PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (P*h*RMA)

SPECIAL 301 SUBMISSION 2026

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PhRMA 2026 SPECIAL 301 OVERVIEW

PhRMA 2026 SPECIAL 301 SUBMISSION

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide this submission for the *2026 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 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 below, biopharmaceutical innovators in the United States face a wide array of damaging government pricing policies abroad that deny fair market value and access to innovative medicines and allow foreign nations to benefit from U.S. biopharmaceutical development without paying their fair share for these innovations.

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 and adopt market access policies that are transparent and timely consistent with the United States-Mexico-Canada Agreement (USMCA); **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

[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. 27, 2026).

[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. 27, 2026).

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 addressing compulsory licensing threats in **Colombia**; the erosion of intellectual property protections in the European Union, including through the new pan-EU compulsory licensing mechanism and General Pharmaceutical Legislation; and longstanding systemic intellectual property failures, including restrictive patentability criteria, in **India**.

Unreasonable and discriminatory pricing policies in **Australia**, **Canada**, **Denmark**, **France**, **Germany**, **Italy**, **Japan**, **Korea**, **Spain**, **Switzerland** and **the United Kingdom** and other countries 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 these and other 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 Trump Administration correct course by vigorously defending, enforcing and strengthening intellectual property protections and market access for U.S.

[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. 27, 2026); 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. 27, 2026).

innovations abroad. PhRMA welcomes efforts by President Trump and USTR to eliminate foreign government acts, policies and practices that have "the effect of forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development, including by suppressing the price of pharmaceutical products below fair market value in foreign countries," as envisioned in Section 3 of President Trump's May 12, 2025, Executive Order.[4] As USTR correctly identified in its 2025 Special 301 Report, U.S. trade policies should ensure that foreign governments "appropriately recognize the value of innovative medicines … so that trading partners contribute their fair share to research and development of new treatments and cures."[5] PhRMA is also encouraged by USTR's 2025 Trade Policy Agenda, which correctly notes that the TRIPS waiver "has not increased access to COVID-19 vaccines but instead may actually negatively impact the development of new treatments and cures for the next pandemic by weakening the standard for intellectual property protections and furthering a false narrative about the role of intellectual property and access to medicines."[6] Consistent with the USTR's mission to protect U.S. innovation abroad, we urge USTR to pursue the elimination of the trade barriers highlighted in this submission.

PhRMA members are committed to advancing public policies that promote U.S. leadership in biopharmaceutical research and manufacturing, support American jobs and ensure that innovative medicines are accessible and affordable for U.S. patients. As the Administration works to counter unfair and non-reciprocal trade practices abroad, it should ensure that any trade measures are carefully crafted to avoid adverse impacts on U.S. patients, health care systems and the global competitiveness of the U.S. innovative biopharmaceutical industry. Most importantly, the Administration should refrain from imposing tariffs on imports of innovative medicines and the ingredients used to produce innovative medicines in the United States, as these actions would be detrimental to U.S competitiveness and increase health care costs at home.[7] PhRMA urges USTR to ensure that trade enforcement actions are calibrated to avoid these adverse consequences for patients and the global competitiveness of the U.S. innovative biopharmaceutical industry.

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[4] Trump, Donald J. *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients*. *Federal Register*, vol. 90, no. 95, May 15, 2025, pp. 20749–20751. Executive Order 14297 at Sec. 3, available at https://www.federalregister.gov/documents/2025/05/15/2025-08876/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients (last visited Jan. 27, 2026).

[5] Office of the United States Trade Representative, *2025 Special 301 Report*, Apr. 29, 2025, p. 29, available at https://ustr.gov/sites/default/files/files/Issue_Areas/Enforcement/2025%20Special%20301%20Report%20%28final%29.pdf (last visited Jan. 27, 2026).

[6] Office of the U.S. Trade Representative, 2025 Trade Policy Agenda and 2024 Annual Report at p. 8, available at https://ustr.gov/sites/default/files/files/reports/2025/2025%20Trade%20Policy%20Agenda%20WTO%20at%2030%20and%202024%20Annual%20Report%2002282025%20--%20FINAL.pdf (last visited Jan. 27, 2026).

[7] *See* Pharmaceutical Research and Manufacturers of America, Comment on Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, Docket No. BIS-2025-0022, May 6, 2025, available at https://www.regulations.gov/comment/BIS-2025-0022-0070 (last visited Jan. 27, 2026).

I. PhRMA's 2026 Special 301 Recommendations

PhRMA's submission for the Special 301 Report identifies priority opportunities and challenges facing the U.S. biopharmaceutical industry in foreign markets that deny adequate and effective protection of intellectual property rights or deny fair and equitable market access. The markets identified in this submission require urgent action to address chronic and emerging concerns. For 2026, PhRMA has identified 17 high-priority foreign markets where members face major barriers but see significant potential for strategic engagement:

Priority Watch List

- Argentina
- Australia
- Brazil
- Canada
- China
- Colombia
- European Union
- India
- Japan
- Korea
- Malaysia
- Mexico

Watch List

- Chile
- Indonesia
- Saudi Arabia
- Switzerland
- United Kingdom

Due to serious IP and market access issues, PhRMA continues to recommend in 2026 a **Priority Watch List** designation for **Argentina**, **Brazil**, **Canada**, **China**, **Colombia**, **India**, **Japan**, **Korea**, **Malaysia** and **Mexico**, and a Watch List designation for **Saudi Arabia**. PhRMA has added **Switzerland** and the **United Kingdom** to its Special 301 submission market list and is recommending a **Watch List** designation for both markets. Ongoing U.S. bilateral negotiations with Switzerland and the United Kingdom present unique opportunities to secure high-standard intellectual property commitments and to address longstanding market access barriers. Moreover, although Egypt, Russia, Taiwan, Thailand and Türkiye are not listed, the biopharmaceutical issues identified in USTR's 2025 Special 301 Report and the Overview section of this submission for these markets continue to limit innovators' ability to fully and fairly rely on effective intellectual property protection and enforcement.

The December 2025 agreement between the Council of the European Union and the European Parliament on the General Pharmaceutical Legislation highlights a material deterioration in biopharmaceutical intellectual property protection in the **European Union (EU)**. Together with other recent legislative measures targeting intellectual property protections, the agreement raises serious questions about the EU's commitment to high-standard intellectual property protection and enforcement as set forth in the Framework for an Agreement on Reciprocal, Fair and Balanced Trade.[8] PhRMA is therefore downgrading its designation recommendation from last year and recommending a

[8] *See* United States-European Union Framework on an Agreement on Reciprocal, Fair, and Balanced Trade, Aug. 21, 2025, available at https://www.whitehouse.gov/briefings-statements/2025/08/joint-statement-on-a-united-states-european-union-framework-on-an-agreement-on-reciprocal-fair-and-balanced-trade/ (last visited Jan. 27, 2026).

Priority Watch List designation for the EU, signaling the need for urgent and sustained U.S. engagement.

Unmitigated compulsory licensing threats in **Colombia** remain a significant risk for biopharmaceutical innovators, as elements of the government have signaled an intent to "suppress patents" and questioned the role of patents in innovation. Although recent assurances from the Ministry of Commerce, Industry and Tourism that no new compulsory licenses or Declarations of Public Interest are being considered are encouraging, concerns persist. Accordingly, PhRMA recommends that Colombia remain on the **Priority Watch List**, and because it does not see immediate opportunities for positive reform, is withdrawing its Out-of-Cycle Review recommendation from last year.

Recent revisions to **Indonesia**'s patent law, including the removal of provisions that previously barred patents for new uses, represent a step forward in aligning the country's patentability standards with international norms. Combined with commitments under the U.S. – Indonesia Framework for an Agreement on Reciprocal Trade to address non-tariff barriers affecting trade in priority areas, including intellectual property issues identified in USTR's Special 301 Report,[9] PhRMA is upgrading its designation recommendation for Indonesia from Priority Watch List to **Watch List**. Last, longstanding and serious intellectual property and market access concerns remain in **Chile** as outlined in the USTR 2025 Special 301 Report and the Overview section of this submission. PhRMA recommends a **Watch List** designation in 2026 to maximize strategic U.S. government engagement in the region.

II. The Innovative Biopharmaceutical Sector

The U.S. biopharmaceutical industry is the world leader in medical research.[10] 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

[9] *See* Joint Statement on Framework for United States-Indonesia Agreement on Reciprocal Trade, Jul. 22, 2025, available at https://www.whitehouse.gov/briefings-statements/2025/07/joint-statement-on-framework-for-united-states-indonesia-agreement-on-reciprocal-trade/ (last visited Jan. 27, 2026).

[10] Ezell S, "Ensuring U.S. Biopharmaceutical Competitiveness," July 2020, available at https://www2.itif.org/2020-biopharma-competitiveness.pdf (last visited Jan. 27, 2026).

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.[11]

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.[12] 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[13] and investing in many of the over 8,000 new drugs currently in development worldwide,[14] with about three quarters having the potential to be first-in-class treatments.[15]

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.[16] 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 2024, U.S. biopharmaceutical goods exports exceeded $107 billion.[17] 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.[18]

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[11] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://cdn.aglty.io/phrma/policy-issues/research-ecosystem/economy/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf (last visited Jan. 27, 2026).

[12] *Id.*

[13] 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. 27, 2026); 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. 27, 2026).

[14] PhRMA analysis of Citeline Pharma projects database (last accessed Oct. 16, 2024).

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

[16] 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. 27, 2026).

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

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

The innovative biopharmaceutical industry is a global leader in U.S. manufacturing, producing $388 billion of gross output in 2023, and supplying nearly two-thirds (by value) of all medicines consumed in the United States.[19] In 2023, U.S. sales of finished biopharmaceuticals totaled $393 billion, of which 64 percent ($251 billion) was produced in the United States and 36 percent ($143 billion) was imported.[20] 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.[21]

PhRMA member companies are continuing to make historic investments in U.S.-based manufacturing and infrastructure. In September, PhRMA announced that the biopharmaceutical industry is delivering $500 billion in new U.S.-based infrastructure investments, which will generate an estimated $1.2 trillion in economic output and create more than 100,000 new jobs including 25,000 biopharmaceutical jobs, but this growth is only possible with the right policies at home and abroad.[22] PhRMA member companies' direct investments create a ripple effect leading to indirect benefits to local economies, creating more demand for goods and services, childcare, education, recreational activities and more.

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[23] – adding trillions of dollars to the U.S. economy.[24] New medicines are responsible for much of this increase. According to a National Bureau of Economic Research working paper, new treatments accounted for three-quarters of life expectancy gains in the United States and other high-income countries between 2000 and 2009.[25]

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[19] U.S. Department of Commerce Bureau of Economic Analysis, Gross Output by Industry, 2023.

[20] Ernst & Young, "Impacts of Potential Tariffs on the US Pharmaceutical Industry," Apr. 2025.

[21] 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. 27, 2026).

[22] PhRMA Announces Major Actions as Part of Industry's Commitment to American Patients and Workers, Sept. 29, 2025, available at https://phrma.org/resources/phrma-announces-major-actions-as-part-of-industry-s-commitment-to-american-patients-and-workers (last visited Jan. 27, 2026).

[23] 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. 27, 2026).

[24] 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. 27, 2026).

[25] 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. 27, 2026).

For example, the AIDS death rate has dropped nearly 87 percent since the approval of antiretroviral treatments in 1995.[26] Today, a 20-year old diagnosed with HIV can expect to live another 50 years.[27] New medicines have cut heart disease deaths by 38 percent, according to the Centers for Disease Control and Prevention.[28] More than 80 percent of the increase in life expectancy of cancer patients since 1980 is attributable to new treatments.[29] New hepatitis C therapies approved since 2013 cure over 90 percent of patients – a more than two-fold increase from previously available treatment options.[30]

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.[31] 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 debilitating disease affecting millions.[32] The mRNA technology platforms, which are the

[26] 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. 27, 2026).

[27] *Id.*

[28] 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://archive.cdc.gov/#/details?q=New%20CDC%20Vital%20Signs:%20CDC%20finds%20200,000%20heart%20disease%20deaths%20could%20be%20prevented&start=0&rows=10&url=https://www.cdc.gov/vitalsigns/heartdisease-stroke/index.html (last visited Jan. 27, 2026); 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. 27, 2026).

[29] 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. 27, 2026); A 2025 report by the American Cancer Society indicates that cancer death rates between 1991 and 2022 declined 34 percent. American Cancer Society, "Cancer Facts and Figures 2025, available at https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2025/2025-cancer-facts-and-figures-acs.pdf (last visited Jan. 27, 2026).

[30] *See*, *e.g.*, "FDA approves Viekira Pak to treat hepatitis C," Dec. 19, 2014, available at https://www.managedhealthcareexecutive.com/view/fda-approves-viekira-pak-treat-hepatitis-c (last visited Jan. 27, 2026).

[31] PhRMA, "2020 Medicines in Development – Infectious Diseases Report," July 2020, available at https://cdn.aglty.io/phrma/attachments/MID_Infectious%20Diseases_2020_FINAL.pdf (last visited Jan. 27, 2026).

[32] *Id.*

backbone of the most effective COVID-19 vaccines, could potentially revolutionize vaccinology and help fight cancer, immune-mediated diseases and rare diseases.[33]

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.[34] Every $24 spent on new medicines for cardiovascular diseases in OECD countries saves $89 in hospitalization costs.[35] Treating high blood pressure according to clinical guidelines would result in annual health system savings of about $15.6 billion.[36] 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.[37] 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[38] 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.[39]

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.[40] In 2017, more than 20 biopharmaceutical companies joined the World Bank and the Union

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[33] PhRMA, "Answering common questions on mRNA technology," July 17, 2025, available at https://phrma.org/blog/answering-common-questions-on-mrna-technology#:~:text=Instead%20of%20using%20weakened%20or,protein%20found%20on%20its%20surface (last visited Jan. 27, 2026).

[34] 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. 27, 2026).

[35] 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. 27, 2026).

[36] 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. 27, 2026).

[37] 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. 27, 2026).

[38] 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. 27, 2026).

[39] 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. 27, 2026).

[40] *See* Global Health Progress, available at http://www.globalhealthprogress.org (last visited Jan. 27, 2026).

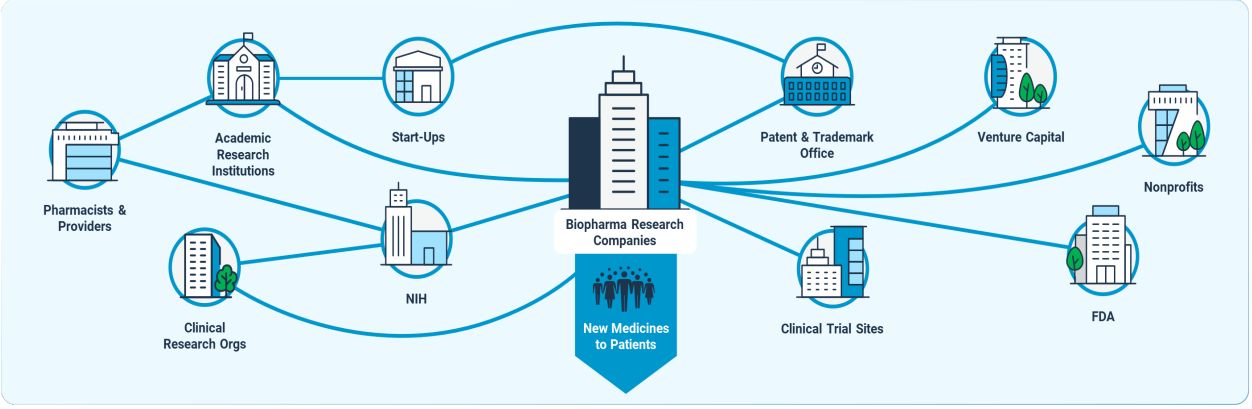
for International Cancer Control to launch Access Accelerated – a first-of-its-kind global initiative to address cancer and other non-communicable diseases that cause more than 28 million deaths per year in low and lower-middle income countries.[41]

Between 2000 and 2011, biopharmaceutical innovators contributed an estimated $98.4 billion dollars toward achieving health-related Millennium Development Goals.[42] 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.[43]

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.

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

[41] 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. 27, 2026).

[42] 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. 27, 2026).

[43] Global Funding of Innovation for Neglected Diseases: G-Finder, available at https://gfinder.policycuresresearch.org/ (last visited Jan. 27, 2026).

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.[44] 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.[45]

Patents and market-based pricing policies promote competition and greater treatment options. In exchange for the limited period of protection that patents provide, 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.[46] 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.[47] European countries have seen similar gains from competition.[48]

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.[49] Generic competitors now challenge patents earlier and more frequently, even as early as four years after the launch

[44] *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. 27, 2026).

[45] 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. 27, 2026).

[46] 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. 27, 2026).

[47] 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. 27, 2026).

[48] 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. 27, 2026).

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

of a new medicine.[50] Today, over 94 percent of innovative medicines experience at least one patent challenge prior to generic entry, compared to 25 percent in 1995.[51] Increasing competition from biosimilars is driving down the cost of cutting-edge treatments.[52]

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.[53] 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 of that medicine.[54] 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.[55] 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.[56] 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

[50] Grabowski HG, Long G, et al., "Updated trends in US brand-name and generic drug competition," J. Med. Econ., Sept. 2016, available at https://pubmed.ncbi.nlm.nih.gov/27064194/ (last visited Jan. 27, 2026).

[51] *Id.*

[52] *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. 27, 2026).

[53] 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. 27, 2026).

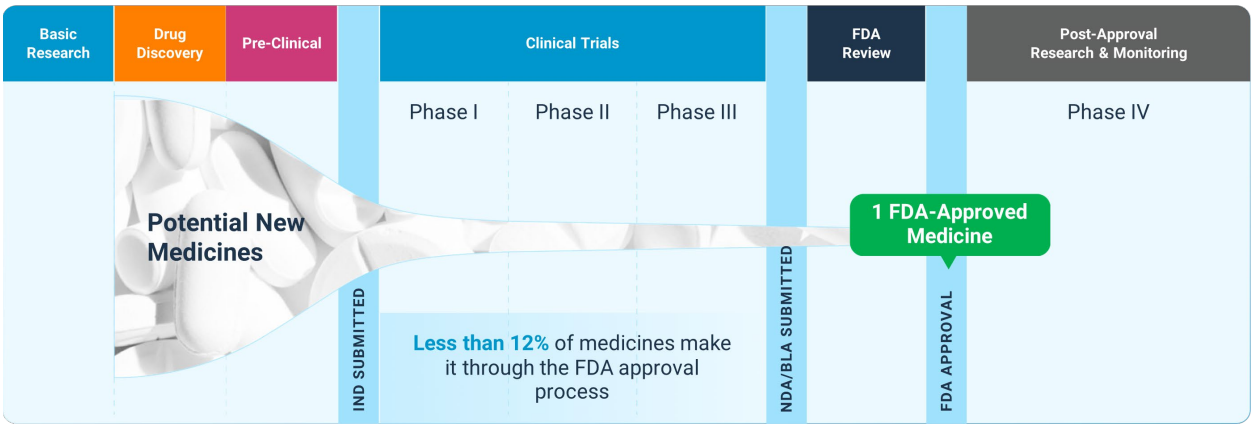
[54] Wilsdon T and Chambers G, "The wider value delivered to patients, healthcare systems and competitors when innovators launch new products," Charles River Associates, Apr. 2013.

[55] 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. 27, 2026).

[56] 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. 27, 2026).

development costs.[57] Of the approximately 1,200 biopharmaceutical companies in the United States, more than 90 percent do not earn a profit.[58]

Figure 2: The biopharmaceutical research and development process



The lengthy approval process for new products makes the research-based biopharmaceutical sector particularly reliant on the temporary protection intellectual property rights provide.[59] 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.[60] 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.[61] Test data generated through those trials is then submitted to national regulatory agencies for marketing approval.

[57] 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. 27, 2026).

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

[59] 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. 27, 2026).

[60] 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. 27, 2026); U.S. Food and Drug Administration, "Development & Approval Process | Drugs," available at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ (last visited Jan. 27, 2026).

[61] TEConomy Partners, "Biopharmaceutical Industry-Sponsored Clinical Trials," Apr. 2019, available at https://cdn.aglty.io/phrma/fact-sheets/clinical-trials/TEConomy_PhRMA-Clinical-Trials-Impacts.pdf (last visited Jan. 27, 2026).

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.[62] In 2022, the U.S. biopharmaceutical industry invested approximately $141 billion in R&D in the United States, accounting for more than 80% of their global R&D.[63] 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.[64] 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.[65]

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.[66] 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.[67] This step-by-step transformation in knowledge has led to increased survival, improved patient outcomes and enhanced quality of life for many patients.[68]

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[62] 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. 27, 2026).

[63] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://cdn.aglty.io/phrma/policy-issues/research-ecosystem/economy/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf (last visited Jan. 27, 2026).

[64] *Id.*

[65] 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. 27, 2026).

[66] 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. 27, 2026).

[67] *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. 27, 2026).

[68] Sweeney N, Goss TF, "The Value of Innovation in Oncology: Recognizing Emerging Benefits Over Time," Boston Healthcare Associates, May 2015.

III. 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 pricing and 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.

The U.S. government has long recognized that foreign price controls on innovative medicines undermine biopharmaceutical innovation and patient access to medicines, and that trade policy can play an important role in addressing such practices. These actions include biased health technology assessments, mandatory price cuts, taxes, revenue clawbacks, international reference pricing, unreasonable reimbursement delays and erosion of intellectual property protections. 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.[69] 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. More recently, a 2018 report by the Council of Economic Advisors (CEA) within the Executive Office of the President concluded that the setting of foreign drug prices at levels below those that prevail in the United States "erode[s] the returns to innovation manufacturers might otherwise see from selling in their Markets" and led to American patients and taxpayers financing global medical innovation.[70] During the first Trump Administration, a 2020 report from the Council of Economic Advisers found that foreign government price controls had worsened over the subsequent 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."[71] The Medicare Prescription Drug, Improvement and Modernization Act of 2003 called for the Administration to develop a strategy to address foreign price controls on

[69] 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. 27, 2026).

[70] Council of Economic Advisors, 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. 27, 2026).

[71] 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. 27, 2026).

pharmaceuticals and related practices through bilateral and multilateral trade negotiations, and trade promotion authority legislation enacted in 2015 recognized the need to ensure that government regulatory reimbursement regimes provide full market access for United States products.[72] Government price controls and reimbursement delays are trade barriers that allow foreign governments to enjoy the benefits of U.S. biopharmaceutical development without paying their fair share for these innovations. Urgent action is needed to address and resolve government price control regulations, policies and practices that are limiting market access for medicines researched and developed in the United States.

In addition, 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 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,[73] 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

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

[73] 166 members as of August 30, 2024.

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.

Since TRIPS took effect in 1994, economic growth has accelerated, billions have been lifted from poverty and global health has improved significantly.[74] 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.[75] 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.[76]

Emboldened by the TRIPS waiver[77] 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

[74] 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. 27, 2026).

[75] 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. 27, 2026).

[76] 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. 27, 2026).

[77] *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. 27, 2026).

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 by promoting acts, policies and practices globally and in specific countries that 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.[78] 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 Pathogen Access and Benefits Sharing Annex of the adopted 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[79] by some WTO members. It is critically important to protect incentives for 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. These measures exacerbate the U.S. trade deficit by inappropriately lowering and delaying payments in foreign countries while these countries take advantage of U.S. investments in innovation. 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 2026 National Trade Estimate Report and to use all available tools to address and resolve them.

A. 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.

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[78] 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. 27, 2026).

