitis C. This action was taken despite the fact that the U.S. manufacturer had agreed to include Malaysia in its voluntary license program. In late 2021, the Ministry of Health (MoH) suggested that remaining courses of treatment manufactured under this CL could be used in a medical tourism program. While this CL has not been renewed, Malaysia's recently enacted 2022 Patents (Amendment) Act, continues to promote ambiguous and inappropriately broad grounds for compulsory licensing. These actions undermine innovator confidence in Malaysia and set a negative precedent for other markets, adoption of which would significantly undermine the R&D model for innovative medicines on which the U.S. biopharmaceutical industry and patients around the world rely.

- **Inadequate IP protection and enforcement**: Malaysia does not have an effective patent enforcement system that allows for early resolution of patent disputes before marketing approval is granted to potentially infringing products during the patent term. In addition, Malaysia's regulatory data protection (RDP) system fails to provide (1) adequate protection for biologics; and (2) effective protection for a sufficient period of time for chemically synthesized drugs from the date of marketing approval in Malaysia.

For these reasons, PhRMA requests that Malaysia be placed on the **Priority Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access

Only 20 percent of new medicines launched globally since 2014 have launched in Malaysia, with patients waiting an average of 38 months after global first launch for new medicines to become available. Only five percent of these new medicines are publicly reimbursed in Malaysia's public national health insurance.[259] The industry shares a common goal with the Malaysian Government to improve patient access to innovative medicines.

[259] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

Halal Pharmaceutical Requirements

PhRMA member companies support religious and cultural sensitivities but believe that it is important to ensure that patients, in partnership with their health care providers, are prescribed the appropriate medicine for their conditions. NPRA recently promulgated two additional regulatory requirements in May 2023 and in June 2024 that reflect the government's focus on Halal certification. The May 2023 Circular requires DNA testing on final biologic products that are manufactured using materials derived from animal sources. If the DNA test produces a positive result, the animal-derived material must be declared on the product label. In June 2024, the NPRA released a Drug Registration Guidance Document[260] requiring manufacturers of biopharmaceutical drugs, as well as medical devices, to declare the source of ingredients derived from animal origin (active and excipient) including in starting materials, gelatin and primary packaging.

PhRMA member companies encourage the Malaysian Government to ensure that the implementation of these requirements are consistent and practical, including consideration for pharmaceutical product components not consumed by patients, scientific confirmation of no residual animal product in final products and extensive purification processes. PhRMA member companies urge the government to ensure that the stipulations and requirements for Halal certification take into consideration and align with the biopharmaceutical industry's rigorous standards and practices already in place that ensure safety, efficacy and good manufacturing processes.

Market Access Delays and Long Regulatory Processes

Product registration and licensing activities are performed through NPRA's QUEST 3+ system, which is becoming increasingly incapable of supporting current regulatory requirements, policies and workflows to keep up with the evolving needs of the pharmaceutical industry, including management of applications for new indications. Currently, companies are unable to register products for multiple new indications concurrently. Instead, they must wait for one indication application to be approved before proceeding with the next one. For an application seeking two indications, the evaluation may take up to 24 months. These delays may lead to further market access barriers for innovative medicines.

In December 2023, NPRA successfully obtained budget approval to modernize and update the QUEST 3+ system to QUEST 5. The QUEST 5 project aims to improve the efficiency of the pharmaceutical product registration process, cosmetic notification, licensing and certification as well as regulatory processes at NPRA. On July 21, 2024, NPRA held an engagement session with industry stakeholders to solicit input on the development of the QUEST 5 system, which is expected to go live by 2028.

[260] NPRA.600-1/9/12(25).

Listing Pharmaceuticals on the National Formulary

The industry welcomed Malaysian Government guidelines introduced in January 2016 that allowed companies to request inclusion on the national formulary. However, the listing process lacks transparency and appears to be based on unclear criteria. In addition, the guidelines require six or 12 months of post-marketing surveillance data prior to listing. As a result, patients in local clinical trials cannot automatically continue receiving the product. In addition, if a product is not approved for listing on the formulary, the applicant should be provided a detailed explanation for that decision so that it can better understand the criteria for listing and to determine if it may negotiate an alternative access scheme with the government. MoH listing decisions, both by the body responsible for conducting HTA and making listing recommendations and the panel responsible for the ultimate listing decision, currently lack transparency and are based on unclear criteria, resulting in backlogs. In early 2024, new guidelines were issued to update the process for submitting pharmaceuticals to the national formulary, aiming to standardize and improve the quality of applications. The new guidelines also highlight the needs for comparative effectiveness and safety analysis against the current practice, including both formulary and non-formulary medicines with similar indications. The time horizon for budget impact analysis is recommended to be five years and all relevant comparators, including non-drug therapies, should be considered in the analysis. The budget impact analysis screening and evaluation stage has been identified as one of the causes of delay. The updated version appears to have improved timelines; however, total time from application to listing is an average of three years.

Further, as the Malaysian Government pursues reforms aimed at improving patient access to medicines, PhRMA member companies hope that sufficient financing is provided to ensure that more patients can receive innovative medicines in a timely manner. Short-term measures, such as cost-containment policies, should not become a barrier to patient access and the government should consider fair mechanisms to value innovations that are proven to raise health care standards in Malaysia.

Preferential Treatment of Local Manufacturers

Malaysia's National Medicines Policy, which prioritizes the medium- and long-term goals set by the government for the biopharmaceutical sector, endorses price controls, automatic generic drug substitution and preferences for generics and local manufacturers for medicines on the National Essential Medicines List. These discriminatory preferences for locally manufactured products discourage an open and competitive marketplace.

Forced Localization Requirements

As part of the broader NIMP 2030, Malaysia recently introduced the ICP, an initiative that mandates technology transfer, human resource development and/or offsets for any procurement surpassing RM50 million (equivalent to USD 10.5 million). Initially designed for sectors like engineering, military and large-scale infrastructure projects, it expanded its scope to include the pharmaceutical industry but only for vaccines. This

expansion is inappropriate and should be reconsidered. The ICP design is incompatible with pharmaceutical procurement, which should be focused on efficiently procuring safe and effective vaccines versus subsidizing industrial development goals. Imposing ICP requirements on pharmaceuticals threatens to create unnecessary risks, increase costs and disrupt the supply of essential medical products, thereby hindering innovation and patient access in Malaysia. PhRMA and its member companies encourage the Malaysian Government to engage and collaborate with industry stakeholders to review the appropriateness of the ICP in the pharmaceutical sector and ensure that patients in Malaysia continue to receive timely, safe and affordable care.

Intellectual Property Protection

Compulsory Licensing

In September 2017, the Malaysian Government utilized a non-transparent process to issue a CL on a patent-protected innovative U.S. medicine to treat hepatitis C. This unnecessary measure was taken despite the fact that the U.S. manufacturer had decided to include Malaysia in its voluntary licensing program. Malaysia's CL reportedly only treated 1,501 patients with hepatitis C over a 12-month period in 2018.[261] In contrast, cooperative discussions and collaborative access policies like voluntary licensing treated over 15,000 patients over the same period in neighboring Vietnam.[262] Indeed, a 2022 study made clear that the CL did not expand access and that issues with health care delivery systems and disease stigmatization were key barriers to hepatitis C treatment.[263]

The CL has sent a signal to America's biopharmaceutical innovators that their patents are not safe in Malaysia. Moreover, the Malaysian Government appears to be inappropriately leveraging the CL to encourage medical tourism and travel to Malaysia.[264]

While this CL has significantly undermined investor confidence in Malaysia, industry is glad to see that the Malaysian Government elected not to renew the CL when it expired in October 2020. This promising action may be undermined, however, by reports that Malaysia is considering CLs for other products and by the Patents

[261] The Star, "Malaysia to make drug to treat Hepatitis C," Mar. 8, 2019, available at https://www.thestar.com.my/news/nation/2019/03/08/malaysia-to-make-drug-to-treat-hepatitis-c (last visited Jan. 26, 2025).

[262] Observer Research Foundation, "Five Takeaways: Bridging access and innovation in healthcare policy," Oct. 31, 2019, available at https://www.orfonline.org/research/five-takeaways-bridging-access-and-innovation-in-healthcare-policy-57163/ (last visited Jan. 26, 2025).

[263] Chan, HK., Hassali, M.A., Mohammed, N.S. et al., "Barriers to scaling up hepatitis C treatment in Malaysia: a qualitative study with key stakeholders," BMC Public Health 22, 371 (2022), available at https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-022-12786-w (last visited Jan. 26, 2025).

[264] *See*, *e.g.*, CAN, "Malaysia hopes to become Asia's treatment hub for hepatitis C; offering treatment at fraction of cost: Health minister," Nov. 16, 2021, available at https://www.channelnewsasia.com/asia/malaysia-hepatitis-c-medical-tourism-2316876 (last visited Jan. 26, 2025).

(Amendment) Act 2022, which promotes vague and ambiguous grounds for compulsory licensing including selling products at "unreasonably high prices."[265]

Regulatory Data Protection (RDP)

Biopharmaceutical innovators work with hospitals, universities and other partners to rigorously test potential new medicines and demonstrate they are safe and effective for patients who need them. Less than 12 percent of medicines that enter clinical trials ever result in approved treatments.[266]

To support the significant investment of time and resources needed to develop test data showing a potential new medicine is safe and effective, governments around the world protect that data submitted for regulatory approval from unfair commercial use for a period of time. TRIPS Article 39.3 requires WTO members, including Malaysia, to protect proprietary test data submitted to market authorizing bodies, including the MoH, "against unfair commercial use" and against "disclosure."

The stated objective of Malaysia's Directive (11) dlm. BPFK/PPP/01/03 Jilid 1 is "to protect the undisclosed, unpublished and non-public domain pharmaceutical test data … for the purpose of scientific assessment in consideration of the quality, safety, and efficacy of any new drug product ...."[267]

Further, paragraph 4.2 of that Directive provides:

> An application for Data Exclusivity shall only be considered if the application in Malaysia for:
>
> (i) New drug product containing a New Chemical Entity is made within eighteen (18) months from the date the product is first registered or granted marketing authorization; AND granted Data Exclusivity / Test Data Protection in the country of origin or in any country, recognized and deemed appropriate by the Director of Pharmaceutical Services ….[268]

As such, Malaysia requires the marketing authorization application of the new medicine to be filed within 18 months from the first worldwide regulatory approval in order

[265] *See*, *e.g.*, The Sun Daily, "MOH mulls implementing compulsory licensing for medicines other than Remdesivir – Dr Adham," Aug. 6, 2020, available at https://www.thesundaily.my/home/moh-mulls-implementing-compulsory-licensing-for-medicines-other-than-remdesivir-dr-adham-CD3342307 (last visited Jan. 26, 2025).

[266] DiMasi JA, Grabowski HG, Hansen RW, "Innovation in the pharmaceutical industry: new estimates of R&D costs," J. Health Econ., 2016;47:20-33, available at https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub (last visited Jan. 26, 2025).

[267] *See* paragraph 1.2 of Directive BPFK/PPP/01/03.

[268] *Id.*

to be considered as a "new chemical entity" and, thus, eligible for RDP in Malaysia. If the 18-month deadline is not met, the product loses data protection, allowing a follow-on molecule to be approved based on the originator's regulatory data during what should have been the RDP period. It is challenging – if not impossible – to meet the 18-month application requirement if the first worldwide registration was not in the EU or the United States (both are relied upon for the Certificate of Pharmaceutical Product application).

In addition to this inappropriate restriction on products eligible for RDP in Malaysia, the actual term of the protection in Malaysia is measured from the date of first approval in the world. Thus, if a new chemical entity is registered in Malaysia one year after first approval in the world, Malaysia only provides four years of RDP. Indeed, the only instance in which an innovator can receive the full five years of RDP in Malaysia is if they seek marketing approval in Malaysia first.

Malaysia's flawed Directive improperly penalizes innovators for first seeking marketing approval in other countries. As in other markets that seek to promote research and development into innovative medicines, Malaysia should measure the term of the RDP protection from the time that the new molecule is approved in Malaysia.

Finally, Malaysia fails to provide any RDP for biologics. Made from living organisms, biologics are complex and challenging to manufacture and may not be protected adequately by patents alone. Without the certainty of a substantial period of exclusivity, innovators may not have the incentives needed to conduct the expensive, risky and time-consuming work to discover and bring new biologics to market.

Effective Patent Enforcement

PhRMA members encourage Malaysia to implement effective patent enforcement mechanisms designed to ensure that competing generic or biosimilar products will not enter the market while relevant patents are still in force. Such mechanisms also provide predictability for generic and biosimilar manufacturers, who do not have to launch at risk, as well as for governments and patients, who do not face the withdrawal of generics from the market if determined to infringe the innovator's patents.

On October 5, 2022, Malaysia ratified the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP), which mandates that Malaysia adopt a patent notification system and make available early dispute resolution mechanisms. Subsequently, the draft "Guideline on Implementation of Patent Linkage for Pharmaceutical Products in Malaysia" was developed by the Ministry of Health to help Malaysia satisfy its CPTPP commitments. While PhRMA members appreciate the Malaysian government's engagement with interested stakeholders regarding the guidelines, it appears further discussion has been postponed until 2027. PhRMA strongly encourages the Malaysian Government to work with industry to ensure that implementation of these CPTPP commitments, including through the guidelines, will strengthen patent enforcement, including for biologics, and enable parties to expeditiously resolve outstanding patent concerns prior to marketing approval and launch of follow-on products.

MEXICO

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in Mexico:

Key Issues of Concern:

- **Mexico is not complying with its USMCA IP commitments to effectively enforce patents and provide regulatory data protection**: In response to its USMCA commitments, Mexico promulgated the Federal Law for Protection of Industrial Property, which entered into force on November 5, 2020. However, secondary regulations have not yet been issued. Also, while PhRMA member companies appreciate COFEPRIS's recent proposal attempting to address challenges in Mexico's patent enforcement regime, shortcomings in the proposal, including the failure to ensure that use patents are included in the Gazette of Patents Protecting Medicines (Gazette), will continue to compromise the ability of right holders to resolve outstanding patent concerns prior to marketing approval and launch of follow-on products. Indeed, the shortcomings are not hypothetical, with COFEPRIS inappropriately granting marketing authorizations at least 10 times in 2023 and 2024 alone. Further, obtaining effective preliminary injunctions or final decisions on cases regarding IP infringement within a reasonable time (as well as collecting adequate damages when appropriate) remains the exception rather than the norm. Additionally, despite its commitments under USMCA, Mexico still lacks measures to restore a portion of the patent term lost during the regulatory approval process and consolidation of substantive regulatory data protection (RDP) in regulations are still pending. Furthermore, the new Mexican Federal Law for Protection of Industrial Property does not provide appropriate RDP for biologics, only for chemical compounds and combinations thereof, contrary to Mexico's USMCA commitments.

- **Market access delays**: The Federal Commission for Protection against Health Risks (COFEPRIS) has severely delayed the marketing authorization process for pharmaceutical products since early 2019. In addition, significant existing market access barriers remain due to lengthy, non-transparent and unpredictable procurement processes. A lack of transparency around the implementation of a National Medicines Compendium and disease-specific treatment guidelines, as well as challenges and uncertainty in accessing the formularies of public health institutions, create additional delays that restrict patient access to innovative medicines. Further, in November 2022, the General Council for Health (CSG) amended the regulations governing the Compendium to require applicants to obtain and submit a letter of necessity from at least one CSG institution member as part of the dossier for inclusion in the National Medicines Compendium. During the past five years, the share of new medicines launched globally over the prior

ten years that are available in Mexico declined from 38 to 25 percent – a worse decline than in any other OECD or Latin American country.[269]

- **Challenges with public procurement practices**: Since 2018, Mexico has made frequent and nontransparent changes to its public procurement system. In 2019, Mexico created uncertainty in the bilateral trade of public purchases by consolidating and transferring authority for the public procurement of medicines from individual public health institutions to the Ministry of Finance and later to the Institute of Health for Well-being (Instituto de Salud para el Bienestar, INSABI). From 2021 to 2022, Mexico decided to outsource a significant proportion of its public purchases of medicines to the United Nations Procurement Office (UNOPS). The UNOPS process lacked transparency, predictability and effectiveness, which ultimately led to the cancellation of its contract. These abrupt reforms have left the procurement process confusing and without due process. Further, in November 2022, the General Council for Health (CSG) amended the regulations governing the Compendium to require applicants to obtain and submit a letter of necessity from at least one CSG institution member as part of the dossier for inclusion in the National Medicines Compendium. And in September 2024, Mexico yet again amended the public procurement process through a presidential decree designating Laboratorio de Biológicos y Reactivos de México (BIRMEX), a state-owned company, in coordination with the Ministry of Health, to oversee public procurement of all drugs and raw medical materials for the ever-changing public health institutions in Mexico. This change came into force the day after publication of the presidential decree and without any stakeholder consultation. These many significant changes and unreasonable implementation timelines created substantial market access barriers for PhRMA member companies, resulting in supply chain challenges and product shortages for Mexican patients and concerns about product traceability and patient safety. Only 12 percent of new medicines launched globally since 2012 are publicly reimbursed in Mexico, with patients waiting an average of 55 months from global first launch for available medicines to become publicly reimbursed.[270]

For these reasons, PhRMA requests that Mexico be placed on the **Priority Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

[269] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[270] PhRMA, "Global Access to New Medicines Report," 2023, available at https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report (last visited Jan. 26, 2025).

Intellectual Property Protection

Weak Patent Enforcement

Several deficiencies have confounded the effective enforcement of patents in Mexico. Recognizing that these deficiencies hinder its new commitments to protect and enforce patents in the USMCA, Mexico enacted the Federal Law for Protection of Industrial Property, which entered into force on November 5, 2020, in order to address them. However, secondary regulations have not been released and at this point PhRMA and its member companies are unable to assess whether the new law will address the deficiencies in Mexico's patent enforcement system as outlined below.

Mexico has taken some positive steps to improve patent enforcement, including adopting the Linkage Resolution of 2003, although the resolution has not been implemented in a comprehensive and consistent manner. The publication in the Gazette is a positive step toward the goal of eliminating unnecessary, costly and time-consuming court actions to obtain appropriate legal protection for all biopharmaceutical patents used in allopathic medicines. However, use patents still require lengthy and costly litigation to achieve inclusion in the Gazette, and even this practice has been recently compromised with a January 2025 court decision finding that use patents should not be published in the Gazette. Furthermore, COFEPRIS appears to apply linkage in an inconsistent, non-transparent and possibly discriminatory manner. In several cases, marketing authorizations have been issued despite patents being listed in the Gazette. Additionally, the lack of secondary regulations for the Federal Law for Protection of Industrial Property has left PhRMA members without key details regarding the scope of the patent enforcement regime, including which patents would be subject to the system. This undermines company confidence in the IP system in Mexico and impedes companies' ability to do business in Mexico.

Despite the efforts of COFEPRIS to timely publish health registration requests, PhRMA member companies are unable to obtain accurate and timely information from COFEPRIS prior to marketing authorization being granted on a generic or biosimilar drug where the innovator product is used as a reference. As a result, innovators have little to no notice that a potentially patent infringing product is entering the market. While COFEPRIS recently proposed a mechanism to improve the notification system, the proposal still falls short of effective patent enforcement as outlined in the USMCA. For example, the proposed process (1) does not ensure that right holders receive direct notification of pending follow-on applications; (2) fails to provide the technical details necessary for the innovator to conduct a proper infringement analysis; and (3) lacks a sufficient period for the innovator to submit information relevant for the coordination between COFEPRIS and IMPI. Also, securing effective preliminary injunctions or final decisions on cases regarding IP infringement within a reasonable time (as well as collecting adequate damages when appropriate) remains the exception rather than the norm. Indeed, PhRMA members are reporting that preliminary injunctions are increasingly being denied and when they are granted (subject to the payment of a bond, counter-

bonds, or in some proceedings only on applications), motions may be submitted by the alleged infringer to lift the injunction and allow the challenged product to enter the market.

Even if an innovator successfully enforces its IP rights in Mexico, seeking monetary damages is extremely burdensome. In order to claim damages from patent infringers in Mexico, litigants are required to first obtain a final administrative action and then seek damages through a civil action, actions that can take longer than ten years.

Mexico has repeatedly committed to providing effective patent enforcement mechanisms in NAFTA, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and most recently in the USMCA. It is critical that Mexico act on its commitments by implementing an effective patent enforcement system. In order for Mexico to succeed in this effort, it will be essential that Mexico reject calls that would inappropriately limit the scope of Mexico's patent linkage system. PhRMA and its member companies encourage the Mexican Government to hasten patent infringement proceedings, use all available legal mechanisms to enforce Mexican Supreme Court decisions and implement procedures necessary to provide timely and effective preliminary injunctions.

Additionally, on December 4, 2024, COFEPRIS issued an executive order allowing the importation of medicines that have not received marketing authorization in Mexico but have been approved by certain foreign regulatory agencies, including the U.S. Food and Drug Administration and the European Medicines Agency.[271] The executive order is limited to public procurement under the BIRMEX scheme. Moreover, once the import permit has been obtained, the process for obtaining marketing authorization from COFEPRIS must commence within 10 business days of the initial importation of the medicine. It remains unclear how COFEPRIS will ensure that medicines approved under this mechanism do not infringe on an innovator's IP rights, including patent rights and regulatory data protection rights, mindful of Mexico's international commitments.