[79] *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. 27, 2026).

Government price controls and reimbursement delays

In many countries outside of the United States, governments are the primary payer of medicines and in effect dictate the price of medicines and the extent and timing of patient access to medicines. 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 and delay patient access to medicines. Foreign governments increasingly employ a range of measures, including biased health technology assessments, mandatory price cuts and revenue clawbacks, international reference pricing, unreasonable reimbursement delays and erosion of intellectual property protections. These measures often are layered to exert maximum pressure to artificially devalue the medical innovation that these countries receive.

Government price controls and reimbursement delays are trade barriers that allow foreign governments to enjoy the benefits of U.S. biopharmaceutical development without paying their fair share for these innovations. Some countries have even resorted to threatening American intellectual property rights when reimbursement "negotiations" fall short of extracting the desired price concessions. These actions deny American inventors and workers the ability to compete on fair and reciprocal terms, and, as highlighted by USTR in its recent Special 301 Report, defeat the expected benefit of intellectual property protections, specifically the ability of "U.S. owners of IP [to] have a full and fair opportunity to use and profit from their IP …."[80] Moreover, these measures exacerbate the U.S. trade deficit by inappropriately lowering and delaying payments in foreign countries while those countries take advantage of U.S. investments in innovation. Examples of policies that devalue U.S. innovation and harm U.S. competitiveness, jobs and exports include:

- **Biased health technology assessments**: Foreign governments use frameworks that deliberately ignore health benefits from innovative medicines to arbitrarily set low prices. Some countries benchmark prices against older inferior medicines and generics or devalue life years based on outdated monetary thresholds that have never been indexed to inflation. Prior to the Agreement in Principle with the **United Kingdom** (UK) on Pharmaceutical Pricing (Pricing Agreement) under the auspice of the U.S.-UK Economic Prosperity Deal (EPD), the UK used a cost-effectiveness threshold that had not been updated since NICE was established in 1999. In the context of implementing the Pricing Agreement, the UK Government has indicated that it will increase these thresholds from £20,000-£30,000 per quality adjusted life year (QALY) to £25,000-£35,000 from April 2026, but this does not account for most of the inflation since NICE was established. Further, medicines are often not funded for their full market authorization, restricting patient access to treatments proven to be effective. **Germany** rejects clinical trial evidence to assert, when setting prices, that 56 percent

[80] Office of the U.S. Trade Representative, 2025 Special 301 Report at p. 29, available at https://ustr.gov/sites/default/files/files/Issue_Areas/Enforcement/2025%20Special%20301%20Report%20(final).pdf (last visited Jan. 27, 2026).

of new innovative medicines provide no added benefit over current treatments.[81] Germany's Federal Joint Committee (G-BA) selects comparators for these required benefit assessments, often using older inferior medicines and generics as price benchmarks.[82] Similarly, **Australia**, **Canada**, **Japan**, **Korea** and **Spain** undervalue new innovative medicines by setting prices based on older inferior medicines and generics, and/or through use of low and outdated monetary thresholds per year of life gained from clinically proven treatments.

- **Mandatory price cuts and revenue clawbacks**: Instead of adequately funding health care budgets, foreign governments impose price cuts and revenue clawbacks that shift financial burdens onto biopharmaceutical companies. 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 mean that some of America's most innovative medicines are significantly undervalued. **France** combines price cuts, rebates, revenue clawbacks and pharmaceutical-specific taxes to drive net prices on innovative medicines to be among the lowest in Europe. **Germany** mandates a seven percent rebate and price freeze for all medicines reimbursed by the statutory health insurance system since 2010.[83] **Italy** imposes revenue clawbacks, driven by underfunded hospital budgets, that have rapidly become unsustainable for biopharmaceutical manufacturers. **Spain** requires mandatory discounts of 7.5 percent for all innovative medicines and a revenue clawback of two percent on all retail pharmacy sales to further reduce spending on already devalued medicines.

- **International reference pricing**: Many foreign governments set drug prices in their own country based on the prices paid in other countries that have much lower gross domestic product (GDP) per capita or that devalue innovation. Egypt continues to implement an international reference pricing regulation that limits and delays patient 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.[84] **Korea** sets

[81] AMNOG-Monitor, "Early Benefit Assessment: Detailed Analysis of All G-BA Resolutions," June 2025, available at https://www.amnog-monitor.com (last visited Jan. 27, 2026). Note: 55 percent of assessed medicines were deemed to not provide an added benefit for any indication. Note: This analysis excludes orphan drugs with sales below a threshold that makes them ineligible to receive a rating of offering no added benefit.

[82] *Id.* Note: The G-BA defines at least one generic comparator in 74 percent of subpopulation assessments. Analysis excludes assessments with non-drug comparators (e.g., surgery).

[83] German Bundestag, "Financial Reform of Statutory Health Insurance Approved," October 20, 2022, available in German at https://www.bundestag.de/dokumente/textarchiv/2022/kw42-de-gkv-finanzierungsstabilisierungsgesetz-916742 (last visited Jan. 27, 2026).

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

prices of new innovative medicines through a combination of referencing the lowest price among OECD countries and using low and outdated monetary thresholds per life year gained from clinically proven treatments.[85] As a result, Korea spends a lower share of its pharmaceutical budget on new innovative medicines than any other high-income OECD country.[86] **Canada** sets ceiling prices for all patented medicines sold to public or private payers by referencing prices in other countries, followed by restrictive health technology assessments that inform additional discounts. In 2021, Canada removed the United States and Switzerland from the Patented Medicine Prices Review Board reference basket to ensure that it referenced more countries with lower incomes and lower drug prices.

- **Unreasonable patient access delays and restrictions**: Many foreign governments have protracted pricing and reimbursement processes that significantly delay and restrict patient access, resulting in lost marketing time and potential use during the expected and otherwise legally required period of intellectual property protection for the product. In **Canada**, only 20 percent of new medicines launched globally since 2014 are reimbursed by public plans, with public plan patients waiting an average of 49 months from global first launch to reimbursement.[87] In **Italy**, pricing and reimbursement processes at the national level delay patient access to new medicines, which is exacerbated by further unnecessary delays and uncertainty in listing products on regional formularies. While the **United Kingdom** claims that the NHS funds 84 percent of new treatments, only 14 percent of all new innovative medicines are funded without access restrictions and for all approved uses.[88] Meanwhile, government agencies in **Korea** force companies through a gauntlet of assessments to access the market, resulting in lengthy patient access delays following marketing authorization.

- **Erosion of IP protections**: The **EU** has finalized legislative proposals that would erode the current regulatory data protection (RDP) term unless companies commit to supply requirements in EU member states or other localization requirements. In turn, companies would be forced to accept the prices set by each government and the resulting spillover from international reference pricing or relinquish an important intellectual property protection. Moreover, nearly all foreign governments have

[85] HIRA references prices from eight countries, but NHIS subsequently references prices from any of the 38 OECD member countries.

[86] Yu, Seung-Rae and Sooyoung Choi. “New Drug Expenditure by Therapeutic Area in South Korea: International Comparison and Policy Implications,” February 2025, available at https://doi.org/10.3390/healthcare13050468 (last visited Jan. 27, 2026).

[87] 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.

[88] McKeown, Sarah and Richard Kane, “Measuring Impact of HTA on Patient Access to New Medicines in NHS England: A Comparison of Public Health Insurance Funding Restrictions and Patient Uptake for New Medicines Across England, France, Germany, and the United States,” December 2024, available at https://www.ispor.org/heor-resources/presentations-database/presentation/euro2024-4015/144637 (last visited Jan. 27, 2026).

implemented powers to override patents, too often on ambiguous and overly broad grounds that include pricing. USTR has highlighted that compulsory licenses "should not be used … as undue leverage in pricing negotiations between governments and right holders."[89]

As a result of these policies that devalue U.S. innovation, other high-income countries do not contribute their fair share to the research and development of new treatments and cures, including **Australia**, **Canada**, **Denmark, France**, **Germany**, **Italy**, **Japan**, **Korea**, **Spain, Switzerland** and the **United Kingdom**. Together, these 11 countries account for more than 70 percent of spending on new innovative medicines by high-income countries outside the United States. As shown in Figure 3 below, these countries spend a much smaller share of GDP per capita on new innovative medicines than the United States and patients in these markets face significant delays and limitations on their access to these lifesaving medicines.

Figure 3: Spending and Market Access Restrictions on New Innovative Medicines in High-Income Countries[90]

Country	Percentage of GDP per Capita Spent on New Innovative Medicines	Percentage of New Innovative Medicines Reimbursed by Public Insurance	Average Delay from Country Regulatory Approval to Public Reimbursement (months)
United States	0.78%	87%	1
Australia	0.26%	24%	25
Canada	0.32%	20%	37
Denmark	0.26%	45%	7
France	0.29%	44%	18
Germany	0.36%	56%	4
Italy	0.46%	45%	21
Japan	0.40%	50%	3
Korea	0.09%	20%	23
Spain	0.53%	40%	21
Switzerland	0.24%	34%	15
United Kingdom	0.28%	42%	22

[89] USTR, 2025 Special 301 Report, at p. *30* (Apr. 2025), available at https://ustr.gov/sites/default/files/files/Issue_Areas/Enforcement/2025%20Special%20301%20Report%20(final).pdf (last visited Jan. 27, 2026).

[90] *See* Pharmaceutical Research and Manufacturers of America. *Comment on Request for Comments Regarding Foreign Nations Freeloading on American-Financed Innovation*, Office of the U.S. Trade Representative, 90 Fed. Reg. 23105 (May 30, 2025), available at https://comments.ustr.gov/s/commentdetails?rid=VB9V88JYC6 (last visited Jan. 27, 2026).

In recent years, America's biopharmaceutical sector has witnessed a surge in the number and severity of arbitrary and discriminatory government price controls abroad. 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.[91]

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 **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, the Thai company needs only to demonstrate that their generic copy is bioequivalent to the originator product to qualify as a pharmaceutical innovator. In December 2025, the UAE announced a review of the drug pricing framework, including evaluating how prices are set and seeking to introduce measures to revise drug price regulation aimed at aligning local medicine prices with official price lists and international benchmarks. PhRMA members report that these changes require immediate downward price adjustments to align prescription medicines with prices in other Gulf Cooperation Council countries by January 31 or face repercussions, depressing prices below levels that appropriately reflect the value of innovative medicines.

Import barriers

High tariffs and taxes can limit U.S. biopharmaceutical exports and prevent access to new treatments in overseas markets.[92] Under the WTO Pharmaceutical Agreement, the United States and the 33 other countries have committed not to impose import duties

[91] 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. 27, 2026).

[92] 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. 27, 2026).

on a wide range of medicines and other health products.[93] However, biopharmaceutical innovators in the United States do not benefit from the same access to 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.[94] For example, **India**'s basic import duties on biopharmaceutical products and active ingredients average about ten percent.[95] 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 six percent.[96] Promisingly, in a 2025 Bill simplifying the tax system, tax rates on certain medicines could be reduced by 60 to 100 percent, and there are proposals to reduce or eliminate VAT on all medicines. However, the transition period will last several years, during which companies will need to operate under two tax regimes simultaneously. 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

Examples of 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.

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

[93] General Agreement on Tariffs and Trade, Trade in Pharmaceutical Products, L/7430, Mar. 1994, available at https://ustr.gov/sites/default/files/WTO%20Pharmaceutical%20Agreement%20March%201994.pdf (last visited Jan. 27, 2026).

[94] 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. 27, 2026).

[95] *Id.*

[96] Brazilian Institute of Tax Planning, 2018.

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. Thailand also applies inconsistent reimbursement criteria, including for high-cost cancer drugs, between different companies and different products, resulting in certain innovator products being deemed not eligible for "direct reimbursement" based on unclear selection criteria or "non-reimbursable" if newly approved. 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 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.

PhRMA welcomes efforts by USTR to address foreign government practices that deny fair and equitable market access to U.S. biopharmaceutical innovators, including by eliminating foreign government acts, policies and practices that have "the effect of forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development, including by suppressing the price of pharmaceutical products below fair market value in foreign countries."[97]

As more markets enact price controls, the burden for financing medical advances will be borne increasingly by U.S. patients, taxpayers 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 appropriately value and increase spending on innovative medicines to levels equivalent to those in the United States.

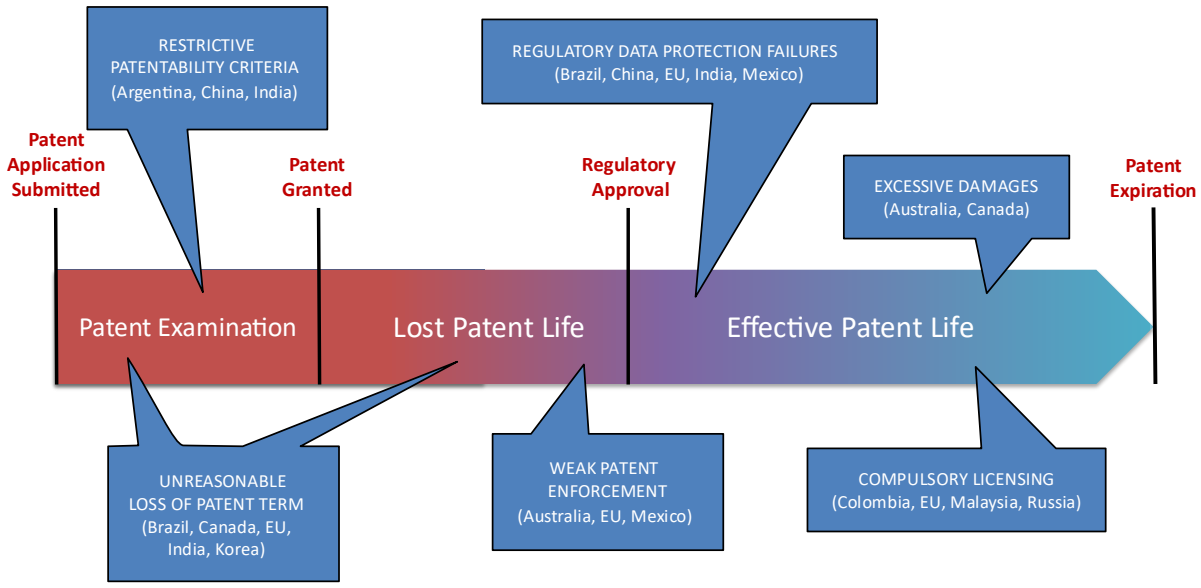
B. Intellectual property practices that undermine biopharmaceutical innovation

The six intellectual property challenges described below and highlighted in Figure 4 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 and enjoying patents (restrictive patentability criteria and unreasonable loss of patent term), maintaining and effectively enforcing

[97] Trump, Donald J. *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients*. *Federal Register*, vol. 90, no. 95, May 15, 2025, pp. 20749–20751. Executive Order 14297 at Sec. 3, available at https://www.federalregister.gov/documents/2025/05/15/2025-08876/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients (last visited Jan. 27, 2026).

patents (market-size damages, weak patent enforcement and compulsory licensing), and protecting regulatory test data (regulatory data protection failures).

Figure 4: 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.[98] 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

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

treatments that can improve health outcomes[99] and reduce costs[100] 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[101] – improvements that are valuable to patients and payers and that require significant investment and research to develop. **Argentina** maintains discriminatory patentability rules that prevent biopharmaceutical 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. National practices are often amplified by multilateral organizations. UNDP and Unitaid advocate actively for patentability restrictions and additional patentability requirements that are inconsistent with international practice. For example, UNDP published patent examination guidelines in 2016 that

[99] 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. 27, 2026).

[100] 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. 27, 2026); 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. 27, 2026); 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. 27, 2026).

[101] 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. 27, 2026); 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. 27, 2026).

mimic Argentina's rules to prevent innovators from securing patents on many kinds of biopharmaceutical inventions.[102]

- *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.[103] 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 not only existing restrictive patentability frameworks, but also emerging initiatives that could further limit innovators' ability to secure patents. PhRMA members look forward to working closely with these agencies to secure concrete progress and real results, recognizing that effective enforcement of U.S. trade agreements is essential both to address existing challenges in specific countries and to prevent others from adopting similar restrictive practices.

Unreasonable loss of patent term

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

[102] 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. 27, 2026).

[103] 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. 27, 2026).

costs.[104] 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.[105] For biopharmaceutical companies, patent backlogs can postpone the introduction of new medicines.[106] 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 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.[107] 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.[108]

Patent backlogs are a challenge around the world, but some countries stand out for persistently long delays. In **Brazil**, a 2026 analysis found that the average patent examination timeline for biopharmaceutical patents granted from January 2020 through November 2025 is 9.15 years. 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. 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.[109] In Egypt, patent grant delays continue to exceed global norms. In 2024, the average time from examination request to first office action was 540 days (versus a 367 day average), and Egypt ranks last among similarly situated

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[104] 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. 27, 2026).

[105] 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. London Economics, "Patent Backlogs and Mutual Recognition report to the UK Intellectual Property Office," Jan. 2010, available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/328678/p-backlog-report.pdf (last visited Jan. 27, 2026).

[106] 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. 27, 2026).

[107] 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. 27, 2026).

[108] *Id.*

[109] 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. 27, 2026).

countries in grants while having the longest examination timelines.[110] Finally, despite ongoing efforts to reduce the backlog, patent grant delays in Thailand remain lengthy and unpredictable, with substantive examination often taking 7–10 years or more.[111] Recognizing that there can be patent prosecution delays even in countries with more timely review systems, PhRMA members support the implementation of patent term adjustment (PTA) mechanisms to compensate for unreasonable patent office delays.

Similarly, the patent term for biopharmaceuticals is eroded by the lengthy development and regulatory approval processes that our industry must meet in order to demonstrate the safety and efficacy of a potential medicine before it may normally be prescribed to patients. Leading economies, including the United States, offer forms of patent term restoration (PTR) that 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. While the **European Union** has its own PTR mechanism (Supplementary Protection Certificates (SPCs)), damaging legislation has reduced the patent protections restored through that mechanism. In addition, the European Commission is proposing to establish a new mechanism for third parties to oppose SPCs. Recent legal changes in **Canada** to implement PTA and PTR consistent with its USMCA commitments are significantly deficient and need to be addressed ahead of the Joint Review of that Agreement.

In addition, the Gulf Cooperation Council (GCC) Patent Office has only recently resumed processing patent applications from Bahrain, Kuwait and Qatar, leaving patent applicants seeking protection in Saudi Arabia, the UAE or Oman to file separately with each national office, increasing the financial and administrative burden on right holders in the region. Further reform is required to restore a truly regional patent process across all GCC member states.

Compulsory licensing

In the 2025 Special 301 Report, USTR restored critical language recognizing the risks posed when "trading partners unfairly issue, threaten to issue, or encourage others to issue compulsory licenses," and renewed its commitment to engage with partners to safeguard innovation and respect for intellectual property.[112] PhRMA members welcomed these statements and urge USTR and other federal agencies to engage to address serious and growing compulsory licensing threats globally.

[110] WIPO IP Statistics Data Center, available at https://www3.wipo.int/ipstats/ips-search/patent (last visited Jan. 27, 2026).

[111] Zico IP, Patent prosecution in Thailand: timelines, challenges, and practical strategies, (Sep. 26, 2025), available at https://www.lexology.com/library/detail.aspx?g=67874de4-4cbe-4328-b848-61a22613c901 (last visited Jan. 27, 2026).

[112] USTR, 2025 Special 301 Report*,* at p. *30* (Apr. 2025), available at https://ustr.gov/sites/default/files/files/Issue_Areas/Enforcement/2025%20Special%20301%20Report%20(final).pdf (last visited Jan. 27, 2026).

Colombia, **Malaysia** and Russia are inappropriately leveraging compulsory licenses (CLs) to allow local entities to make, use, sell, or import patented medicines without the consent of the patent holder, raising concerns about consistency with international rules. **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 more CLs are forthcoming and that Colombia will "lead or support the position of abolishing patents."[113] 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.[114] Even some developed economies, like the **European Union**, that proclaim support for intellectual property protection are adopting measures that promote or provide broad discretion to issue CLs, 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.

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 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)

[113] 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. 27, 2026).

[114] *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. 27, 2026).

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. Similarly, PhRMA members welcomed the introduction of patent enforcement mechanisms in Taiwan as an important step for IP protection, but they note that the system's narrow scope limits its effectiveness, as it only provides meaningful protection primarily for small-molecule drugs.

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.[115] 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

[115] 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. 27, 2026).

and could pose significant risks. 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.[116] In fact, some stakeholders are now calling for an extension of the grace period as Bangladesh approaches LDC graduation in November 2026. Moreover, the adoption of a new patent law in anticipation of graduation has raised concerns about whether its patentability standards are fully aligned with international best practices. Taken together, these developments underscore the importance of completing the graduation process in a timely fashion and ensuring that Bangladesh fully complies with its TRIPS commitments.

Effective early resolution mechanisms are also needed in Egypt, **India**, **Russia,** Türkiye 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

[116] *Id*.

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 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,[117] 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[118] to Australia's trade minister, USTR raised concerns about the significant and negative impact that the Therapeutic Goods Act amendments permitting

[117] *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. 27, 2026).

[118] Letter from U.S. Trade Representative Robert B. Zoellick to Australian Minister of Trade Mark Vaile, Nov. 17, 2004, available at

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.

Regulatory data protection failures

Regulatory data protection (RDP) provides temporary protection for the comprehensive information innovators submit to regulatory authorities to demonstrate a medicine's safety and efficacy. It applies to all products, including small molecules and biologics, that are new to a specific country and require new clinical test data to prove safety and efficacy. The term is calculated from first approval in that country, thereby offering distinct protection that incentivizes investment in new treatments and cures. Moreover, RDP provides a distinct form of protection from patents, operating independently and without extending patent life.

A new study shows just how important RDP is for improving patient access to medicines worldwide.[119] 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.[120]

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https://ustr.gov/archive/assets/Trade_Agreements/Bilateral/Australia_FTA/Implementation/asset_upload_file393_6951.pdf (last visited Jan. 27, 2026).

[119] 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. 27, 2026).

[120] *See*, *e.g.*, Grabowski H et al., "Data exclusivity for biologics," Nature Reviews – Drug Discovery, Jan. 2011, available https://fds.duke.edu/db/attachment/1592 (last visited Jan. 27, 2026).

Unfortunately, many U.S. trading partners do not provide RDP. Examples, some of which are described further in the market profiles below, include **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. Thailand does not provide adequate RDP; regulations only protect against the physical disclosure of confidential information. 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 (including physical distribution and other forms of dissemination) and unfair commercial use. In Russia, despite its commitment to provide six years of RDP upon joining the WTO in 2012, such protection is no longer effectively in place. 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, the **European Union** has finalized proposals which will reduce the RDP term across the region and provide illusory opportunities to restore the lost years if certain conditionalities or localization requirements are met. That approach mirrors **China**'s coercive tactics seeking to reduce IP protections for companies that choose to first launch their products outside Chinese borders.

Other countries have adopted mechanisms inconsistent with international rules that enable governments to circumvent RDP. Türkiye undermines RDP in several ways: the RDP term begins from the first EU approval rather than from the date of first approval in Türkiye; RDP ends upon patent expiration, despite being independent from patent protection; and certain products requiring new clinical test data, such as combination products without a new indication, do not receive RDP. Israel similarly limits RDP by tying the term to first approval in a "Recognized Country," which can shorten the term for products launched internationally before Israel, and by excluding biologics from comparable data protection. Egypt also undermines RDP terms by calculating the protection period from the date data is submitted to the Egyptian Drug Authority rather than from the date of marketing approval. Moreover, PhRMA members report that Egyptian regulators permit reliance on confidential innovator test data to approve follow-on pharmaceutical products, resulting in unfair commercial use. In **Canada**, legislation was passed 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.

In 2022, the United Arab Emirates (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).

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.

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**, **the European Union**, **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,[121] an alarming number are seeking to grow their economies by discriminating against innovators in the United States and other countries. For example, **China** defines new drugs in a manner that discriminates against American manufacturers who first launch their products outside of China. Similarly, the **EU** is proposing to reduce its RDP term unless companies seek approval in the EU within 90 days of first global submission. 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. Thailand continues to implement procurement policies that favor the domestic Thai industry, creating a discriminatory and unpredictable investment climate that creates challenges for U.S. companies seeking to compete on a level playing field.

[121] 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. 27, 2026).

- *Mandatory technology transfer.* **China** continues to maintain a regulation that requires mandatory IP sharing with a local partner if the research conducted by a foreign company uses certain Chinese human biological samples. 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.[122] 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.[123]

PhRMA members urge USTR to take action to remove these barriers and to discourage other countries from adopting similar acts, policies and practices.

[122] *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 https://www.oecd.org/content/dam/oecd/en/publications/reports/2015/05/emerging-policy-issues_g17a264f/5js1m6v5qd5j-en.pdf (last visited Jan. 27, 2026); 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. 27, 2026); 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. 27, 2026).

[123] 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. 27, 2026).

Biopharmaceutical innovators in the United States look forward to concrete progress and real results in 2026.

IV. 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. Ensure high-income countries pay their fair share for biopharmaceutical innovation

PhRMA members are, and seek to remain, global leaders in the development and production of innovative medicines for patients in the United States and around the world. However, many foreign governments, including in high-income countries, maintain pricing and reimbursement policies that deny fair market value and access to innovative medicines and discriminate against medicines made in America. As stated above, these measures are trade barriers that allow foreign governments to enjoy the benefits of U.S. biopharmaceutical development without paying their fair share for these innovations and deny American inventors and workers the ability to compete on fair and reciprocal terms.

PhRMA members welcomed President Trump's directive for USTR and the Department of Commerce to eliminate foreign government acts, policies and practices that have "the effect of forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development, including by suppressing the price of pharmaceutical products below fair market value in foreign countries."[124] Consistent with this objective, PhRMA members encourage USTR to use trade tools and negotiations to secure the elimination of foreign government acts, policies and practices that devalue and undermine the biopharmaceutical innovation that the United States enables for the world, prioritizing engagement with the following high-income economies: **Australia**, **Canada**, **Denmark**, **France**, **Germany**, **Italy**, **Japan**, **Korea**, **Spain**, **Switzerland**, **the United Kingdom** and **EU**. To effectively address these acts, policies and practices, USTR should require high-income countries to adopt binding and enforceable trade commitments to achieve an appropriate level of spending on new innovative medicines, including through the implementation of specific policy reforms. USTR also should establish mechanisms

[124] Trump, Donald J. *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients*. *Federal Register*, vol. 90, no. 95, May 15, 2025, pp. 20749–20751. Executive Order 14297 at Sec. 3, available at https://www.federalregister.gov/documents/2025/05/15/2025-08876/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients (last visited Jan. 27, 2026).

for bilateral consultation with trading partners to ensure implementation and sustained compliance with these obligations.

The U.S.-UK Agreement in Principle on Pharmaceutical Pricing, announced on December 1, 2025, established important first steps by the UK to pay its fair share for innovative medicines.[125] PhRMA welcomes this Agreement and looks forward to working with the Administration to ensure full and prompt implementation of the UK's commitments. PhRMA encourages the Administration to seek similar agreements with the other high-income economies identified above, consistent with President Trump's directives to ensure that foreign nations contribute their fair share toward biopharmaceutical innovation and to promote fair and reciprocal trade.

The U.S. Government also can play a critical role in ensuring transparency and due process of pricing and reimbursement policies abroad. PhRMA members appreciate commitments that USTR has previously secured in certain trade agreements to 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.

B. 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.

[125] *See* USTR, U.S. Government Announces Agreement in Principle with the United Kingdom on Pharmaceutical Pricing, Dec. 1, 2025, available at https://ustr.gov/about/policy-offices/press-office/press-releases/2025/december/us-government-announces-agreement-principle-united-kingdom-pharmaceutical-pricing (last visited Jan. 27, 2026).

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.[126] China has never implemented this obligation, despite agreement to do so during the 2012 U.S.-China Joint Commission on Commerce and Trade meeting.[127] 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.

Despite making multiple commitments in the USMCA to provide an innovation ecosystem that is akin to that afforded to companies operating in the United States, both **Canada** and **Mexico** have failed to faithfully implement those commitments within the generous transition periods provided, denying American manufacturers and their workers of reciprocal access to those markets. As such, it is critical for USTR to engage with its Canadian and Mexican counterparts to ensure full implementation of these commitments *ahead of* the Joint Review to be held this year.

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

[126] 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. 27, 2026).

[127] 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. 27, 2026).

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.[128] 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."[129] 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. PhRMA appreciates the U.S. government's recent Section 301 investigation into Brazil's intellectual property and innovation practices, especially regarding the lack of RDP for biopharmaceuticals and the absence of mechanisms to mitigate the excessive patent backlog (i.e., PTA), and looks forward to working with the U.S. and Brazilian governments to ensure a binding agreement is reached to resolve these concerns.

The National Trade Estimate Report 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.

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

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

[128] 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. 27, 2026).

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

Trade Enforcement Act of 2015 (TFTEA).[130] 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."[131] 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."[132] PhRMA encourages USTR to pursue and accomplish these statutory objectives.

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

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. PhRMA members are encouraged that recent trade frameworks with the United Kingdom, the European Union, Switzerland, Argentina and other partners include the ambition to negotiate high-standard IP commitments and address certain longstanding IP issues.[133] PhRMA urges USTR to secure and build on such commitments as negotiations progress.

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[130] Public Law 114–125 (Feb. 24, 2016), available at https://www.congress.gov/114/plaws/publ125/PLAW-114publ125.pdf (last visited Jan. 27, 2026).

[131] *Id*.

[132] *Id.*

[133] General Terms for the United States of America and the United Kingdom of Great Britain and Northern Ireland Economic Prosperity Deal, May 8, 2025, available at https://ustr.gov/sites/default/files/files/Press/fs/US%20UK%20EPD_050825_FINAL%20rev%20v2.pdf (last visited Jan. 27, 2026); and Joint Statement on a United States-European Union Framework on an Agreement on Reciprocal, Fair, and Balanced Trade; Aug. 21, 2025, available at

The United States also should leverage the 2026 Joint Review of the USMCA to strengthen the Agreement's IP provisions consistent with President Trump's original vision for the Agreement. The original USMCA text signed in 2018 would have required Canada and Mexico to provide at least ten years of RDP for biologic medicines – a major advance that would have incentivized American innovation and rectified the failure of these countries to afford reciprocal IP protections to U.S. innovators. The United States should ensure that this and other critical IP provisions are restored as an outcome of the Joint Review to incentivize stronger North American supply chains and fulfill President Trump's original objective for the USMCA to "reflect a standard of [IP] protection similar to that found in U.S. law."[134]

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.[135]

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.[136] This challenge is exacerbated by the ease with which counterfeiters can offer

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https://www.whitehouse.gov/briefings-statements/2025/08/joint-statement-on-a-united-states-european-union-framework-on-an-agreement-on-reciprocal-fair-and-balanced-trade/ (last visited Jan. 27, 2026); Joint Statement on a Framework for a United States-Argentina Agreement on Reciprocal Trade and Investment; Nov. 13, 2025, https://www.whitehouse.gov/briefings-statements/2025/11/joint-statement-on-framework-for-a-united-states-argentina-agreement-on-reciprocal-trade-and-investment/ (last visited Jan. 27, 2026).

[134] Summary of Objectives for the NAFTA Renegotiation, Office of the U.S. Trade Representative, July 17, 2017, available at https://ustr.gov/sites/default/files/files/Press/Releases/NAFTAObjectives.pdf (last visited Jan. 27, 2026).

[135] 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. 27, 2026).

[136] 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. 27, 2026). *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. 27, 2026).

fake medicines over the Internet[137] and ship them by mail[138] to patients and consumers worldwide.[139] Unfortunately, the pandemic provided yet another arena in which counterfeiters sought to profit from unsuspecting consumers.[140]

Counterfeit medicines are a potential danger to patients everywhere, including in the United States. During 2024, the Pharmaceutical Security Institute documented more than 6,400 incidents of pharmaceutical crime in the United States.[141] 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.[142] 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[143] and elsewhere,[144] though many other jurisdictions are

[137] 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. 27, 2026).

[138] 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. 27, 2026).

[139] 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. 27, 2026). The IOM notes that "because the internet facilitates easy international sales, online drug stores have spread the problem of falsified and substandard drugs ...." *Id.*

[140] *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. 27, 2026), (highlighting seizures of counterfeit COVID-19 countermeasures).

[141] Pharmaceutical Security Institute, "Incident Trends," available at https://www.psi-inc.org/incident-trends (last visited Jan. 27, 2026).

[142] 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. 27, 2026).

[143] Homeland Security, "Intellectual Property Rights (IPR) Seizures," available at https://www.cbp.gov/newsroom/stats/intellectual-property-rights-ipr-seizures (last visited Jan. 27, 2026).

[144] *See*, *e.g.*, "Report on EU customs enforcement of intellectual property rights: Results at the EU border and in the EU internal market 2023," Nov. 2024, available at https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/2024_EU_Detentions/2024_EU_Enforcement_of_IPRs_FullR_en.pdf (last visited Jan. 27, 2026).

involved – particularly in online sales.[145] 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.[146]

PhRMA member 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

[145] 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. 27, 2026).

[146] 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, FY2017-2019, available at https://obamawhitehouse.archives.gov/blog/2016/12/12/supporting-innovation-creativity-and-enterprise-charting-path-ahead (last visited Jan. 27, 2026).

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. 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,[147] with one regional WHO office openly asserting that compulsory licensing is "important and to be encouraged."[148] 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.[149]

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;[150] 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.[151]

Federal agencies should ensure that intellectual property matters are addressed in organizations with the appropriate mandate and expertise, and with full visibility of the

[147] 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. 27, 2026).

[148] 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. 27, 2026).

[149] 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. 27, 2026).

[150] 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. 27, 2026).

[151] 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. 27, 2026).

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.

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.[152] This new-to-the-world definition is inconsistent with international standards, under which new drugs are those that are new to a specific market, 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,[153] the full benefit of proposals to provide regulatory data protection (RDP), new opportunities for early dialogue on comparator selection for health technology assessment (HTA), certain determinations of innovativeness in the National Reimbursement Drug List (NRDL) price negotiations and the NRDL price renegotiation pathway. The definition 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.

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

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

- **Patent term adjustment (PTA) and patent term extension (PTE)**: Industry welcomed the language in the revised Patent Law to provide PTA and PTE. After 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). In addition, PTE terms on compound patents are limited to only one of the approved indications, eroding the rights of the originator drug and significantly limiting the purpose of the PTE system. 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. The RDP proposal released by NMPA in March 2025, like prior proposals, does not meet these standards.

- **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.[154] 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.

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

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 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, including disparate reimbursement percentages between regions and populations, 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, HTA 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) that integrates with and supplements the existing Basic Medical Insurance (BMI) system. We encourage further clarity in the implementation of China's new CHI innovative drug list. 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 2026 Special 301 Report, and that the U.S. Government continue to seek prompt and effective resolution of the problems described herein.

Intellectual Property Protection

PhRMA and its member 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.

Weak Patent Enforcement

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.

In recent years, 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. Moreover, compound patent protection during the PTE period should cover all indications for which the compound has been approved prior to the expiration of the PTE. If subsequently approved new indications are not subject to PTE, generic manufacturers can obtain market approval of those indications and physicians would be enabled to prescribe these medicines for the first indications – effectively circumventing PTE. Consistent with the practices of major jurisdictions (e.g., the United States and European Union), PTE for compound patents should cover all indications.

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,[155] as affirmed in the chapeau to Section C of Chapter One of the Trade Agreement, 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 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.

On May 18, 2025, PhRMA, joined by industry associations in Europe and Japan, submitted industry comments to NMPA's draft "Implementing Measure for Pharmaceutical Test Data Protection" and "Working Procedures for Pharmaceutical Test Data Protection."[156] Like previous drafts and proposals,[157] PhRMA and its members remain concerned with China's continued efforts to condition fundamental IP rights, such as RDP, on localization or market access conditions. The March 2025 Draft Measures seek to reduce RDP periods for innovative products that are approved outside China before the drug application is filed in China. This reduction – calculated as the time difference between the ex-China approval and acceptance of the Chinese marketing application – undermines innovator protection, contradicts global standards and may severely impact patient access to new medicines in China. Innovative drugs first approved overseas should enjoy the same, full RDP period as those first approved in China, similar

[155] 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.

[156] NMPA, Implementing Measures for Pharmaceutical Test Data Protection (for Trial Implementation, Draft for Comment) and Working Procedures for Pharmaceutical Test Data Protection (Draft for Comment), Mar. 19, 2025, available (in Chinese) at https://www.nmpa.gov.cn/xxgk/zhqyj/zhqyjyp/20250319181537196.html (last visited Jan. 27, 2026).

[157] 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.

to the protections afforded by the United States, the European Union, Japan and other countries to products first approved in other jurisdictions.

RDP should be granted in full to any product that is "new" to China, i.e., has not been approved by NMPA. The March 2025 and 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. 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 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 new specific therapeutic methods should be provided by the patent system because 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).[158] 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 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:

[158] NHC took over HGR management responsibilities from MOST, effective May 1, 2024. See MOST's announcement, available in Chinese at https://www.most.gov.cn/tztg/202404/t20240425_190494.html (last visited Jan. 27, 2026).

> *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, HTA 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 CHI, including by ensuring that the relationship between 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. 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.

PhRMA welcomes the NHSA priorities 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. NHSA also announced the establishment of the Innovative Drug List (IDL) for CHI in 2025 and completed the inaugural listing negotiation with manufacturers.[159] This new mechanism has potential to expand patient access to certain innovative medicines not listed on the NRDL. PhRMA urges the Chinese Government to

[159] NHSA announcement on Multiple Measures to Support Innovative Medicine High Quality Development , available in Chinese at https://www.gov.cn/zhengce/zhengceku/202507/content_7030260.htm (last visited Jan. 27, 2026).

ensure a strong implementation of IDL, particularly on developing a coordinated measure to allow IDL drugs to be listed in hospitals and reimbursed efficiently.

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. Only 13 percent of new medicines launched globally since 2014 are available in China's public national health insurance and patients wait an average of 60 months from global first launch for new medicines to be reimbursed in the public national health insurance.[160]

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 and reimbursement caps that restrict patient access. Although NHSA and local Health Security Bureaus have issued numerous policies to expedite the hospital listing of NRDL medicines, these measures are largely ineffective. Hospitals require strong real world evidence and supportive frameworks, such as flexible DRG/DIP and effective CHI policies, to ensure that doctors can prescribe medicines and patients can afford them.

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.

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

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

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 (both of 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, transparent criteria 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 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)

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.

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 through clear, science-based policies on naming, pharmacovigilance, interchangeability, extrapolation of approved indications of reference biologics and production capability. Until the appropriate regulatory framework is in place and the safety risks of patients switching treatments are addressed, PhRMA opposes VBP on biologics.

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.[161] 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-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

[161] 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 in Chinese at www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20240731184417109.html?type=pc&m= (last visited Jan. 27, 2026).

(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 highly 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. While we understand the importance of regulatory oversight, we would welcome the opportunity to discuss how information requests might be aligned with international practices that balance regulatory needs with protection of CCI. 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.

In January 2026, NMPA issued a policy on "Further Optimizing the Review and Approval of Drugs Marketed Overseas That Are Urgently Needed in Clinical Practice." While it is encouraging to see the testing sample requirements being simplified, the industry still seeks clarification on how the policy will be implemented for innovative medicines.

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 several 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.[162] 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.[163] 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 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.[164]

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

[162] Announcement from the Ministry of Commerce, NHC and NMPA on the pilot work of expanding openness in the healthcare sector, available in Chinese at https://www.mofcom.gov.cn/zwgk/zcfb/art/2024/art_f0a5d342d5054b9bb48ad778df866f83.html (last visited Jan. 27, 2026).

[163] *Id*.

[164] 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. 27, 2026).

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.[165] 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 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

[165] *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.

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 welcome the newly announced Framework for a United States–Argentina Agreement on Reciprocal Trade and Investment (Framework Agreement) under which Argentina has committed to addressing longstanding issues identified in USTR's 2025 Special 301 report, such as patentability criteria and the patent backlog, and to aligning its intellectual property (IP) regime with international standards.[166] While details are still pending, PhRMA is hopeful that implementation of the Framework Agreement will help resolve the following systemic 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) – which Argentina aspires to join – 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.

- **Flawed cost containment measures and discriminatory reimbursement policies**: The former 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. Further, with the March 2025 announcement establishing a new health technology assessment (HTA) agency, it is critical for the Argentine Government to maintain separate marketing

[166] *See* Joint Statement on Framework for a United States-Argentina Agreement on Reciprocal Trade and Investment, Nov. 13, 2025, available at https://www.whitehouse.gov/briefings-statements/2025/11/joint-statement-on-framework-for-a-united-states-argentina-agreement-on-reciprocal-trade-and-investment/ (last visited Jan. 27, 2026).

authorization and HTA processes to ensure that access to vital new medicines is not restricted. Unfortunately, the government has issued several statements indicating that the HTA evaluation process would precede marketing authorization. PhRMA and its members are hopeful that the new Argentine Government will not pursue these plans, which could result in discriminatory barriers to access and defeat Argentina's efforts to create a more attractive environment for investment and innovation.

For these reasons, PhRMA requests that Argentina remain on the **Priority Watch List** in the 2026 Special 301 Report subject to progress in terms of implementing the Framework Agreement and that the U.S. Government continue to seek prompt and efficient resolution of the problems described herein.

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 new uses, 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.

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

The guidelines and Regulation 283/2015 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.[167] Indeed, the guidelines and resolution continue to be challenged in federal court.[168]

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. Innovators often face immediate generic competition and unfair pricing pressures after launching their products. In one example, generic competitors squeezed an innovator from the market and started charging 20 percent more for the 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.

PhRMA and its members welcome Argentina's commitment to address this concern as set forth in the Framework Agreement.

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.[169]

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[167] *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. 27, 2026).

[168] 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.

[169] 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. 27, 2026).

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

Argentina should seek to remedy its lack of RDP, consistent with its commitment in the Framework Agreement to align its IP regime with international standards.

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 protects a pharmaceutical product would help patent holders to anticipate and mitigate potential patent infringements. Such a mechanism would also allow for an initial determination—shared with the patent owner—of whether any patents may be infringed by the sale or marketing of a product under regulatory review and would provide patent owners with an opportunity to take corrective action. 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, contravening Law No. 27.275 on Access to Public

Information which compels government entities to facilitate transparency and publish all administrative acts, resolutions and related documentation in a timely and accessible manner.

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.

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. 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.

Patent application delays can be lengthy in Argentina, where life science innovators wait an average of 6.6 years for patents to be granted.[170] 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. Argentina should establish a PTA mechanism to compensate for administrative delays, consistent with Argentina's commitment in the Framework Agreement to address its structural challenges related to patent backlogs.

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.

[170] 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. 27, 2026).

Market Access

Flawed Cost Containment Measures

Prior to the December 2023 presidential 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 30 percent of new medicines launched globally since 2014 have launched in Argentina, with patients waiting an average of 33 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.[171] PhRMA and its members are hopeful that the new Argentine Government will not pursue these plans to avoid discriminatory barriers to access and will continue its efforts to create a more attractive environment for investment.

However, in March 2025, the current Argentine Government announced the creation of a new HTA agency, the National Agency for the Evaluation of Financing of Health Technologies (ANEFiTS). While there have been no official or draft r guidelines, official announcements have indicated that the proposed HTA body will be a prerequisite to marketing authorization in Argentina, conditioning the launch of new medicines in Argentina on economic evaluations and delaying or denying patients access to life-saving new medicines. Any new HTA should be conducted separate from granting marketing authorization, be transparent with clear guidelines, take into account the full value of an innovative medicine, including enhancing quality of life, and allow for stakeholder engagement throughout the process. PhRMA and its member companies welcome the opportunity to provide public comments on the creation of ANEFiTS and urge the Argentine government to provide separate marketing authorization and HTA processes to ensure that access to vital new medicines is not restricted.

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

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

manufactured in Argentina that have the same active ingredient as products manufactured abroad. PhRMA and its members are hopeful that the new Argentine Government will reconsider these policies to avoid discriminatory and non-reciprocal barriers to market access.

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 private insurers face financial challenges due in part to Argentina's economy, 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.

Substandard Biologics Regulation

On March 17, 2025, the Argentine Government implemented regulatory changes in biosimilar approvals through ANMAT's Provision No. 1741/2025. The new Provision, issued without meaningful stakeholder engagement, establishes an abbreviated pathway for biosimilar approval in Argentina that (1) removes the requirement for comparative efficacy clinical trials for biosimilars; (2) permits unrestricted extrapolation of indications; (3) lacks clear labelling requirements; (4) mandates local clinical trials while not recognizing high-quality foreign trials; and (5) fails to set out robust post-market safety, traceability and interchangeability controls. These elements risk patient safety, reduce transparency, delay or distort market access, and create regulatory uncertainty and potential discrimination against products already approved in trusted jurisdictions. PhRMA and its members urge the Argentine Government to reconsider these provisions to ensure patient safety while maintaining reasonable regulatory standards that recognize international best practices and avoid discriminatory barriers to access.

AUSTRALIA

Building on the agreements successfully negotiated by the United States with several trading partners in 2025, PhRMA members encourage Australia and the United States to conclude an agreement in which they agree to improve the business environment for innovative biopharmaceutical companies operating in Australia. As part of this agreement, Australia should commit to address the pricing and reimbursement concerns identified below and the Parties should reach an Agreement on Pharmaceutical Pricing (akin to the agreement in principle concluded with the United Kingdom)[172] to ensure that Australia bears a more proportionate share of the cost of developing innovative medicines.

Key Issues of Concern:

- **Undervaluing innovative medicines**: 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 and devalue innovative medicines, restricting access for Australian patients. 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 and in 2025 an Implementation Advisory Group provided guidance to the Health Minister on how and when to implement the recommendations. We encourage the Australian Government to implement the recommendations as a priority, which are aimed at reducing access delays to new medicines for Australian patients and are necessary to ensure the attractiveness of Australia as an early launch country.

- **Weak patent law enforcement**: Contrary to its obligations under Art. 17.10(4) of the U.S.–Australia Free Trade Agreement (AUSFTA), Australia has not yet

[172] *See* USTR, U.S. Government Announces Agreement in Principle with the United Kingdom on Pharmaceutical Pricing, Dec. 1, 2025, available at https://ustr.gov/about/policy-offices/press-office/press-releases/2025/december/us-government-announces-agreement-principle-united-kingdom-pharmaceutical-pricing (last visited Jan. 27, 2026).

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).

- **Inappropriate patent term extension (PTE) limitations**: Following a December 2025 Full Federal Court decision, IP Australia (Australia's patent office) recently indicated that it has temporarily paused processing PTE applications related to pharmaceutical formulation patents. The court ruling limited PTEs to active pharmaceutical ingredients and created a per se exclusion for formulation patents. The decision puts at risk existing formulation PTEs and raises significant compliance concerns under the AUSFTA.