Urgent action is required to address the lack of an effective patent enforcement system in Mexico. In 2023 and 2024, COFEPRIS granted marketing authorizations to at least 10 different entities for follow-on products despite the existence of valid patents. The risk of government procurement entities facilitating infringement of valid patents is real and difficulties with securing injunctions and monetary damages compounds the problem significantly.

Regulatory Data Protection Failures

Biopharmaceutical innovators work with hospitals, universities and other partners to rigorously test potential new medicines and demonstrate they are safe and effective

[271] Official Federal Gazette, Executive Order (December 4, 2024), available at: https://dof.gob.mx/nota_detalle.php?codigo=5744429&fecha=04/12/2024#gsc.tab=02020 (last visited Jan. 26, 2025).

for patients who need them. Less than 12 percent of medicines that enter clinical trials ever result in approved treatments.[272]

To support the significant investment of time and resources needed to develop test data to prove that a new medicine is safe and effective, the international community has developed a mechanism recognized as essential to biopharmaceutical innovation whereby the data submitted is protected from unfair commercial use for a period of time. The mechanism is enshrined in TRIPS Article 39.3, which requires WTO members to protect undisclosed test and other data submitted for marketing approval in that country against disclosure and unfair commercial use.

RDP is essential for all medicines and particularly critical for biologic therapies. Produced using living organisms, biologics are complex and challenging to manufacture and may not be protected adequately by patents alone. Unlike generic versions of traditional chemical compounds, biosimilars are not identical to the original innovative medicine and there is greater uncertainty about whether an innovator's patent right will cover a biosimilar version. Without the certainty of some substantial period of market exclusivity, innovators will not have the incentives needed to conduct the expensive, risky and time-consuming work to discover and bring new biologics to market. Unfortunately, the new Mexican Federal Law for Protection of Industrial Property does not appear to provide appropriate RDP for biologics or chemical compounds, contrary to Mexico's commitments under Articles 20.48 and 20.49 of the USMCA, which must be implemented by July 2025.

In June 2012, COFEPRIS issued guidelines to implement RDP for a period not less than five years – an important step toward fulfilling Mexico's international obligations. PhRMA members initially welcomed this decision as an important confirmation of Mexico's obligations and its intention to fully implement the NAFTA and TRIPS provisions. As guidelines, however, their validity may be questioned when applied to a specific case. Further, they are not automatically conferred upon marketing approval, routinely require litigation to order COFEPRIS to grant the protection, and to grant a term of protection commensurate with the time, expense and risk incurred to obtain the subject data. Further they could be hard to enforce and may be revoked at any time. Therefore, PhRMA members strongly urge the passage of binding federal regulations on RDP, including appropriate duration of protections for biologics, to provide certainty regarding the extent and durability of Mexico's commitment to strong IP protection, consistent with Mexico's international commitments under the USMCA.

[272] DiMasi JA, Grabowski HG, Hansen RW, "Innovation in the pharmaceutical industry: new estimates of R&D costs," J. Health Econ., 2016;47:20-33, available at https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub (last visited Jan. 26, 2025).

Lack of Patent Term Restoration (PTR)

Mexico remains one of the few members of the OECD that does not provide PTR for effective patent term lost during the lengthy development and regulatory approval process. This situation is exacerbated by the current delays of COFEPRIS in approving medicines, resulting in significant patent term lost due to no fault of the inventor or patent owner. Mexico agreed to implement patent term restoration in the USMCA subject to a 4.5-year transition (i.e., before December 2024). Nonetheless, Mexico has yet to promulgate the necessary regulations, which undermines the ability of our members to sustainably bring new therapies to Mexican patients. PhRMA urges USTR and other federal agencies to encourage Mexico to implement appropriate PTR provisions immediately.

Potential Abuse of the "*Bolar*" Exemption

Mexico allows generic manufacturers to import active pharmaceutical ingredients and other raw materials contained in a patented pharmaceutical for purposes of preparing marketing authorizations during the medicine's patent term, per the *Bolar* exemption. However, since the implementing regulations of the new IP Law are still pending, Mexico fails to impose any limits on the volume of raw materials that can be imported under this exception.

Given some of the import volumes reported, PhRMA's members are very concerned that some importers may be abusing the *Bolar* exemption by stockpiling and/or selling patent-infringing and potentially substandard medicines in Mexico or elsewhere. PhRMA members encourage Mexican authorities to establish clear criteria for the issuance of import permits that respect patent rights and appropriately limit imports to quantities legitimately required for generating data necessary for filing follow-on drug applications.

Market Access

Market Access Delays

In addition to delays during the regulatory review process, the local innovative pharmaceutical industry association, Asociación Mexicana de Industrias de Investigación Farmacéutica (AMIIF), has estimated that it takes five years on average for Mexican patients to access innovative medicines following regulatory approval and that this delay is increasing. COFEPRIS previously made improvements to the marketing authorization process despite limited resources; however, since early 2019, progress has backtracked. The New Molecules Committee has made progress in the last year; however, improvement is inconsistent and delays remain a problem with many marketing authorizations for new molecules and new indications still pending review.

Once COFEPRIS grants a marketing authorization, there remain significant barriers for patients, primarily those covered by public institutions, in accessing important

medicines. This additional delay is caused by the lengthy, non-transparent and uncertain public procurement system used in Mexico, which adds, on average, two years to patient access timelines in the public sector (if a medicine is made available at all). In addition, inclusion into the basic formulary or catalog of a public health institution does not automatically result in the purchase and subsequent availability of those medicines to patients.

More specifically, after COFEPRIS grants marketing authorization, the National Health Council (NHC) decides which medicines should be included in the National Compendium, a process that further delays patient access to those medicines. Only 24 percent of new medicines launched globally since 2014 have launched in Mexico, with patients waiting an average of 32 months from global first launch for new medicines to become available.[273] During the past five years, the share of new medicines launched globally over the prior ten years that are available in Mexico declined from 38 to 24 percent – a worse decline than in any other OECD or Latin American country.[274]

In November 2022, the CSG amended the regulations governing the Compendium to require applicants to obtain and submit a letter of necessity from at least one health institution for new medicines. The letter must detail the public health and patient need for procurement by the procuring entities. These new criteria were made without public consultation, a requirement of the USMCA. Further, these criteria lack clear procedures, including governance and due process for letter submission, and present new access barriers.

Challenges with Public Procurement Practices

In 2019, the Mexican Government further consolidated and transferred authority for the public procurement of medicines from the individual public health institutions (e.g., IMSS, ISSSTE, INSABI, etc.) to the Ministry of Finance. In 2023, another amendment was introduced to permit the Ministry of Public Service and the Ministry of Health to conduct public procurement of medicines in particular cases. The NHC supports this centralized process by developing disease-specific treatment guidelines aimed at reducing the number of medicines on the National Medicines Compendium but without up-to-date guidelines, clear criteria (including treatment algorithms) and transparency. Several tenders and public purchases without tenders were conducted under this process based on new rules that lacked transparency in process and requirements, and that are inconsistent with Mexican public procurement, as well as Mexico's obligations under NAFTA (in force at that time) and USMCA (see below). For example, Mexico bypassed its normal procurement process and conducted open international tenders. While the Mexican Government asserted that the price preference granted under such tenders for Mexican products would be extended to products originating from FTA trading partners,

[273] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[274] PhRMA, "Global Access to New Medicines Report," 2023, available at https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report (last visited Jan. 26, 2025).

the rush and lack of transparency regarding how the awards were granted raised questions as to whether those assurances were honored.

In 2020 Mexico outsourced its purchases of medicines to UNOPS. However, the UNOPS agreement proved unsuccessful in this role leading to huge shortages in the public sector. PhRMA member companies further experienced significant challenges with the UNOPS procurement process that negatively impacted commercial operations in Mexico and patient access to procured medicines. The system suffered from (1) fragmented management of the end-to-end process for procuring, supplying and distributing medicines due to non-interoperability between the Mexican Government and UNOPS; (2) logistical barriers for distributors and hospitals that lack needed information to verify and accept delivery of procured medicines; and (3) lack of transparency and meaningful engagement with affected stakeholders to resolve concerns.

As a result, in October 2022, the contract with UNOPS was terminated and INSABI resumed temporary control of purchasing. In early 2023, the President of Mexico presented a reform bill to the Organic Law of the Federal Public Administration to the House of Representatives. This bill centralized public procurement and spending in the Ministry of Public Administration (SFP). The SFP is additionally responsible for internal control, the prevention of acts of corruption and the oversight and evaluation of public administration.

These sweeping changes were made without meaningful stakeholder consultation, presented safety concerns and are further contributing to an unviable, confusing, non-transparent and uncertain business environment for PhRMA member companies.

- In January 2020, the Mexican Government published executive orders that would allow procurement and importation of medicines that have not been approved by COFEPRIS. Instead, the products simply needed regulatory approval from either (1) the country of origin; (2) regulatory authorities in Australia, Canada, Europe, Switzerland or the United States; (3) PAHO/WHO Regional Reference Authorities which additionally include Argentina, Brazil, Chile, Cuba and Colombia; or (4) any of the 53 authorities participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S). PhRMA has urged the Mexican Government to limit the procurement process to products that meet all relevant regulatory standards and to adopt specific measures to honor IP protections (both patent rights and regulatory data protection) in the context of these approvals. The Mexican Government rescinded this policy in September 2024 then issued a similar policy in December 2024 that allows procurement and importation of medicines that have not been approved by COFEPRIS but have been approved by regulatory authorities in Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Japan, Netherlands, Norway, Portugal, Singapore, Spain, Sweden, Switzerland, United Kingdom or the United States.

- In August 2020, the Mexican Government amended the Federal Procurement Law to permit the procurement of medications, vaccines and medical equipment directly

from international organizations – such as the Pan American Health Organization (PAHO) and UNOPS – outside of Mexico's normal procurement process. The legal changes apply to open tenders, restricted tendering, qualification of suppliers and selective tendering. They do not establish a clear methodology or government accountability for procurement through international organizations or include any specifications on how market research will be conducted to determine whether it is appropriate and efficient to purchase medicines through international organizations. Nor do they ensure the protection of patent and other intellectual property rights by requiring exclusive procurements for patented medicines or medicines still subject to RDP (e.g., UNOPS initially issued an open tender for molecules with intellectual property protection in Mexico). Moreover, the measure does not ensure that U.S. suppliers are able to participate in the tenders, contrary to the intent of the USMCA. This exclusion opens a wide range of pharmaceutical procurements to being conducted outside of the normal legal framework.

- In September 2020, the Mexican House of Representatives began discussions to further amend the Federal Procurement Law. Discussions on these proposals are ongoing but do not appear to have considered Mexico's government procurement commitments. On the contrary, many of the proposals deviate from those commitments and could become barriers to trade. For example, certain proposals suggest that market research provisions could be used to exclude tenders from certain countries, including the United States. This raises broad national treatment concerns as well as inconsistencies with Mexico's government procurement commitments under the USMCA. The innovative biopharmaceutical industry is concerned that if these proposals are enacted, many of the benefits anticipated by U.S. manufacturers under the USMCA would be eliminated.

- In June 2021, the Executive Branch amended the implementing regulations of the Federal Procurement Law to permit the simultaneous supply in the purchase method known as the *direct award*, the equivalent to the limited tendering provided by the USMCA. That amendment may have the effect of circumventing public tendering, contrary to Mexico's commitments under Chapter 13 of the USMCA (see below).

- In December 2023, Mexico once again amended the public procurement process through a presidential decree designating BIRMEX, a majority state-owned company, in coordination with the Ministry of Health, to oversee public procurement of all drugs and raw medical materials for public health institutions in Mexico, namely: Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (ISSSTE), Instituto Mexicano del Seguro Social (IMSS) and Health Services of the Instituto Mexicano del Seguro Social para el Bienestar (IMSS-BIENESTAR).[275] This change came into force the day after publication of the

[275] Official Federal Gazette, Presidential Decree (Dec. 12, 2023), available at https://www.dof.gob.mx/nota_detalle.php?codigo=5712407&fecha=22/12/2023#gsc.tab=0 (last visited Jan. 26, 2025).

presidential decree. Further, BIRMEX must issue, within a period of 15 business days following the entry into force of this agreement, guidelines and requirements for the procurement process and distribution of drugs and health supplies. To date there have been no guidelines published or public consultation for industry input.

Under Chapter 13 of the USMCA, Mexico has generally committed to procure goods and services through open tendering procedures (Article 13.4.4). One of the limited exceptions to this commitment (Article 13.2.4) states that Chapter 13 does not apply to procurement conducted "under the particular procedure or condition of an international organization, or funded by international grants, loans, or other assistance if the applicable procedure or condition would be inconsistent with this Chapter." While Article 13 enables government projects to allow for the participation of international organizations, it does not provide a mechanism for the Mexican Government to sidestep its USMCA commitments by procuring all products from an international organization. As such, the amendment to the Federal Procurement Law, which permits the direct procurement of medicines with international organizations without restrictions, appears to exceed the limited exception provided by Article 13.2.4 of the USMCA. Also, recent Executive Branch modifications to the regulations of the Procurement Law permit governmental entities to circumvent the tendering process by procuring products and services (medicines included) through a direct award. PhRMA's member companies are concerned that these modifications could lead to increased use of procurements with limited tenders, in violation of Mexico's commitment to open tendering under USMCA.

Due to the ongoing and multiple changes in Mexico's procurement process, Mexico has experienced significant supply chain challenges, resulting in persistent shortages of medicines, including treatments for diabetes, hypertension, cancer and HIV. PhRMA member companies are deeply concerned that these continuing procurement changes and shifting implementation timelines could result in further shortages of medicines for Mexican patients and create concerns for pharmacovigilance and patient safety. Only 12 percent of new medicines launched globally since 2012 are publicly reimbursed in Mexico, with patients waiting an average of 55 months from global first launch for available medicines to become publicly reimbursed.[276]

PhRMA urges the Mexican Government to provide greater clarity in process and requirements, ensure consistency with Mexican law and international commitments and allow for appropriate lead times so that companies can make any necessary operational adjustments to ensure supply continuity.

[276] PhRMA, "Global Access to New Medicines Report," 2023, available at https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report (last visited Jan. 26, 2025).

RUSSIA

PhRMA members have identified the following key issues of concern in Russia:[277]

Key Issues of Concern:

- **Compulsory licensing**: Actions have been taken at the legislative, executive and judicial level to facilitate compulsory licensing in Russia. This includes passage of federal legislation to allow for the issuance of compulsory licenses (CLs) both for use in Russia and for export, as well as the imposition of several CLs between 2020-2024 on a COVID-19 therapeutic and a diabetes medication. Similarly, PhRMA members are witnessing a rising trend in court cases seeking CLs for dependent patents based on insufficient use. Russian courts, in at least two cases, have granted CLs for dependent patents to generic companies for innovative foreign medicines based on an extremely low evidence test and standard of proof. Beginning in 2021, the Civil Code was amended to provide the Russian Government with unfettered authorities to quash intellectual property (IP) rights, including patents. In March 2024, the Russian authorities issued Resolution No. 380 which created an interagency apparatus authorized to review applications for compulsory licenses. The resolution also mandates that compensation for right holders from "unfriendly" countries be paid into special accounts in Russian banks. As of the end of mid-December 2024, reports indicate that five Russian pharmaceutical companies have secured CLs for innovative medicines since 2020.

- **Weak patent enforcement**: Biopharmaceutical innovators face significant legal challenges in seeking to effectively protect their innovative products against infringement, resulting in significant damages that are rarely compensable. This practice is out of step with the rest of the world and considerably weakens Russia's IP protection regime. There is no effective mechanism in place in Russia to provide patent holders with an opportunity to resolve patent disputes prior to the launch of a follow-on product. This has led to the approval and marketing of follow-on products during the period of patent protection. Further, Russian courts rarely grant preliminary injunctions in patent infringement cases related to pharmaceuticals. Despite recent legislative proposals to implement a Unified Register of Active Pharmacological Substances Protected by Patents, the proposals have not advanced. While initial proposals are limited to compound patents only, all

[277] PhRMA and its member companies condemn the invasion of Ukraine and the suffering it continues to cause. Overcoming the challenges that this humanitarian crisis poses for patients is our primary concern. We are united in our mission of providing treatments and vaccines to all those affected by the war, wherever they are. We remain deeply concerned about the deteriorating regulatory environment and the impact that it is and will continue to have on patients. Recognizing the current reduced ability of the U.S. Government to engage on these issues, we provide only a summary of key concerns most impeding industry's ability to ensure that Russian patients continue to have access to medicines. The full range of issues identified in PhRMA's comments on the 2023 National Trade Estimate Report remain significant concerns.

necessary medicine patents should be included in the register in order to ensure its utility and effectiveness.

- **Regulatory data protection failures**: As part of its accession to the World Trade Organization (WTO) in 2012, Russia agreed to provide six years of regulatory data protection (RDP) for all medicines. Article 18 of the Federal Law No. 61-FZ ostensibly provided this protection by prohibiting follow-on manufacturers (unless with the innovator's consent) from securing approval for their product based on the preclinical and clinical trial data submitted by the innovator for the reference product for a period of six years. However, when the new Eurasian Economic Union rules for registration of new medicines across the Union went into effect on January 1, 2021, this aspect of Federal Law No. 61-FZ formally ceased to exist. To date, no action has been taken to ensure that Russia honors its WTO commitment to provide RDP.

- **Localization barriers and government procurement restrictions**: Despite being in the process of acceding to the World Trade Organization Agreement on Government Procurement, Russia continues to favor local production of medicines through its government procurement system with 15-25 percent price preferences for locally produced products and the "Third is Out" rule (whereby if at least two bids to supply Essential Drug List (EDL) medicines from the Eurasian Economic Union (EAEU) are received, then bids with foreign goods must be declined). Moreover, in August 2024 Federal Law No. 318-FZ was adopted introducing additional regulations that further favor locally produced products (44-FZ and 223-FZ). Beginning in January 2025, new regulations for medicine procurement will replace the "Third is Out" rule with the "Second is Out" rule (whereby if at least one bid to supply EDL medicines from a domestic manufacturer is received, then all foreign offers will be declined). Starting in September 2025, the "Second is Out" rule will also be applied to medicines on the Strategic Drug List Further details on the Draft Government Decree are expected later in 2025.

- **Government subsidies to Russian manufacturers and exporters**: Russian authorities are pursuing various mechanisms to support Russian biopharmaceutical manufacturers and suppliers. These include Government Decree No. 1347 dated July 28, 2022, which provided manufacturers and suppliers of high-tech products with government subsidies for up to 80 percent of the costs of export transportation. The Russian Government also established subsidies for the development of pharmaceutical (including biopharmaceutical) product analogues protected by patents owned by persons and organizations from countries implementing sanctions against Russia, which is also known as the "patents on the shelf" initiative (Decree No. 299 dated March 2022).

- **Discriminatory government pricing environment**: In October 2018, a pricing methodology for products included on Russia's EDL came into force that introduced recurrent obligations to decrease EDL prices when prices from the reference basket are lower than in Russia. In addition, in December 2019 the

Russian Government approved Resolution No. 1683 that mandated re-registration of all maximum selling prices for EDL medicines (subject to exemptions on a case-by-case basis for products experiencing shortages). More recently, the Russian Government introduced the right to exercise specific price control measures on medicines not included in the EDL. In 2022 and 2024, the Government again updated the rules and regulations for registration and re-registration for EDL medicines, designed to avert shortages of low-priced products, by allowing price increases (Government Decree No. 1771).

For these reasons, PhRMA requests that Russia remain on the **Priority Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

THAILAND

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in Thailand:

Key Issues of Concern:

- **Uncertain IP protections and enforcement**: Uncertain IP protections and lack of enforcement hinder the ability of U.S. innovators – in particular, biopharmaceutical innovators – to fairly access the Thai market. Key IP concerns in Thailand include patent backlogs and failure to provide meaningful regulatory data protection (RDP). PhRMA welcomes improvements Thailand has made to its patent system, including increasing the number of patent examiners to improve processing time for patent applications. We also welcome the proposed amendments to the Patent Act that seek to build upon this progress, such as provisions that seek to speed up the patent registration process by decreasing the period of time of requesting substantive examination from five years from the application date to three years. In light of Thailand's significant patent delays, these improvements will be key to helping to reduce the patent backlogs and improving efficiencies in Thailand's patent system. While these developments make progress towards improving the registration and availability of patents in Thailand, barriers to patent ownership in the country remain an obstacle to innovation and certain provisions in the amended Patent Act threaten to undermine effective patent protection and enforcement.

- **Maximum price setting for government procurement**: The Thai Ministry of Public Health and the National Drug System Development Committee are authorized to establish a maximum procurement price (MPP) for pharmaceuticals. The MPP process, combined with Thailand's preference for domestic companies, lacks transparency and harms both patients and innovators by furthering delays and preventing the introduction of new medicines. Industry stands ready to work with the Thai Government to standardize the MPP process and to ensure increased transparency and predictability.

- **Discrimination and unpredictability in government procurement policies**: The Thai Government continues to implement procurement policies that facilitate procurement privileges for the domestic Thai industry. These policies have created a discriminatory and unpredictable investment climate that creates challenges for U.S. companies seeking to compete on a level playing field in Thailand.

For these reasons, PhRMA requests that Thailand be placed on the **Priority Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Patent Backlogs, Protection and Enforcement

Although the Department of Intellectual Property (DIP) has taken some important initial steps to help clear the patent backlog – including hiring more patent examiners – patent review timelines in Thailand remain unpredictable and averages 10-15 years after application submission. As such, we welcome the proposed amendments to the Patent Act that seek to speed up the patent registration process by decreasing the period for requesting substantive examination from five years after the application date to three years.

Long patent grant delays create uncertainty regarding investment protection and increase the risk that a third party will use a patentable invention that is the subject of a pending patent application during the pending/review periods. Indeed, at least one PhRMA member has experienced a third-party launch of a product that was the subject of a pending patent application. In that instance it took over 18 years for the patent to be granted and, even then, the member was unable to obtain meaningful enforcement of the patent. Patent term adjustments are not available in Thailand to compensate for unreasonable patent office delays, thereby reducing the effective patent term and further exacerbating the uncertainty caused by its patent grant delays.

Additionally, though some of the draft amendments to the Patent Act seek to streamline some procedures during the patent application process, other draft provisions could undermine efforts to support innovation and further exacerbate Thailand's backlog. For example, one of the proposed amendments seeks to introduce a mechanism that would allow third parties to file challenges against a patent application up to the date of patent grant as well as to allow for pre-grant opposition after the substantive examination. These proposed opposition mechanisms would compound the existing patent backlogs and undermine the investment climate in Thailand. Other provisions, such as Section 17/1 of the Act, could impose procedural barriers by requiring applicants to disclose information regarding the use of genetic resources as part of their patent application. In some cases, compliance with such requirements is impossible, particularly where the existence or origin of any genetic resources incorporated into a product may be unknown or untraceable. Such disclosure requirements could present significant barriers to patentability and should be removed from the draft amendments.

The proposed amendments also raise concerns that patent owners will be deprived of their patents for late payment of patent maintenance fees, without sufficient notice or opportunity to make payment prior to revocation. In addition, Thailand's restrictive application of patent eligibility criteria denies adequate protections to valuable new uses of existing pharmaceuticals.

Compulsory Licensing

Despite assurances that Thailand would be judicious in its use of compulsory licenses (CLs) and consult with affected parties as required by the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Thailand continues to improperly facilitate the use of CLs. Thailand's compulsory licensing regime lacks sufficient due process and dialogue with affected companies and suffers from a lack of transparency in the reasoning behind CL decisions. DIP's proposed amendments to the Patent Act to add provisions on compulsory licensing raise concerns that Thailand may be seeking to increase its use of compulsory licensing in the future. Even the mere potential that Thailand may use compulsory licensing in the future brings into question the predictability and enforceability of patents in Thailand. Such doubts undermine incentives for development of new medicines and innovative treatments, thereby threatening to slow the introduction of new medicines in Thailand and decrease access to medicine for Thai patients. If DIP moves forward with amendments to its compulsory licensing regime, it should do so in a manner that adopts international best practice and adheres to Thailand's international treaty obligations under Articles 31 and 31*bis* of the TRIPS Agreement.

PhRMA believes governments should grant CLs in accordance with international rules and only in exceptional circumstances and as a last resort. Decisions should be made through fair and transparent processes that involve participation by all stakeholders and consider all relevant facts and options.

Regulatory Data Protection Failures

Ministerial regulations issued by the TFDA regarding the Trade Secrets Act of 2002 do not provide RDP that would prevent generic or biosimilar drug applicants, for a fixed period of time, from relying on the innovator's regulatory data to gain approval for their versions of the innovator's product. The Act aims only to protect against the "physical disclosure" of confidential information.

PhRMA's member companies strongly encourage the Royal Thai Government to institute meaningful RDP. Specifically, Thailand should: (1) implement new regulations that do not permit generic or biosimilars producers to rely directly or indirectly on the originators' data, unless consent has been provided by the originator, for the approval of generic or biosimilar pharmaceutical products during the designated period of protection; (2) bring the country's regulations in line with international standards by making clear that data protection is provided to test or other data submitted by an innovator to obtain marketing approval; (3) provide protection to new indications; and (4) require TFDA officials to protect information provided by the originator by ensuring it is not improperly made public or relied upon by a subsequent producer of a generic or biosimilar pharmaceutical product.

Market Access

Maximum Price Setting for Government Procurement

The MPP process, combined with Thailand's preference for domestic companies, lacks transparency and harms both patients and innovators by furthering delays and preventing the introduction of new medicines. Currently, only 21 percent of new medicines launched globally since 2014 have launched in Thailand, with patients in Thailand waiting an average of 36 months after global first launch for new medicines to become available.[278] Fortunately, the Public Procurement Act introduced in August 2017 mandates the creation of a Reference Price Subcommittee for Pharmaceutical and Medical Supplies, which would be responsible for handling reference price issues and standardizing the process. The innovative biopharmaceutical industry seeks the expedited formation of this subcommittee, as well as the inclusion of members from the private sector so that all stakeholders may collaborate on appropriate policies that address the fiscal concerns of the Thai Government in the procurement of pharmaceuticals, as well as the concerns of innovators and the needs of Thai patients. As part of improving the pricing and reimbursement process, PhRMA and its member companies encourage the Thai Government to explore innovative pricing and reimbursement schemes that improve therapeutic outcomes and clinical needs of patients. Further, while industry welcomed the Thai Government's issuance of an annual plan related to the MPP process, additional relevant details are needed to increase transparency and predictability.

Preferential Procurement of Domestic Innovation

In 2016, the Thai Government established the Thai Innovation List and the Made in Thailand initiatives to develop domestic industrial capacity in several innovation sectors, including pharmaceuticals. Only Thai majority-owned companies qualify to be listed. Once listed, Thai companies receive special government procurement privileges, including an earmark for at least 30 percent of orders by Thai Government agencies. Paradoxically, it appears that to qualify as a pharmaceutical innovator and be eligible for inclusion on the list, the Thai company needs only to demonstrate that their generic copy is bioequivalent to the originator product. As such, the so-called Thai Innovation List exists solely to favor local generic companies to the exclusion of U.S. and other foreign research-based biopharmaceutical companies.

The Innovation List was created under the Thailand 4.0 policy to incentivize innovation development. However, by excluding international companies, it deters international collaborative investment to promote innovation in Thailand. A more inclusive criteria that values research investment and embraces the creation of innovation without a nationality focus would foster a more investment-friendly environment.

[278] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

Preferential Procurement Privileges for the Government Pharmaceutical Organization (GPO)

The GPO, a Thai State-owned enterprise that manufactures pharmaceutical products in Thailand, benefits from preferential procurement privileges. Per Ministerial Regulation B.E.2560 (2017), government hospitals must procure at least 60 percent of their medicines budget from the NLEM. Specific procurement methods are required if the product on the NLEM is manufactured by the GPO or the Thai Red Cross Society. Purchases from other suppliers are permitted only when the GPO or the Thai Red Cross Society is unable to produce and distribute the product. In addition to these procurement preferences, under the Drug Act B.E. 2510 (1967), the GPO is not required to obtain FDA approval prior to launching medicines on the Thai market. There is no such exemption for private sector manufacturers or sellers, all of whom must obtain appropriately market authorization from the Thai FDA prior to selling their products in the Thai market. Further procurement privileges are also being extended to local vaccine producers under National Vaccine Committee Regulations on "Vaccine Procurement in Government Sector" that went into effect on August 14, 2020.

Inconsistent and Nontransparent Oncology Preauthorization System (OCPA)

The OCPA was established in 2006 as a direct reimbursement system to hospitals for "high-cost cancer drugs" administered to patients under the Civil Servants Medical Benefit Scheme (CSMBS). The system was intended to reduce out-of-pocket disbursements for its beneficiaries and to ensure rational use of certain innovative cancer medicines by identifying those products for which government hospitals would be directly reimbursed through prior authorization and approval based upon a pre-defined protocol of individual cancer medicines. Unfortunately, the process and criteria involved in the OCPA lack predictability and are applied inconsistently between different companies and different products. Further, revisions to the OCPA will result in certain innovator products being deemed not eligible for "direct reimbursement" based on unclear selection criteria or "non-reimbursable" if newly approved.

Specifically, while many innovative medicines, including cancer medicines, had been directly reimbursable by the CSMBS immediately upon being granted marketing authorization, revisions to OCPA procedures in February 2018 structured reimbursements on a tiering system: Group 1 (OCPA) or Group 2 (certain innovative and non-OCPA) products continue to be directly reimbursable, Group 3 (other innovative and non-OCPA) products require patients to provide advance payment for their medicines with no guarantee of reimbursement and then apply for government reimbursement and Group 4 (newly-approved) products are non-reimbursable and fully paid by the patient. These revisions, which were due to government budget constraints, will create access barriers to patients who cannot pay out-of-pocket for medicines and will limit provider and patient choice. For example, only one medicine per indication will be allowed in Group 1, meaning that patients treated by other medicines will be forced to pay out-of-pocket or switch treatments. Moreover, the criteria for how products are placed into each group are unclear and potentially are based on which products have the lowest procurement price.

To ensure patient access to innovative medicines and to respect physician determinations regarding the most appropriate treatment for a given patient, the government should establish transparent procedures and criteria for OCPA reimbursement evaluation, with consideration to clinical outcomes and needs rather than pure cost-containment. In addition, Thailand should provide greater flexibility to allow for negotiation of alternative financial models with manufacturers so that patients have better access to new medicines and the government is afforded greater certainty over health care spending. PhRMA members urge the Thai Government to engage with a range of stakeholders, including industry, to optimize the OCPA procedures and thereby improve patient access to innovative therapies.

TÜRKİYE

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in Türkiye:

Key Issues of Concern:

- **Arbitrary pricing policies**: The Turkish Government continues to set an insufficient budget for medicines that disregards exchange rate fluctuations and patient needs. Türkiye regulates pharmaceutical prices using international and therapeutic reference pricing and a fixed exchange rate instead of a market-based exchange rate to convert the value of the Euro into local currency. Although Turkish regulations had specified that the exchange rate would be updated at the beginning of each year to reflect 70 percent of the average exchange rate the preceding year, the Turkish Government changed the regulation a day before implementation to 60 percent of the average exchange rate in 2019. Such discretionary actions create significant uncertainty in the Turkish market. The practice of using an artificially low exchange rate, which is applied only to the biopharmaceutical sector, coupled with Türkiye's currency fluctuations and inflation threaten both supply continuity and the sustainability of the industry.

- **Local inspection requirements and delays**: PhRMA and its member companies welcome efforts by the Turkish Drug and Medical Device Agency (TITCK) to improve the regulatory approval procedures of highly innovative and/or life-saving products with limited therapeutic alternatives in Türkiye. Specifically, prioritizing Good Manufacturing Practices (GMP) inspection procedures and allowing a parallel marketing application process decreased delays in approving these products. However, while products deemed highly innovative or that address public health threats are eligible to receive preferential reviews, products without this designation face increased delays due to the lack of resources and efficient procedures for GMP inspections. PhRMA and its member companies commend Türkiye for becoming a PIC/S (Pharmaceutical Inspection Convention and Co-operation Scheme) member to better align its GMP inspections with other members of the scheme. However, GMP inspection delays continue to add to registration delays, hindering patient access to innovative medicines and negating the benefits of the patent and data protection periods for many products.

- **Weak patent enforcement and regulatory data protection failures**: While innovation and regulatory test data have received IP protection in Türkiye since 1995 and 2005, respectively, significant improvements are still needed. For instance, while Türkiye's Industrial Property Law, which was passed by the Turkish Parliament in 2016, better aligns Türkiye with the European Patent Convention, certain provisions in the new law inappropriately expand the possibility of granting compulsory licenses (CLs) in Türkiye. In addition, Türkiye does not provide an effective mechanism for resolving patent disputes before the marketing of follow-on products. Further, Türkiye inappropriately ties the RDP period to the patent term

and the lack of RDP for combination products is still an unresolved issue. Critically, the RDP term begins with first marketing authorization of the original product in any of the EU- Türkiye Customs Union Area Member States and thus, as a result of significant regulatory approval delays in Türkiye, the effective RDP term is reduced significantly. Consistent with Türkiye's international obligations, the RDP term should begin when a product receives marketing authorization in Türkiye.

- **Forced localization measures**: Following implementation of the 10th Development Program and provisions in Article 46 of the 64th Government Action Plan released in December 2015, the Turkish Government initiated a forced localization program which called for delisting imported products from the Social Security Institution (SSI) reimbursement list if they are not produced locally and provide preferential reimbursement for domestic products. In April 2019, the European Union (EU) launched a World Trade Organization (WTO) dispute against these forced localization measures, halting further waves of product delistings. In April 2022, the WTO Panel ruled in favor of the EU,[279] a decision that was affirmed on July 25, 2022, through arbitration under Article 25 of the WTO Dispute Settlement Understanding (DSU).[280] Since then Türkiye has taken a number of actions to implement these decisions.[281] PhRMA will continue to monitor Türkiye's response accordingly.

For these reasons, PhRMA requests that Türkiye be placed on the **Priority Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Weak Patent Enforcement

In January 2017, Türkiye enacted a new Industrial Property Law (No. 6769) that addresses IP, including patents. While the specialized IP courts have improved IP enforcement options in Türkiye, adjudication of cases is still a lengthy process, and IP Court judges lack relevant technical training and capacity to effectively resolve patent

[279] Notification of Appeal of Turkey, *Turkey – Certain Measures concerning the Production, Importation and Marketing of Pharmaceutical Products*, WT/DS583/12 (Apr. 28, 2022), available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/DS/583-12.pdf&Open=True (last visited Jan. 26, 2025).

[280] Award of the Arbitrators, *Turkey – Certain Measures concerning the Production, Importation and Marketing of Pharmaceutical Products*, WT/DS583/ARB25 (July 25, 2022), available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/DS/583ARB25.pdf&Open=True (last visited Jan. 26, 2025).

[281] Status Reports from Türkiye, *Turkey – Certain Measures Concerning the Production, Importation and Marketing of Pharmaceutical Products*, WT/DS583/18 and related addendums, available at https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(@Symbol=%20wt/ds583/*)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true# (last visited Jan. 26, 2025).

disputes. Consequently, the quality of IP trials remains insufficient, all the more as the Court of Appeals case law requires that all patent validity cases are referred to court-appointed expert panels, which often consist of a single patent attorney and lecturers from universities. Despite the new law on court appointed experts, the expert examination system also lacks appropriate procedural safeguards. While relevant case law provides that the IP Court judge can deviate from the expert panel's opinion where he or she provides a reasoned opinion to the contrary, in practice, decisions in the majority of cases mirror the opinions of the panel.

Compulsory Licensing

In addition, PhRMA and our member companies are concerned about the CL provisions of Industrial Property Law No. 6769. That law inappropriately expands the discretion to consider CLs in cases of non-use of the patent and in cases where a third-party claims that domestic demands are not being met. The vagueness of that provision creates significant uncertainty for patent holders and may be abused by competitor third parties. In December 2021, TITCK published the updated "Regulation on the Registration of Medicinal Products for Human Use" (Registration Regulation). While the Registration Regulation includes a provision on compulsory licensing, the regulation does not clarify essential substantive and procedural requirements. PhRMA believes governments should grant CLs in accordance with international rules and only in exceptional circumstances and as a last resort. Decisions should be made on public health grounds through fair and transparent processes that involve participation by all stakeholders and consider all relevant facts and options.

Regulatory Data Protection Failures

In 2005, the Turkish Government took positive steps toward establishing protection for the commercially valuable regulatory data generated by innovative pharmaceutical companies and now provides RDP for a period of six years for products starting from the first MA registration in any of the EU-Türkiye Customs Union Member States. Several aspects of this regime are however of significant concern for the innovative pharmaceutical industry.

The period of RDP currently begins on the earliest marketing authorization in any country of the EU-Türkiye Customs Union. Considering the extended regulatory approval times and delays stemming from the GMP certification approval period current estimates are that it could take up to three years, and longer in some cases, to register a new medicine in Türkiye, i.e., long after approval in the EU. Under these adverse circumstances, new products receive, in practice, no more than one to two years of RDP in Türkiye, undermining incentives needed for innovators to undertake risky and expensive research and testing.

In addition, if a product is patented in Türkiye, RDP ends when that patent expires, even if this is prior to the end of the six-year RDP term. RDP is a form of protection that

serves a different purpose than patent protection and is independent and separate from patent protection. Therefore, it should not be limited to the period of patent protection.

RDP in Türkiye is further undermined by the Regulation to Amend the Registration Regulation of Medicinal Products for Human Use. This Regulation, contrary to EU standards, does not provide RDP for combination products, unless the combination product introduces a new indication. Innovative companies invest considerable amounts of time and effort to develop products that provide increased efficacy and safety for the benefit of patients, as well as new indications, from new combinations of separate molecules.

Market Access

Arbitrary Pricing Policies

In Türkiye, pharmaceutical pricing is regulated by TITCK under the Decree for Pricing of Medicinal Products for Human Use, which sets prices at a discount below the lowest price in a basket of five European countries (France, Portugal, Spain, Italy and Greece) and the country of origin and the country of batch release. In addition, TITCK uses a fixed exchange rate instead of a market-based exchange rate to convert the value of the Euro into local currency. Over the last few years, TITCK has begun to annually adjust the fixed Euro/Turkish Lira exchange rate used to set prices under the Decree. However, per this Decree, the fixed exchange rate is currently set at 60 percent of the preceding year's actual exchange rate, automatically building in further discounts for the Turkish Government. To exacerbate the problem, the percentage coefficient was not met in 2021, 2022 nor in 2023, despite semi-annual adjustments in both 2022 and 2023. For 2024, the exchange rate was announced early (in December 2023). This has only temporarily eased the pressure and in October 2024, the Turkish government announced an exchange rate increase of 23.5 percent effective October 25, 2024. Biopharmaceutical companies continue to be confronted with uncertainty of the likelihood and parameters of the update year after year.

Industry remains concerned that the situation has become unsustainable and that without significant reform, there will be further deterioration in patient access to new medicines. Over the past five years, patient access to new medicines has significantly worsened in Türkiye. Five years ago, 30 percent of new medicines launched globally over the prior ten years were available; today, only 21 percent of new medicines launched globally over the prior ten years have launched in Türkiye, with patients waiting an average of 35 months (almost three years) for new medicines to become available.[282]

[282] PhRMA, "Global Access to New Medicines Report," 2023, available at https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report (last visited Jan. 26, 2025); PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

By definition, Türkiye's arbitrary fixed exchange rate discriminates not only against pharmaceuticals – the only sector subject to this fixed exchange rate – but also against imported pharmaceuticals contrary to Türkiye's national treatment obligations. Whereas prices for imported products are determined based on the fixed exchange rate, domestic manufacturers of innovative products that are only available in Türkiye and for which there is no international reference product available would be permitted to negotiate prices directly with the MoH based on clinical and economic evidence. The practice also appears inconsistent with Article II:3 of the Bilateral Investment Treaty (BIT) between the United States. and Türkiye, which requires that investments "shall at all times be accorded fair and equitable treatment and shall enjoy full protection and security in a manner consistent with international law." Failure to update the exchange rate to reflect the actual exchange rate at the time of calculation has continued to undermine the U.S. biopharmaceutical industry's "legitimate expectations" as to the how prices would be calculated. It is also "tantamount to expropriation," in that it substantially deprives the U.S. pharmaceutical industry of the reasonably-to-be-expected economic benefits of its investments in Türkiye to the obvious benefit of the Turkish Government, contrary to Article III:1 of the BIT.

Nontransparent Reimbursement Policies

The public reimbursement system is based on a positive list and reimbursement decisions are made by the inter-ministerial Reimbursement Commissions, led by the SSI under the Ministry of Labor and Social Security (MoLSS). The reimbursement decision process lacks transparency and is not subject to clearly defined decision criteria. Further, the process is not based on pre-defined evaluation criteria, does not require the publication of an official medical evaluation report to support the assessment and does not consider the perspectives of patients, physicians and other relevant stakeholders. Companies requesting reimbursement are required to submit a cost-effectiveness analysis, but the assessment of these submissions is opaque. On the rare occasion that a company receives a formal written decision, it is a simple one-page document stating acceptance or rejection, without any explanation of the grounds upon which the decision was made. Companies are expected to offer additional price concessions and rebates through poorly defined managed entry agreements. In 2022, the Alternative Reimbursement route, which was the pathway for most innovative products, was effectively suspended on the basis of legal ambiguity. In May 2023, the Alternative Reimbursement route was revised and re-established allowing for innovative products to utilize this pathway again. Details on this new process are forthcoming and PhRMA welcomes collaboration with Türkiye on its implementation.

The insufficient budget allocated to the health care system, especially for medicines, fuels the problems described above and remains a major concern for PhRMA member companies. Compared to other OECD countries, of which Türkiye is a member, the Turkish Government's budget does not support an innovative health care ecosystem and patient needs. In turn, Türkiye's spending on medicines is below one percent of GDP, among the lowest in the OECD.

Forced Localization Measures

In 2018, the Turkish Government began implementing policies to delist imported products from the reimbursement list.[283] With just 22 percent of new medicines launched globally since 2012 available in Türkiye,[284] the vast majority of all medicines sold in Türkiye are distributed through the SSI reimbursement list and exclusion from this list effectively bars market access for these products.

As part of the first wave of delisting notices, which impacted 71 products with additional products in 2018, PhRMA member companies began receiving notices in February 2017 that their products would be delisted within 12 months unless they submitted plans to "localize" these products in Türkiye. The second wave of delisting notifications was announced in May 2017 and affected 176 products, of which 119 products were delisted as of July 2018 with an eventual 185 products delisted over 2018 and 2019. Further rounds of de-listings were halted when the European Union initiated a WTO dispute in 2019 against the localization measures on the basis that they were inconsistent with Türkiye's national treatment obligations under several WTO agreements.