- **Insufficient regulatory data protection (RDP)**: Australia should provide RDP for all products whose marketing authorization requires the generation of new clinical data to demonstrate safety and efficacy. At present, RDP does not extend to new indications, formulations, dosage forms or patient populations, raising concerns about Australia's compliance with its obligations under the AUSFTA. Moreover, Australia provides a five-year RDP term for both small molecules and biologics, which falls short of global best practices, particularly in light of the longer RDP term afforded to biologics in the United States and other jurisdictions, as well as Australia's own ten-year RDP term for agricultural and veterinary products.

For these reasons, PhRMA requests that Australia be placed on the **Priority Watch List** in the 2026 Special 301 Report and that the U.S. Government continue to seek prompt and effective resolution of the problems described herein.

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 allows for the listing of generic or biosimilar products on the Pharmaceutical Benefits Scheme (PBS), even when it has received a certificate submitted by the patent holder that:

- patent infringement proceedings 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."[173] 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 public listing on the Australian Register of Therapeutic Goods (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

[173] *See* Article 17.10(4) of the AUSFTA.

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 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.[174] 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, the Australian Government 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

[174] *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. 27, 2026).

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 later 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 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.

Inadequate Patent Term Extension

PTE is available in Australia, generally, for patents covering pharmaceutical substances that are included in the ARTG. A December 2025 Full Federal Court of Australia decision[175] reversed longstanding practice by holding that PTEs should be limited to active pharmaceutical compounds, thereby excluding, per se, formulation patents. In the meantime, IP Australia has temporarily paused the processing of PTE applications while the patent office considers the decision. The practice of the Patent Office will be settled only after the special leave application, and an appeal if leave is granted, have been determined.[176] The decision puts at risk existing formulation PTEs and raises significant compliance concerns under the AUSFTA.

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.[177]

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 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

[175] *Otsuka Pharmaceutical Co Ltd v Sun Pharma ANZ Pty Ltd [2025] FCAFC 161*, available at https://www.wipo.int/wipolex/en/text/597114 (last visited Jan. 27, 2026).

[176] This Full Federal Court decision is now the subject of an application for special leave to enable an appeal to the High Court of Australia. The special leave application will likely be decided upon this quarter, and if leave is granted it is expected that a decision will not be issued until 2027.

[177] 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. 27, 2026).

compete for foreign investments in the knowledge- and innovation-intensive biomedical sector that can drive future economic growth. 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.

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.

Restrictive Patent Disclosure Requirements

Australia requires a complete patent specification to disclose the best method known to the applicant for practicing the invention at the filing date. Recent court decisions have actively relied on this requirement and have invalidated patents where preferred methods for practicing the inventions were not disclosed. In contrast, in the United States, failure to disclose the best method cannot be used to invalidate a patent. PhRMA members encourage the United States to leverage the AUSFTA to secure reciprocal alignment in patent disclosure requirements.

Market Access

Undervaluing Innovative Medicines

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.[178] 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, including duplicative and redundant HTA evaluations and price renegotiations for newly approved indications, cause significant delays between regulatory approval and reimbursement listing, or result in no reimbursement. Moreover, HTA and pricing policies

[178] *See* Medicines in the health system 2022, available at https://www.aihw.gov.au/reports/medicines/medicines-in-the-health-system (last visited Jan. 27, 2026).

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 87 percent of new medicines launched globally since 2014 are available in the United States, just 24 percent are available in Australia's public national health insurance, with Australian patients waiting an average of 38 months from global first launch for medicines to be reimbursed.[179]

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. This policy also affects medicines already listed on the PBS by triggering mandatory price reductions when a new product enters the market at the same price as the lowest cost comparator, a price that has often been driven down through ongoing price disclosure. This effectively penalizes sponsors of existing medicines and increases the risk of product withdrawals, compromising patient access and care. 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

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

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 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 report of the HTA Review 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.[180] 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).[181] The IAG will help guide critical reforms in response to the findings and recommendations of the HTA Review report. PhRMA and its member companies welcome the IAG and its mission to address the HTA system so that innovative products are valued appropriately and patients can access new medicines without unnecessary delay. The final report of the IAG will be delivered in early 2026.

[180] 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. 27, 2026).

[181] 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. 27, 2026).

It is important that the PBS and associated PBAC processes streamline and evolve as new and more advanced health technologies become available accompanied by an appropriately and adequately funded PBS budget that ensures medicine prices reflect the true value and impact of these innovations. 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 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. 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, this protection has been removed 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 has not implemented a unique naming convention for biologics. 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. Of particular concern are proposals from generic and biosimilar companies calling on the Government to enforce biosimilar prescribing for new patients from launch, stripping away the critical choice of clinicians and patients. It is critical that policies seeking 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.

BRAZIL

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

Key Issues of Concern:

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

- **Patent backlogs**: Historically, patent applicants in Brazil have experienced some of the longest patent pendency times in the world. A 2026 analysis concluded that the average patent examination timelines for biopharmaceutical patents is 9.15 years, and the lack of a mechanism to restore a portion of the patent term lost due to unreasonable examination delays (i.e., patent term adjustment (PTA)) 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. However, these efforts are not a substitute for a PTA mechanism that provides a durable and systemic solution to address Brazil's excessive patent office delays.

  In parallel, Brazil is considering draft amendments to its patentability guidelines that would impose restrictive criteria, further limiting the ability of biopharmaceutical innovators to obtain patent protection for key innovations.

- **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 six percent.[182] On December 15, 2023, and subsequently on December 16, 2025, through a complementary bill, 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, and there are proposals to reduce or eliminate VAT on all medicines.

- **Restrictive government pricing, reimbursement and access policies**: The Drug Market Regulation Chamber (CMED) of Brazil's Health Regulatory Agency (ANVISA) 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

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

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 35 percent of new medicines launched globally since 2014 have launched in Brazil, with patients waiting an average of 29 months from global first launch for the new medicines that become available. Further, only eight percent of these new medicines are publicly reimbursed by the *Sistema Unico de Saude* (SUS), with patients waiting an average of 63 months from global first launch to public reimbursement by the SUS.[183] In December 2025, CMED published Resolution No. 3, introducing changes to the regulatory framework for drug pricing. The changes restructure pricing categories, criteria, definitions, and procedures that companies must follow when seeking reimbursement, including shorter deadlines for pricing decisions.

- **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. In 2023, the Federal Audit Court (TCU) issued a decision instructing the Ministry of Health to suspend the initiation of new PDPs until certain issues identified within the program are addressed.[184] Despite changes to the legal framework to address TCU concerns introduced by MoH in 2024, the current 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 2026 Special 301 Report and that the U.S. Government continue to seek prompt and effective resolution of the problems described herein.

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

[184] 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/acordao-completo/*/NUMACORDAO%253A2015%2520DTRELEVANCIA%253A%255B20230101%2520to%2520 20231231%255D/DTRELEVANCIA%2520asc%252C%2520NUMACORDAOINT%2520asc/2 (last visited Jan. 27, 2026).

Intellectual Property Protection

In July 2025, the U.S. Trade Representative launched a Section 301 investigation into whether Brazil's IP policies, among other practices, are actionable under U.S. trade law. This inquiry offers a key opportunity to address, through consultations, two longstanding discriminatory IP practices that restrict U.S. commerce and harm biopharmaceutical innovation — the lack of biopharmaceutical regulatory data protection and the patent backlog that effectively halves biopharmaceutical patent terms. We also urge Brazil to pursue constructive negotiations rather than retaliatory measures authorized under Law No. 15.122/2025, which allows suspension of IP rights including through compulsory licensing in response to tariffs. Such measures would undermine patient access to innovative treatments, deter investment and heighten trade tensions.

Lack of Regulatory Data Protection

Consistent with U.S. law and international rules, it is critical that Brazil provide RDP for the confidential data that biopharmaceutical innovators must submit to Brazil's Health Regulatory Agency (ANVISA) to demonstrate the safety and efficacy of a medicine for marketing approval. RDP must protect against both disclosure of test data and, for a reasonable term, unfair commercial use (e.g., third-party reliance on the data). Further, RDP should be available for both small and biologic molecules, and should be granted based on the date of marketing approval in Brazil.

Brazilian Law (10.603/02) provides RDP only to "veterinary pharmaceutical products, fertilizers, bioinputs and pesticides …." The explicit omission of human-use pharmaceutical products creates a discriminatory policy inconsistent with U.S. and international practices. It provides a windfall to third-party entities by enabling improper reliance on an innovator's confidential test data to accelerate marketing approval for competing products without undertaking equivalent research and development expenditures. A recent analysis found that if Brazil introduces RDP for human-use pharmaceutical products, the number of innovative medicines available in the country could increase by 34 to 39 percent (equivalent to approximately 570 additional new treatments) and the number of clinical trials in Brazil could more than double.[185] Indeed, Brazil recognizes that the number of clinical trials conducted in the country has been declining and does not reflect its full potential. The Clinical Research Law (Decree No. 12,651 of October 7, 2025) was designed to reverse this trend. However, the law did not include provisions for RDP, limiting innovators' incentive to conduct clinical trials in Brazil.

[185] Copenhagen Economics, "Regulatory Data Protection for Pharmaceuticals in Brazil: How Adopting Regulatory Data Protection Will Impact Patients, Industry, and Brazilian Society," September 2023, available at https://copenhageneconomics.com/wp-content/uploads/2023/03/Regulatory-Data-Protection-for-Pharmaceuticals-in-Brazil_092023.pdf (last visited Jan. 27, 2026).

Patent Backlogs

Patent backlogs in Brazil directly reduce the value of granted patents and negatively impact the launch of new medicines. The issue is especially significant for U.S. innovators, who file the largest proportion (approximately 30 percent) of patent applications in Brazil.[186] While complementary initiatives, including expanding the Patent Prosecution Highway, hiring additional personnel and appropriately funding the National Institute of Industrial Property, are important to combat the patent backlog, Brazil must establish a PTA mechanism to compensate for the unreasonable delays in the Brazilian patent examination process.

Brazil's patent examination backlog is particularly egregious for biopharmaceutical innovators. According to a recent analysis, the average patent examination timeline for biopharmaceutical patents granted from January 2020 through November 2025 in Brazil was 9.15 years. It is critical for Brazil to establish a PTA mechanism to ensure that innovators are not harmed by undue delays in Brazil's patent examination process. Indeed, Brazil stands in stark contrast to many countries in the region which provide PTA, including Chile, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras and Nicaragua.

The need for PTA in Brazil is even more acute following the Brazilian Supreme Court's 2021 decision eliminating the sole paragraph of Article 40 of the Patent Law, which provided a minimum patent term across all sectors to offset Brazil's egregious patent office examination delays. Even worse, the Supreme Court applied its holding retroactively to biopharmaceutical and other health-sector innovator patents – and their patents alone – eliminating overnight thousands of patents and raising significant discrimination concerns. Moreover, a recent key court ruling confirmed that Brazilian law does not currently permit adjustments to the patent term to compensate for unreasonable administrative delays, further underscoring the need for Brazil to establish a PTA mechanism. Together, these decisions reveal a critical gap in Brazil's patent framework, leaving innovators exposed to significant uncertainty regarding their intellectual property.

Encouragingly, in 2025, the Brazilian National Congress introduced legislation to implement PTA in Brazil. These efforts are critical to addressing deficiencies in the country's IP framework, including concerns raised in USTR's Section 301 investigation.

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.

[186] World Intellectual Property Office, Intellectual property statistical country profile 2023 – Brazil, available at https://www.wipo.int/edocs/statistics-country-profile/en/br.pdf (last visited Jan. 27, 2026).

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.

We urge GIPI to coordinate with stakeholders, including the innovative biopharmaceutical industry, as it works to implement its national IP strategy, including the 2025-2027 Action Plan, and to clearly define actions to eliminate the patent examination backlog (i.e., provide for PTA) and address RDP failures. Also, 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.[187] High tariffs and taxes can prevent access to new treatments for patients that need them. On December 15, 2023, and subsequently on December 16, 2025, through a complementary bill, 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 over the next seven years. Under the new law, medicines for serious illnesses and other high-priority categories (including cancer treatments, rare diseases, vaccines, neglected diseases and anti-retroviral medicines) are now exempt from VAT. The list of exempted medicines will be reviewed every 120 days. PhRMA and its member companies are encouraged by the new tax law, look forward to its implementation and continue to support reform proposals to reduce or eliminate taxes on all medicines.

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 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

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

proportion of medicines distributed around the world are potentially subject to tariffs.[188] 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.

In December 2025, CMED finalized Resolution No. 3, establishing a new approach for pricing in Brazil, which will take effect on April 29, 2026. The revision expands the scope of price regulation, increases the number of pricing and classification categories, redefines criteria and definitions for drugs, and shortens the deadlines for pricing decisions. While the Resolution provides greater clarity in some areas, important gaps remain, especially related to pricing for advanced therapies which remains discretionary. Member companies also have concerns related to the revised pricing pathway, which requires new price requests to be submitted after a marketing authorization is filed with ANVISA but before approval, raising the risk of potential delays and more rigid evaluation processes. The full impact will become clear after implementation begins in April 2026. PhRMA and its member companies welcome the opportunity to engage with CMED and provide feedback on the updated regulation.

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 Federal Court has imposed new access limitations on advanced therapies (including CAR-T) that also affect patients with private insurance. Only 35 percent of new medicines launched globally since 2014 have launched in Brazil, with Brazilian patients waiting an average of 29 months from global first launch for the medicines that become available.[189] Further, only eight percent of these new medicines are publicly reimbursed by the SUS, with patients waiting an average of 63 months from global first launch to public reimbursement by the SUS.[190]

[188] *Id*.

[189] 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. 27, 2026).

[190] *Id*.

In 2021, the Brazilian government introduced a new Bill, PL 667/2021, to create a legal framework for risk-sharing agreements for the incorporation of new technologies and medicines in the SUS. While the proposed framework could allow for innovative therapies to enter the market faster, there remain many uncertainties in definitions, confidentiality and procedure. The bill is still under consideration in the House of Representatives before moving to the Senate. Importantly, PhRMA and its member companies welcome the opportunity to engage in future stakeholder consultations to ensure flexibility and fit for purpose mechanisms.

The Brazilian government is also considering other reforms including the possibility for confidential pricing in public procurement and a broader reform of the public procurement process for high-cost medicines. The latter is intended to establish global reference prices for several medicines and enable more effective price negotiations. PhRMA is closely monitoring developments in this process to ensure sufficient legal certainty is provided and the value of innovative medicines is not undermined.

Finally, a recent ruling by the Brazilian Supreme 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 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[191] 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.[192]

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 five percent with an additional ten percent if the active pharmaceutical ingredient is also produced locally. A ten percent preference is applied for medical and surgical devices that can demonstrate domestic development and innovation.

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[191] 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. 27, 2026).

[192] 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. 27, 2026).

CANADA

PhRMA and its members urge Canada to implement the commitments that it made in the U.S.-Mexico-Canada Agreement (USMCA) and thereby address several of the intellectual property (IP) challenges and market access barriers identified below. This year's Joint Review of the USMCA offers an important opportunity to strengthen the USMCA's IP commitments and thereby fulfill President Trump's original objective for the agreement to "reflect a standard of [IP] protection similar to that found in U.S. law."[193] Building on the agreements successfully negotiated by the United States with several trading partners in 2025, PhRMA members also encourage Canada and the United States to conclude an agreement in which they agree to improve the business environment for innovative biopharmaceutical companies operating in Canada. As part of this agreement, Canada should commit to address the pricing and reimbursement concerns identified below and the Parties should reach an Agreement on Pharmaceutical Pricing (akin to the agreement in principle concluded with the United Kingdom)[194] to ensure that Canada bears a more proportionate share of the cost of developing innovative medicines.

Key Issues of Concern:

- **Patient access delays due to restrictive health technology assessments (HTAs) and protracted 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. Canada currently ranks last among G7 countries in terms of access to new medicines. On average, biopharmaceutical innovators marketing their products in Canada must wait 37 months after domestic regulatory approval until medicines are approved for public reimbursement.[195] This is among the worst in the OECD.[196] In addition, only 20 percent of new medicines launched globally since 2014 are reimbursed on Canada's public plans, compared to 87 percent in the United States.[197] These barriers significantly delay the benefits of new medicines and vaccines for

[193] Summary of Objectives for the NAFTA Renegotiation, Office of the U.S. Trade Representative, July 17, 2017, available at https://ustr.gov/sites/default/files/files/Press/Releases/NAFTAObjectives.pdf.

[194] *See* USTR, U.S. Government Announces Agreement in Principle with the United Kingdom on Pharmaceutical Pricing, Dec. 1, 2025, available at https://ustr.gov/about/policy-offices/press-office/press-releases/2025/december/us-government-announces-agreement-principle-united-kingdom-pharmaceutical-pricing (last visited Jan. 27, 2026).

[195] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023. A medicine is considered publicly reimbursed in Canada if 50 percent or more of the population lives in a province where it is publicly reimbursed.

[196] 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. 27, 2026).

[197] 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.

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. While all provinces have entered bilateral funding deals with the federal government, provinces have made different and inconsistent funding selections from the federal "common list" of drugs resulting in coverage and patient access that varies by province. 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, including removing the United States and Switzerland, two countries with a more pro-innovation approach to valuing medicines, and adding six countries with more onerous price controls. Final guidelines were issued in June 2025 and took effect in January 2026. PhRMA and its member remain very concerned that the amended PMPRB regulatory regime 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 USMCA requires Canada to provide PTA for unreasonable delays during the prosecution and issuance of any patent. 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 (PTR) 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")[198] include several key

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

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)[199] to implement reforms not required by that Agreement, which expose innovators to even greater potential liability under Section 8 of the PM(NOC) Regulations.

- **Inadequate patent term restoration**: By way of implementing CETA, Canada promulgated the Certificate of Supplemental Protection (CSP) Regulations,[200] which provide a "*sui generis* protection" of no more than two years to restore a portion of the patent life lost during the lengthy development and regulatory approval process for pharmaceuticals in Canada. This is significantly shorter than the maximum term of five years that may be restored in the United States. In addition, Canada adopted restrictive time limits and eligibility criteria that will unduly and unreasonably limit PTR eligibility in Canada in a manner that is contrary to the intent of the USMCA. Consistent with the Administration's intent to ensure that its trading partners are providing reciprocal access and protections, this year's Joint Review of the USMCA offers a critical opportunity to remedy these deficiencies in Canada's CSP system. Canada should provide five years of PTE that runs consecutively with PTA instead of concurrently. In addition, Canada should eliminate its "export" exception to PTE, which is inconsistent with the fundamental purpose of restoring a portion of the patent term lost due to the marketing approval process.

For these reasons, PhRMA requests that Canada be placed on the **Priority Watch List** in the 2026 Special 301 Report and that the U.S. Government continue to seek prompt and effective resolution of the problems described herein.

Market Access

Patient Access Delays Due to Restrictive Health Technology Assessments and Protracted 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

[199] *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. 27, 2026).

[200] Available at https://gazette.gc.ca/rp-pr/p2/2017/2017-09-07-x1/html/sor-dors165-eng.html (last visited Jan. 27, 2026).

subsequent reimbursement 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 wait for 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 biopharmaceutical innovators marketing their products in Canada must wait 37 months after domestic regulatory approval until medicines are approved for public reimbursement.[201] 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, in December 2024, Canada's Premiers issued a joint statement signaling their interest in driving work to continue accelerating patient access to medicines.[202] The governing Federal Liberal party also included accelerated access in their 2025 election platform with a commitment to "significantly reduce wait times for life-saving medications."[203] In October 2025, the Province of Ontario launched a new FAST policy – Funding Accelerated for Specific Treatments – a pilot program aimed at accelerating access to breakthrough cancer medications. This is a progressive policy that would benefit from expansion beyond oncology and into other provinces. PhRMA and its member companies are encouraged by these commitments and look forward to continued action to ensure timelier and more predictable patient access to innovative new medicines.

Eighty-seven percent of new medicines launched globally since 2014 have launched and are publicly reimbursed in the United States compared to just 20 percent available on Canadian public drug plans, with Canadian public plan patients waiting an average of 49 months from global first launch to reimbursement for the new medicines that do become reimbursed in public drug plans.[204]

Further, the CDA uses restrictive and rigid price reduction recommendations based on incremental cost effectiveness ratios (ICERs) that undervalue innovation. The

[201] PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023. A medicine is considered publicly reimbursed in Canada if 50 percent or more of the population lives in a province where it is publicly reimbursed.

[202] 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. 27, 2026).

[203] *See* 2025 Liberal Platform, available at https://liberal.ca/wp-content/uploads/sites/292/2025/04/Canada-Strong.pdf (last visited Jan. 27, 2026).

[204] 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.

subsequent joint negotiations across all public payers demand highly-aggressive price discounts as a condition for an agreement to fund new medicines, often with much stricter listing conditions than what is authorized for safe and effective use by Health Canada. Currently the pCPA negotiations are overly focused on achieving the lowest budget impact rather than valuing patient needs, access and health outcomes.

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 and, at a minimum, update outdated pricing thresholds that artificially devalue innovative 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 launches. 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 was allocated to provinces and territories to cover a small set of new and emerging drugs consistently across the provinces and territories. However, implementation plans and specific terms vary greatly across the country and the process lacks transparency as to which drugs are included per province and as to how funds will be allocated to support these rare disease agreements. There has been no indication to date of any continued budget allocations beyond those funds announced in 2023.

While this policy is a positive step, this funding is insufficient to meet the needs of Canadians and there is still work remaining to reduce disparities in access to medications across the provinces and territories. Further, the policy provides 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."[205] 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[206] as part of the PMPRB's professed role as a "counterweight to the patent rights of pharmaceutical manufacturers."[207] 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[208] 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.[209] On July 1, 2022, the only element of the Amended PMR upheld by the courts, namely, the changes to the basket of reference countries, came into force.[210]

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 largest trading partner and the pharmaceutical markets in both countries share many

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

[206] 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. 27, 2026).

[207] PMPRB 2015-16 Report on Plans and Priorities, available at http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1163 (last visited Jan. 27, 2026).

[208] 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. 27, 2026).

[209] Government of Canada, Order in Council, available at https://orders-in-council.canada.ca/attachment.php?attach=41417&lang=en (last visited Jan. 27, 2026).

[210] 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. 27, 2026).

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 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.[211] Any expansion of the PMPRB's mandate is therefore unnecessary and would harm U.S. innovative biopharmaceutical companies and the patients they serve.[212]

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.[213] Additionally, patented medicines accounted for only 5.9 percent of Canadian health care spending in 2024[214] and have not grown in real terms over the last decade.[215] 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.

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[211] 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.

[212] 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. 27, 2026). 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.

[213] 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. 27, 2026)

[214] Based on analysis of information from the Canadian Institute for Health Information, available at https://www.cihi.ca/en/national-health-expenditure-trends/nhex-trends-reports/national-health-expenditure-trends-2024-snapshot (last visited Jan. 27, 2026) and the PMPRB Annual Report 2024, available at https://www.canada.ca/en/patented-medicine-prices-review/services/annual-reports/annual-report-2024.html (last visited Jan. 27, 2026).

[215] *Id.*

In June 2025, the PMPRB published its final guidelines, which came into force January 2026, marking a significant milestone in Canada's regulatory framework for patented medicines and biopharmaceuticals. While the removal of punitive measures such as the Lowest International Price and the restriction of complaint mechanisms to public-sector entities represent progress, the guidelines fall short in several critical areas that risk patient access to innovative therapies. The final guidelines do not grandfather existing medicines in the Canadian market, creating additional and duplicative regulatory processes for products already compliant with previous rules. Moreover, the guidelines do not adequately address therapeutic specific market access areas such as antimicrobials, which are essential in combating antimicrobial resistance but face persistent barriers to market entry, or vaccines, which are already subject to competitive tendering processes that ensure value for payers. The already expanded international reference basket introduced unresolved operational challenges, including exchange rates. Without further refinements to balance affordability with innovation, Canada risks eroding incentives for investment, delaying the introduction of new medicines and weakening its global competitiveness in life sciences.