Ahead of the WTO Panel issuing its decision which ruled in favor of the EU, the Parties agreed to arbitration under Article 25 of the WTO DSU. Per that process, the Panel Report was included in Türkiye's Notice of Appeal.[285] The Arbitration Award issued on July 25, 2022, affirmed the findings of the Panel that Türkiye's localization requirement was inconsistent with the national treatment obligation in Article III:4 of the GATT 1994. In so finding, the Panel rejected Türkiye's arguments that the measures were exempt either under the "government procurement" derogation in Article III:8(a) of the GATT 1994 or under the general exemption for measures necessary to protect human life and health under Article XX(b) of the GATT 1994. Türkiye has since taken a number of actions to implement these decisions.[286] PhRMA will continue to monitor Türkiye's response accordingly.

[283] *See*, *e.g.*, Article 46 of the 64th Government Immediate Action Plan.

[284] PhRMA, "Global Access to New Medicines Report," 2023, available at https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report (last visited Jan. 26, 2025).

[285] Notification of Appeal of Turkey, *Turkey – Certain Measures concerning the Production, Importation and Marketing of Pharmaceutical Products*, WT/DS583/12 (Apr. 28, 2022), available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/DS/583-12.pdf&Open=True (last visited Jan. 26, 2025).

[286] Status Reports from Türkiye, *Turkey – Certain Measures Concerning the Production, Importation and Marketing of Pharmaceutical Products*, WT/DS583/18 and related addendums, available at https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(@Symbol=%20wt/ds583/*)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true# (last visited Jan. 26, 2025).

Biopharmaceutical Product Registration

Although efforts have been taken to improve the regulatory process, an AIFD 2023 survey indicated that the median regulatory approval period was 521 days for high priority products, 688 days for prioritized products and 836 days for normal priority products. TITCK amended its previous method for regulatory procedures and is now required to assess and authorize the registration of all medicinal products, regardless of prioritization, within 210 days; however, without additional resources to complete product registrations, delays will continue. TITCK has recently announced that it intends to increase capacity for product registrations to help alleviate the backlog.

It is estimated that the licensing process of approximately 1,800 registration dossiers is ongoing. TITCK has committed to work on solutions, but progress has been limited to date. TITCK implemented additional measures such as increasing the number of employees and announcing new guidelines. Accelerated and flexible regulatory pathways (reliance, verification, mutual recognition, etc.) are needed to reduce the backlog and ensure that Turkish patients have timely access to needed medicines. Promisingly, TITCK has shown receptivity on allowing for greater regulatory reliance, including for registrations (Regulation on the Amendment of the "Regulation on the Authorization of Medicinal Products for Human Use" announced on September, 25, 2022 and recently updated on 26th August, 2023), variations ("Regulation on Variations in Registered Medicinal Products for Human Use" announced on December 18, 2021), and in guidelines related to GMP evaluations, analysis, pharmacovigilance activities and clinical trials, and registrations. TITCK has recently started to collaborate with the WHO to enhance the regulatory process for pharmaceutical products, particularly through reliance on licensing by other authorities. TITCK further began accepting electronic submissions of clinical trial data. PhRMA and its member companies welcome the progress in variation assessment timelines and continue to request greater transparency and clarification on new marketing authorization assessment timelines.

Finally, PhRMA and its member companies are encouraged to see TITCK recognized as a Maturity Level 3 in the WHO's classification of regulatory authorities for medicines and vaccines as of 2023. Additionally, the Analysis and Control Laboratories Department of the Turkish Medicines and Medical Devices Agency has become a full member of the General European OMCL Network (GEON), coordinated by the European Directorate for the Quality of Medicines and Health Care (EDQM) as of August 2024.

Local Inspection Requirements and Delays

The MoH's revisions to the Registration Regulation have compounded the country's registration delays.[287] Effective March 1, 2010, a GMP certificate issued by the

[287] Regulation to Amend the Registration Regulation of Medicinal Products for Human Use, Official Gazette No. 27208 (Apr. 22, 2009) (Amended Registration Regulation); MoH, "Important Announcement Regarding GMP Certificates," Dec. 31, 2009 (establishing an implementation date for the GMP certification requirement).

Turkish MoH must be submitted with each application to register a medicinal product for each of the facilities at which the product is manufactured. The GMP certificate can only be issued by the MoH following an on-site inspection by Ministry inspectors, or by the competent authority of a country that recognizes the GMP certificates issued by the MoH.

Furthermore, although the Amended Registration Regulation permits applicants to submit GMP certificates issued by competent authorities in other countries, it does so only to the extent that the pertinent country recognizes the GMP certificates issued by Türkiye. While PhRMA commends Türkiye for joining PIC/S in January 2018, this is but the first of many steps that will be required before Türkiye could enter into mutual recognition agreements with the United States and other trading partners. Until mutual recognition agreements are in place, Türkiye, at a minimum, should allow for parallel processing of the GMP review and the review of the registration submission.

In response to the COVID-19 pandemic, TITCK exercised further flexibility regarding GMP submissions and GMP Certification dates. On June 2020, TITCK announced Supplementary Measures to be Applied During the Pandemic regarding GMP Inspections and Certifications, including an extension for validity of certificates and acceptance of file-based inspection submissions for high-priority products. According to an AIFD 2023 Survey, file-based inspections were carried out with an inspection period of 178 days and on-site inspections with an average of 172 days. As of December 2021, file-based inspection submissions were expanded to priority products and the number of inspectors allowed to increase through 2023. Following an extension of the validity period of GMP certificates to June 2024, provisions were made to further extend the validity period for products scheduled for on-site inspections or that have undergone risk-based inspection twice but do not meet the conditions outlined in the guideline – provided that a current and valid GMP certificate from certain stringent regulatory authorities is submitted.

Financial Impact Projection Request in GMP and Registration Prioritization Applications

TITCK requested price commitments and a “two-year financial impact projection” in their assessment process for “prioritization of good manufacturing practices (GMP)” and “prioritization of registration” applications for innovative products. In June 2023, TITCK revised its Prioritization Guideline to remove this budget impact requirement. This change is a positive sign for biopharmaceutical companies in Türkiye, as prioritization of GMP inspections should be based on a clinical and technical evaluation of the scientific data, not the proposed price of the drug or its price in other markets.

Orphan Drug Guidelines

Since 2009, the MoH has been developing a pathway for orphan medicines in Türkiye. In August 2015, the Ministry of Industry and Technology (MoIT) published an in-depth analysis of the impact of rare diseases on Türkiye’s population in its “Pharmaceutical Sector Strategy and Action Plan of 2015.” In 2022, the MoH published a “Rare Diseases Health Strategy Document” and developed an Action Plan for 2023-2027. This Action Plan was developed with significant industry consultation to establish a

market access pathway and appropriate incentives to facilitate the development and commercialization of medicines to treat rare diseases and thereby better ensure that Turkish citizens have access to the medicines they need. As part of this process, it will be critical for Türkiye to define rare diseases and orphan drugs based on international best practices, including current EU prevalence standards. PhRMA is encouraged by the recently launched Rare Diseases Health Strategy Document and Action Plan, along with the revised marketing authorization regulation, which makes it possible to apply for an exceptional license for orphan drugs.

WATCH LIST

AUSTRALIA

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in Australia:

Key Issues of Concern:

- **Weak patent law enforcement**: Contrary to its obligations under Art. 17.10(4) of the AUSFTA, Australia has not yet implemented a system by which patent holders, as a matter of practice, receive advance notice of third-party applications for marketing approval of potentially patent-infringing pharmaceutical products. The lack of adequate patent holder notification makes it difficult to resolve patent challenges prior to competitor market entry, creating significant uncertainty for patent right holders. In the rare circumstances where any such advance notice is provided, the amount of notice may be inadequate to enable the final resolution of any patent infringement claims *before* the relevant third-party product obtains regulatory approval for market entry during the term of the relevant patent(s).

- **Market-size damages**: In cases of patent invalidation by the courts, the Australian Government has joined legal action against innovators for damages attributed to a delay in the PBS price reduction due to a preliminary injunction on generic launch while the patent dispute is being resolved. These so-called “market-size damages” create significant uncertainty for pharmaceutical patent owners, who need to be able to rely on the rights conferred by granted patents (unless and until they are finally invalidated). It also undermines the rights of patent holders in Australia by introducing a strong disincentive to exercise their core right to enforce their IP protections and is inconsistent with Australia’s international commitments under the AUSFTA and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

- **Compulsory licensing**: In August 2019, the Government passed amendments to the intellectual property legislation which appear inconsistent with the AUSFTA and which could unnecessarily broaden the scope of compulsory licensing. These amendments could permit compulsory licensing on grounds that are not related to a judicially or administratively determined remedy for anticompetitive behavior, public non-commercial use, a national emergency or other circumstance of extreme urgency as agreed in Article 17.9.7 of the AUSFTA.

- **Difficulties in listing new medicines on the PBS**: PhRMA member companies continue to face challenges and uncertainty in securing positive recommendations from the Pharmaceutical Benefits Advisory Committee (PBAC) to list new medicines on the Pharmaceutical Benefits Scheme (PBS) (or Medical Benefits Schedule (MBS)). Unnecessary supplemental data requests, infrequent PBAC meetings and other administration motions cause significant delays between regulatory approval and reimbursement listing. The PBS remains one of the few

health programs in the world required to demonstrate a particular standard of cost-effectiveness and investment remains low in comparison to the overall health budget. Policies such as lowest cost comparator selection, legislated price reductions for innovative therapies and restrictive subsidy caps that can result in prices far below the cost-effectiveness standard do not support investment in innovation and ultimately result in delayed access to innovative medicines for Australian patients. The Health Technology Assessment (HTA) Review, as part of the 2022 Strategic Agreement between Medicines Australia and the Australian Government, provided an opportunity to address the difficulties in listing new medicines on the PBS and improve access for patients. The HTA Review final report was released by the Health Minister in September 2024. We encourage the Australian Government to implement the report's recommendations aimed at reducing delays to access of new medicines for Australian patients and maintaining the attractiveness of Australia as a first wave launch country.

For these reasons, PhRMA requests that Australia be placed on the **Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Weak Patent Law Enforcement

Mechanisms that provide for the early resolution of patent disputes before a potentially infringing product is allowed to enter the market are critical to ensuring adequate and effective protection of IP rights for the research-based pharmaceutical sector. Such mechanisms prevent marketing of a product potentially covered by a patent until expiration of the patent or until any dispute relating to infringement or validity of such a patent is resolved. An effective early resolution mechanism provides a procedural safeguard to avoid irreparable harm caused by an infringing product entering the market.

The Australian Government does not provide effective early resolution mechanisms for patent disputes because it continues to list generic products on the Pharmaceutical Benefits Scheme (PBS), even when it has received a certificate submitted by the patent holder that:

- patent infringement proceedings in respect of that product have been commenced in good faith;
- the proceedings have reasonable prospects of success;
- the proceedings will be conducted without unreasonable delay; and
- even when a court has granted a preliminary injunction preventing the generic company supplying that generic product.

The AUSFTA provides that when marketing approval is sought by an applicant for a generic product or "product for an approved use," where the product or approved use is claimed by a patent, the Party (here, Australia) should "provide measures in its

marketing approval process to prevent" marketing of the generic product or use during the patent term without the consent or acquiescence of the patent owner. Further, if Australia permits a third party to request marketing approval for a product or approved use claimed by a patent identified as claiming that product or approved use, it "shall provide for the patent owner to be notified of such request and the identity of any such other person."[288] This should include a database or other mechanism by which a third party may determine whether there are patents that may be infringed by the product or use for which the third party is seeking approval.

However, originator pharmaceutical companies in Australia generally do not receive any notice of a third party's intention to enter the market with a product that may infringe a valid and enforceable patent prior to its listing on the ARTG.

Originator companies are significantly impacted when generic medicines enter the market prior to the expiry of the originator patent, in part through mandatory and irreversible price cuts for innovator products listed on the PBS, and through market share erosion. The only legal option available to the innovator patentee to prevent the generic company from launching is to obtain preliminary injunctive relief (or equivalent relief), which in the case of PBS listing must be obtained in the weeks between the time marketing approval of the generic product is published on the ARTG and the next possible PBS listing date, in order to prevent the price reduction. The preliminary injunction process also comes with risk of market-sized damages as discussed below.

Currently, the lack of effective mandatory notification, the absence of an effective mechanism for the early resolution of patent disputes before an infringing product is launched in Australia and the unduly prejudicial penalties being sought by the Australian Government from patent holders for seeking to defend their IP (including liability for market-sized damages as discussed in detail below) significantly weakens the level of IP protection for pharmaceutical innovation in Australia, serving to deprive patent holders of expected benefits under international agreements including the AUSFTA.

In light of these shortcomings, PhRMA welcomed the Australian Government's efforts in 2019 to introduce legislative reforms requiring effective notification of follow-on applications submitted to the Therapeutic Goods Administration (TGA). Unfortunately, those reform efforts were abandoned after 2020. PhRMA urges USTR to prioritize engaging the Australian Government to refocus on addressing longstanding AUSFTA enforcement issues – including provisions requiring Australia to "provide measures in its marketing approval process to prevent" marketing of the generic product or use during the patent term without the consent of the patent owner.

Market-Size Damages

Biopharmaceutical innovators must be able to rely on and enforce patents issued by competent government authorities. Laws or policies that allow governments or other

[288] *See* Article 17.10(4) of the AUSFTA.

non-parties to join a patent dispute to collect "market-size damages" from innovators that pursue unsuccessful patent claims after being granted a preliminary injunction unfairly penalize and discourage the use of provisional enforcement measures as part of well-functioning early resolution mechanisms. These policies undermine legal certainty, predictability and the incentive provided by patents to invest in new treatments and cures.

Australia's Therapeutic Goods Act, as amended by the legislation implementing the AUSFTA, provides for the awarding of damages in limited specific circumstances, where a court determines that the patent holder has engaged in improper conduct specifically identified in that legislation in commencing proceedings or seeking a preliminary injunction.[289] Damages under this scheme have not been sought since its introduction. However, outside of that scheme, and pursuant to the usual undertaking as to damages provided by patent holders as a requirement for obtaining a preliminary injunction, since around 2012 the Australian Government has stated its intent to seek – and has sought – market-size damages from biopharmaceutical innovators that have legitimately but ultimately unsuccessfully pursued patent claims. It has done so even where the preliminary injunction was granted several years before the Australian Government first stated its intention to seek such damages. Those claims are purported to compensate the PBS for the effect of any delays in price reductions for patented medicine during the period of a preliminary injunction. The PBS imposes automatic price cuts on medicines as soon as competing versions are listed on the PBS, but the policy does not include any corresponding mechanism for PBS to reimburse innovators if it is found that those competing versions listed on the PBS were infringing the innovator's patents.

By pursuing market-size damages, the Australian Government is unfairly tipping the scales in pharmaceutical patent disputes and discouraging innovators from enforcing their granted patents. This policy permits the same court that granted a provisional enforcement measure in a patent dispute to allow that measure to be used as the basis for a claim for compensation by the government or another non-party to the dispute. It exposes innovators to significant additional compensation claims that may be difficult to quantify at the time the preliminary injunction was granted. The punitive size of these additional claims effectively equates legitimate patent enforcement, in circumstances where the market effects of infringing generic entry are difficult to quantify, with patent abuse. Allowing governments or other non-parties to a patent dispute to collect market-size damages undermines legal certainty, predictability and the incentives that patents provide for investment in new treatments and cures. Australia's practice appears to be inconsistent with the AUSFTA and with WTO intellectual property rules, including with respect to provisional measures.

Indeed, in the course of claiming market-size damages, representatives of the Australian Government have stated that the Australian Government will grant an

[289] *See* Schedule 7 of the U.S. Free Trade Agreement Implementation Act 2004, available at https://www.legislation.gov.au/Details/C2004A01355/ (last visited Jan. 26, 2025).

application to list a competing generic product on the PBS (the effect of which is an automatic price cut), even when:

- the patentee has lodged a certificate, required as a result of the amendments to the Therapeutic Goods Act as a result of the legislation implementing the AUSFTA as a precondition for commencing patent infringement proceedings, stating that infringement proceedings in respect of that product have been commenced in good faith, have reasonable prospects of success and will be conducted without unreasonable delay; and/or

- A preliminary injunction has been granted by a court which prohibits the supply of that product by the generic company.

Such comments typify the disregard paid by the Australian Government to the legitimate interests of innovators in enforcing their granted patent rights.

PhRMA members urge USTR and other federal agencies to prioritize actions to address Australia's pursuit of market-size damages. The Australian Government should immediately and publicly abandon its policy of seeking market size damages, or any damages, when a patent holder has legitimately sought to enforce its patent rights.

Compulsory Licensing

October 2019 amendments to Australia's intellectual property legislation on compulsory licensing, including Crown use, are unnecessary, weaken patent protection, discourage investment and limit the potential benefits of innovation for Australians. These changes may encourage or make it easier for third parties to acquire innovative technologies without authorisation, which could have significant unintended consequences. The amendments could also permit compulsory licensing on grounds that are potentially broader than the circumstances outlined in AUSFTA Article 17.9.7.

Inadequate Regulatory Data Protection (RDP)

Biopharmaceutical innovators work with hospitals, universities and other partners to rigorously test potential new medicines and demonstrate that they are safe and effective for patients who need them. Less than 12 percent of medicines that enter clinical trials ever result in approved treatments.[290]

To support the significant investment of time and resources needed to develop test data showing that a potential new medicine is safe and effective, governments around the world protect such data submitted for regulatory approval from unfair commercial use

[290] DiMasi JA, Grabowski HG, Hansen RW, "Innovation in the pharmaceutical industry: new estimates of R&D costs," J. Health Econ., 2016;47:20-33, available at https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub (last visited Jan. 26, 2025).

for a period of time. Indeed, TRIPS Article 39.3 requires each WTO member to protect undisclosed test and other data submitted for marketing approval in that country against disclosure and unfair commercial use.

RDP is essential for all medicines and is particularly critical for biologic therapies. Made from living organisms, biologics are complex and challenging to manufacture, and may not be protected adequately by patents alone. Unlike generic versions of traditional chemical compounds, biosimilars are not identical to the original innovative medicine such that there can be greater uncertainty about whether an innovator's patent right will cover a biosimilar version. Without the certainty of some substantial period of market exclusivity, innovators may not have the incentives needed to conduct expensive, risky and time-consuming work to discover and bring new biologics to market.

Strengthening RDP in Australia – in terms of the length and scope of protection – so it is aligned with global best practice would further enhance Australia's ability to compete for foreign investments in the knowledge- and innovation-intensive biomedical sector that can drive future economic growth. Australia should implement RDP terms that are consistent with international best practices. Presently, RDP for biologic products in Australia is five years (i.e., the same duration as for small molecule products), in contrast to other markets that provide longer durations for biologic products. In addition, extending RDP for new indications, new formulations, new patient populations and new dosage forms would result in consistency with other markets. In further contrast, Australia provides a 10-year RDP term for agricultural or veterinary products, highlighting an unreasonable discrepancy between incentives to deliver life changing medicines for animals compared to humans.

Market Access

Difficulties in Listing New Medicines on the PBS

The purpose of the PBS is to provide timely, reliable and affordable access to medicines for all Australians. Prescription medicines accessed via the PBS constitute the vast majority of prescription medicines dispensed in Australia.[291] Accordingly, the reimbursement process to obtain PBS listing, as well as PBAC guidelines and decision making, in effect dictate access to the Australian market. Unnecessary supplemental data requests, cost-containment focused assessments and other administration motions cause significant delays between regulatory approval and reimbursement listing, or result in no reimbursement. Moreover, HTA and pricing policies such as lowest-cost comparator selection, legislated price reductions and subsidy caps that can result in prices below the cost-effectiveness standard do not support investment in innovation and ultimately result in delayed access, and often no access, to innovative medicines for Australian patients. In fact, these policies can have a chilling effect – while 84 percent of new medicines launched globally since 2014 are available in the United States, just 24 percent are

[291] *See* Medicines in the health system 2022, available at https://www.aihw.gov.au/reports/medicines/medicines-in-the-health-system (last visited Jan. 26, 2025).

available in Australia's public national health insurance, with Australian patients waiting an average of 33 months from global first launch for the fewer medicines that do become available.[292] New medicines listed on the PBS experience delays of over a year, on average, between receiving TGA marketing authorization and PBS listing.[293]

The PBAC's approach of comparing new innovative products to the lowest cost comparator, rather than the most appropriate clinical comparator, combined with low thresholds for cost-effectiveness, creates an increasingly difficult barrier to patient access. In too many cases, comparators are old, off-patent medicines that are subject to generic or biosimilar competition (and recently some are biosimilars themselves) and have undergone several rounds of price reductions. This practice undermines the intent of Australia's split F1 and F2 formulary system, which was originally designed to recognize the value of innovation by excluding patented products from the price reductions applied to off-patent products. Today's innovative medicines offer more personalized and targeted treatments for some of the most serious conditions. Comparing these medicines to older existing medicines that are less complex and developed decades earlier does not represent fair value for the innovation involved and is an additional disincentive to bringing innovative medicines to Australia. Recent activities to provide clarity on this issue have not led to widespread selection of the most appropriate comparator. Industry welcomes the Australian Government's commitment to address the issue of comparator selection and recommends a revision to the National Health Act to give PBAC the discretion to select comparators that are not the lowest cost comparator.

Medicines Australia signed a five-year Strategic Agreement (2022-2027) with the Australian Government to secure greater predictability and stability in the PBS and policy environment, including resolution of the comparator selection issue. This Agreement was not without significant cost to the industry by cementing the application of a structured series of price reductions for patented medicines in the single-brand F1 formulary at 5, 10 and 15 years post PBS listing.

Additionally, the Agreement aimed to resolve issues with the interpretation of section 99ACB of the National Health Act and committed to no new determination of therapeutic groups during the term of the Agreement. The Strategic Agreement also lessens the statutory price reduction for patented medicines in the single-brand F1 formulary at 10 years and deepens the reduction at 15 years if no generic or biosimilar has entered the market. The application of "catch-up" price reductions in April 2023 had a significant impact on older medicines in the F1 formulary. Further, it was predicted to deliver $1.8 billion (AUD) additional savings to Australia in return for policy and process improvements for the benefit of patients, the Government and the industry. Several issues

[292] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[293] Centre for Innovation in Regulatory Science, "R&D Briefing 89: Review of HTA Outcomes and Timelines in Australia, Canada, Europe and the UK 2018-2022," Sept. 28, 2023, available at https://www.cirsci.org/publications/cirs-rd-briefing-89-review-of-hta-outcomes-and-timelines-in-australia-canada-europe-and-the-uk-2018-2022/ (last visited Jan. 26, 2025).

have arisen with implementation and industry is concerned that the Australian Government is not meeting the intent of the Agreement. Any outcome that does not deliver on the intent of the Strategic Agreement will ultimately impact patient access to innovative medicines.

A House of Representatives Inquiry into the approval processes for new drugs and novel medical technologies resulted in substantial stakeholder interest with over 200 submissions. Issues raised focused on the slow time to access, the importance of access to treatments for rare diseases and the undervaluation of innovation in HTA. The committee report was published in November 2021 and included many recommendations that are aligned with industry asks. The Australian Government responded in November 2023 and accepted 26 of the 31 recommendations, looking to the recently completed HTA Review for implementation of many of the recommendations.

In September 2024, the final HTA Review report, first initiated in 2022, was published and details 50 strategic recommendations aimed at improving access to medical technologies, enhancing equity for diverse patient groups and increasing the use of real-world data.[294] It also includes a reduction to the base case discount rate of no more than 3.5 percent for health technologies that have upfront costs and benefits that are claimed to accrue over a long period of time (such as gene therapies and some vaccines), aligning with international best practices when implemented. Key recommendations include accelerating access to medicines through the PBS to reduce delays in introducing innovative treatments, enhancing patient and clinician engagement to ensure decisions reflect patient needs and values, and the importance of collaboration between the government, industry and patient advocacy groups to maintain reform momentum.

On November 20, 2024, the Australian Government announced the creation and members of the new HTA Review Implementation Advisory Group (IAG).[295] The IAG will help guide critical reforms in response to the findings and recommendations of the September HTA Review Report. PhRMA and its member companies welcome the IAG and its mission to address the HTA system so patients can access new medicines without unnecessary delay.

It is important that the PBS and associated PBAC processes streamline and evolve as new and more advanced health technologies become available. Significant progress has been made in consultation with industry to improve regulatory review with the implementation of the Medicines and Medical Devices Review, including new fast-track regulatory pathways such as Priority Review and Provisional Approval. However, there is

[294] Health Technology Assessment Policy and Methods Review – Final report, Sept. 10, 2024, available at https://www.health.gov.au/resources/publications/health-technology-assessment-policy-and-methods-review-final-report?language=en (last visited Jan. 26, 2025).

[295] Speech, Minister for Health and Aged Care, Nov. 20. 2024, available at https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/minister-for-health-and-aged-care-speech-20-november-2024 (last visited Jan. 26, 2025).

currently no corresponding change in the HTA and reimbursement system to accommodate these new pathways, although changes could be considered as part of the HTA Review. Industry looks forward to continued work with the Australian Government to implement a fit-for-purpose HTA and reimbursement system to ensure that Australians have timely access to lifesaving and life-changing innovative medicines.

Government-Initiated Post-Market Reviews of PBS Listed Medicines

The Australian Government conducts post-market reviews of PBS-listed medicines to inform decision-making and to improve health outcomes for all Australians.[296] While the stated objective of these reviews has been to improve the use of medicines, most reviews have had an imbalanced focus on cost-containment. Industry hopes that considering the statutory price reductions included in the Strategic Agreement, the focus of future post-market reviews will be to improve the quality use of medicines. The Strategic Agreement also aims to reduce the time for these post-market reviews to less than 12 months. Industry and government worked together to design a post-market review system to help meet this goal while retaining transparency and public consultation. The revised post-market review framework was implemented in January 2024.

Public Summary Document Changes

The PBAC has implemented new requirements for Public Summary Documents in which it will publish all clinical evidence relied upon by the PBAC to inform its decision-making. The only exception has been for academic-in-confidence information. Unfortunately, however there is a current proposal to remove this protection based on journal editors removing the need for trial data to remain unpublished prior to journal publication. The PBAC does not consider that commercial-in-confidence issues should apply to the publication of clinical data used for deliberations. While there has been ongoing consultation with the industry on this matter, industry remains concerned that the clinical data redaction criteria are too narrow and may discourage submission of commercial-in-confidence data in PBAC submissions. To that end, industry will monitor this issue to address any unintended consequences or access barriers that arise.

Biosimilars

Contrary to Australia's goal of fostering a biotechnology industry, the government elected in early 2018 not to implement a unique naming convention for biologic medicines. The current government, elected in 2022, has also made no indications they would implement unique naming conventions. The absence of such a policy has the potential to weaken pharmacovigilance, post-market monitoring and confidence in the introduction of biosimilar medicines. Moreover, the impact of the government's policy of allowing substitution between biologic and biosimilar products at the pharmacy level, particularly in a health system that does not support unique naming conventions for biological medicines, has not yet been assessed. It will be important to ensure that policies seeking

[296] *See* http://www.pbs.gov.au/info/browse/reviews (last visited Jan. 26, 2025).

to increase the use of biosimilars do not inadvertently disincentivize or hamper competition and discourage innovative manufacturers of original biologics to enter and remain in the Australian market, and that the evolving multi-brand biologic medicines and biosimilars sector delivers savings and creates headroom for innovative medicines. PhRMA strongly encourages the Australian Government to deepen consultation with industry as it seeks to develop evidence-based, consistent and comprehensive biosimilars policies that support appropriate use of biologics and biosimilar medicines.

EGYPT

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in Egypt:

Key Issues of Concern:

- **Weak patent enforcement and compulsory licensing threats**: Egypt lacks effective patent enforcement , enabling manufacturers to obtain marketing licenses for follow-on products prior to the expiration of the patent on the original product. Also, in 2020, the Egyptian Government established a ministerial committee with broad discretion to issue compulsory licenses.

- **Government pricing, reimbursement and procurement**: While Egypt has significantly improved registration and pricing timelines,[297] the Egyptian Government continues to implement an international reference pricing (IRP) regulation that limits and delays patient access to innovative medicines. In addition, the UPA government procurement processes lack transparent criteria, contracting terms and timelines that further hinder the ability of PhRMA member companies to plan and invest in bringing new medicines to the market. UPA is also currently planning to implement a new health technology assessment (HTA) system to inform pricing and reimbursement decisions, but important details have not been announced. For both the public and private market, there is a need to establish a fair, transparent and predictable pricing system that can adapt to currency and inflation fluctuations.

- **Clinical trials**: While Egypt has improved its framework for clinical trials by better aligning with international standards, the process for approvals remains uncertain and confusing. In response to industry engagement, the Egyptian Government established an independent council that will oversee the regulatory landscape with the aim of expediting approval timelines and increasing the number of sponsored clinical trials conducted in Egypt.

For these reasons, PhRMA requests that Egypt remain on the **Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Egypt announced a National IP Strategy in 2022, which includes high level national goals and targets to reform its legislative and institutional IP frameworks. The IP strategy

[297] IQVIA, "Assessment of Access-to-Medicine Timelines in Selected Countries in Middle East and Africa," 2022, available at https://www.iqvia.com/locations/middle-east-and-africa/library/white-papers/assessment-of-access-to-medicine-timelines-in-selected-countries-in-middle-east-and-africa (last visited Jan. 26, 2025).

is set to take place over five years. Pursuant the IP Strategy, the Egyptian House of Representatives approved in June 2023 a law to establish the Egyptian Authority for Intellectual Property (EAIP) that would oversee and manage all forms of IP in Egypt. The EAIP named a chairman in August 2024 and is expected to be fully operational in 2025. While the establishment of the EAIP is important for centralizing and streamlining the management of IP matters within a single authority, limited progress has been made to address IP challenges faced by biopharmaceutical innovators.

Weak Patent Enforcement

Despite recognizing the value of protecting biopharmaceutical innovations through its patent system, Egypt does not provide an effective mechanism to ensure that follow-on marketing licenses are not granted to companies making products that potentially infringe on an originator's patent. Egyptian officials need to put in place an effective patent enforcement system similar to the process used by the United States or in other neighboring countries. The newly established EAIP should prioritize addressing effective patent enforcement in Egypt.

In neighboring countries, regulators who receive a marketing application from a generics company are required to check for any existing patents applying to the reference drug. Egypt should seek to provide innovators transparent and effective early dispute resolution mechanisms to avoid the marketing authorization of possible patent infringing products. At a minimum, the EAIP should oversee an early dispute resolution mechanism that (1) provides notification to right holders when third parties apply for marketing approval of generic or biosimilar versions of medicines; (2) enables the holder of a patent on a biopharmaceutical product to seek provisional enforcement measures, such as a stay, preliminary injunction or interlocutory injunction, to prevent the marketing of a potentially infringing generic or biosimilar version of that product; and (3) allows for the timely resolution of patent disputes before an infringing follow-on product is allowed to launch on the market.

Compulsory Licensing Decree No. 251/2020

In early February 2020, the Prime Minister issued Decree No. 251/2020 forming the Ministerial Committee stipulated in Article 23 of the Law with the authority to compulsory license or expropriate any patented product or process. The Decree and Egypt's Patent Law (Law no. 82/2002) give the committee broad discretion to take patents. The votes of only three of the five members of the committee are necessary to issue a compulsory license (CL).

The fact that the Government of Egypt established a ministerial committee nearly two decades after the Patent Law entered into force – and without any prior notification to or engagement with the private sector – sent an alarming signal to the companies we represent and to many other innovative industries.

Experience and research demonstrate that compulsory licensing is not an effective way to improve access or achieve other public health objectives. It does not necessarily lower prices or speed access in the short-term or provide sustainable or comprehensive solutions to longer-term challenges. It does not address systemic barriers to access – from weak health care delivery systems to low national health care funding and high taxes and tariffs on medicines. Compulsory licensing is particularly ineffective relative to the many alternatives available, such as voluntary licensing. Biopharmaceutical innovators support different tools and programs that make medicines available to patients who could not otherwise afford them.

PhRMA believes governments should grant CLs in accordance with international rules and only in exceptional circumstances and as a last resort. Decisions should be made through fair and transparent processes that involve participation by all stakeholders and consider all relevant facts and options.

Regulatory Data Protection Failures

Egypt's Patent Law (Law no. 82/2002) contains language which attempts to protect the confidential data that biopharmaceutical innovators submit to regulatory authorities to demonstrate the safety and efficacy of a medicine as part of the marketing approval process. One critical deficiency in the law revolves around how Egypt calculates the period of protection. Instead of providing protection from the date of marketing approval, Egypt provides protection from the date the data is submitted to EDA. Moreover, some members report that regulatory authorities are allowing reliance on test data submitted by originators in other countries when granting marketing approval for follow-on pharmaceutical products, resulting in unfair commercial use.

Egypt should remedy these deficiencies and provide adequate regulatory data protection (RDP). Providing effective RDP is not only sound policy consistent with global best practices but also required under Egypt's international treaty commitments as a member of the World Trade Organization.

Market Access

Government Pricing and Reimbursement

Through Pricing Decree No. 499/2012, EDA continues to implement IRP, which limits and delays access to innovative medicines. Only 21 percent of new medicines launched globally since 2014 have launched in Egypt, with Egyptian patients waiting an average of 37 months from global first launch for new medicines to become available.[298] Although some progress has been made, PhRMA and its member companies remain concerned that Egypt has yet to systematically address the drawbacks of its current pricing system, including by establishing a method to adjust for exchange rate fluctuations

[298] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

and address concerns regarding the basket of reference countries and the formula used to set prices. Ultimately, the current policies are incompatible with the country's goal of establishing a value-based health care system. Industry seeks to work with EDA to resolve the challenges of Pricing Decree No. 499/2012, put a hold on the implementation of any new pricing mechanism not required by an existing national law or decree, and transition toward a value-based pricing and reimbursement system.

Government Procurement

Established in 2019, the UPA is the government authority responsible for national procurement, tendering, medical supplies and HTA. The UPA aims to accelerate access to medicine through value-based procurement and reimbursement methodologies, but it currently lacks required capabilities and policies. As a result, PhRMA member companies face many challenges regarding government procurement of medicines. Frequent price renegotiations have limited predictability and fair competition, and the lack of transparent criteria, contracting terms and timelines for the procurement process have hindered the ability of companies to plan and invest in bringing new medicines to market. Clarity and predictability in the mechanisms for tendering price adjustments would provide patients greater access to innovative medicines. Unfortunately, the UPA continues to prioritize cost containment over quality when procuring drugs for public institutions. Finally, contrary to current practice, UPA should not disclose confidential negotiated net prices, as doing so harms competition and access to innovation.

Clinical Trials

PhRMA and its member companies are encouraged by EDA's commitment to support clinical trials in Egypt and its announcement that all clinical trials will follow international best practices in conjunction with EDA-supported training sessions for trial sponsors. However, the process and timeline for clinical trial approval remains undefined, prolonged and opaque. PhRMA submitted a compilation of best practices to the MoH, highlighting these issues and requesting enhanced coordination. In response to industry engagement, the Egyptian Government established an independent council reporting to the Prime Minister that will oversee the regulatory landscape with the aim of expediting approval timelines and increasing the number of sponsored clinical trials conducted in Egypt. One of the first decisions taken by the council was to allow for parallel submissions, targeting an average approval timeline of 120 days.

EUROPEAN UNION

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in the European Union:

Key Issues of Concern:

- **EU Pharma and Patent Packages**: The EU's Member States in 2016 tasked the EC with reviewing and assessing current EU legislative instruments and related incentives. The legislative proposals that derived from this exercise, published in 2023, would weaken existing incentives, including RDP, Bolar exemption mechanisms and incentives related to medicinal products to treat rare diseases. The proposals introduce the concept of conditioning IP incentives on product launches in all EU Member States within two years of obtaining an EU marketing authorization. That conditionality is wholly outside of the control of innovator biopharmaceutical manufacturers. In parallel, the EC's Patent Package seeks to create an unnecessary pan-EU CL mechanism that, as proposed, is contrary to the EU's commitments under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and would establish a new pre-grant mechanism for third parties to oppose Supplementary Protection Certificates (SPCs). These proposals follow concerning amendments in 2019 introducing an export and stockpiling waiver to SPCs for medicinal products. The SPC manufacturing waiver reduces the scope of the exclusive rights conferred by an SPC and undermines the EU's commitment to IP incentives and innovation. Both legislative packages are actively pending and continue to threaten further eroding IP incentives in the European Union.

- **Government price controls and patient access to innovative medicines**: Among numerous government price controls in effect, many EU and EFTA Member States set prices of patent-protected innovative medicines based on policies that restrict availability, limit patient access and fail to recognize the value of state-of-the-art medicines for patients and societies. Some examples include regulations that set prices based on the prices in less wealthy countries or in countries with policies that do not support innovation and based on the prices of older and less innovative products deemed to be comparable, including generics. These and other government practices, coupled with rigid health technology assessment (HTA) interpretations of value, put at risk biopharmaceutical innovation and seriously harm patient access to needed medicines. As such policies and regulations continue to ratchet European prices lower, there are increased calls for cross-border sharing of confidential price information that undermines the ability to adapt to the different needs of each country. Eighty-four percent of new medicines launched globally since 2014 are available in the United States compared to just 34 percent being reimbursed in each EU Member State,

on average.[299] These requirements for transparent and timely processes need to be enforced more rigorously across Europe and with broader oversight of national practices.

For these reasons, PhRMA requests that the European Union be placed on the **Watch List** in the 2025 Special 301 Report. Further, in light of the EU's ongoing assessment of its pharmaceutical regime, we urge USTR to conduct an **Out-of-Cycle Review** of the European Union so that the U.S. Government can evaluate progress on these critical issues and dedicate the required bilateral attention necessary to make progress on the barriers confronted by U.S. businesses in this important region.

Intellectual Property Protection

EU Pharmaceutical Package

In June 2016, the EU Member State Health Ministers requested the EC to undertake a review of existing IP-related incentives for the biopharmaceutical industry to gauge their effectiveness and impact on innovation and the availability, accessibility and affordability of medicines. The EC undertook a review process which concerns the following pieces of legislation: SPCs (Regulation EC 469/2009), Medicinal products for human use (Directive 2001/83/EC and Regulation EC 726/2004), Orphan medicinal products (Regulation EC 141/2000) and Pediatric medicinal products (Regulation EC 1901/2006).

In April 2023, the EC released a number of legislative proposals that would undermine core elements of the EU's IP regime. First, the EC proposed a number of revisions to Directive 2001/83/EC and Regulation EC 726/2004 that would reduce the RDP baseline in the EU by two years with illusory opportunities to restore those lost years of protection if the medicinal product is "released and continuously supplied" to all Member States within two years from obtaining an EU marketing authorization.[300] This condition is outside of the control of the innovator given that market launch in each Member State depends on timely pricing and reimbursement determinations, when many Member States routinely fail to meet the procedural timelines set forth in the Transparency Directive (Directive 89/105/EEC). As such, the proposed legislation practically represents a significant diminution of the RDP term in the EU. In addition, the EC is proposing to reduce the orphan market exclusivity (OME) for rare disease medicines and expand the EU's Bolar exemption to include the conduct of studies and trials and other activities needed not only for the marketing authorization but also for applications for either HTA or pricing and reimbursement. Industry is highly concerned that this definition may further undermine effective patent enforcement in the EU, given

[299] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[300] Proposed revisions to the Directive and Regulation are available at https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en (last visited Jan. 26, 2025).

that listing on pricing formularies is currently the trigger in many countries for seeking injunctive relief (clear indication that the follow-on product is threatening to infringe the innovator's patent).

EU Patent Package

Compulsory Licensing

PhRMA has serious concerns with the EC's proposed regulation (COM(2023)224) to establish a pan-EU compulsory licensing (CL) mechanism for "crisis" management.[301] Although most respondents during the consultation process supported a limited, coordinating role for the EU institutions related to CLs, the proposed regulation goes significantly further. At a time when IP rights are being opportunistically challenged by certain countries – often to support their own industrial policy goals – this unjustified, unprecedented and likely impermissible proposal to create another CL mechanism in the EU is counterproductive. Separate from the question of the EC's competency to implement a pan-EU CL that would override patents granted at the Member State level (the proposal is not limited to unitary patents), the proposed regulation is inconsistent with the WTO TRIPS Agreement. Specific concerns include that the original proposal fails to consider CLs on their individual merits, disregards the value of voluntary negotiations prior to granting a CL, lacks appropriate judicial review and imposes a four percent royalty cap, contrary to the TRIPS requirement (Article 31(h)) that the right holder "be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization." Further, the proposed regulation would cover patent applications and includes provisions that would extend the CL to cover other "measures complementing the [CL], which are necessary to achieve the objective of the [CL]." While not defined, "other measures" is broad enough that it could – and was even suggested as such in ancillary text – implicate other IP rights, including measures that would be inconsistent with the EU's obligations to protect trade secrets and regulatory data under TRIPS Art. 39.

Supplementary Protection Certificates (SPCs)

The EC's proposal (COM(2023)231) establishes a new pre-grant mechanism for third parties to oppose the grant of SPCs is misguided and should be abandoned.[302] While PhRMA supports the general intent of the proposed recast of the SPC Regulation, as well as the Unitary SPC Regulation to establish a centralized process for seeking SPCs in the EU without altering the substance of that protection, the proposed procedure includes redundant and unnecessary opportunities for third parties to oppose SPCs before they

[301] COM(2023)224 - Proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006, available at https://single-market-economy.ec.europa.eu/publications/com2023224-proposal-regulation-compulsory-licensing-crisis-management_en (last visited Jan. 26, 2025).

[302] EC, Medicinal & plant protection products – single procedure for the granting of SPCs, available at https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13353-Medicinal-plant-protection-products-single-procedure-for-the-granting-of-SPCs_en (last visited Jan. 26, 2025).

are even granted. These mechanisms are in addition to the ability to submit observations, appeal an SPC decision to the Board of Appeals and, in turn, the General Court of the European Union, as well as existing processes to contest the validity of the underlying basic patent and the SPC. While SPCs are fundamentally important in terms of restoring a portion of the effective patent term lost due to the lengthy development and regulatory approval process for new medicines, the determination of whether an application for an SPC meets the criteria and procedural requirements as set forth in the SPC Regulation does not require an opposition mechanism. Whereas Article 19(2) of the current SPC Regulation No. 469/2009 expressly excludes oppositions from the process of granting an SPC, the proposed recast takes the opposite approach without any explanation, despite the fact that over 99 percent of SPCs granted in the EU are not contested. SPC applications do not require nor merit the level of scrutiny proposed in the recast Regulation, especially given the risk of strongly negative effects upon the efficiency and effectiveness of the overall SPC review process, and risk of abuse by third parties that would potentially prevent patentees from obtaining legitimate and enforceable rights.