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. Specifically, Canada should restore the United States and Switzerland within the PMPRB's regulatory basket to more accurately reflect the value of innovative medicine. 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. 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,[216] and related regulatory amendments were published on December 18, 2024.[217] Before finalizing the regulatory framework, the Canadian Intellectual Property Office had launched consultations for stakeholder feedback.[218, 219] 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 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.

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[216] 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. 27, 2026).

[217] 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. 27, 2026).

[218] 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. 27, 2026).

[219] 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. 27, 2026).

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.[220] 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 final PTA term determination.

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.

[220] *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. 27, 2026). 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.

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[221] 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 IP rights.

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

[221] 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. 27, 2026).

assigned drug identification number.[222] 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 contrary to the law of damages and reflects a punitive as opposed to a compensatory theory of damages.[223, 224]

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[222] 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. 27, 2026). 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. 27, 2026). That decision has been appealed to Canada's Federal Court of Appeal.

[223] 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. 27, 2026). 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.

[224] 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

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.

However, PhRMA has concerns with Canada's implementation of this commitment under the Certificate of Supplemental Protection (CSP) Regulations.[225] 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.[226] Implementing PTR so that it does not confer full patent

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. 27, 2026). Lilly was denied leave by the Supreme Court of Canada on November 8, 2018.

[225] Available at http://www.gazette.gc.ca/rp-pr/p2/2017/2017-09-07-x1/html/sor-dors165-eng.php (last visited Jan. 27, 2026).

[226] *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. 27, 2026).

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.

Further, 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 international law, including CETA.[227] However, the Federal Court's decision was overturned on appeal.[228]

[227] 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. 27, 2026).

[228] 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. 27, 2026).

We urge the U.S. Government to engage with the Canadian Government on this issue in all available fora – including the upcoming Joint Review of USMCA – and require 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, including restoring up to five years of lost patent life. CSP eligibility should not be circumscribed by overly restrictive enumerated exclusions on medicinal ingredients and patents.

Standard for the Disclosure of Confidential Business Information (CBI)

PhRMA members are concerned with provisions in the *Food and Drugs Act*,[229] (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,[230] 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.

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.

[229] Available at https://laws-lois.justice.gc.ca/eng/acts/f-27/ (last visited Jan. 27, 2026).

[230] 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. 27, 2026).

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.[231] This guidance document was later updated and more recently in June 2021 to include the medical devices regulations.[232] 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.[233]

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.[234] 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

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[231] *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. 27, 2026).

[232] *Id*.

[233] *See, e.g.*, 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. 27, 2026).

[234] 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. 27, 2026).

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.[235] 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.

[235] *Doshi v Canada* (Attorney General), 2018 FC 710, available at https://cdn.dal.ca/content/dam/dalhousie/pdf/sites/noveltechethics/nte-Doshi%20v.%20A-G%202018%20FC%20710.pdf (last visited Jan. 27, 2026).

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 (RDP) 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. This order was revoked by the Consejo de Estado, eliminating the obligation for INVIMA and the Ministry to proceed with these plans. In December 2024, the Administrative Court of Cundinamarca again mandated the continuation of an urgent response plan to address ongoing medicine and supply shortages. As of December 15, 2025, there remained 12,336 drug evaluations pending. In the 2026 General Nation Budget proposal submitted to Congress, INVIMA's budget is projected to be underfinanced by approximately 40 percent, raising questions about INVIMA's operational sustainability.

- **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 2026 Special 301 Report and that the U.S. Government continue to seek prompt and effective resolution of the problems described herein.

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.[236] 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. USTR has specifically called out such practices and made clear that compulsory licensing should not be used as undue leverage in pricing negotiations.[237]

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 for some new chemical entities simply because they share a minor portion of their chemical structure with previously approved products, exhibit vague chemical or biological similarities or belong to a previously approved class of drugs. Denied applicants must resort to administrative appeals or lawsuits to challenge INVIMA's rejections.

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

[236] Colombian Fund for High-Cost Diseases, "HIV," available in Spanish at https://cuentadealtocosto.org/enfermedades-de-alto-costo/vih/ (last visited Jan. 27, 2026).

[237] *See*, *e.g.*, USTR, 2025 Special 301 Report, at p. *30* (Apr. 2025), available at https://ustr.gov/sites/default/files/files/Issue_Areas/Enforcement/2025%20Special%20301%20Report%20(final).pdf (last visited Jan. 27, 2026).

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. INVIMA should only approve follow-on products after verifying with the SIC that the reference product is not under patent protection. Additionally, it should leverage its open data portal to enhance transparency and provide notice to rights holders when follow-on applicants seek marketing approval.

Market Access

Numerous market access barriers have had a detrimental effect on patient access to innovative medicines in Colombia. Overall, only 18 percent of new medicines launched globally since 2014 have launched in Colombia, with Colombian patients waiting an average of 37 months from global first launch for new medicines to become available. Only 11 percent of these new medicines are reimbursed in Colombia's public national health insurance.[238]

Substandard Biologics Regulation

On September 18, 2014, Colombia issued Decree 1782, which established 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

[238] 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.

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 in 2025 was not sufficient to ensure access to health for Colombian patients.

In December 2025, the Ministry of Health (MoH) announced a nine percent increase in the UPC. However, various analyses indicate that a 17 percent increase was necessary to cover actual costs. In addition, considering the five percent inflation rate in 2025, the nine percent increase translates to a mere four percent real increase. This shortfall exacerbates the financial sustainability of the system and places additional pressure on companies, which are now burdened with over five billion pesos in accumulated debts (roughly US$1.35 billion). 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. Finally, plans for a centralized procurement model for pharmaceutical products, as included in the original health care reform proposals in 2022, remain opaque and lack implementation guidelines.

Aligned with the national government’s cost-containment measures, nine intervened HMOs and four non-intervened HMOs have launched joint negotiations with the pharmaceutical industry to purchase medicines and devices directly. This direct-purchase strategy aims to address rising health-care spending, access barriers, and fragmentation in procurement. Authorized by the Superintendence of Industry and Commerce (SIC) Resolution 35379 (2025), the negotiations follow a three-stage plan — high-cost drugs, then diapers and Foods for Special Medical Purposes (FSMP), and finally low-cost and generic medicines — with the goal of cutting intermediaries and reducing costs. The initiative supports national cost-containment objectives, but its effects on access to innovative therapies and new technologies remain uncertain.

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.

Persistent Regulatory Barriers and INVIMA Delays

In recent years, the pharmaceutical industry has experienced significant delays in regulatory approval times, resulting in market access barriers. 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. 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. As of December 15, 2025, there were 12,336 pending drug evaluations. On September 19, 2025, INVIMA published Resolution 202504628, extending the contingency plan by six months to continue reducing the backlog of regulatory approvals. The resolution also included prioritization criteria to ensure high priority products, including vaccines, and vital medicines get approved faster to mitigate the risk of drug shortages and a public health crisis. 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.

Further, Colombia’s 2014 – 2018 National Development Plan, which was enacted as part of Law 1753, included Article 72, which stated that for certain identified drugs, including innovative medicines, IETS must conduct an HTA that is then used by the MOH to inform the price setting of the drug before granting marketing approval and renewal. Following intervention by the Colombian Constitutional Court, and MOH Decrees 433 and 710, the IETS was required to run the process in parallel with INVIMA. Nonetheless, industry remains concerned that this will be duplicative and further delay approvals for innovative drugs.

In December 2025, MoH published a draft Decree to modify and replace the 1995 Decree that governs sanitary registration, quality control and market surveillance of medicines in Colombia. The draft decree establishes a new regulatory regime for sanitary registration, including new procedural requirements for approval, renewal and post-authorization monitoring and requires registration holders and related entities to report interruptions in commercialization, notify INVIMA of potential shortages and contribute to mechanisms that prevent drug supply disruptions. The Decree significantly expands post-

market obligations, including pharmacovigilance and supply-continuity reporting, and requires onerous administrative burdens and obligations for industry. PhRMA and its member companies continue to urge the Colombian government to provide greater clarity and predictability on this new proposed mechanism and ensure patient access remains the highest priority.

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, updating the price caps for available medicines in Colombia.

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 Instituto de Evaluación Tecnológica en Salud (IETS), a process that lacks transparency and could bias the value assessment, including narrowly focusing on cost-containment measures to determine benefit, and with limited stakeholder engagement.

PhRMA and its member companies remain very concerned about these new price regulation methodologies, including the increasing 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 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 cost 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.

EUROPEAN UNION

As the United States and the European Union (EU) work together to build out the recently announced Framework for an Agreement on Reciprocal, Fair and Balanced Trade,[239] we strongly encourage both governments to address the intellectual property (IP) challenges and market access barriers identified below. This should include concluding an Agreement on Pharmaceutical Pricing (akin to the agreement in principle concluded with the United Kingdom)[240] to improve the overall operating environment for innovative pharmaceutical companies and ensure that EU Member States (particularly leading economies such as Denmark, France, Germany, Italy and Spain) bear a more proportionate share of the cost of developing innovative medicines.

Key Issues of Concern:

- **General Pharmaceutical Legislation (GPL)**: In December 2025, the EU finalized GPL proposals that would weaken existing IP incentives, including fundamentally altering RDP and patent enforcement provisions (e.g., Bolar exemption) and incentives related to medicinal products to treat rare diseases. In particular, the Council of the EU (Council) and Parliament reached an agreement that would reduce the overall RDP term and inappropriately condition restoration of the lost term on criteria such as conducting clinical trials in the EU, seeking approval in the EU within 90 days of first global submission, or "adequately" satisfying a Member State's request to launch a product in that market. Such conditions pressure companies into entering commercial agreements with governments that do not value innovation or risk losing IP protections. The agreement also expands inappropriately the Bolar exemption to patent infringement to exclude from patent infringement clear commercial activities such as seeking pricing and reimbursement and participating in procurement tenders. In short, the EU appears to be exploiting IP rights to achieve localization objectives, mirroring approaches taken by China to reduce IP protections for those companies that do not seek approval in China before first global approval.

- **EU Patent Package**: In parallel to the GPL, the EU finalized compulsory licensing (CL) legislation to create an unnecessary pan-EU CL mechanism. At a time when IP rights are being opportunistically challenged by certain countries – often to support their own industrial policy goals – this unjustified, unprecedented proposal to create another CL mechanism in the EU is counterproductive. Similarly, the EU

[239] *See* United States-European Union Framework on an Agreement on Reciprocal, Fair, and Balanced Trade, Aug. 21, 2025, available at https://www.whitehouse.gov/briefings-statements/2025/08/joint-statement-on-a-united-states-european-union-framework-on-an-agreement-on-reciprocal-fair-and-balanced-trade/ (last visited Jan. 27, 2026).

[240] *See* USTR, U.S. Government Announces Agreement in Principle with the United Kingdom on Pharmaceutical Pricing, Dec. 1, 2025, available at https://ustr.gov/about/policy-offices/press-office/press-releases/2025/december/us-government-announces-agreement-principle-united-kingdom-pharmaceutical-pricing (last visited Jan. 27, 2026).

is finalizing amendments to regulations on Supplementary Protection Certificates (SPCs).

- **Emerging forced localization objectives**: Building on the recent amendments to the GPL, the EU Commission is currently pursuing various legislative proposals that would create preferential IP and market access treatment for companies that meet domestic manufacturing conditions.

- **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. Furthermore, many EU countries, including the largest markets, have put in place cost-containment measures such as clawbacks, with spiraling industry repayment rates over the past years. 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 sharing confidential price information among EU Member States that would undermine the ability to adapt to the different needs of each country. Eighty-seven percent of new medicines launched globally since 2014 are available in the United States compared to just 37 percent being reimbursed in each EU Member State, on average.[241] The EU Pharmaceutical Transparency Directive aims to ensure that EU Member States' pricing and reimbursement decisions for medicines are objective, transparent and timely, so that national controls on pharmaceutical spending do not unduly restrict market access or distort trade within the EU single market. 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 EU be placed on the **Priority Watch List** in the 2026 Special 301 Report and that the U.S. Government continue to seek prompt and effective resolution of the problems described herein.

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

Intellectual Property Protection

General Pharmaceutical Legislation

The EU's revision of the General Pharmaceutical Legislation (Directive 2001/83/EC and Regulation EC 726/2004) is nearing an end with the EU Parliament and Council announcing an agreement on the legislation on December 11, 2025. While the EU currently provides strong RDP, the agreement threatens to significantly erode IP protections within the EU, upend global IP norms and broaden exemptions to patent infringement that would disproportionately affect American innovators.

The agreement sets a troubling precedent by exploiting IP rights to achieve localization objectives by conditioning regulatory data protection on product launch requirements, conducting clinical trials in several EU Member States or submitting EU marketing approval applications within 90 days of their first global submission. This approach mirrors China's tactics seeking to reduce IP protections for companies that choose to first launch their products outside Chinese borders. For example, China's current proposal on regulatory data protection (RDP) seeks to force companies to seek approval in China before first global approval in order to receive the full RDP term. Similarly, China limits patent term extensions on biopharmaceutical patents to those products that are "new-to-the-world" versus new to China.

In addition, the agreement seeks to inappropriately expand the "Bolar" exemption to patent infringement beyond the intended purpose of that policy. Developed under U.S. law, the Bolar exemption allows for the experimental, non-commercial use of a patented invention by third parties to collect data for follow-on regulatory approval of medical devices and biopharmaceutical products. The agreement would expand the exemption to include the conduct of third-party studies, trials and other activities needed not only for follow-on marketing authorizations but also for conducting HTA and obtaining reimbursement (including tendering) – activities that are commercial and not considered by the Bolar exemption in the United States or any other jurisdiction with similar policies. Such an expanded definition would undermine effective patent enforcement in the EU because formulary price listing applications are currently the trigger in many countries for seeking injunctive relief – a clear indication that the follow-on product is threatening to infringe the innovator's patent.

EU Patent Package

Compulsory Licensing

PhRMA had serious concerns with the EC's new regulation (COM(2023)224) to establish a pan-EU CL mechanism for "crisis" management.[242] Although most

[242] 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

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 proposal to create another CL mechanism in the EU is counterproductive. The CL proposal was finalized by the Council of the European Union in June 2025. While the most concerning provisions in the ingoing EU Commission text were addressed (e.g., trade secret sharing was explicitly excluded), the need for a new CL mechanism remains questionable given public consultation responses at the time, especially given the success of voluntary actions taken during the pandemic.

Supplementary Protection Certificates (SPCs)

The EU continues to consider proposals (e.g., (COM(2023)231)) that would create inappropriate and unnecessary pre-grant mechanisms for third parties to oppose the grant of SPCs.[243] PhRMA continues to support 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. Negotiations continue within the Council, but resolving conflicts between national SPC law and the Unitary SPC Regulation have proven challenging. For example, the ability to secure preliminary injunctions during an SPC term varies significantly across EU Member States compared to the Unitary Patent Court (UPC). Additionally, the involvement of the UPC – representing a centralized competent forum for technical legal issues that may be raised in Unitary SPC examination – as the preferred route to appeal, remains unclear.

Market Access

Emerging Forced Localization Objectives

Critical Medicines Act

The "Buy European" mechanism proposed in the March 2025 draft Critical Medicines Act, introduces preferential treatment for locally manufactured pharmaceutical products, including procurement prioritization, faster regulatory pathways and access to EU funding. These proposed policies have the potential to create trade and access barriers for pharmaceutical companies without manufacturer presence in the EU and inhibit access to life saving innovative medicines for EU patients.

https://single-market-economy.ec.europa.eu/publications/com2023224-proposal-regulation-compulsory-licensing-crisis-management_en (last visited Jan. 27, 2026).

[243] 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. 27, 2026).

European Biotech Act

Under the draft European Biotech Act, eligibility for "strategic" and "high-impact" biotechnology projects is explicitly limited to investments in the EU. Eligible projects benefiting from accelerated permitting and licensing, priority administrative and financial support, fast-tracked dispute resolution and additional IP incentives. For example, the draft act includes a proposed SPC extension mechanism that conditions SPCs on the performance of at least one manufacturing step in the EU, directly linking regulatory benefits to EU manufacturing. The draft proposal has entered the interinstitutional legislative process and risks introducing *de facto* localization incentives that seek to influence investment decisions and threatens to disrupt globally integrated R&D and supply chains.

Government Price Controls and Patient Access to Innovative Medicines

As detailed further below, many EU Member States 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. In turn, as highlighted by the President, this results in U.S. patients and taxpayers bearing a disproportionate share of the cost of R&D for innovative medicines.[244] 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 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. These restrictions have prevented more than half of new medicines from being launched in Europe compared to the United States; 87 percent of new medicines launched globally since 2014 are available in the United States compared to just 37 percent in EU Member States, on average.[245] The EU Pharmaceutical Transparency Directive requirements for transparent and timely processes[246] need to be enforced more rigorously across the EU and broader oversight of national and subnational practices should be in place.

Further, a new EU HTA regulation entered into application in January 2025, introducing a new system of joint clinical assessments for the EU. While impact on patient access to new medicines and market access barriers remain uncertain, the risk of additional administrative processes may generate little-to-no efficiency gains, be overly

[244] Trump, Donald J. *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients*. *Federal Register*, vol. 90, no. 95, May 15, 2025, pp. 20749–20751. Executive Order 14297 at Sec. 3, available at https://www.federalregister.gov/documents/2025/05/15/2025-08876/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients (last visited Jan. 27, 2026).

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

[246] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31989L0105 (last visited Jan. 27, 2026).

cumbersome adding lengthy wait times to gain market entry and apply restrictive methodological approaches.

Austria

Austria has implemented a spate of 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 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 focused on high-cost, low-incidence medicines in hospitals, 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. All of these measures were made without meaningful opportunity for engagement by industry. Overall, just 47 percent of new medicines launched globally since 2014 are reimbursed in Austria's public national health insurance, with Austrian patients waiting an average of 27 months after global first launch for medicines to be reimbursed.[247]

Belgium

The Belgian Government sets maximum prices for all prescription medicines by referencing prices in other EU countries and Norway. Medicines reimbursed in the public health insurance program experience further price reductions (50 percent below the maximum price, on average) through rigid HTA and access restrictions that undermine the value of innovative medicines. In addition, revenue clawbacks are imposed when the public budget for medicines is exceeded, using a tax that offsets up to four percent of the public medicines budget each year. Manufacturers also face a turnover tax (7.73 percent) and marketing tax (0.13 percent) that are applied to the sales of reimbursed medicines. Only 35 percent of new medicines launched globally since 2014 are reimbursed in Belgium's public national health insurance, with Belgian patients waiting an average of

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

27 months after global first launch for medicines to be reimbursed.[248] Currently, a series of "Roadmap" reforms are being prepared and implemented to help accelerate the reimbursement process.

Bulgaria

Bulgaria's public pharmaceutical expenditure remains among the lowest in the European Union on a per capita basis, amounting to €140 for 2024. In fact, only 22 percent of new medicines launched globally since 2014 are reimbursed by Bulgaria's public health insurance and available to Bulgarian patients.[249] The government heavily regulates the prices of prescription pharmaceuticals, using international reference pricing to ensure that manufacturer prices do not exceed the lowest price for the same product across ten EU reference countries. Further, a 20 percent VAT is applied to all pharmaceuticals, including those that are reimbursed by the public health insurance program. Despite stringent pricing regulations, the National Health Insurance Fund (NHIF) budget does not meet the increasing demand for innovative pharmaceutical treatments. To compensate for this, a revenue clawback is implemented, requiring pharmaceutical companies to offset budget deficits. The clawback consists of three mandatory components: an entry rebate for new medicines of a non-specified amount; a fixed 10 percent rebate on the reimbursement of all single-source products; and a growth rebate compensating for any remaining annual budget overages. In 2024, the total annual revenue clawback averaged 27 percent of pharmaceutical companies' reimbursement revenues, primarily impacting manufacturers launching new products and reducing patient access to life-saving medicines.

Czech Republic

While the Czech Government more than doubled investment in health care over the last decade (2015-2025),[250] the country's pharmaceutical share of total health spending has declined considerably from 26 percent in 2010 to 15 percent in 2025 due to rigid cost-containment regulations such as its "double referencing" system.[251] 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.[252] Moreover, innovative medicines in the Czech Republic are subject to non-transparent and lengthy reimbursement processes that reduce patient access. Only 31 percent of new medicines launched globally since 2014 are reimbursed in the Czech Republic's public national health insurance, with Czech

[248] *Id*.

[249] *Id*.

[250] Czech Statistic Office (ČSÚ) Report 2024; Reports of the Analytical Committee.

[251] European Commission, "State of health in the EU, Czechia Country Health Profile 2025," available at https://health.ec.europa.eu/document/download/0dfbae43-4d8a-41ed-9b29-4a9c29f18f98_en?filename=2025_chp_cz_english.pdf (last visited Jan. 27, 2026).

[252] *Id*.

patients waiting an average of 35 months after global first launch for medicines to be reimbursed.[253] Furthermore, many drugs enter the reimbursement system under a "centric" limitation, meaning they are only accessible through specialized treatment centers. The target timeline for pricing decisions is 75 days from receipt of an application and 165 days for joint pricing and reimbursement decisions. However, in practice, decisions take more than a year on average and broader usage of innovative medicines is often limited by volume caps imposed through managed entry agreements.

Denmark

The Danish Government decides which medicines are reimbursed by public health insurance and sets prices for reimbursed medicines through a combination of international reference pricing, price caps, tendering and other cost-containment measures. The procurement of hospital medicines is centralized through public tenders managed by the regional procurement organization, Amgros. Hospital medicine list prices are set by referencing prices in other European countries, most of which have a lower GDP per capita than Denmark. Hospital medicine list prices are also subject to overall annual reductions (2.1 percent in July 2025, 2.1 percent in February 2026, and 0.8 percent in February 2027) and additional price reductions or rebates are typically required through the tendering process. Further, evaluations by the Danish Medicines Council (DMC), which makes recommendations for hospital medicines using HTA largely based on artificially low monetary values per year of life gained, has limited patients' access to new medicines, including new cell and gene therapies, while also recommending low prices for the tendering process. 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. The Danish Medicines Agency (DKMA) determines public health insurance reimbursement for retail medicines and sets prices using the lowest-priced product within each DKMA-determined reimbursement group, though further price reductions occur in the procurement process based on DMC recommendations or other factors.[254] 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 medicines to be reimbursed.[255]

Finland

The Finnish pricing and reimbursement environment is restrictive and lacks support for innovative medicines. There are two access channels for medicines, both of

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

[254] Under a pilot program that started in 2025, the DMC and Amgros will make recommendations to inform reimbursement and pricing decisions for eligible non-hospital medicines.

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

which require a lengthy HTA. In the hospital channel, the process is lengthy, unpredictable and non-transparent, with little to no dialogue with industry. In the outpatient channel 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.[256] 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 29 percent of new medicines launched globally since 2014 are reimbursed in Finland's public national health insurance, with Finnish patients waiting an average of 36 months after global first launch for the medicines that are reimbursed.[257]

France

France heavily regulates the price of new innovative medicines, including adopting policy mechanisms that devalue innovation and imposing aggressive and increasing cost containment measures designed to meet arbitrary budget goals. Since 2004, France established annual plans of budget savings through price cuts, including a goal of saving €856 million in 2024 and €1.4 billion in 2026 according to the new Social Security Financing Law. Over time, France has adopted several policies that negatively impact the biopharmaceutical industry, including layering mechanisms such as taxes, annual price cuts, 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 layered mechanisms are rediscussed yearly, creating policy unpredictability for companies. While industry payback schemes were intended to be limited, rebates have grown from €0.5 billion in 2012 to €7.1 billion in 2024 and revenue clawbacks and pharmaceutical-specific taxes further reduced spending on medicines by €2.5 billion in 2024.[258]

[256] Global Data International Reference Pricing Guidebook (2022).

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

[258] Leem, "Economic Assessment of Pharmaceutical Companies - 2024 Edition," March 2025, available at https://www.leem.org/sites/default/files/2025-03/Bilan%20Eco%202024_0.pdf (last visited Jan. 27, 2026); Social Security Accounts Commission (CCSS) Report, June 2025, available at https://www.securite-sociale.fr/files/live/sites/SSFR/files/medias/CCSS/2025/Rapport%20CCSS%20juin_BAT_%20avec%20couverture.pdf (last visited Jan. 27, 2026).

Additionally, innovative medicines are devalued by serious challenges and flaws with France's HTA system. The system 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 benefit or no clinical benefit due to overly stringent methodological standards and evidentiary expectations. For certain products that treat 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. However, approval rates for this program have roughly halved since 2022 (from 80 percent in 2022 to currently ~40 percent). 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 medicines to be reimbursed.[259]

These policies have discriminated against innovative companies despite the government having initially sent positive signals to the innovative biopharmaceutical sector. The framework agreement signed in March 2021 between the local innovative pharmaceutical industry association, Les Entreprises du Médicament (LEEM), and the French Government, aimed to reduce market access delays and promote investment for innovative products. During the CSIS[260] 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 without waiting for the finalization of price negotiations to speed timely access to patients. The ATU process was also replaced by two fast tracks: the primary one, the "accès précoce," process is intended for innovative products that could apply either prior to marketing authorization or post marketing authorization before funding, and "accès compassionnel" for specific patient populations or physician-prescribed off-label use. The pharmaceutical sector suffers from underinvestment in innovative medicines as well as an increasingly volatile policy environment, including a low and decreasing medicines budget as the government seeks budget savings from medicines to prioritize maintaining social security finances, strict budget regulations and political and policy fluctuations that are difficult to monitor and adapt to as companies. Market growth has been mostly flat since 2009 and lower than in peer countries.

PhRMA and its member companies urge the French government to appropriately value innovative medicines by eliminating the use of outdated comparators for pricing, reforming benefit evaluations, and providing stable pricing that is not subject to unpredictable budget-driven price cuts.

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

[260] CSIS: Conseil stratégique des industries de santé is a meeting organised by French Government with global CEOs of pharmaceutical companies.

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 with barriers and evidentiary standards that devalue innovation. 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 can be 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.[261] In addition, Germany has implemented 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. AMNOG has led to an average 23 percent price reduction worth €12bn in 2025. By assessing each indication, the same medicine can be subjected to multiple price reductions with two-thirds of AMNOG medicines experiencing at least two price reductions and almost half seeing prices reduced at least three times.[262]

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 and determining comparator therapies, focusing on technical requirements set by the Institute on Quality and Economic Efficiency in Healthcare (IQWiG), instead of alignment with medical treatment guidelines. 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.[263] 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 eight percent of potential patients.[264] 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 56 percent of new medicines launched globally since 2014 are available in Germany compared to 87 percent in the United States), but they can heavily influence

[261] 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. 27, 2026).

[262] Die forschenden Pharma-Unternehmen, "Spotlight Pharma Market AMNOG-MARKT," Mar. 2025, available in German at https://www.vfa.de/download/amnog-markt.pdf (last visited Jan. 27, 2026).

[263] AMNOG-Monitor (https://www.amnog-monitor.com/). Sept. 2023.

[264] *Id.*

physicians' ability to prescribe new medicines to patients without repercussions.[265] 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.[266] The German system should offer greater flexibility in its assessments, taking into account real-world health outcomes instead of rigid cost-containment policies.

In 2022, the Statutory Health Insurance (SHI) Financial Stabilization Act went into effect, introducing fixed formula pricing rules into the AMNOG drug pricing process, significantly limiting the scope of price negotiations in certain scenarios. New drug prices are still determined through a negotiation-based methodology; however, they are now constrained by statutory guardrails. 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 for medicines with patent protected comparators, deemed to have minor, non-quantifiable or no added benefits.[267] In addition, the Act lowered the annual sales threshold (from €50 million to €30 million) to exempt orphan drugs from the AMNOG process; 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 biopharmaceutical industry.[268] In 2024, an external evaluation of the Act, and its potentially negative effects on investment and the availability of innovative medicines, concluded that the legislation had negatively influenced the investment climate.[269]

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 seven percent.[270] 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

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

[266] PhRMA analysis of regulatory data and IQVIA data on launches.

[267] The "guardrails" apply when the comparator is also patent protected.

[268] 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. 27, 2026).

[269] Evaluationsbericht IGES (2024).

[270] 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. 27, 2026).

attractive as a research and production location for the pharmaceutical industry by exempting new medicines from the price-lowering guardrails, but only if five percent 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 limited flexibility to the guardrails, this was outweighed by the overall negative effects on value-based pricing from the measures under the SHI Financial Stabilization Act. PhRMA and its member companies encourage the German Government to instead abolish the "guardrails" and to not discriminatorily provide more favorable reimbursement terms only to companies that locate their R&D in Germany.

PhRMA and its member companies remain engaged in the ongoing Pharma Dialogue with the German government and encourage continued and meaningful stakeholder engagement.

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 2023 and 2024, the total industry amount for clawbacks, rebates and discounts (€3.9 billion and €4.3 billion, respectively) exceeded total public spending on medicines (€2.8 billion and € 3.00 billion, respectively). 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 37 months after global first launch for medicines to be reimbursed.[271]

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.[272] Since 2015, the public budget for medicines has remained flat while the industry payback amount for clawbacks and rebates has grown. In 2024, total mandatory paybacks (clawbacks & rebates) and discounts accounted for 53 percent of the total reimbursed market.[273] 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

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

[272] 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. 27, 2026).

[273] SFEE IOVE, The Pharmaceutical Market in Greece, Facts & Figures 2025.

rebates onto U.S. and other non-domestic companies.[274] 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, however the increase in industry clawbacks has far exceeded any targets, despite the government adding €50, €150, €300 and €400 million in 2022, 2023, 2024 and 2025, respectively. The government has further committed to add €100 million annually, plus GDP growth, to the total pharma budget until 2028. Finally, 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, but details have not yet been finalized in spite of the Government's willingness to have the Innovation Fund in place from the beginning of 2026. PhRMA and its member companies seek continued engagement regarding the creation of this Fund and the expanded access it could being to patients.

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 to the average of the three lowest prices at launch in EU countries. 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.[275] Only 13 percent of new medicines launched globally since 2014 are reimbursed in Hungary's public national health insurance, with Hungarian patients waiting an average of 51 months after global first launch for medicines to be reimbursed.[276]

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

[274] 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. 27, 2026).

[275] IQVIA (2023). Pricing and Reimbursement Concise Guide: Hungary.

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

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 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 was 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. In January 2025, the Hungarian government reduced the clawback rate back to 20 percent.

As of January 2025, specific named-patient reimbursement decisions are handled by the newly established public-benefit foundation, Batthyány-Strattmann László Alapítvány. The foundation reviews applications on a case-by-case basis for medicines and medical aids that are clinically recognized in Hungary but not included in the standard reimbursement list. Coverage is granted for individual patients and specific treatments, rather than through the usual national reimbursement process. This new process introduces uncertainty and procedural complexity and unpredictable timelines for early or compassionate access pathways, as approval timelines and criteria remain undefined and without confirmed guidelines.

Finally, in April 2025, a new government decree was published allowing abbreviated procedures for price increases of products on the 'strategic drug list' that are produced domestically, giving preferential treatment to local manufacturers. These government measures came simultaneous to additional pharmaceutical price controls, including price freezes, voluntary price cap schemes and new rigid and cost-containment focused HTA guidelines.

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 25 percent of new medicines launched globally since 2014 are reimbursed in Ireland's public national health insurance, with patients waiting an average of 34 months after global first launch for medicines to be reimbursed.[277] The process to assess and reimburse new medicines has been excessively slow. During the 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

[277] *Id*.

of a manufacturer's application to the Health Service Executive (HSE) decision on reimbursement. The IPHA 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.

Finally, at the end of 2025, the IPHA agreed on terms for a new Framework Agreement with the HSE that should improve access and pricing for new innovative medicines. PhRMA and its member companies welcome this coming agreement and the commitment to innovation, and will closely monitor its implementation to ensure timely, accurate and appropriate implementation.

Italy

Italy restricts patient access due to unfair and restrictive pricing policies as well as industry revenue clawbacks and other cost-containment measures designed to address pharmaceutical budget shortfalls. Only 45 percent of new medicines launched globally since 2014 are reimbursed in Italy's public national health insurance, with Italian patients waiting an average of 30 months after global first launch for medicines to be reimbursed.[278] Patients wait even longer in some regions. Industry revenue clawbacks are triggered in Italy when public spending exceeds the significantly underfunded public budget, with clawbacks disproportionately impacting U.S. manufacturers' portfolio of medicines. In 2024, there was an overall budget shortfall of €3.3 billion for medicines that was made worse by an unbalanced allocation of the budget across the retail channel and the hospital / direct purchasing channel. In 2024, the hospital / direct purchasing channel recorded a budget deficit of €4.0 billion, while the retail channel posted a surplus of €692 million. In accordance with the clawback rules, the budget surplus in the retail channel could not be used to offset the hospital drug overspending. Biopharmaceutical companies operating in the hospital / direct purchasing channel were required to refund 50 percent of the €4.0 billion budget deficit. In 2024, manufacturers were required to pay back €2.0 billion out of €17.0 billion in hospital medicine revenues.

Revenue clawbacks have become unsustainable for biopharmaceutical companies, as they are increasingly being used to offset regional budget deficits. Given that more innovative medicines are sold in the hospital / direct purchasing channel, the unbalanced clawback rules disproportionately penalize innovative U.S. biopharmaceutical companies, which so far have paid 42 percent of the cumulative €10.1 billion in clawbacks from 2019 to 2023 even though they only account for 30 percent of sales in the market. In 2025, the Italian government announced draft legislation to reorganize and rationalize its pharmaceutical legislation by December 2026. The draft law authorizes the Government to set new rules for access to medicines, how pharmaceutical spending is monitored and controlled, and how the payback system operates. PhRMA and its member companies urge the Italian government to engage in meaningful stakeholder consultation to ensure the reforms expand access to innovative

[278] *Id.*

medicines for Italian patients and redesign the payback system to ensure it does not function as a substitute for adequate public health funding.

In addition to access delays and clawbacks, other policies present challenges for innovation and patient access to medicines. For example, the Italian Drug Agency (AIFA) can determine comparators for setting prices for 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, creating an unpredictable business environment for industry.

The Netherlands

The Netherlands maintains increasingly aggressive cost-containment measures that restrict access to innovative medicines. Innovative medicines are placed into a reimbursement "lock" system that denies patients access until completion of a HTA and subsequent pricing decision. 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.[279]

In January 2023, the Minister of Health announced that the lock criteria for new medicines would become more stringent, along with the use of lower monetary thresholds for the value of a year of life gained.[280] These new cost-driven criteria greatly expanded the number of medicines placed in the lock and there has been no time limit on the lock period, which is currently estimated to be 380 days.[281] In addition, the Netherlands use of QALY-based cost-effectiveness thresholds has become more central in decision making. Initially these monetary threshold amounts, which have not been updated nor indexed for inflation since 2006, only served as an informal reference and were not strictly adhered to in decision making. However, it has since become common for the outcomes of HTA decisions to rely on the threshold amounts.

In 2024, the government further eroded 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.

[279] IHS Global Insights (May 2018). Netherlands expands criteria for inclusion of high-cost drugs in "reimbursement lock," renegotiates price of Tecentriq® and Soliris®.

[280] 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. 27, 2026).

[281] Association of Innovative Medicines in the Netherlands, June 2020.

It is estimated this change reduced prices in the Netherlands by five to 10 percent and reduced annual spending on medicines by around €300 million.[282] 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 reimbursement. Only 33 percent of new medicines launched globally since 2014 are reimbursed in the Netherlands' public national health insurance, with Dutch patients waiting an average of 32 months for medicines to be reimbursed.[283] Recognizing this challenge, the Medicines Evaluation Board and the Dutch National Healthcare Institute have introduced a "parallel procedure" in collaboration with industry to reduce reimbursement delays, which to date has been relatively unsuccessful.

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).[284] The Norwegian Medical Products Agency (NOMA) uses international reference pricing to set a maximum price for new medicines based on an average of the three lowest prices in a basket of nine European countries. NOMA also performs QALY-based cost-effectiveness evaluations to further reduce reimbursement prices for new medicines. Through the national centralized procurement agency of the Norwegian Government, four regional health authorities establish pharmaceutical formularies and conduct price negotiations and purchases. 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. Only 36 percent of new medicines launched globally since 2014 are reimbursed in Norway's public national health insurance, with Norwegian patients waiting an average of 32 months for medicines to be reimbursed.[285]

In 2025, the parliament asked the government to increase the cost-effectiveness threshold; this matter is now under review by the government. PhRMA and its member companies strongly urge the Norwegian Government to raise its artificially low monetary value for cost-effectiveness evaluations and to reform its use of international reference pricing in order to improve patient access and pricing for new innovative medicines..

[282] IQVIA (2023). Market Prognosis: Netherlands.

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

[284] IQVIA, Understanding Net Pharmaceutical Expenditure Dynamics in Europe, Apr. 2022.

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

Poland

Poland caps the share of public spending on medicines through an industry clawback mechanism, which is triggered when National Health Fund (NHF) expenditures on reimbursed medicines exceed 17 percent of the NHF budget. In 2021, the Polish Government drafted amendments to the Reimbursement Act 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. New amendments to the Reimbursement Act are currently in development with an expected draft by January 2026. PhRMA and its member companies have provided expertise and welcome the opportunity to further engage to ensure positive outcomes for patient access to innovative medicines.

Public spending on medicines is further constrained by a combination of therapeutic reference pricing, which can link the price of patented medicines to the lowest-cost generics, mandatory price cuts, fixed wholesale and retail margins, high patient co-payments and restricted reimbursement criteria that limit access to certain groups of patients. Poland's government pricing and reimbursement system is also underfunded and significantly backlogged. Only 27 percent of new medicines launched globally since 2014 are reimbursed in Poland's public national health insurance, with Polish patients waiting an average of 47 months after global first launch for medicines to be reimbursed.[286] 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.[287] This underfunding has led to various issues, including delays in the 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 medical services. In addition, pharmaceutical companies are subject to a revenue clawback currently equal to 25 percent of revenues. Only 20 percent of new medicines launched globally since 2014 are reimbursed in Romania's public national health insurance, with patients waiting an average of 48 months for medicines to be reimbursed.

[286] *Id.*

[287] 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. 27, 2026).

Patients in Romania face some of the longest waiting times in Europe for accessing new medicines.

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. Romania's dual-pricing system for pharmaceuticals uses international reference pricing to set public reimbursement prices based on the lowest price in a basket of 12 EU countries (CANAMED), while the Public Catalogue price, referenced by other countries, is based on the average of the three lowest prices. 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 reimbursement decisions for new medicines in the national health insurance were finalized. New legislation introduced in 2025 included timelines for new drugs to be included for reimbursement in the national health insurance and the Romanian Government aims to identify alternative funding to improve access for innovative medicines by creating a Health Innovation Program. Progress has been made; however, implementation is still 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 40 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 medicines to be reimbursed.[288] 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

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

co-payment, subject to caps and other limits).[289] Additional market access challenges emerged with more recent administrations, including: use of broad therapeutic reference groups (by ATC5 level) as comparators, which means older inferior medicines and generics can be used to set price for innovative medicines; industry revenue clawbacks, and international reference pricing.

On December 10, 2024, 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. Reforms to Spain's Medicines Law and HTA process are currently ongoing and expected to be approved by the Council of Ministers in early 2026, although it is unlikely to gain enough support to be formally adopted into law. A draft royal decree on medicine price setting is also being considered for publication in the course of 2026. PhRMA and its member companies urge the Spanish government to implement pricing reforms and improve patient access to new medicines.

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 post-launch re-assessments of reimbursed medicines, which result in price cuts and potentially additional restrictions on patient access. 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, the New Therapies Council (NTC) performs HTA that influence pricing and procurement, but there is no process for manufacturers to appeal. Only 38 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 medicines to be reimbursed.[290]

[289] IQVIA (2023). Pricing and Reimbursement Concise Guide: Spain.

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

INDIA

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

Key Issues of Concern:

- **Regulatory data protection (RDP) failures**: There is no RDP in India. 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. Promisingly, India has recognized that its existing drug approval process, which includes the lack of RDP, in India creates an unlevel playing field between innovators and follow-on manufacturers, and has issued a Notice seeking comments on how to address this imbalance. India should implement an RDP framework aligned with international best practices. This includes ensuring that RDP is: (1) calculated from the date of first approval in India; (2) independent of patents; and (3) not tied to regulatory filings in other jurisdictions, to promote predictability and confidence in India's regulatory system.

- **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, India has deployed a new framework concerning inventions based on digital sequence information on biological resources accessed from India which could significantly compromise 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 there is no requirement for the Central or State Drug Regulators to ascertain the existence of any subsisting patent before providing approval to a generic drug. After four years from the date of a medicine's first approval in India, the drug is no longer considered "new." As a result, the CDSCO or any state/union territory (UT) drug regulator is not required to consider existing patents on innovative products when approving follow-on medicines, thereby allowing follow-on applicants to infringe the innovator's patents. Patent holders are unable to take preemptive judicial action because there is no legal mechanism to obtain information about third-party marketing or manufacturing applications.

- **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 includes free medicines provided under Patient Assistance Programs (PAP), which results in deep price cuts on patented and proprietary medicines and discourages innovators from making drugs more accessible to patients through such programs. Further, the 2019 amendment to Paragraph 32 of the DPCO allow manufacturers of patented medicines to apply for exemption from price controls for only a period of five years from the commencement of marketing in India (as well as a permanent exemption for 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 meet local content requirements 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). While the GTE process provides a limited opportunity to qualify for public procurement without localization, it is unpredictable, often delayed, subjective and restrictive. 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), at the 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,

exemptions for additional patented drugs are needed because public entities are facing challenges in procuring these drugs, which adversely impact patients who depend on government programs for their medicines. To avoid subjective application of these provisions, drugs that are patented in India should automatically be included in the GTE list, without having to follow an annual committee process.

- **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. Before the reforms to the Integrated Goods and Services Tax (GST) in September 2025, the effective tax was as high as 28 percent. New GST rates helpfully reduce the GST to five percent for most medicines and zero for 36 "lifesaving" drugs, but the basic import duties remain for the majority of pharmaceutical products.

- **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 operationalized Rule 101 of the New Drugs and Clinical Trials Rules 2019 (NDCT) by announcing 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. In practice, Rule 101 is being applied subjectively, at the discretion of the Subject Expert Committees on a case by case basis. Further, this provision is limited to only a narrow category of drugs or to those where a "significant therapeutic advantage" is required to be demonstrated to the Committee. The process for seeking waivers remains ill-defined and related provisions in 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. 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.

- **Counterfeits and imports of unauthorized medicines**: Counterfeit medicines and the import of unauthorized medicines pose serious and pervasive health and safety threats, and according to recent reports, as much as half of the counterfeit medicines seized originated in India. Moreover, illicit trade in counterfeit medicines is growing globally and the need to stem the flow of these counterfeit medications is more pronounced given their facilitation by unregulated e-commerce platforms.

For these reasons, PhRMA requests that India remain on the **Priority Watch List** in the 2026 Special 301 Report and that the U.S. Government continue to seek prompt and effective resolution of the problems described herein.

Intellectual Property Protection

India announced its National IPR Policy in May 2016.[291] 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 nine 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[292] and the August 2022 Economic Advisory Council to the PM report on India's patent ecosystem,[293] is necessary to reassure India's commitment to a strong IP framework.

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.[294] 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.

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[291] 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. 27, 2026).

[292] 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. 27, 2026).

[293] Economic Advisory Council to the PM, "Why India Needs to Urgently Invest in its Patent Ecosystem," August 2022, available at https://www.ies.gov.in/pdfs/why-India-needs-to-urgently-invest-in-its-IPR-ecosystem-16th-Aug-2022.pdf (last visited Jan. 27, 2026).

[294] *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. 27, 2026).

This indirect reliance results in unfair commercial use, which is prohibited by TRIPS Article 39.3.

Promisingly, India has recognized that the existing drug approval process, including the lack of RDP, in India creates an unlevel playing field between innovators and follow-on manufacturers, and has issued a Notice seeking comments on how to address this imbalance.[295] PhRMA and its member companies are committed to engaging with the Indian Government to seek implementation of RDP in India in a manner that is consistent with India's commitments and international best practices.

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.

Enhanced Efficacy Requirement in Section 3(d): 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.

[295] *See* Notice, CDSCO, Request for Comments on Ensuring a Level Playing Field in New Drug Approval in India-reg, F. No. SND-16011(11)/102/2025-eoffice (Oct. 8, 2025), available at https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM0ODA= (last visited Jan. 27, 2026).

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.[296]

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.

Pre- and Post-Grant Opposition: 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,"[297] 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, which is often longer than the effective patent terms. 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, should help improve India's pre-

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

[297] 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. 27, 2026).

grant opposition regime. Specifically, requiring that the Controller consider the "maintainability" of the pre-grant petition is a positive development which should help provide some certainty and predictability to innovators.

PhRMA recommends that DPIIT develop clear 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 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.

Digital Sequence Information Requirement: Finally, in December 2024, through the Biological Diversity Rules 2024, and subsequently in May 2025, through the Biological Diversity (Access to Biological Resources and Knowledge Associated thereto and Fair and Equitable Sharing of Benefits) Regulations 2025, India deployed a new, and problematic, framework concerning inventions based on digital sequence information (DSI). The new regime applies to any invention implicating Indian biological resources, including DSI, which are accessed from India or repositories outside of India. Under this new regime, 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. Additionally, foreign entities are required to share benefits arising from accessing biological resources, including DSI, and associated knowledge from India for purposes such as research, bio-survey, bio-utilization or commercial use. Conversely, 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.[298] 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

[298] 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 ….*"

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.[299] At a minimum, through the draft Drugs, Medical Devices, and Cosmetics Bill, 2023, India should amend its rules for "new drugs" in the New Drugs and Clinical Trials Rules 2019 (NDCT), by increasing the period a drug is considered "new" from four years to 10 years (thereby extending the period before which a manufacturer can seek approval for a follow-on product without having to obtain a marketing approval from the CDSCO first).[300]

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[301] to omit Item 8 which previously required new drug applicants to disclose the "patent status of the drug."[302] 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.

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

[300] 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.

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

[302] *Id.*

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.

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 Indian 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 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 newly revised Form 27 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 countries.[303] 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

[303] *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. 27, 2026). 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.

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

Market Access

Discriminatory and Nontransparent Government Pricing Policies

Despite decades of government price controls ostensibly seeking to improve patient access to medicines, just 15 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.[304] 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 prices of medicines in the world.[305] 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.[306] 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.

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

[305] Analysis based on IMS MIDAS Data.