Both legislative packages are actively pending and continue to threaten further eroding IP incentives in the European Union.

Market Access

Government Price Controls and Patient Access to Innovative Medicines

As detailed further below, many EU countries engage in government pricing and reimbursement practices that restrict availability, limit patient access and fail to recognize the value of state-of-the-art medicines for patients and societies. Moreover, since the U.S. research-based industry is the world leader in the development of new medicines, PhRMA member companies and their innovative products disproportionately bear the brunt of these measures as they undermine the financial incentives for privately sponsored R&D. Not only does this threaten the development of new treatments and cures, it also directly threatens the competitiveness of the U.S. biopharmaceutical industry and its workers. Eighty-four percent of new medicines launched globally since 2014 are available in the United States compared to just 41 percent in EU Member States, on average.[303] These requirements for transparent and timely processes need to be enforced more rigorously across Europe and broader oversight of national and subnational practices should be in place.

Austria

Since 2017, Austria has adopted a spate of new cost-containment measures. Despite being one of the wealthiest countries in Europe, Austria sets relatively low prices on new medicines and imposes controls on utilization. Specifically, Austria sets a ceiling price for reimbursed new medicines based at or below the average price across all EU

[303] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

countries in the retail sector. In addition, Austria sets reimbursement conditions for new medicines using a traffic light colored box system: medicines in the red box are restricted while awaiting a reimbursement decision; medicines in the yellow box face prescribing restrictions as a condition of reimbursement; medicines in the green box are automatically allowed to be a prescriber's first choice but face additional automatic price cuts via therapeutic class reference pricing. Medicines outside the box system are prescribed, approved and reimbursed on a case-by-case basis, and face a reduction of 6.5 percent versus the EU average price if ex-factory revenue exceeds €750,000 for a period of 12 months. Although patients in hospitals typically have been able to access medicines immediately after regulatory approval, a new national evaluation board has been established to implement an HTA process for the hospital sector. The evaluation board generally focusing on high-cost, low-incidence medicines, started in 2024. Medicines reimbursed by the statutory social insurance system, as well as in the hospital sector, are subject to additional rebates during the patent term and to price cuts when off-patent. Moreover, after the manufacturer's sales price is set, a review of the average EU price and resulting Austria reimbursement price occurs on a regular basis. Industry has grown increasingly concerned about the unilateral nature of these measures, which are made without meaningful opportunity for engagement by industry. Overall, just 51 percent of new medicines launched globally since 2014 are reimbursed in Austria's public national health insurance, with Austrian patients waiting an average of 23 months after global first launch for the medicines that are reimbursed.[304]

Belgium

The Belgian Government sets maximum prices for all reimbursed prescription medicines and uses several cost-containment measures that impact innovative medicines. For example, a turnover tax (7.73 percent) and marketing tax (0.13 percent) are applied to sales of reimbursed medicines. For orphan medicines, the turnover tax ranges from zero to five percent depending on the turnover. In addition, when the government's medicines budget is exceeded, manufacturer revenues are clawed back through a subsidiary tax of up to four percent of the medicines budget. Only 36 percent of new medicines launched globally since 2014 are reimbursed in Belgium's public national health insurance, with Belgian patients waiting an average of 27 months after global first launch for the medicines that are reimbursed.[305]

Czech Republic

While the Czech Government has increased investment in health care and expanded access to innovative medicines, the country's pharmaceutical share of total health spending has declined considerably in the past decade from 26 percent in 2010 to 16 percent in 2023 due to rigid cost-containment regulations such as its "double

[304] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[305] *Id*.

referencing" system.[306] Under this system, the price of a new medicine cannot exceed the average price of the lowest three countries among 19 EU countries. In addition, in most cases, the reimbursed price is set at the lowest EU price of a therapeutic cluster of medicines, which can combine patented, off-patent and generic medicines.[307] Moreover, innovative medicines in the Czech Republic are subject to non-transparent and lengthy reimbursement processes that reduce patient access. Only 35 percent of new medicines launched globally since 2014 are reimbursed in the Czech Republic's public national health insurance, with Czech patients waiting an average of 33 months after global first launch for the medicines that are reimbursed.[308] The target timeline for pricing decisions is 75 days from receipt of an application and 165 days for joint pricing and reimbursement decisions. In practice, decisions take more than a year on average and broader usage of innovative medicines is often limited by volume caps imposed by managed entry agreements for new medicines and/or indications.

Denmark

Although Danish law does not directly regulate prices, the government decides which medicines are reimbursed and in effect sets prices through an agreement with the local innovative pharmaceutical industry association that requires international reference pricing, price caps, tendering and other cost-containment measures. In effect, the prices of medicines have been capped since 2006.[309] HTAs conducted by the Danish Medicines Council apply overly conservative approaches to evidence standards and sometimes reject reimbursement applications over concerns that the medicines might be used outside of the target patient population. Further, the Council's conservative approach affects the evaluation and approval of new cell and gene therapies, to which Danish patients have much worse access than in neighboring countries, such as Sweden and the United Kingdom.[310] Manufacturers also face pricing competition from parallel imports across Europe, which comprise approximately 13 percent of the Danish overall market for medicines, and which are eligible for hospital tenders. Overall, these practices have created uncertainty for biopharmaceutical innovators and patient access. Only 45 percent of new medicines launched globally since 2014 are reimbursed in Denmark's public national health insurance, with Danish patients waiting an average of 15 months after global first launch for the medicines that are reimbursed.[311]

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[306] European Commission, "State of health in the EU, Czechia Country Health Profile 2023," available at https://health.ec.europa.eu/document/download/24740e6e-1508-4b96-a098-8b8de9cc81e8_en?filename=2023_chp_cz_english.pdf (last visited Jan. 26, 2025).

[307] *Id*.

[308] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[309] IQVIA (2023). Pricing and Reimbursement Country Guide: Denmark.

[310] Life Science Insights Center, ATMP A Fact-Finding Mission, Aug. 2021.

[311] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

Finland

The Finnish pricing and reimbursement environment is both restrictive and lacks support for innovative medicines. Initially, nearly all new products are granted only basic reimbursement status (including innovative therapies for serious conditions, such as new cancer therapies and orphan drugs), leaving patients to cover 60 percent of costs. For chronic and/or severe illnesses there is a possibility for greater coverage that leaves patients to cover between zero percent and 35 percent of costs. Manufacturers seeking greater coverage must apply for special reimbursement status through a lengthy, complex and non-transparent process where there is little dialogue with manufacturers. In addition, manufacturers must submit information on wholesale prices and reimbursement status in European Economic Area (EEA) countries since Finland includes all EEA countries in its international reference pricing system, with reports indicating that Finland's drug prices are at the lower end of EEA countries.[312] New medicines in Finland also undergo frequent reimbursement reviews, with the first approved price valid for less than two years. Although a risk-sharing system established in 2017 has improved reimbursed access, cost-containment measures over the past 15 years have brought the country's pharmaceutical spending as a percentage of total health spend well below the OECD average. Only 28 percent of new medicines launched globally since 2014 are reimbursed in Finland's public national health insurance, with Finnish patients waiting an average of 28 months after global first launch for the medicines that are reimbursed.[313]

France

France heavily regulates the price of new innovative medicines and has established since 2004 annual plans of budget savings through price cuts, including a goal of saving €850 million in 2023 through price cuts alone. Over time, France has adopted several policies that negatively impact the biopharmaceutical industry, including layered mechanisms such as taxes, price-volume clauses that trigger price cuts, traditional rebates and an industry-wide clawback when national spending growth on reimbursed medicines exceeds a target level specified by the government each year. These industry payback schemes were intended to be limited to €200 million in 2023, for a cumulative €1.1 billion contribution from the biopharmaceutical industry, but they could grow much larger.[314]

Additionally, there are serious challenges with France's HTA system, which rates the clinical added value of a product as major (ASMR I), important, (ASMR II), moderate (ASMR III), minor (ASMR IV) or no clinical improvement (ASMR V), with corresponding impacts on pricing. In practice, few innovative medicines are assigned ASMR ratings of I, II or III, which means that health authorities deem most new innovative medicines as providing only a minor or no clinical improvement. However, for certain products that treat

[312] Global Data International Reference Pricing Guidebook (2022).

[313] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[314] IQVIA (2023). Pricing and Reimbursement Concise Guide: France.

severe or rare diseases and that have not yet received European marketing authorization, this delay in market access can be moderated through the French Early Access Program, formerly known as Temporary Use Authorization (ATU) process. Only 44 percent of new medicines launched globally since 2014 are reimbursed in France's public national health insurance, with French patients waiting an average of 26 months after global first launch for the medicines that are reimbursed.[315]

However, there have been some important positive signals to the innovative biopharmaceutical sector. A new agreement signed in March 2021 between the local innovative pharmaceutical industry association, Les Entreprises du Médicament (LEEM), and the French Government aims to reduce market access delays and promote investment for innovative products. During the CSIS[316] in 2021, President Macron announced that a pilot program for accelerated access would be implemented in 2022; however, it has been delayed. In this new system, products rated with ASMR I to IV would be available on the market following the HTA and during price negotiations. Recently, the ATU process was replaced by two fast tracks: the primary one, the "accès précoce," process is intended for innovative products prior to marketing authorization, and "accès compassionnel" for specific patient populations or physician-prescribed off-label use. Nevertheless, the medicines budget remains challenging and the impact of the new measures on patient access are yet to be seen. Market growth has been mostly flat since 2009, and lower than in peer countries as the French Government seeks budget savings from medicines to preserve social security finances.

Germany

Germany's Pharmaceutical Market Restructuring Act (AMNOG) of 2011 restructured its pricing and reimbursement process away from market-based pricing toward a government-managed and payer-led system of clinical evaluation and price-setting. Under AMNOG, the Federal Joint Committee (G-BA) oversees a rigid early clinical benefit assessment and subsequent price negotiations with the umbrella organization of the German payers (i.e., Statutory Health Insurances) that are tied to the outcome of the G-BA assessment. The prices of products deemed not to provide considerable or major clinical benefits are generally set at or below the price of the comparator determined by the G-BA. Lowest-cost comparators and generics are often considered by the G-BA to be appropriate comparators; however, research shows that scientific medical societies, in more than 50 percent of cases, oppose the comparator selected because it was clinically inappropriate.[317] In addition, Germany has implemented

[315] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[316] CSIS: Conseil stratégique des industries de santé is a meeting organised by French Government with global CEOs of pharmaceutical companies.

[317] Bleß H et al., "Inclusion of scientific societies in the early benefit assessment of drugs: simulated participation or valuable additional information?," Nov. 2, 2017, available in German at https://pubmed.ncbi.nlm.nih.gov/29103831/ (last visited Jan. 26, 2025).

a price freeze on reimbursed medicines since 2009 (now extended through 2026) that has reduced the comparator prices used to set the prices of many new medicines.

One of the chief complaints with the AMNOG procedure concerns the strict requirements on the types of study designs and clinical endpoints that are admissible for demonstrating proof of additional clinical benefit as well as determining comparator therapies. These rigid assessment requirements have contributed to the G-BA concluding in 61 percent of assessments that an innovative medicine demonstrates no additional clinical benefit in the specified patient subpopulation.[318] When accounting for the varying sizes of the specified patient subpopulations, the G-BA has deemed innovative medicines to have no additional benefit for 72 percent of potential patients and a considerable or major benefit for less than 8 percent of potential patients.[319] In contrast, many of these treatments have been widely recognized as important and even breakthrough therapies in the United States and other countries. G-BA benefit assessments not only affect the availability of medicines (only 54 percent of new medicines launched globally since 2014 are available in Germany compared to 84 percent in the United States), but they can heavily influence physicians' ability to prescribe new medicines to patients without repercussions.[320] Although Germany has the highest share of newly launched medicines among EU countries, it has become less likely to be the country of first European launch since AMNOG was implemented in 2011. Prior to AMNOG, roughly one in ten new medicines launched in Europe were launched in another European country before Germany; since AMNOG, that ratio has grown to one in four.[321]

In 2022, the Statutory Health Insurance (SHI) Financial Stabilization Act went into effect, shifting the AMNOG process from a negotiation-based methodology toward an algorithm-based one. The Act shortened the period of free pricing (when manufacturers can set prices prior to the G-BA assessment and the negotiations for a reimbursement amount) from 12 months to six months. It also introduced "guardrails" leading to lower prices than comparators for medicines deemed to have minor, non-quantifiable or no added benefits.[322] In addition, the Act lowered the annual sales threshold (from €50 million to €30 million) to exempt orphan drugs from the AMNOG process, raising concerns that patient access could be negatively impacted; imposed a 20 percent rebate on the reimbursement amount for patent-protected products used in combinations; and increased the mandatory rebate on medicines from seven to 12 percent for one year.

A study showed that the Financial Stabilization Act would restrict patient access to medicines and decrease the attractiveness of Germany as an innovative hub for the

[318] AMNOG-Monitor (https://www.amnog-monitor.com/). Sept. 2023.

[319] *Id.*

[320] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[321] PhRMA analysis of regulatory data and IQVIA data on launches.

[322] The "guardrails" apply when the comparator is also patent protected.

biopharmaceutical industry.[323] In 2024, an external evaluation of the Act, and its potentially negative effects on investment and the availability of innovative medicines, concluded finding that the legislation had negatively influenced the investment climate.

In 2023, the German Government announced its intention to adopt a dedicated strategy for strengthening Germany as a pharmaceutical location, including pledging to permanently reduce the mandatory discount back to 7 percent.[324] As a result of Germany's pharmaceutical strategy, Germany also adopted the Medical Research Act (Medizinforschungsgesetz, MFG) in 2024. It is designed to make Germany more attractive as a research and production location for the pharmaceutical industry by exempting new medicines from the price-lowering "guardrails," but only if a specified portion of the new medicine's clinical trial participants and the R&D department, including dedicated projects and public private partnerships, are located in Germany. While this adds more flexibility to the guardrails, PhRMA and its member companies encourage the German Government to abolish the "guardrails" rather than discriminatorily providing more favorable reimbursement terms to those who locate their R&D in Germany.

Greece

PhRMA and its member companies are concerned about excessive and growing mandatory clawbacks and rebates in Greece, which undermine innovation and delay patient access to new medicines. In 2022, the total industry amount for clawbacks and rebates (€2.8 billion) exceeded total public spending on medicines (€2.6 billion). Only 29 percent of new medicines launched globally since 2014 are reimbursed in Greece's public national health insurance, with patients waiting an average of 32 months after global first launch for the medicines that are reimbursed.[325]

Greece's biopharmaceutical environment remains among the most challenging in Europe, due especially to drastic reductions in public spending on medicines alongside growing clawbacks and rebates required from industry. The public budget for medicines declined by 58 percent between 2009, the last year before the financial crisis, and 2015 (from €5.9 billion to €2.5 billion) due to the austerity measures triggered by the Economic Adjustment Program.[326] Since 2015, the public budget for medicines has remained flat while the industry amount for clawbacks and rebates has grown. In 2023, total mandatory returns (clawbacks & rebates) accounted for 50% of the total reimbursed market.[327]

[323] Vfa, "Evaluation of GKV-FinStG," Sept. 2023, available in German at https://www.vfa.de/de/wirtschaft-politik/amnog/evaluation-gkv-finanzstabilisierungsgesetz (last visited Jan. 26, 2025).

[324] Federal Chancellery Germany, "10-Points to promote Germany as a business location," July 2023, available in German at https://www.bundesregierung.de/resource/blob/992814/2216780/a029b42247352acf780077f39e3bda99/2023-07-29-10-punkte-fuer-den-wirtschaftsstandort-deutschland-data.pdf (last visited Jan. 26, 2025).

[325] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[326] Hellenic Government, Joint Ministerial Decision B1/ok.48568/2022, available in Greek at https://www.e-nomothesia.gr/kat-ygeia/farmakeia/kya-b1-oik-48568-2022.html (last visited Jan. 26, 2025).

[327] SFEE IOVE, The Pharmaceutical Market in Greece, Facts & Figures 2023.

Essentially, all growth in Greece's biopharmaceuticals market over the past nine years has been paid for by industry clawbacks and rebates, or by increased patient copayments. The Greek Government introduced industry offsets that reduce clawbacks and rebates for companies who invest in R&D and production; however, the mechanism is designed such that primarily domestic companies and local producers are eligible, thereby shifting more of the growing burden of clawbacks and rebates to U.S. and other non-domestic companies.[328] In 2022, through the Recovery and Resilience Facility (RRF) the Greek Government committed to reducing clawback payments for the years 2022-2025 by €900 million and the government is engaged in ongoing discussions to create an Innovation Fund for specific innovative medicines, such as Advanced Therapy Medicinal Products (ATMPs) and those designated as PRIME medicines.

Hungary

Government pricing and reimbursement of medicines in Hungary has been under substantial pressure since the Pharma Economic Act of 2007 and the two Széll Kálmán austerity plans. Following the financial crisis, the biopharmaceutical budget was frozen, only returning to pre-crisis levels, in real terms, in 2018. However, Hungary is capping the prices for new products in Hungary to the lowest price at launch in any EU country. Hungary also engages in a "blind bidding system" for therapeutic reference pricing groups which can be comprised of both patented medicines that have been marketed for at least one year and off-patent medicines. The system requires manufacturers to submit "blind" price reductions to the National Health Insurance Fund of Hungary (NEAK) every six months.[329] Only 17 percent of new medicines launched globally since 2014 are reimbursed in Hungary's public national health insurance, with Hungarian patients waiting an average of 39 months after global first launch for the medicines that are reimbursed.[330]

In late 2020, the Hungarian Government granted a compulsory license (CL) on a COVID-19 treatment conditionally approved by the EMA, citing newly promulgated emergency Law Decrees 283/2020 and 478/2020. This action was unnecessary as Hungary had full access to the medicine via the EC's Joint Procurement Agreement (JPA) with the patent holder and continues to use it to meet its national needs. Further, it was contrary to the EC's IP Action Plan, which states that CLs can only "be used as a means of last resort and a safety net, when all other efforts to make IP available have failed." Throughout this process, the Hungarian Government did not contact the patentee to suggest that a CL was needed and the CL was granted with only a day's notice to the patentee. Although the CL action was challenged in the national court system, the lower court ruled that the patentee did not have standing to challenge the grant of the CL per se, a standard which would make it impossible to challenge the grant of any CL in

[328] Deloitte, "Offsetting pharmaceutical expenditure clawback from October 2021 to December 2023," Oct. 25, 2021, available at https://www.taxathand.com/article/20448/Greece/2021/Offsetting-pharmaceutical-expenditure-clawback-from-October-2021-to-December-2023 (last visited Jan. 26, 2025).

[329] IQVIA (2023). Pricing and Reimbursement Concise Guide: Hungary.

[330] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

Hungary. In October 2023, that decision as well as the grant of the CL was annulled by Hungary's Constitutional Court, finding that the patentee had been deprived of its fundamental right to be heard and defend its rights.

In April 2022, the Hungarian Government instituted an increased clawback requirement whereby the clawback is raised from 20 to 28 percent for drugs having an ex-factory price (MSP) higher than 10,000 HUF. In June 2023, the 28 percent clawback rate was further raised to 40 percent for drugs having an MSP higher than 10,000 HUF. In 2023, the Hungarian Government also introduced a policy allowing manufacturers to reduce their clawback payments by up to 50 percent, based on the value of their investment and R&D expenditures in Hungary.

Ireland

Ireland's biopharmaceutical industry is among the Irish economy's strongest performers, with robust growth in exports of pharmaceutical products contributing positively to gross domestic product (GDP). However, Ireland continues to lag many other European countries when it comes to the availability of new medicines. Only 23 percent of new medicines launched globally since 2014 are reimbursed in Ireland's public national health insurance, with patients waiting an average of 38 months after global first launch for the medicines that are reimbursed.[331] The process to assess and reimburse new medicines is excessively slow. During the current 2021-2025 Framework Agreement on the Supply and Pricing of Medicines between the Irish Government and the Irish Pharmaceutical Healthcare Association (IPHA), it has taken nearly 22 months, on average, from the time of a manufacturer's application to the Health Service Executive (HSE) decision on reimbursement. The IPHA has proposed several steps, including early access procedures and a greater role for clinicians in advising on the prioritisation of medicines to be available to patients in Ireland. In March 2023, the Minister for Health set up a first-ever internal working group aimed at making the reimbursement process more efficient. However, the final report of this working group has yet to be published. In 2025, the IPHA will negotiate a new Framework Agreement with the HSE. Central to this will be reform of the process to ensure greater efficiency and faster and fairer access to medicines for patients. PhRMA urges the U.S. Government to engage with its counterparts in the Irish Government on achieving and sustaining patient access to innovative medicines through a combination of process reforms and continued annual funding commitments.