[306] 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. 27, 2026).

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. 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.[307] For example, even therapies and vaccines offered free of charge often do not reach the

[307] "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. 27, 2026).

patients who need these medicines.[308] 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.[309] 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.[310] 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 the country. Patented drugs should not be included under the NLEM as their price fixation will nullify the IPR so granted."[311] 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.

[308] *See*, *e.g.*, Patra N, "'When Will They Ever Learn?': The Great Indian Experience of Universal Immunisation Programme," Dec. 2009, available at https://www.researchgate.net/publication/238790732_'WHEN_WILL_THEY_EVER_LEARN'_THE_GREAT_INDIAN_EXPERIENCE_OF_UNIVERSAL_IMMUNISATION_PROGRAMME (last visited Jan. 27, 2026).

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

[310] 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. 27, 2026); 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. 27, 2026).

[311] 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.

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.[312] 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 128 drugs, but this mechanism is subjective, unpredictable and not regular in its timing. PhRMA and its member companies encourage the Indian Government to automatically exempt all patented drugs that have obtained a patent in India. For remaining drugs, an automated biannual process of inclusion may be followed.

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. Basic import duties on pharmaceutical products average about 10 percent and the effective taxes on imported medicines have exceeded 20 percent and were as high as 28 percent due to the integrated GST imposed on imports. Promisingly, in September 2025, the Indian Government introduced several reforms and changes to the GST, simplifying the rate structure and reducing rates for many goods and services. Under the new structure, GST rates on most medicines were reduced to five percent and zero for 36 “life-saving” drugs.[313] PhRMA and its member companies welcome the reforms to the GST and the positive business environment it helps facilitate,

[312] 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. 27, 2026).

[313] Ministry of Finance, Recommendations of the 56th Meeting of the GST Council held at New Delhi, (Sep. 3, 2025), at p.2, available at https://gstcouncil.gov.in/sites/default/files/2025-09/press_release_press_information_bureau.pdf (last visited Jan. 27, 2026).

and encourage the Indian Government to further expand exemption from customs duties and GST on all medicines.

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. Instead, they depend on the private health care system to get commercially available drugs in India. While one gene therapy drug is exempted from import duties and all are fully exempt from GST, the current duty policy on rare disease treatments adversely affects patient access to these crucial medicines. 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, and apply to all commercially available rare disease drugs.

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,[314] 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. This has become the world's largest health assurance scheme, representing over 50 percent of the Indian market. 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 1:811[315] in the country assuming 80 percent availability of

[314] *See* National Health Policy, available at https://mohfw.gov.in/sites/default/files/9147562941489753121.pdf (last visited Jan. 27, 2026).

[315] See Response of Ministry of Health and Family Welfare to Lok Sabha Question No. 2256 on Doctor-Population Ratio, Aug. 1, 2025, available at

registered allopathic doctors.[316] This is significantly lower than the norms set by the World Health Organization (WHO).[317] 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 1.84 percent of GDP in FY24.[318] Without continued increased resources (both in terms of government spending and through reducing barriers for commercial health insurance) 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.

PhRMA and its member companies 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 rarely utilized, ill-defined and open to subjective

https://sansad.in/getFile/loksabhaquestions/annex/185/AU2256_qD4i4E.pdf?source=pqals (last visited Jan. 27, 2026).

[316] MoHFW, "Enhancement of Healthcare Workforce," Mar. 25, 2022, available at https://pib.gov.in/PressReleasePage.aspx?PRID=1809812 (last visited Jan. 27, 2026).

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

[318] India Ministry of Finance, "Economic Survey 2024-2025," at p. 330, available at https://www.indiabudget.gov.in/economicsurvey/ (last visited Jan. 27, 2026).

interpretation. Immediate operationalization of Rule 101 in the Indian clinical trial rules would provide reciprocal access for U.S. pharmaceutical companies and ensure that drug approvals of the FDA, a stringent regulatory authority, are recognized by the Indian board of health and such drugs are automatically approved in India. This may be achieved by removing the restrictive categories of drugs for which the Rule 101 pathway is available and publishing standard operating procedures for subject expert committees.

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. 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).

In addition, 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.[319] 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.

Finally, 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

[319] 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. 27, 2026).

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.

PhRMA members welcome the recently released CDSCO – SEC Guidelines, Ver. 1.0 – 2025. While the Guidelines are a step in the right direction, concerns remain that recommendations, including those related to local clinical trial waivers, will be subjective and arbitrary. These issues perpetuate a burdensome environment for clinical research, early phase clinical trials and new drug approvals that undermine the availability of new treatments and vaccines for Indian patients.

Counterfeits and Imports of Unauthorized Medicines

Illicit trade in counterfeit and unapproved pharmaceutical products poses significant global public health risks given that they are not inspected by relevant regulatory authorities and are often produced using unsafe manufacturing practices. As such, counterfeit and unapproved 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 and unapproved medicines, studies indicate that more than half the counterfeit medicines seized in recent years originated in India.[320] As the USTR has highlighted, this illicit trade is facilitated by e-commerce platforms that conduct little to no vetting of the legality of pharmaceutical products offered for sale and are estimated to account for more than 50 percent of counterfeit products sold.[321] To date, Indian authorities have taken insufficient action to address such platforms' role in the sale of counterfeit and illegal medicines. Indeed, reports point to the existence of a thriving "grey" market involving counterfeit and unapproved oncology and hepatology medicines, including products still under patent protection.[322] The Indian Government should work with all relevant stakeholders to address the growing illicit trade in counterfeit and unregulated medicines which is putting lives at risk.

[320] *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. 27, 2026).

[321] USTR, 2024 Review of Notorious Markets for Counterfeiting and Piracy, Jan. 8, 2025, at pp. 3-10 and 26, available at https://ustr.gov/sites/default/files/2024%20Review%20of%20Notorious%20Markets%20of%20Counterfeiting%20and%20Piracy%20(final).pdf (last visited Jan. 27, 2026).

[322] *See*, *e.g.*, The Times of India, "Illegal cancer drugs from Bangladesh flood local market." Nov. 18, 2019, available at https://timesofindia.indiatimes.com/business/india-business/illegal-cancer-drugs-from-bdesh-flood-local-market/articleshow/72100024.cms (last visited Jan. 27, 2026).

JAPAN

As the United States and Japan work together to build out and implement the recently announced U.S.–Japan Strategic Trade and Investment Agreement,[323] we strongly encourage both governments to address the intellectual property (IP) challenges and market access barriers identified below. This should include concluding an Agreement on Pharmaceutical Pricing (akin to the agreement in principle concluded with the United Kingdom)[324] to improve the overall operating environment for innovative pharmaceutical companies and ensure that Japan bears a more proportionate share of the cost of developing innovative medicines.

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 FY2025, the Japanese Government applied 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. In December 2025, the Japanese Government announced plans for another off-year price revision in FY2027 without stakeholder engagement or consultation. PhRMA requests that the Japanese Government abolish annual price cuts and transition 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

[323] *See* Fact Sheet: President Donald J. Trump Secures Unprecedented U.S.–Japan Strategic Trade and Investment Agreement, July 23, 2025, available at https://www.whitehouse.gov/fact-sheets/2025/07/fact-sheet-president-donald-j-trump-secures-unprecedented-u-s-japan-strategic-trade-and-investment-agreement/ (last visited Jan. 27, 2026).

[324] *See* USTR, U.S. Government Announces Agreement in Principle with the United Kingdom on Pharmaceutical Pricing, Dec. 1, 2025, available at https://ustr.gov/about/policy-offices/press-office/press-releases/2025/december/us-government-announces-agreement-principle-united-kingdom-pharmaceutical-pricing (last visited Jan. 27, 2026).

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. Through these changes, the PMP coverage increased to 80 percent among newly listed products in FY2024 and FY2025. However, PMP eligibility is restricted to products with a smaller-than-average *yakka-sa* between the NHI reimbursement price and the surveyed wholesaler price to providers, and the average *yakka-sa* has shrunk significantly in recent years. In December 2025, the Chuikyo merely renamed the PMP to the "Patent-period Price Maintenance Program for Innovative Drugs," which did not address concerns on price maintenance. 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 decade, the Japanese Government has applied new or more draconian re-pricing rules to cut the prices of patented medicines following launch. These rules target clinically successful products that are used in greater volumes than expected (i.e., market expansion re-pricing) or target products that are pharmacologically similar to products that have undergone market expansion repricing (i.e., spillover re-pricing). In 2016, the huge seller re-pricing rule was introduced; since 2018, several re-pricing rules have been applied more frequently than the original biennial basis; and in 2020, a special rule for indication change re-pricing was introduced. In December 2025, the Japanese Government announced that it would abolish spillover re-pricing but expand the frequency and criteria for market expansion re-pricing and merely rename huge-seller pricing. Such frequent application and worsening 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 undervalue innovation and need to be abolished (e.g., huge-seller re-pricing) or restructured by examining their requirements, impacts and appropriateness (e.g., exempting regenerative medicines that lack economies of scale).

- **Misuse of health technology assessment (HTA)**: MHLW implemented an HTA system in April 2019 that remains severely inconsistent with international norms, focusing solely on use of outdated cost-effectiveness thresholds to cut the prices of innovative medicines and ignoring many product benefits to patients and the health care system. By December 2025, 39 of 51 (76 percent) innovative medicines that completed assessments had their prices cut and none had prices increased. 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 appreciates the planned "objective

verification" of the HTA system in FY2026 before making future reform decisions but remains concerned that the price-cut range will be expanded beyond the scope of the usefulness premium, 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 U.S.-Japan trade understandings and significantly undervalue U.S. innovation. There remains a strong need to improve the transparency and scientific basis of how the HTA system operates and makes decisions.

- **Inadequate system for pricing new medicines and additional indications**: The current methods used to set initial NHI prices of new medicines or to reward additional innovative indications have restrictive criteria that do not appropriately recognize the value that these medicines bring to Japan's patients, health care system and society. The situation is particularly challenging for highly innovative medicines with new treatment modalities such as regenerative medicines, which lack appropriate comparators under the current pricing method criteria. To improve initial NHI price-setting for innovative medicines, the Japanese Government should grant usefulness and innovation premiums in line with product value, expand the scope of admissible comparators and evidence for these premiums and reward additional innovative indications.

- **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, if at all. 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 and reassess MHLW obligations under Japan's Administrative Procedure Act.

- **Pharmaceutical regulatory reform and related issues**: To ensure that Japanese patients have prompt access to the latest medicines and to prevent the expansion of drug loss, more flexible and transparent 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, with priority review or a new expedited system; and (3) 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 Immunization 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) sometimes 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, including 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 is considering reforms to Japan's early patent dispute resolution practice and is piloting an "Expert Committee" mechanism to determine whether a follow-on product falls within the scope of an innovator's patent. PhRMA encourages MHLW to provide industry with 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 2026 Special 301 Report and that the U.S. Government continue to seek prompt and effective resolution of the problems described herein.

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 87 percent of new medicines launched globally since 2014 are available in the United States, just 50 percent are available in Japan's public national health insurance, with Japanese patients waiting an average of 15 months after global first launch for the medicines to be reimbursed.[325]

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 FY2025, 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. In December 2025, the Japanese Government announced plans for another off-year price revision in FY2027 without stakeholder engagement or consultation.

Both the increased frequency of price cuts to patented medicines and the negative impacts from the other pricing measures noted in sections below severely undervalue U.S. innovation and make Japan an outlier among leading economies. Moreover, 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 the industry or other stakeholders prior to its formal announcement. The scope also marked a major departure from prior 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. In reality, the current *yakka-sa* threshold captures 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

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

broad range of products. PhRMA requests that the Japanese Government abolish annual price cuts and transition to a new system that allows prices to be maintained during the patent period.

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.

Through these changes, the PMP coverage increased to 80 percent among newly listed products in FY2024 and FY2025. However, PMP eligibility was restricted to products with a smaller-than-average yakka-sa between the NHI reimbursement price and the surveyed wholesaler price to providers, and the average yakka-sa has shrunk significantly in recent years. In December 2025, the Chuikyo merely renamed the PMP to the "Patent-period Price Maintenance Program for Innovative Drugs," which did not address concerns on price maintenance. 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 decade, the Japanese Government has applied new or more draconian re-pricing rules to cut the prices of patented medicines following launch. These rules target clinically successful products that are used in greater volume than expected (i.e., market expansion re-pricing) or target products that are pharmacologically similar to products that have undergone market expansion repricing (i.e., spillover re-pricing). In 2016, the huge seller re-pricing rule was introduced; since 2018, several re-pricing rules have been applied more frequently than the original biennial basis; and in 2020, a special rule for indication change re-pricing was introduced. In December 2025, the Japanese Government decided to abolish spill-over repricing but retained and merely renamed huge-seller repricing based on an assertion that it is an essential mechanism for maintaining universal health coverage. Additionally, the scope of huge-seller repricing and quarterly repricing were expanded without any justifiable reasons (e.g., 66.7 percent price-cut at the maximum for products with annual sales of more than 300B JPY exceeding 10 times versus its original forecast).

Such frequent application and worsening of the re-pricing rules significantly devalues innovation, reduces the predictability of drug prices and disincentivizes investment in R&D for additional indications. PhRMA believes that these complex re-pricing rules undervalue innovation and need to be abolished (e.g., huge-seller re-pricing) or restructured by examining their requirements, impacts and appropriateness (e.g., exempting regenerative medicines that rely on individualized, autologous manufacturing processes lacking economies of scale).

Misuse of Health Technology Assessment

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 an HTA system after cutting the prices of several leading innovative medicines that were subject to an ongoing cost-effectiveness evaluation pilot program in 2018. The HTA system is severely inconsistent with international norms in both methods and processes. 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 December 2025, 39 of 51 (76 percent) innovative medicines that completed assessments had their prices cut and none had prices increased. 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. In December 2025, MHLW announced that it plans an "objective verification" of the HTA system in early FY2026, and subsequently aims to expand the system, including expanding the price cut range beyond the scope of the price premium. PhRMA has testified that expanding the price cut 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 this flawed approach, the resulting price of a new product would be set paradoxically lower than the price of a clinically inferior comparator. Nonetheless, the Japanese Government introduced a special price adjustment scheme for Leqembi® and Kisunla®, which may go beyond the scope of the usefulness premium (i.e., a maximum price reduction rate of 66.7 percent instead of 50 percent). Although the cases of Leqembi® and Kisunla® may be exceptional, PhRMA remains concerned that these decisions 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 U.S.-Japan trade understandings. There remains a strong need to improve the transparency and scientific basis of how the HTA system operates and makes decisions.

Inadequate System for Pricing New Medicines and Additional Indications

The current methods used to set initial NHI prices of new medicines or to reward additional innovative indications have restrictive criteria that do not appropriately recognize the value that these medicines bring to Japan's patients, health care system and society. The industry also recommends that the following unreasonable rules be corrected as follows:

1. 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, new pricing methods to appropriately recognize the value of new modalities (e.g., regenerative medicines) should be discussed and implemented.

2. 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.

3. Reward additional innovative indications

MHLW should improve 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, the introduction of a reward that evaluates the addition of innovative indications was not implemented in the FY2026 system reform. PhRMA continues to request the introduction of premiums for the addition of innovative indications.

<u>Lack of Transparency and Predictability in Government Decision-Making</u>

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's 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. Finally, while in 2025 the Japanese Government organized the Public-Private-Council for Enhancing Drug Discovery Capability that includes industry representatives, the opinions expressed at the meetings have not been reflected in government policies. It is necessary to create an environment that enables industry to be involved in the policy process on an equal footing with other stakeholders.

More promisingly, under the Takaichi Cabinet inaugurated in October 2025, the ruling Liberal Democratic Party and Japan Innovation Party have set forth to "reform … the Central Social Insurance Medical Council (Chuikyo) to strengthen hospital functions, enhance drug discovery capabilities, reflect patients' voices, and realize data-driven system design." PhRMA welcomes this initiative and calls for its swift implementation, but such a process must include all stakeholder voices.

Moving forward, PhRMA requests 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, and that it reassesses its obligations under Japan's Administrative Procure Act. 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.

<u>Ease Requirements to Withdraw Off-patent Brand Medicines</u>

In a 2024 government effort to encourage a research and development-driven business model and encourage uptake of generic medicines, MHLW revised market withdrawal rules for off-patent brand medicines. However, under these rules, companies wanting to withdraw off-patent brand medicines from the market must first obtain two forms of written consent: (1) from companies that will supply an alternative product and (2) from relevant academic societies. In both cases, obtaining written consent has proven difficult. For U.S. and other foreign biopharmaceutical research companies developing

innovative medicines, onerous market withdrawal rules result in commercial losses and negatively impact investment decisions in Japan. PhRMA urges MHLW to resolve this issue promptly.

Pharmaceutical Regulatory Reform and Related Issues

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), and increase investment in Japan, 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, including international harmonization or definitions and target, 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 2024, 21 products in the United States received Breakthrough Therapy designation, five products in the European Union received PRIME designations and approved, while zero products in Japan received approval through the *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 improve 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. Important changes occurred over the past decade, including a revision in 2013 of the Immunization Act, implementation of a National Immunization Plan and adoption of eight vaccines into the National Immunization Program (NIP). The Japanese Government revised the Plan for the first time in 2025 and expressed its intention to promote digitization but only made minor changes to other issues. 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

Prior amendments to the Immunization Act 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

<u>Patent Term Restoration</u>

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, sometimes 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.[326]

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 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 generic product, without involving the market authorization holder of the innovative product in the process. In 2023, MHLW approved a generic version for an indication even though that indication in the innovative product was still subject to patent protection. In addition, in the past two years, there are multiple cases where MHLW approved a generic drug during the restored patent term of the reference product based on the generic version being a different salt or hydrate. Once 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 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

[326] 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. 27, 2026).

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.[327] As a result of that exercise, MHLW is piloting an "Expert Committee" mechanism to determine whether a follow-on product is within the technical scope of a patent reported by an innovator. Aside from concerns as to how this Expert Committee will operate, PhRMA and its members remain concerned that this internal process will not support the early judicial resolution of patent disputes for small molecule and biologic products, and ensure that all relevant patents (including formulation, process, salt and hydrate patents) are included in the patent enforcement regime. PhRMA encourages further industry engagement to discuss potential reforms to Japan's patent enforcement system.

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.

[327] PHARMA JAPAN, "MHLW Mulls System to Seek Expert Input for Patent Linkage," 2024, available at https://pj.jiho.jp/article/251400 (last visited Jan. 27, 2026).

KOREA

As the United States and Korea work together to build out and implement the recently announced U.S.–Japan Strategic Trade and Investment Deal[328] and ensure faithful implementation of the United States–Korea Free Trade Agreement (KORUS), we strongly encourage both governments to address the intellectual property (IP) challenges and market access barriers identified below. This should include concluding an Agreement on Pharmaceutical Pricing (akin to the agreement in principle concluded with the United Kingdom)[329] to improve the overall operating environment for innovative pharmaceutical companies and ensure that Korea bears a more proportionate share of the cost of developing innovative medicines.

Key Issues of Concern:

- **Restrictive government pricing and reimbursement policies**: Korea's government-set prices are among the lowest in the OECD. 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. In November 2025, the Ministry of Health and Welfare (MoHW) announced a plan to reform the pharmaceutical pricing system, including raising the ICER threshold. However, the specific reform plan has not yet been released. For medicines not subject to the cost-effectiveness threshold, HIRA continues to recommend the lowest international price from a basket of eight countries. Following HIRA's review and recommendations, the National Health Insurance Service (NHIS) can also require additional concessions (e.g., risk-sharing agreements, reference prices from additional OECD countries) 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. Combined, these numerous price control policies 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.

[328] *See* USTR, Fact Sheet: The United States and Korea Agree to the Korea Strategic Trade and Investment Deal, Nov. 14, 2025, available at https://ustr.gov/about/policy-offices/press-office/fact-sheets/2025/november/fact-sheet-united-states-and-korea-agree-korea-strategic-trade-and-investment-deal (last visited Jan. 27, 2026).

[329] *See* USTR, U.S. Government Announces Agreement in Principle with the United Kingdom on Pharmaceutical Pricing, Dec. 1, 2025, available at https://ustr.gov/about/policy-offices/press-office/press-releases/2025/december/us-government-announces-agreement-principle-united-kingdom-pharmaceutical-pricing (last visited Jan. 27, 2026).

- **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**: 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. Promisingly, the Korean Government is working to lower thresholds so that foreign companies can obtain innovative-company certification. However, in practice, U.S. and multinational firms still face difficulties in achieving certification, and even when certified, price advantages granted under post-listing price management remain limited. 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 Ministry of Food and Drug Safety (MFDS) 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 amendments to Korea's PTE mechanism passed in 2024 fail to address these longstanding, fundamental issues with Korea's approach to PTE, and instead introduced additional constraints that further tip the balance against innovators, making it more challenging for innovators to protect their patent rights effectively.

- **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 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 be placed on the **Priority Watch List** in the 2026 Special 301 Report and that the U.S. Government continue to seek prompt and effective resolution of the problems described herein.

Market Access

Restrictive 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-seven percent of new medicines launched globally since 2014 are available in the United States compared to just 20 percent in Korea's National Health Insurance Service (NHIS), with Korean patients waiting an

average of 44 months after global first launch for the medicines to be reimbursed by the NHIS.[330] Moreover, only 13.5 percent of total pharmaceutical expenditures by the NHIS, which covers 97 percent of the population, is for new medicines.[331]

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 (approximately KRW 25 million) and has not been increased for most innovative medicines even though Korean GDP per capita has since doubled (approximately KRW 50 million as of 2025).[332] In late November 2025, MoHW released a pricing reform plan, acknowledging that the current cost-effectiveness evaluation framework has limitations in appropriately valuing innovative medicines. The plan includes proposals for greater flexibility in value assessments, including raising the ICER threshold for some types of medicines. While this policy proposal is promising and signals greater investment in innovation, it is important to note that key details of the proposal are still unknown. PhRMA and its member companies encourage continued dialogue with the Korean government to more fully develop and implement this policy.

Even when a price is recommended following the cost-effectiveness evaluation, the Korean Government tends to impose additional price concessions in the form of further cuts, expenditure caps and excessive rebates as a condition of reimbursement. Manufacturers are often required to make repeated price concessions as they move through the many DREC subcommittees. 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. 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. The Korean government's recent policy proposal includes some broader reforms, such as indication-based pricing; however, the details are still unknown. PhRMA and its member companies encourage continued dialogue with the Korean government to more fully develop and implement this policy.

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

[331] *Id*. Korea National Assembly Forum Report, "NHI Expenditure Status on Medication" Oct. 4, 2023.

[332] The World Bank, GDP per capita local currency units data series. Sept. 2024.

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. 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 prices 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."[333] 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.[334] 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."[335] This TRIPS jurisprudence supports a parallel reading of KORUS Article 18.8(3).

[333] TRIPS Article 28.

[334] *Id.* Article 30.

[335] 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. 27, 2026). 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,

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).[336]

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

"[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 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.

[336] 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.

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 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 (IPC) Accreditation

The MOHW designates certain companies to be 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 a reform plan in 2025 to lower thresholds so that foreign companies can obtain IPC certification. However, in practice, U.S. and multinational firms still face difficulties in achieving certification, and even when certified, price advantages granted under post-listing price management remain limited for new product launches. 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

Amendments to Korea's Patent Term Extension (PTE) mechanism that went into effect in July 2025, introduce additional constraints that further tip the balance against innovators, rather than addressing longstanding, fundamental issues with Korea's approach to PTE.