Italy

PhRMA and its member companies are concerned about industry revenue clawbacks and other cost-containment measures for innovative medicines in Italy. Only 44 percent of new medicines launched globally since 2014 are reimbursed in Italy's public national health insurance, with Italian patients waiting an average of 28 months after

[331] *Id*.

global first launch for the medicines that are reimbursed.[332] And, patients wait even longer in some regions. Industry revenue clawbacks are triggered in Italy when public spending exceeds the significantly underfunded public budget. There is currently an overall budget shortfall of €3.2 billion for medicines that is made worse by a suboptimal allocation of the budget across the retail channel and the hospital / direct purchasing channel. In 2023, there was a budget surplus in the retail channel (€600 million) and a budget deficit (€3.8 billion) in the hospital / direct purchasing channel. But, in accordance with the clawback rules, it was not possible to compensate a deficit in one channel with a surplus in the other channel; companies operating in the hospital / direct purchasing channel were required to refund 50 percent of the €3.8 billion budget deficit. Given that more innovative products have been in the hospital / direct purchasing channel, the unbalanced clawback rules disproportionately penalize U.S. innovative biopharmaceutical companies, which have so far paid 43 percent of the cumulative €8,4 billion in clawbacks from 2019 to 2022 even though they only account for 30 percent of sales. In addition, a recent study found that 98 percent of the clawback has been paid by non-domestic companies.[333]

In addition to delays and clawbacks, other policies present challenges for innovation and patient access to medicines. The Italian Drug Agency (AIFA) can determine comparators for P&R negotiations of innovative therapies without using transparent and agreed scientific criteria. Further, AIFA can re-open pricing and reimbursement negotiations for review prior to the conclusion of the agreement period.

The Netherlands

PhRMA and its member companies are concerned about the rising interest in the Netherlands regarding the use of compulsory licensing as a way to lower spending on medicines. In 2019, the government commissioned an academia-led compulsory licensing committee to examine legal and economic issues related to the use of compulsory licensing. In June 2020, the commission completed its work, unable to reach a joint conclusion. The Ministry of Economic Affairs took note of the commission's work and concluded that the existing legal framework was sufficient. However, some legislators have refocused discussions on compulsory licensing around COVID-19 related technologies, including both vaccines and therapies. PhRMA believes that future discussions about compulsory licensing need to consider the devasting effects on innovation and the R&D environment more generally. PhRMA welcomes the Prime Minister's statements making clear the government's position that compulsory licensing would not improve access to COVID-19 technologies and that the Ministry of Economic Affairs remains strongly opposed to any form of compulsory licensing.

[332] *Id.*

[333] The European House – Ambrosetti, "Increasing the attraction of foreign investment for the competitiveness of Italy. What strategy for the pharmaceutical sector?," Sept. 2, 2023, available at https://www.ambrosetti.eu/en/news/increasing-the-attraction-of-foreign-investment-for-the-competitiveness-of-italy-what-strategy-for-the-pharmaceutical-industry/ (last visited Jan. 26, 2025).

The Netherlands has also intensified cost-containment measures on innovative medicines. For example, the government began a pilot program in 2015 that places innovative medicines into a reimbursement "lock" system that denies patient access until completion of a HTA and subsequent price negotiations. The Netherlands initially implemented this system on a case-by-case basis, but announced in May 2018 that it would apply to all new medicines with an annual cost exceeding €50,000 per patient (when combined costs exceed €10 million) or a combined cost of €40 million.[334] In January 2023, the Minister of Health announced that the lock criteria for new medicines would become more stringent, applying lower cost thresholds.[335] New criteria stipulated an accumulated cost trigger that would lock all new and future indications of a product should it exceed €20 million or more per year. Further, if the expected costs of providing the medicinal product to treat a new indication is €50 thousand or more per patient per year and the expected cost impact of the dispensations is €10 million or more per year, the new indication will be placed in the lock. The decision-making criteria lack transparency and there is no time limit on the lock period, which is currently estimated to be 380 days.[336] In addition, the Netherlands application of QALY-based cost-effectiveness thresholds has become more central in decision making. Initially these threshold amounts, which have not been updated since 2006, only served as a reference and were not strictly adhered to in decision making. However, it has become more common for the outcome of HTA decisions to rely on the threshold amounts when determining access.

The government also plans in 2024 to further erode the prices of innovative retail medicines deemed by the Ministry of Health, Welfare and Sport to be therapeutically interchangeable by recalculating reimbursement limits to not exceed the average price of a therapeutic group, which can include off-patent medicines and generics. Beginning in 2020, all medicines were subject to an updated international reference pricing system that replaced Germany with Norway, where prices are an average of nine to 13 percent lower than those in the Netherlands. This change was delayed from April to October 2020. It is estimated this change reduces prices in the Netherlands by five to 10 percent and reduce annual spending on medicines by around €300 million.[337] In September 2022, an Integral Healthcare Agreement was signed by various health care stakeholders. The high-level Agreement referred to several of the above mechanisms, but the biopharmaceutical sector was not included in any stage of the process.

In addition to facing these cost-containment measures, most new medicines in the Netherlands are required to navigate a complex path from regulatory approval to

[334] IHS Global Insights (May 2018). Netherlands expands criteria for inclusion of high-cost drugs in "reimbursement lock," renegotiates price of Tecentriq® and Soliris®.

[335] Letter to Parliament about changes in policy rules for the application of the lock for expensive medicines (Jan. 24, 2023), available in Dutch at https://www.rijksoverheid.nl/ministeries/ministerie-van-volksgezondheid-welzijn-en-sport/documenten/kamerstukken/2023/01/24/kamerbrief-over-wijziging-beleidsregels-voor-de-toepassing-van-de-sluis-voor-dure-geneesmiddelen-op-grond-van-artikel-24a-van-het-besluit-zorgverzekering (last visited Jan. 26, 2025).

[336] Association of Innovative Medicines in the Netherlands, June 2020.

[337] IQVIA (2023). Market Prognosis: Netherlands.

reimbursement. Only 29 percent of new medicines launched globally since 2014 are reimbursed in the Netherlands' public national health insurance, with Dutch patients waiting an average of 36 months for the medicines that are reimbursed.[338] Recognizing this challenge, the Medicines Evaluation Board and the Dutch National Healthcare Institute began a pilot in collaboration with industry to reduce reimbursement delays.

Norway

Despite its considerable wealth and universal health coverage, Norway has one of the lowest levels of spending on medicines as a share of total health care spending in Europe (eight percent in 2019 compared to an average of 15 percent for Europe).[339] Through the national centralized procurement agency of the Norwegian Government, four regional health authorities establish pharmaceutical formularies and conduct price negotiations and purchases. This agency determines the maximum price of new medicines based on the average of the three lowest prices in a basket of nine European countries. Additionally, Norway obtains substantial price discounts on some innovative medicines through its centralized procurement process, which uses therapeutic tenders that often include older medicines and generics. In previous years, there have been concerning disclosures of PhRMA member company confidential net prices. While the Norwegian Government maintains that these disclosures were unintentional, repeated disclosures indicate weak safeguarding of trade secrets, thus becoming a barrier to fair competition in the Norwegian market. Only 26 percent of new medicines launched globally since 2014 are reimbursed in Norway's public national health insurance, with Norwegian patients waiting an average of 23 months for the medicines that are reimbursed.[340]

Poland

Poland caps the share of public spending on medicines using industry clawbacks; however, the share of National Health Fund spending on medicines has always remained relatively stable and under the 17 percent ceiling at which point industry clawbacks are mandated. In 2021, the Polish Government drafted an amendment to increase industry clawbacks above the cap from 50 to 100 percent and remove exemptions from the cap for risk-sharing schemes, but industry successfully pushed back on this proposal. The government has constricted public spending on medicines through a combination of therapeutic reference pricing that can tie the price of patented medicines to the lowest price generics, price cuts, fixed margins, high co-pays, restricted access to limited beneficiaries and other cost-containment measures. Poland's government pricing and reimbursement system is underfunded and significantly backlogged. Only 27 percent of new medicines launched globally since 2014 are reimbursed in Poland's public national

[338] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[339] IQVIA, Understanding Net Pharmaceutical Expenditure Dynamics in Europe, Apr. 2022.

[340] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

health insurance, with Polish patients waiting an average of 43 months after global first launch for the medicines that are reimbursed.[341] To promote access to innovation needed by patients, Poland should ensure that public health spending is allocated a sufficient share of public spending and implement market access measures that promote patient access to innovative medicines.

Romania

PhRMA and its member companies are concerned about the lack of health care funding, onerous pricing policies and long delays in accessing innovative medicines. Romania imposes significant market access barriers for medicines, including government price controls, other cost-containment measures and administrative hurdles that significantly restrict patient access. As of 2023, the Romanian health care system continues to face significant underfunding challenges. Health expenditure in Romania accounts for only 6.5 percent of GDP (public and private), which is less than half the EU average.[342] This underfunding has led to various issues, including delays in reimbursement of new medicines, limited access to quality care, negative impacts on the retention of medical practitioners and an overreliance on out-of-pocket payments for many services. Only 21 percent of new medicines launched globally since 2014 are reimbursed in Romania's public national health insurance, with patients waiting an average of 41 months for the medicines that are reimbursed. Patients in Romania face some of the longest waiting time for accessing new medicines in Europe.

Romanian prices for medicines are some of the lowest in the European Union. A dual-pricing system is in place aimed at relieving shortages caused by parallel exports to other EU Member States. The pricing policy is based on: 1) the lowest price in a basket of 12 EU countries for CANAMED (used for public reimbursement process); and 2) the average of the lowest three countries for the Public Catalogue (used for international reference pricing by other EU countries). While this pricing policy was originally intended to protect patients in a lower GDP per capita country, it has ultimately led to further product shortages and a lack of patient access due to wealthier European countries both referencing lower Romanian prices and also importing lower-priced products from Romania.

In Romania the inclusion of new medicines on the reimbursement list is an unpredictable process, often delayed by budget constraints. In 2023, due to budgetary constraints, no managed entry agreements for new medicines were finalized. The Romanian Government aims to identify alternative funding to improve access to innovation by creating a Health Innovation Program. Progress has been made in this direction with the regulation of the Health Innovation Program through new legislation part

[341] *Id.*

[342] European Commission, "State of health in the EU, Romania Country Health Profile (2023), available at https://eurohealthobservatory.who.int/docs/librariesprovider3/country-health-profiles/chp2023pdf/chp-romania.pdf?sfvrsn=773136b7_5&download=true (last visited Jan. 26, 2025).

of the National Plan for Preventing and Combating Cancer; however, implementation and operationalization of this program remains pending.

Spain

PhRMA and member companies are concerned that patient access to innovative medicines is being negatively impacted by rejections and delays in pricing and reimbursement procedures that lack transparency and consistent criteria. Only 39 percent of new medicines launched globally since 2014 are reimbursed in Spain's public national health insurance, with patients waiting an average of 28 months after global first launch for the medicines that are reimbursed.[343] In addition, there are varying sub-national access delays across Spanish regions after national reimbursement decisions have been made.

During the fiscal crisis of 2010-2012, Spain imposed aggressive cost-containment measures that remain in place despite the country's economic rebound. Since 2010, these measures have collectively reduced pharmaceutical spending by 30 percent, however since 2021, pharmaceutical spending has increased by 7.6 percent, partially due to the COVID-19 pandemic response. Specific measures include the reimbursement delisting of more than 400 medicines, frequent direct and indirect price cuts, imposition of a 7.5 percent mandatory discount on reimbursed innovative medicines, 15 percent price rebate on medicines with more than 10 years on the market with no generic or biosimilar, restricted access for certain patient subpopulations and changes in pharmaceutical co-payment policies (e.g., pensioners began contributing a 10 percent co-payment, subject to caps and other limits).[344] Additional market access challenges have emerged with recent administrations, including: therapeutic reference pricing of innovative medicines based on a group of products that includes generics and biosimilars and mandatory prescribing by active ingredient for small molecules and biologics. Industry claw-backs, market sales caps and reference pricing will all continue to curb public pharmaceutical expenditure, placing increasing pressure on industry margins.

On December 10, the Council of Ministers approved the 2024-2028 Strategy for the Pharmaceutical Industry with the goal to (1) improve patient access to innovative medicines, (2) strengthen leadership in R&D, and (3) reinforce strategic autonomy and industrial and supply chain resilience. It is the first time the Spanish Government approved a strategy focused exclusively on the pharmaceutical sector. The industry looks forward to working with relevant authorities to ensure meaningful policy change and implementation.

[343] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

[344] IQVIA (2023). Pricing and Reimbursement Concise Guide: Spain.

Sweden

Biopharmaceutical innovators face an increasingly challenging and non-transparent environment for government pricing and reimbursement in Sweden. In making pricing decisions, the Swedish Dental and Pharmaceutical Benefits Agency (TLV) employs an opaque "value-based" system that compares new products against comparators it deems therapeutically equivalent, including medicines used outside the reimbursement system and medicines used off-label, to arrive at a lowest-cost comparator. The TLV also engages in frequent re-assessments of reimbursed medicines, which can result in price cuts and new restrictions. Manufacturers may request the possibility to present a proposed price as part of their combined pricing and reimbursement application, but their request can be rejected in a nontransparent fashion. For hospital medicines, manufacturers cannot apply for pricing and reimbursement and there is no process for appeal. Only 36 percent of new medicines launched globally since 2014 are reimbursed in Sweden's public national health insurance, with patients waiting an average of 20 months after global first launch for the medicines that are reimbursed.[345]

Switzerland

Switzerland has compulsory private health insurance, but the government regulates which medicines are reimbursed and sets the prices of those products based on the prices in other European countries (all with lower GDP per capita) as well as based on the prices of alternative therapies that may represent a lower standard of care. Moreover, the pricing and reimbursement system lacks predictability and transparency and fails to appropriately account for changes in currency exchange rates. For example, in 2015 Switzerland expanded the basket of countries used in its international reference pricing system for setting and adjusting prices of patented medicines. However, given the increasing strength of the Swiss franc relative to other currencies in the basket (Euro, UK Pound, Swedish Krona and Danish Krone), the practice has become even more damaging as many of these currencies continue to lose value relative to the Swiss franc. Compounding this issue, in 2017 the Swiss Government began setting prices based on giving equal weight to the average international reference price and the average therapeutic reference price. The products chosen for the therapeutic reference price are often unpredictable and lack scientific evidence. Every year, one-third of the reimbursement list is subject to price adjustments based on this approach. Between 2017 and 2023, the prices of more than 2,700 medicinal products were reduced by an average of 14 percent. In 2024 alone, nearly 300 innovative medicines saw their prices reduced by an average of 12 percent. Manufacturers may also be required to pay back revenue after a product's first triennial price review if the price was reduced by more than three percent and if the previous price generated more than CHF 20,000 in "excess revenue."

Starting in 2024, the Swiss Government is implementing revisions to Article 71 a-d of the Ordinance on Health Insurance that threatens to reduce patient access to

[345] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

medicines for rare diseases. Article 71 a-d establishes the process by which patients can seek reimbursement from compulsory health insurance plans for rare disease treatments not on the government's positive reimbursement list. The revisions require compulsory health insurance plans to use a benefit assessment tool (OLU tool) to evaluate patient requests and limit reimbursement amounts for unlisted medicines. The new provisions threaten patients' access to rare disease treatments.

Over the past two years, government pricing authorities have begun using additional tools such as capitation, pay for performance, indication-based pricing, budget impact tests and rebating for medicines used in combination or for multiple indications. Recently, the Swiss Parliament instituted new capitation criteria for pharmaceutical companies requiring paybacks if sales exceed a defined sales threshold. As a result of these combined policies, Switzerland has experienced more pronounced market access delays for certain innovative medicines in recent years and further erodes the period of effective IP protections for innovative medicines. Only 35 percent of new medicines launched globally since 2014 are reimbursed in Switzerland's public national health insurance, with patients waiting an average of 26 months after global first launch for the medicines that are reimbursed.[346]

[346] *Id*.

SAUDI ARABIA

PhRMA members have identified the following intellectual property (IP) challenges and market access barriers in Saudi Arabia:

Key Issues of Concern:

- **Ineffective patent protection, patent enforcement and regulatory data protection (RDP)**: In mid-2017, the Saudi Food and Drug Authority (SFDA) started granting marketing approval to generic versions of innovative medicines during the term of the patent(s) protecting those treatments or the period of RDP. SFDA's repeated approval and related price listings of generic copies of innovative medicines is contrary to Saudi Arabia's own patent enforcement and data protection rules. These actions are also inconsistent with the country's World Trade Organization (WTO) commitments. Saudi Authority for Intellectual Property (SAIP) missed a significant opportunity to ensure effective patent enforcement in its final Procedure published on November 28, 2022. While taking some steps to improve patent enforcement, the Procedure falls short of ensuring effective patent enforcement in the Kingdom and exacerbates future risks of improper SFDA approvals of patent infringing follow-on products. SAIP has also issued draft regulations on compulsory licensing and RDP that would further weaken IP protections in Saudi Arabia.

- **Government procurement lacks transparency and discriminates against foreign manufacturers**: Frequent renegotiation of tenders, combined with the lack of clear timelines, have resulted in an unpredictable government procurement system. The creation of the Local Content and Government Procurement Authority (LCGPA) to identify lists of products that must be procured from local manufacturers, combined with up to 30 percent price preferences for medicines made with locally manufactured active pharmaceutical ingredients (API), serve to discriminate against foreign manufacturers and increase uncertainty in the Saudi market. Further complicating matters, in November 2022, the LCGPA released, without public consultation or private sector input, the Economic Participation Policy (EPP) mandating that foreign companies locally invest 35 percent of the value (based on certain multipliers) of any government tender fulfilled with more than 100 million Saudi Riyal of imported products. In addition, in February 2021, the Ministry of Investment announced that multinational companies must establish their Regional Headquarters in Saudi Arabia to be eligible to participate in government tenders. This requirement was endorsed by a royal decree in December 2022.

- **Pricing guidelines do not appropriately value innovative medicines**: The SFDA pricing guidelines set prices for medicines in Saudi Arabia based on prices in a basket of reference countries, in practice taking the lowest price and subsequently imposing other re-pricing rules. This flawed approach does not appropriately recognize the value of innovative medicines for the Saudi health

system and patients. Although SFDA reduced the basket of reference countries from 30 to 20 countries, it still includes countries with very different health care and reimbursement systems. While the revised guidelines are a step forward compared to earlier drafts, the current rules are inconsistent with Saudi Arabia's vision to incentivize innovation and establish a more value-based approach to health care. Some efforts to enhance the pricing process include the option of registering products for tender only with an exemption from pricing.

- **Ensuring the new health technology assessment system supports value-based health care**: Industry stands ready to work with the Saudi authorities to ensure that the new health technology assessment (HTA) system is not used exclusively as a cost-containment tool, but rather supports timely Saudi patient access to innovative medicines and moves the country towards the value-based health care system outlined in the Saudi Health Sector Transformation Strategy.

- **New Council of Health Insurance (CHI) Policy risks patient affordability, product choice and investment**: In October 2022, the CHI issued a new policy for private sector health plans that sets co-payments for generics at 20 percent of the product price up to a maximum of $8 versus co-payments for off-patent original brands at 50 percent of the product price with no maximum. In addition, the guidelines mandate the dispensing of generic products. This large and sudden change will substantially decrease the affordability of off-patent original brands for patients. It will also immediately threaten roughly half of originator company revenues in Saudi Arabia as well as local manufacturing infrastructure investments and other local partnerships often required by the government to participate in government tenders.

For these reasons, PhRMA requests that Saudi Arabia be placed on the **Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Ineffective Patent Protection, Patent Enforcement and RDP

Despite creating mechanisms to provide for effective patent enforcement and RDP, in mid-2017 the SFDA started granting marketing authorization to domestic drug companies to produce copies of innovative medicines produced in the United States and other countries during the period of patent or RDP protection. Furthermore, the National Unified Procurement Company for Medical Supplies (NUPCO) has proceeded to procure the potentially infringing products despite multiple appeals from the relevant innovators and, in one case, despite a favorable Saudi court decision. The local drug companies are now distributing these copies to the MoH and selected hospitals. Despite Saudi Arabia being on the Priority Watch List between 2019-2021 and multiple political commitments to solve ongoing cases, rather than end this practice, SFDA continues to ask follow-on

manufacturers to seek approval for generic products even where the innovative product is still subject to IP protections, including RDP.

SFDA's actions appear designed to benefit Saudi Arabia's local industry, as evidenced by the tenders awarded by NUPCO. These actions harm U.S. manufacturers, potentially infringe proprietary technology and damage U.S. exports. Contrary to the country's aspirations to promote local investment, IP infringement and the lack of effective enforcement sends a hostile message to U.S. inventors and investors that their valuable IP rights are not secure in Saudi Arabia.

These actions also appear contrary to Saudi law and to Saudi Arabia's WTO commitments. For example, Article 5 of a Council of Ministers' Trade Secrets Protection Regulation (decision No. 3218, dated 25/03/1426 H, May 4, 2005), as amended by Ministerial Decision No. 431 of 1.5.1426H (June 8, 2005) states that the submission of confidential tests or other data, obtained as a result of substantial efforts, for the approval of the marketing of drugs or agricultural products which utilize a new chemical entity, shall be protected by the competent authority against unfair commercial use for at least five years from the approval date. Unfortunately, the Kingdom of Saudi Arabia has not complied with its own regulation and WTO commitments which gave rise to the regulations. Specifically, Saudi Arabia confirmed during its accession to the WTO that:

> [Its] Regulations provided for protection of undisclosed tests and other data submitted to obtain approval of a pharmaceutical or agricultural chemical against unfair commercial use for a minimum period of five years from the date of obtaining the approval including the establishment of the base price. No person other than the person who submitted such data could, without the explicit consent of the person who submitted the data, rely on such data in support of an application for product approval. Any subsequent application for marketing approval would not be granted a market authorization unless the applicant submitted its own data, meeting the same requirements applied to the initial applicant, or had the permission of the person initially submitting the data to rely on such data.[347]

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) imposes more than a non-disclosure obligation. Rather, TRIPS Article 39.3 additionally requires WTO Member States to prevent "unfair commercial use" of data generated by others. This is fulfilled by preventing reliance on regulatory test data and approvals based on such data for a fixed period of time. In other words, protected data may not be used to support marketing approval for follow-on products for a set amount of time unless authorized by the original submitter of the data. Unfortunately, the SFDA is

[347] Report of the Working Party on the Accession of the Kingdom of Saudi Arabia to the World Trade Organization, WT/ACC/SAU/61 (Nov. 1, 2005) ¶ 261, available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/ACC/SAU61.pdf (last visited Jan. 26, 2025).

interpreting the Saudi Regulations in a restrictive way limited to non-disclosure that allows it to rely on the innovator's regulatory data or limited data published in scientific journals.

In September 2020, SAIP published new draft regulations for the protection of confidential business information, including regulatory test data. Far from improving on a prior draft issued in 2019, the 2020 draft would further weaken RDP in Saudi Arabia. Among other things, the draft contains a general provision on RDP without specifying the term of protection and explicitly states that reliance on the clinical data package submitted by the innovator to SFDA does not constitute unfair commercial use. The draft also lacks clarity with respect to the scope of products covered, contains overly broad exceptions to RDP and continues to lack the necessary mechanisms for effective enforcement.

In addition to making no progress on RDP, in April 2020, SAIP issued damaging final regulations on the compulsory licensing of patents, which have the potential to frustrate Saudi Arabia's efforts to promote innovation and economic growth. The final regulations largely disregard comments biopharmaceutical innovators provided on draft regulations SAIP published in July 2019. PhRMA believes governments should grant compulsory licenses (CLs) in accordance with international rules and only in exceptional circumstances and as a last resort. Decisions should be made through fair and transparent processes that involve participation by all stakeholders and consider all relevant facts and options. By allowing SAIP to take patents away three years after they are lawfully granted for almost any reason and without prior notice to the patent holder, the regulations risk encouraging excessive use of CLs and denying patent holders the right to adequately defend their property interests.

After signaling in 2020 positive intentions to strengthen patent protection through a new initiative on protecting IP, SAIP missed a significant opportunity to ensure effective and efficient patent enforcement in the Kingdom. On November 28, 2022, SFDA issued its final Procedure, which went into effect on January 1, 2023. While the Procedure recognizes the need to ensure that patents are respected when considering generic applications for marketing authorization, it falls short of the mechanisms needed to provide effective and efficient enforcement of biopharmaceutical patents. For example, the Procedure does not provide notice to patent holders when third parties apply for marketing approval of follow-on products. Also, while the Procedure does include a mechanism for innovators to report their patents (including patents issued by the Gulf Cooperation Council (GCC) Patent Office), and requires generic applicants to obtain a "Freedom to Operate" statement from a licensed IP agent before they can apply for a marketing authorization from the SFDA, right holders were only granted 30 days to report their existing patents before the entry into force of the procedure in January 2023. Moreover, the Procedure does not anticipate the availability of provisional enforcement measures or include measures to facilitate the timely resolution of patent disputes. Finally, right holders are unable to ascertain the sufficiency of the Freedom to Operate statement, which further compromises the Procedure.

Biopharmaceutical innovators have repeatedly engaged or sought to engage SAIP and other relevant Saudi ministries to address these concerns and to improve IP

protection in the Kingdom. While some good progress has been achieved, PhRMA will continue engaging and maintaining an open dialogue with the Saudi authorities to best improve the IP environment in the country. The National IP Strategy launched in 2022 is an important opportunity to achieve this goal and PhRMA looks forward to engaging on the concrete measures falling under this strategy. In particular, PhRMA urges SAIP to work towards finalizing robust regulations on the enforcement of RDP.

Market Access

Government Procurement Lacks Transparency and Discriminates Against Foreign Manufacturers

Government procurement of pharmaceuticals in Saudi Arabia presents many challenges. Although the tendering system is supposed to be closed, the practice of routine price renegotiations limit predictability, sustainability and fair competition. The lack of clear timelines for the procurement process hinders the ability of companies to plan and invest in bringing new medicines to the market and exposes Saudi Arabia to the risk of supply shortages. In addition, Saudi Arabia has adopted a newly designed therapeutic class review process, whereby only a single product is identified for inclusion on formularies and for procurement. Such approaches unduly restrict patient and physician choice in identifying the most appropriate treatment for each patient. Finally, contrary to current practice, NUPCO should not disclose confidential negotiated net prices as it harms competition and access to innovation.

In addition to these deficiencies in the procurement process, Saudi Arabia constituted the LCGPA to identify lists of products that government institutions must procure from local manufacturers. The first list of products has been released and it identifies more than 100 medicines that are limited to local providers. Additionally, Saudi Arabia has announced a price preference initiative of up to 30 percent for 42 locally manufactured products made using API manufactured in the country. These actions discriminate against foreign manufacturers and increase uncertainty in the Saudi market. Further complicating matters, in November 2022, the LCGPA released, without public consultation or private sector input, the EPP mandating that foreign companies locally invest 35 percent of the value (based on certain multipliers) of any government tender fulfilled with more than 100 million Saudi Riyal of imported products. Despite calls from PhRMA and other bodies representing U.S. industry to postpone the application of this policy to allow a robust consultation with the public sector, the policy was finalized in late 2023. Recently, LCGPA signaled consideration for amending the policy with provisions specific to the health care sector. PhRMA welcomes the opportunity to provide input to LCGPA to ensure \fit-for-purpose policies. In addition, in February 2021, the Ministry of Investment announced that multinational companies must establish their Regional Headquarters in Saudi Arabia to be eligible for contracting with the government, including participation in government tenders. This requirement was endorsed by a royal decree in December 2022, and went into effect January 1, 2024.

Pricing Guidelines Do Not Appropriately Value Innovative Medicines

The SFDA relies heavily on international reference pricing (IRP) to set the prices of medicines, in practice taking the lowest price from a basket of reference countries and subsequently imposing other re-pricing rules. IRP suffers from serious flaws as a mechanism for pharmaceutical pricing. It assumes similarity across countries in the reference basket and implicitly imports the pricing policies of those countries without accounting for circumstances that justify price differentiation. Importantly, IRP ignores the local value of medicines by ignoring the local standards of care, patterns of disease burden and socioeconomic factors. IRP also imports circumstances unrelated to a product's value, such as budget overruns in reference countries that lead to government price cuts. Only 41 percent of new medicines launched globally since 2014 have launched in Saudi Arabia, with Saudi patients waiting an average of 27 months from global first launch for new medicines to become available. Only 35 percent of these new medicines are reimbursed in Saudi Arabia's public national health insurance.[348]

In August 2020, SFDA issued draft pricing regulations that would have compounded many flaws in the existing system. Following consultation with industry, a new version of the guidelines was implemented in January 2021 that makes several improvements over the draft version that will increase transparency and predictability. These included reducing the number of countries in the reference basket from 30 to 20 countries, limiting the circumstances for repricing after two years (with five years remaining the rule), and capping price reductions at 30 percent. Additionally, in July 2022, the SFDA further reduced the number of countries in the reference basket to 16, although several countries with very different health care and reimbursement systems remain in the basket. While the system still does not appropriately value innovation and several provisions still require clarification, the industry acknowledges that these changes are a step forward.

Ensuring the New HTA System Supports Value-based Health Care

Saudi Arabia is intensifying efforts to establish a formal HTA system. In 2021, a new HTA department was created under the MoH and is expected to be the leading body for HTA in the country, though the new system is yet to be clarified.

When designed well and used appropriately, HTA of medical tests, treatments and health care services can represent one of many tools to support well-informed, patient-centered health care. When misapplied, HTA has the potential to impose one-size-fits-all policies that impede patients' and physicians' ability to tailor care to individual needs and preferences. Poor forms of HTA can also hinder progress in developing innovative new therapies that address unmet medical needs.

[348] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

PhRMA and its member companies recognize the ongoing efforts of the Saudi authorities to build an HTA system and stand ready to offer their expertise based on international experience. While we appreciate that the primary goal is to inform decisions on effective use of resources, it is critical that HTA not be used as a cost-containment tool, but rather be designed to improve patient choice and access. In the context of ongoing discussions on economic assessments and cost-effectiveness thresholds, PhRMA calls for a collaborative dialogue with all relevant stakeholders, as implementing restrictive assessment methods will inevitably create barriers to patient access. Recently, the MoH concluded a study which aimed to arrive at a cost-effectiveness threshold that would be applied during economic evaluations of new drugs. The new cost-effectiveness threshold was determined at SAR50-75,000 per QALY. Procedures, timelines and details on the HTA system, including on explicit application of cost-effectiveness thresholds, remain unclear. Moreover, rather than overlaying the proposed HTA system on the already complex pricing and reimbursement framework, PhRMA recommends that the new HTA system replace and enhance features that contribute to the value-based health care approach that Saudi Arabia aims to achieve through its Health Sector Transformation Strategy.

In July 2024, SFDA announced the Economic Evaluation Studies (EES) Guidelines. The new regulations aim to ensure pharmaceutical products are evaluated effectively for their added value to the healthcare system. These new guidelines require manufacturers to submit EES to receive marketing authorization, to keep marketing authorization and for price re-evaluations and renewals. The new guidelines are duplicative of the new HTA system, inappropriately link regulatory approval to pricing and overly burden manufacturers with parallel processes and opaque guidance. PhRMA encourages the Saudi Government to align processes and policies that increase access to innovative medicines.

New CHI Policy Risks Patient Affordability, Product Choice and Investment

In October 2022, the CHI issued a new policy for private sector health plans that risks patient affordability, product choice and current SFDA and Ministry of Investment priorities to encourage investment from the innovative biopharmaceutical industry. The new policy will set private-sector health plan co-payments for generics at 20 percent of the product price up to a maximum of $8. In contrast, co-payments for off-patent original brands will be set at 50 percent of the product price with no maximum. In addition, the guidelines mandate the dispensing of generic products. This large and sudden change will substantially decrease the affordability of off-patent original brands for patients. It will also immediately threaten roughly half of originator company revenues in Saudi Arabia as well as local manufacturing infrastructure investments and other local partnerships often required by the government to participate in government tenders.

PhRMA and its members support policies that improve the efficiency of markets for off-patent medicines to create budget headroom for innovative medicines. However, the current policy would create a sudden shock to originators without improving patient affordability or establishing funding for innovative medicines that SFDA seeks to attract.

TAIWAN

PhRMA members have identified the following intellectual property challenges and market access barriers in Taiwan:

Key Issues of Concern:

- **Government pricing and reimbursement barriers**: Taiwan's pricing and reimbursement process for innovative medicines lacks transparency, due process and meaningful opportunities to provide stakeholder input, contrary to the GRP commitments included in the First Agreement under the 21st-Century Trade Initiative. In this regard, the National Health Insurance Administration's (NHIA) negotiations of Managed Entry Agreements (MEAs) and Price Volume Agreements (PVAs), and application of Health Technology Reassessments (HTRs) have created significant barriers to patient access and uncertainty for industry. In addition, under the Pharmaceutical Benefit & Reimbursement Scheme (PBRS), average prices and approval rates for new medicines continue to be low and do not appropriately recognize the value of innovative medicines. Further, the approval process is inefficient and negotiations can be lengthy, resulting in overall timelines that can exceed two years. Finally, the system fails to recognize various forms of biopharmaceutical innovation, instead focusing on cost-containment. Industry stands ready to engage in full and meaningful consultations with the Taiwan Government as it moves forward with proposed amendments to its pricing and reimbursement system, consistent with Taiwan's GRP commitments.

- **Insufficient budget for innovative medicines and indications**: Under the current structure, most new medicines and indications are either rejected or experience delays in inclusion in the formulary due to insufficient budget allocation. This challenge significantly impacts patient access to treatments for life-threatening diseases such as cancer. PhRMA urges the Taiwan Government to plan a more realistic budget for new medicines and indications in 2025 and beyond to improve patient access.

- **Drug expenditure target (DET)**: PhRMA recognizes the efforts of the Ministry of Health and Welfare (MoHW) to use the DET to improve predictability for the industry and supports continued piloting in coordination with the industry to improve methodologies and implementation. However, PhRMA and its members are newly concerned that the NHIA plans to impose international reference pricing (IRP) as a method for price adjustment under the DET. PhRMA continues to request that the Taiwan Government to include industry early and throughout the process of developing these policies and methods.

- **Intellectual property protection**: In July 2019, the Taiwan Food and Drug Administration (TFDA) published the final patent linkage (PL) regulation on its website and shortly thereafter the Executive Yuan announced implementation of a

PL system effective August 20, 2019. While we applaud the establishment of a PL system, we are concerned that the TFDA is excluding patents that protect new doses, new dosage forms or new unit strengths. If allowed to continue, this action will seriously undermine the value of Taiwan's PL system. PhRMA and its member companies stand ready to work with the Taiwan Government to support full implementation of the PL regulation and other reforms.

For these reasons, PhRMA requests that Taiwan be placed on the **Watch List** in the 2025 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Effective Patent Enforcement

In July 2019, the TFDA published the final patent linkage (PL) regulation and shortly thereafter the Executive Yuan approved implementation of the PL system effective August 20, 2019. While PhRMA applauds the establishment of a PL system, we are concerned that the TFDA is interpreting Taiwan's new linkage system in a way that is unduly narrow. Specifically, the TFDA has interpreted Taiwan's Pharmaceutical Affairs Act (PAA) to exclude patents protecting new doses, new dosage forms or new unit strengths from the linkage system. According to TFDA, drugs in these categories are not "new drugs," and consequently, the permit holders for these drugs are not eligible to submit patent information to the PL system under Article 48-3 of the PAA. This interpretation is inconsistent with the PAA and contradicts the purpose and policy behind a linkage system, as well as the expectations by all stakeholders that the system provide an efficient means to timely resolve any patent dispute before a generic or biosimilar version of an innovative drug is launched.

PhRMA urges TFDA to acknowledge that permit holders are, and must be, eligible to submit patent listing information on patents claiming a drug's new dosage form, new dose or new unit strength. Delisting, or not being allowed to list, the patents for a drug's new dosage form, new dose or new unit strength provides a significant loophole to follow-on manufacturers who may seek to sidestep the PL enforcement mechanism and the protections that it provides to an innovative product by simply seeking approval of the new dosage form, new dose or new unit strength.

In the longer-term, this action would undermine the certainty that PL is designed to provide and would discourage companies from researching, developing and launching new dosage forms, new doses or unit strengths in Taiwan. It is vital to encourage this type of development because a drug's dosage form, dose, or unit strength can have a valuable impact on its safety, effectiveness or convenience – and better serve patient needs. For example, changes to the formulation and delivery of a drug have been shown to be effective in encouraging adherence across a number of therapeutic areas. Implementing a robust PL system in Taiwan is a critical step towards ensuring that companies continue to innovate in ways that improve patient outcomes in Taiwan. We

look forward to continuing to work with the Government of Taiwan to ensure full and timely implementation of the new PL system.

Market Access

Government Pricing and Reimbursement Barriers

An immediate concern is the lack of transparency, predictability and due process in Taiwan's pricing and reimbursement system, including through the negotiation and renegotiation of MEAs and PVAs. These mandatory agreements often contain excessive clawbacks that are not based on the financial data provided by manufacturers and that are inconsistent with the principle of risk-sharing between manufacturers and government. During the renegotiation period, the coverage of new patients for the product is suspended. The renegotiation process is misused as an opportunity to unilaterally secure further price reductions. In addition, the NHIA has unfettered discretion to renegotiate the price, providing no predictability to the manufacturer at the time of termination or renewal of the agreement. There is currently no standard procedure for exiting renewal negotiations when consensus on terms is not reached. Further, there is no mechanism for renegotiation if the actual spending consistently exceeds the budget cap set in MEAs. The lack of transparency, predictability and due process in renegotiation has created significant barriers to patient access to innovative medicines and uncertainty for industry.

Equally concerning is NHIA's HTR mechanism. Before implementing HTR, the NHIA did not provide stakeholders an opportunity to review and provide input on the mechanism. In addition, stakeholders were not given an opportunity to participate in the HTR process and express their opinions in the assessment, which is an action that lacks due process and transparency. NHIA established the Center for Health Policy and Technology Assessment, CHPTA, from January 1, 2024. PhRMA recognizes NHIA's effort to establish CHPTA and the parallel review mechanism to expedite new drug reimbursement approval and urge the NHIA to continue meaningful discussions with industry on clear operating procedures, transparency, predictability and evaluation of the effectiveness of the mechanism. As Taiwan moves forward with proposed amendments to its pricing and reimbursement system, it will be critical that Taiwan address these deficiencies to promote certainty for PhRMA member companies operating in Taiwan and improve patient access to innovative medicines.

Despite constructive engagement with the NHIA regarding the PBRS, average new drug prices in Taiwan continue to be low compared to median A10 countries and even by global standards.[349] A key factor suppressing the prices of new medicines in Taiwan is that prices are determined based on comparator products, which sometimes have experienced several rounds of annual price cuts at the time of the comparison. Moreover,

[349] Chen GT, Chang SC, Chang CJ, "New Drug Reimbursement and Pricing Policy in Taiwan" Value Health Reg Issues, 2018 May; 15:127-132, available at https://pubmed.ncbi.nlm.nih.gov/29704659/ (last visited Jan. 26, 2025).

under the current NHI reimbursement mechanism, the lowest price among new drugs in the same therapeutic group is used as the benchmark price for reimbursement. This mechanism fails to reflect the clinical differences among new products and does not appropriately recognize the value of innovative medicines.

Uncertainty over the prices approved by NHIA has also increased. NHIA-approved prices are often much lower than what companies had forecasted based on NHIA's pricing methodologies and re-submission and re-negotiation of prices takes considerable time. This results in overall timelines that can exceed two years, particularly for specialty medicines including in oncology. PhRMA recognizes NHIA's initiatives of drug policy reform that is still undergoing and urges NHIA to engage in meaningful dialogue with the industry to improve the transparency and predictability of its pricing processes, so that companies may bring new medicines to patients in Taiwan with reasonable certainty of their timing and reimbursement.

In summary, low reimbursement prices and the introduction of IRP decrease incentives to bring innovative medicines to Taiwan and to make further investments. Only 35 percent of new medicines launched globally since 2014 have launched in Taiwan, with Taiwanese patients waiting an average of 32 months from global first launch for new medicines to become available. Only 23 percent of these new medicines are reimbursed in Taiwan's public health insurance.[350] PhRMA and its member companies urge NHIA to review and revise the current pricing system to value innovative medicines more appropriately and stand ready to engage with the Taiwan Government as it seeks to reform the design and application of MEAs and HTRs, including through the amendment of the PBRS administrative rules.

Insufficient Budget for New Medicines and Indications

In March 2017, the Taiwan Government implemented a price adjustment designed to maintain spending targets that ultimately granted only compound and combination patented products some protection from price cuts, creating an unfair pricing environment for other patented medicines. In order to encourage innovation, these price protections should be available to all products during their patent term, as well as to all products during their regulatory data protection (RDP) term. As a starting point, we recommend that NHIA provide price protection to single-source products for which no alternatives are available, including products which carry no patent protection, but have been granted 5 years of RDP.

Under the current structure, most new medicines and indications are either rejected, restricted in access or experience delays in formulary listing due to insufficient budget allocation. This challenge significantly impacts patient access to needed treatments for life-threatening diseases, such as cancer. We urge the Taiwan Government to use horizon scanning, which is a tool to forecast future budgets through

[350] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

systematic information collection and analysis to plan a more realistic budget for new medicines and indications to improve patient access to new medicines. The establishment of the Cancer Drug Fund to improve access to cancer drugs with clinical uncertainties is welcomed and urge NHIA to have meaningful discussions with industry on clear operating procedures, transparency, predictability and stakeholder engagement in the operation of the fund before the new regulations are implemented.

PhRMA and industry are concerned that the government is developing and implementing the budget planning methodology in a non-transparent manner for new drugs. As a key stakeholder in the process, industry should be allowed to provide its proposed new medicine budget planning methodology to the NHIA for consideration and should also be included in the NHIA working group for new medicine budget planning. PhRMA welcomes the opportunity to support a health care dialogue with the Taiwan Government that appropriately addresses this and other related challenges, thereby resulting in a more transparent, timely and value-based pricing and reimbursement system for innovative medicines.

Drug Expenditure Target (DET)

PhRMA recognizes the efforts of MoHW to use the DET to improve predictability for the industry and supports continued piloting in coordination with the industry to improve the methodologies and implementation. However, PhRMA and its members are newly concerned that the NHIA plans to impose IRP as a method for price adjustment under the DET. IRP imports policies from other markets without accounting for the local conditions driving price differentials, such as differing incomes, current standards of care and regulatory requirements. The artificially low prices that often result from IRP can lead to product withdrawals and launch delays in the market implementing IRP and also undermine the availability of medicines in referenced markets. PhRMA encourages NHIA to explore more effective and meaningful measures, with industry stakeholders, to reduce the risk of drug shortages and negative effects on industry.

More broadly, PhRMA continues to request that the Taiwan Government engage the innovative biopharmaceutical industry through regular and direct dialogue and consultations to ensure that these policies are transparent, offer due process and predictability to interested stakeholders, and are based on scientific evidence and patient needs and benefits.