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, however, 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 MFDS for product approval. This exclusion disproportionately disadvantages pharmaceutical companies conducting trials abroad. In 2020, the Korean IP High Court held that foreign clinical trials should be considered in PTE calculations, which was appealed and is currently pending before the Korean Supreme Court. In the interim, Korea has taken no steps to reflect that holding in its policies or in the recent amendments to Korea's PTE mechanism, pending the Supreme Court's final decision.

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 the entire PTE term by challenging the accuracy of a PTE term calculated by the Ministry of Intellectual Property (MOIP, formerly the Korean Intellectual Property Office (KIPO)). In the event of an unsuccessful challenge, even the previously allowed 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." While Korean courts have ruled in certain cases that the scope of PTE is not necessarily limited to the exact API or indication specified in the initial drug approval, it still remains unclear whether all derivative forms of the active pharmaceutical agreement such as different salts or esters, or all subsequent indications fall within the scope of protection. This restrictive 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 substantially identical medicinal products.

The July 2025 amendments further constrain innovation incentives by limiting PTE eligibility to a single patent and capping the effective patent term at 14 years from the date of first marketing approval. These changes were introduced without resolving the structural deficiencies described above and selectively incorporate restrictive elements from foreign systems without adopting the corresponding safeguards that protect innovators' rights in those jurisdictions.

Taken together, the amendments represent a missed opportunity to establish a balanced and predictable PTE framework that supports pharmaceutical innovation and patient access. A comprehensive reform—developed through meaningful stakeholder engagement and aligned with international best practices—is essential to restore confidence in Korea's patent system.

We urge the U.S. government to engage in a thorough dialogue with the MOIP 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 Article 60-2 of the Amended Enforcement Decree 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 methodology for calculating those damages excludes patient co-payments (typically 30 percent of the drug price) or out-of-pocket payments. As such, 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 no legislative steps have been taken to fix the underlying law. 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 to the detriment of public health in Korea.

Patent Enforcement

Consistent with its IP obligations under KORUS,[337] 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 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.

Invalidation Decision Pre-Notification System

Korea is considering amending its Preliminary Notification of Invalidation Decisions system, under which the patent authority would provide advance notice of a potential invalidation decision prior to issuing a final ruling. While such a mechanism could enhance procedural transparency and predictability, the current draft proposals raise serious concerns regarding its interaction with Korea's existing patent linkage framework. PhRMA is monitoring amendments that seek to exclude patents from pre-notification procedures related to products subject to Korea's patent linkage system. In turn, patents otherwise preventing premature generic entry during ongoing litigation could be invalidated without the procedural safeguards that the pre-notification system is intended to provide. The proposals would undermine the practical effectiveness of Korea's patent linkage regime, legal certainty for patent holders and the balance between timely generic entry and effective patent protection.

[337] *See* U.S.-Korea Free Trade Agreement, Art. 18.9, para. 5.

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. Under the new U.S. – Malaysia Agreement on Reciprocal Trade, PhRMA and its member companies are encouraged by Malaysia's commitment to not impose halal-related certification requirements on industrial goods, including pharmaceuticals. This helps 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 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, further delaying patient access to innovative drugs. 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. Finally, products listed in the formulary may not be sufficiently funded, resulting in insufficient coverage for all eligible patients.

- **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 2026 Special 301 Report and that the U.S. Government resolve these challenges as part of implementation of the U.S. – Malaysia Agreement on Reciprocal Trade in which Malaysia committed to "a robust standard of protection for intellectual property" and provided certain assurances regarding market access.[338]

[338] *See* Agreement between the United States of America and Malaysia on Reciprocal Trade, Oct. 26, 2025, available at https://www.whitehouse.gov/briefings-statements/2025/10/agreement-between-the-united-states-of-america-and-malaysia-on-reciprocal-trade/ (last visited Jan. 27, 2026).

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.[339] The industry shares a common goal with the Malaysian Government to improve patient access to innovative medicines.

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. In 2023 and 2024, NPRA promulgated two additional regulatory requirements 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[340] 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 and its member companies are encouraged by Malaysia's commitment in the U.S.–Malaysia Agreement on Reciprocal Trade to not impose halal-related certification requirements on industrial goods, including pharmaceuticals.

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.

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

[340] NPRA.600-1/9/12(25).

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.

Finally, PhRMA and its member companies are encouraged by the recent U.S.–Malaysia Agreement on Reciprocal Trade and Malaysia's commitment to adopt good regulatory practices to improve transparency, predictability and stakeholder participation. Ensuring implementation of these practices will help eliminate market access barriers and promote greater patient access to new and innovative medicines.

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.[341] In contrast, cooperative discussions and collaborative access policies like voluntary licensing treated over 15,000 patients over the same period in neighboring Vietnam.[342] Indeed, a 2022

[341] 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. 27, 2026).

[342] 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. 27, 2026).

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.[343]

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.[344]

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 (Amendment) Act 2022, which promotes vague and ambiguous grounds for compulsory licensing including selling products at "unreasonably high prices."[345]

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.[346]

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

[343] 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. 27, 2026).

[344] *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. 27, 2026).

[345] *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. 27, 2026).

[346] 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. 27, 2026).

… for the purpose of scientific assessment in consideration of the quality, safety, and efficacy of any new drug product ...."[347]

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 ….[348]

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 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.

[347] *See* paragraph 1.2 of Directive BPFK/PPP/01/03.

[348] *Id.*

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 and its members urge Mexico to implement the commitments that it made in the U.S.-Mexico-Canada Agreement (USMCA) and thereby address several of the intellectual property (IP) challenges and market access barriers identified below. This year's Joint Review of the USMCA offers an important opportunity to strengthen the USMCA's IP commitments and thereby fulfill President Trump's original objective for the agreement to "reflect a standard of [IP] protection similar to that found in U.S. law."[349]

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 U.S.-Mexico-Canada Agreement (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 Mexico's recent attempts to address challenges in Mexico's patent enforcement regime, shortcomings 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 the Federal Commission for Protection against Health Risks (COFEPRIS) inappropriately granting marketing authorizations at least 11 times between 2023 and 2025. 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 that provide sufficient clarity to innovators on how 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.

- **Market access delays**: 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 and unpredictable procurement processes, and continuous uncertainty regarding the roles and responsibilities of all the Institutions that participate in the procurement process. A lack of transparency and criteria 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

[349] Summary of Objectives for the NAFTA Renegotiation, Office of the U.S. Trade Representative, July 17, 2017, available at https://ustr.gov/sites/default/files/files/Press/Releases/NAFTAObjectives.pdf.

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 five years that are available in Mexico declined from 20 to 11 percent – a worse decline than in any other OECD or Latin American country.[350]

- **Challenges with public procurement practices**: Since 2018, Mexico has made frequent, unpredictable 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. 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. On June 2, 2025, the Mexican Government introduced a Presidential Decree aimed to provide certain advantages in the public procurement process to suppliers of medicines having a manufacturing plant or other investments in Mexico. On September 26, 2025, the government further proposed amendments to the General Health Law granting preferential and expedited marketing authorization for locally produced products. The final Bill was approved with an amendment requiring the Law to be applied in compliance to international trade agreements, therefore excluding goods from free-trade agreement partners from these provisions. The expedited marketing authorization process was also eliminated in the approved Law. PhRMA and its member companies are encouraged to see these positive amendments to the Law. Nonetheless, these many significant changes and unreasonable implementation timelines create 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 15 percent of new medicines launched globally since 2014 are publicly

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

reimbursed in Mexico, with patients waiting an average of 51 months from global first launch for available medicines to become publicly reimbursed.[351]

For these reasons, PhRMA requests that Mexico remain on the **Priority Watch List** in the 2026 Special 301 Report and that the U.S. Government continue to seek prompt and effective resolution of the problems described herein.

Intellectual Property Protection

Weak Patent Enforcement

USMCA requires Mexico to implement effective patent enforcement mechanisms to ensure that patent-infringing follow-on products (i.e., generics or biosimilars) are not approved for marketing prior to the expiration of patents on the relevant innovative product. Annex 20-A of USMCA preserves Mexico's ability to maintain its existing framework based on coordination between the patent office (IMPI) and the marketing approval authority (COFEPRIS) to prevent the authorization of patent-infringing pharmaceutical products. Nonetheless, Mexico has not implemented a patent enforcement mechanism that satisfies its USMCA commitments. Mexico's patent enforcement system fails to: consider all relevant patents related to an innovator product, provide adequate notice to a patent holder when a third party seeks marketing approval for a follow-on product, and afford the patent holder a reasonable opportunity to present facts and arguments to IMPI related to the relevant patents before the follow-on product is authorized for marketing. 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. Even when preliminary injunctions are granted, they have in some cases been lifted or stayed before full adjudication, raising concerns about their practical efficacy.

Earlier this year COFEPRIS announced a collaboration scheme with IMPI that requires applications for follow-on products to be published on its website and that patent holders would be able to submit information to determine possible infringement. However, this action does not satisfy USMCA because it does not enable a patent holder to present facts and arguments to IMPI related to all relevant patents before the follow-on product is authorized due to the limited information available on generic and biosimilar applications. In addition, a Bill was recently introduced in Mexico that seeks to revise language in Article 162 of the Mexican Federal Law for the Protection of Industrial Property in an attempt to facilitate the listing of use patents in Mexico's Linkage Gazette. In addition, COFEPRIS has released a special edition of the IMPI Medicines Gazette which includes use patents. While these are welcome steps, legislation or secondary regulations are necessary to formalize the procedure for listing use patents and to provide a durable legal framework supporting their listing.

[351] 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. 27, 2026).

To operationalize a patent enforcement mechanism that is effective and consistent with USMCA, Mexico must issue secondary regulations that:

(i) confirm that all relevant patents, including use patents, are subject to such mechanism;
(ii) require IMPI to inform (i.e., provide proper notice to) a patent holder when IMPI has received a request from COFEPRIS and to provide the patent holder with IMPI's preliminary determination;
(iii) if IMPI has made a preliminary determination that there is no infringement, provide the patent holder with an opportunity to demonstrate to IMPI that the follow-on product would infringe an existing patent before IMPI responds to COFEPRIS;
(iv) provide the patent holder with the relevant, necessary and sufficient information to determine whether patent infringement exists, including confidential access to the marketing authorization dossier solely for that purpose; and
(v) ensure that a preliminary injunction cannot be lifted absent compelling evidence of changed circumstances, lack of irreparable harm or invalidity of the underlying claim.

Regulatory Data Protection Failures

To comply with USMCA, Mexico must issue federal legislation and secondary regulations to provide RDP that covers all pharmaceutical products, including small molecules and biologics. Article 20.48 of the Agreement requires Mexico to protect, for at least five years, the comprehensive test data that pharmaceutical innovators submit to regulatory authorities to demonstrate the safety and efficacy of a medicine as part of the marketing authorization process. After the RDP term has ended, third parties are allowed to references and/or rely on the data submitted by innovative companies to obtain marketing authorizations for follow-on products. Currently, RDP is subject solely to internal guidelines at COFEPRIS, is not automatically granted and routinely requires litigation against COFEPRIS in order to secure protection and/or an appropriate term, adding unnecessary uncertainty, complexity and costs for U.S. innovators. Moreover, the internal guidelines apply only to new chemical entities, thereby excluding key biopharmaceutical innovations such as biologics, new therapeutic uses, new dosage forms, new routes of administration and new formulations.

Inadequate Patent Term Adjustment (PTA) and Patent Term Restoration (PTE)

Article 20.44 of USMCA requires Mexico to provide PTA to compensate for unreasonable patent office delays. Although Mexico has adopted legislation to provide for PTA, it has yet to issue secondary regulations to provide a mechanism for securing that protection without relying on judicial intervention.

Similarly, Article 20.46 requires Mexico to implement PTE to restore a portion of the patent term lost during the lengthy development and regulatory approval process for

new medicines. Despite committing to implement PTE by the end of 2024, Mexico has yet to approve federal legislation and secondary regulations to comply with this commitment. While a bill has recently been introduced that would establish a PTE mechanism in Mexico, the draft text is highly general with several substantive and procedural details requiring further clarification, making it difficult to assess whether the proposed mechanism would meet Mexico's USMCA commitments.

Potential Abuse of the "*Bolar*" Exemption

Article 20.47 of USMCA requires Mexico to ensure that its Bolar Exemption to patent rights is "solely for purposes related to generating information to meet requirements for marketing approval for the product." To comply with this commitment, Mexico should issue secondary regulations that ensure the exemption is limited to this sole purpose of securing marketing approval of a follow-on product so that it can be launched in Mexico after all relevant patents on the innovative product have expired.

Market Access

Market Access Delays

Article 12.F.6.4 of the Agreement requires Mexico to administer marketing authorizations "reasonably, including by … providing an applicant that requests marketing authorization for a pharmaceutical product with a determination within a reasonable period of time." Article 29.7 also requires Mexico to ensure that its pricing and reimbursement procedures for pharmaceuticals are fair and transparent, and Article 29.6 affirms the need for Mexico to appropriately value pharmaceuticals through relevant procedures or the operation of competitive markets.

Despite these commitments, biopharmaceutical innovators continue to face significant regulatory approval delays at COFEPRIS that inhibit timely patient access to innovative medicines. Once COFEPRIS has approved a medicine, the National Health Council (NHC) evaluates and recommends which medicines should be included in the National Compendium, the formulary defining which medicines may be procured and reimbursed. This process further delays patient access to innovative medicines. Only 23 percent of new medicines launched globally since 2014 have launched in Mexico, with patients waiting an average of 30 months from global first launch of those new medicines to become available.[352] During the past five years, the share of new medicines launched globally over the prior five years that are available in Mexico declined from 20 to 11 percent – a worse decline than in any other OECD or Latin American country.[353] It is critical that COFEPRIS and the NHC address these delays and provide transparent and

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

[353] 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. 27, 2026).

fair pricing, reimbursement and procurement processes to reverse this troubling trend and improve patient access to innovative medicines.

Challenges with Public Procurement Practices

Mexico committed in Chapter 13 of USMCA to open, fair and transparent government procurement procedures. Since 2018, Mexico has made frequent and nontransparent changes to its public procurement system, resulting in supply chain challenges and product shortages for Mexican patients. Only 15 percent of new medicines launched globally since 2014 are publicly reimbursed in Mexico, with patients waiting an average of 51 months from global first launch for available medicines to become publicly reimbursed.[354] These modifications could also lead to increased use of procurements with limited tenders, in violation of Mexico's commitment to open tendering procedures in Article 13.4.4. These procurement challenges in Mexico are compounded by the lack of effective patent enforcement mechanisms, as described above.

In addition, Mexico continues to advance proposals to inappropriately grant preferential treatment to local manufacturers in its procurement processes. For example, on June 2, 2025, the Mexican Government introduced a Presidential Decree "to promote investment within the national territory to strengthen the development of the pharmaceutical industry, health supplies manufacturing, and national scientific research" by granting advantages in the public procurement process for manufacturers having investments in Mexico, including manufacturing plants, laboratories and warehouses. Such requirements are inconsistent with Mexico's obligations under Article 13.4 of the USMCA, which explicitly prohibits discrimination against U.S.-supplied goods and the use of "offsets" – including local content requirements, investment or technology transfer – as a condition for public procurement.

[354] *Id*.

WATCH LIST

CHILE

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

Key Issues of Concern:

- **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 in public procurement processes, bids submitted by third parties have been selected notwithstanding the fact that they involved attempts 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 (ISP) are not "unjustified administrative delays."

- **Proposed trademark limitations**: As part of the "Medicines II" bill, Chile's Congress is considering provisions that would significantly limit the use of trademarks in all pharmaceutical products packaging, mandate the use of International Non-Proprietary Names (INNs) in drug prescriptions and restrict 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 deficiencies continue to deny innovators appropriate regulatory data protection (RDP), and recent administrative initiatives risk further undermining Chile's RDP regime.

- **Compulsory licensing**: The Medicines II Bill, introduced in Chile in 2015, remains pending. It permits compulsory licensing on broad grounds—such as labeling most medicines as being of "public interest" or citing "economic inaccessibility"—which conflicts with international norms and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). PhRMA and its members are concerned that this approach, along with previous congressional resolutions advocating for compulsory licensing, reflects a growing

perception that intellectual property (IP) hinders access to medicines and poses challenges for innovators in Chile.

- **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.

- **Sale of unregistered pharmaceutical products**: Chilean legislation allows for the import, provisional sale and use of unregistered pharmaceutical products in situations of emergency or serious public health risk for up to six months. While this provision was originally intended for genuine public health emergencies, it is currently being used as an alternative pathway and a *de facto* commercial channel for drugs that lack marketing approval, even when authorized therapeutic alternatives are available.

For these reasons, PhRMA requests that Chile be placed on the **Watch List** in the 2026 Special 301 Report and that the U.S. Government continue to seek prompt and effective resolution of the problems described herein.

Intellectual Property Protection

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.[355] 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 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. In 2025, the Ministry of Health, through the National Health Service System (CENABAST), launched a voluntary registry for biopharmaceutical manufacturers to disclose whether their products are protected by patents and/or regulatory data protection, aiming to facilitate procurement without infringing IP rights. While this initiative enhances transparency in the public procurement process, it is voluntary, non-binding and does not address Chile's obligations under the U.S.-Chile FTA as described above. Until effective legislative action is taken, oversights in the public and private procurement system have the potential to further weaken 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 (i.e., delays the patent applicant is not responsible for) 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

[355] *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. 27, 2026).

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 ISP 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

Chile should reform its RDP framework to comply with the U.S.–Chile FTA, enhance legal certainty, and align with international best practices. Current policies, such as conditioning RDP on seeking marketing approval in Chile within twelve months of the global first launch or terminating RDP following the issuance of compulsory licenses, undermine predictability and raise concerns regarding Chile's compliance with the FTA. RDP should be granted on a country-by-country basis, based solely on when the product is approved in Chile (versus in other markets on which Chile may rely). The system also contains additional flaws, including the inappropriate requirement that innovators request RDP for specifically identified data and the potential denial of RDP where subsets of clinical trial data were disclosed publicly. Furthermore, Chilean law does not require regulators to protect clinical trial and other data from disclosure once the five-year RDP term has expired. Addressing these issues would strengthen the effectiveness, credibility and consistency of Chile's RDP regime. Chile should not compound these challenges by creating new follow-on dossier review processes during the innovator's RDP term or by introducing Bolar-style exceptions.

Compulsory Licensing

The Medicines II bill, introduced in Chile's Congress in 2015, is still pending. The Conference Committee has approved an article allowing compulsory licenses on broad and unclear grounds—such as declaring nearly all medicines a "public interest" and adding "economic inaccessibility" as a criterion. PhRMA and its members are concerned that this could be applied in ways inconsistent with international best practices and the

TRIPS Agreement. Also, in recent years, Chile's Congress has passed multiple non-binding resolutions urging compulsory licensing of various medicines, including hepatitis C treatments. These actions reflect a misplaced view that intellectual property is a barrier to access and highlights the challenges faced by innovators in Chile.

While the Chilean Government is not currently reviewing any compulsory licensing 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.

Market Access

Government Price Controls

Only 17 percent of new medicines launched globally since 2014 have launched in Chile, with patients waiting an average of 37 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.[356]

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. 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 and to enhance the attractiveness of Chile as a launch market for innovative medicines.

Sale of Unregistered Pharmaceutical Products

As established in Article 21 of Supreme Decree No. 3 of 2010, and amended by Decree No. 50 of December 20, 2019, Chilean legislation allows for the import, provisional sale and use of unregistered pharmaceutical products in situations of emergency or

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

serious public health risk, or for urgent medicinal use intended exclusively for the personal consumption of the importer, for up to six months. While this provision was originally intended for genuine public health emergencies or strictly for personal use in exceptional cases, it is currently being used as an alternative pathway for drugs and by informal intermediaries to operate as a *de facto* commercial distribution channel that lack marketing approval, even when authorized therapeutic alternatives are available. As a result, PhRMA and its member companies are concerned about the misuse of this exceptional regime for commercial purposes, the associated public health risks and the erosion of intellectual property protections.

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 three percent of new medicines launched globally since 2014 are reimbursed by the JKN, with patients in Indonesia waiting an average of 79 months after global first launch for JKN reimbursement.[357] 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), adopting a value-based and patient-focused approach rather than one based strictly on cost. PhRMA further welcomed the 2024 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 vaccines and therapeutics, could have unexpected negative implications on patient health and broader public health priorities.

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

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

- **Burdensome and vague disclosure obligations**: 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." 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 this requirement.

For these reasons, PhRMA requests that Indonesia be placed on the **Watch List** in the 2026 Special 301 Report and that the U.S. Government resolve these challenges through implementation of the U.S. – Indonesia Framework for an Agreement on Reciprocal Trade, under which Indonesia committed to address non-tariff barriers affecting trade in priority areas, including intellectual property issues identified in USTR's Special 301 Report.[358]

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

[358] *See* Joint Statement on Framework for United States-Indonesia Agreement on Reciprocal Trade, Jul. 22, 2025, available at https://www.whitehouse.gov/briefings-statements/2025/07/joint-statement-on-framework-for-united-states-indonesia-agreement-on-reciprocal-trade/ (last visited Jan. 27, 2026).

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.

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 in government procurement contracts 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. In late 2025, the Ministry of Industry issued a revision to the methodology and certification framework for calculating local content requirements, introducing additional incentives for domestically conducted R&D activities. PhRMA and its member companies urge the Indonesian government to ensure implementation of these requirements do not discriminate against multinational manufacturers and ensure access to innovative drugs for Indonesian patients.

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.

Further, 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.

In July 2025, a Joint Statement on the Framework for a U.S.–Indonesia Agreement on Reciprocal Trade was released.[359] In the statement, Indonesia agreed to exempt U.S. goods from local content requirements. However, shortly after the conclusion of that agreement, the Coordinating Ministry for Economic Affairs issued a press release noting that the pharmaceutical sector would not be included in the exemptions to local content requirement obligations and limited the exemptions to telecommunications, data centers and medical devices. PhRMA and its member companies are concerned that excluding pharmaceuticals from local content requirement exemptions will further harm market access, IP protection, patient health and investment in Indonesia. 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 eleven percent of new medicines launched globally since 2014 have launched in Indonesia compared to an average of 36 percent across all G20 countries.[360] Further, only three percent of new medicines launched globally since 2014 are publicly reimbursed by the National Health Insurance (JKN), with patients waiting an average of 79 months for JKN reimbursement.[361] 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 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.

In the 2024 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. Despite revisions to the HTA process, it remains opaque and inclusion of

[359] White House, Joint Statement on Framework for United States-Indonesia Agreement on Reciprocal Trade, July 22, 2025, available at https://www.whitehouse.gov/briefings-statements/2025/07/joint-statement-on-framework-for-united-states-indonesia-agreement-on-reciprocal-trade/ (last visited Jan. 27, 2026).

[360] 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. 27, 2026).

[361] *Id*.

drugs recommended through the HTA process on the national formulary is not guaranteed.

In October 2024, the Ministry of Health launched the "One Door, One Standard" HTA process, merging medicine selection and medical-device selection into a single unified HTA pathway for inclusion in FORNAS in order to improve outcomes and curb costs. Promisingly, the new HTA process allows Stakeholder-Led Submissions (SLS), comprised of industry, patient groups, clinicians and academics, to submit their own HTA dossiers to the MOH for appraisal, beyond government-commissioned topics. While the framework signals progress toward evidence-based decision-making, MOH's recent emphasis on cost and budget impact analysis raises concerns that innovative medicines may be excluded from the national formulary, undermining the value of innovation.

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. In 2025, the government revised its procurement framework to allow multiple suppliers but subject to a JKN-linked price ceiling, functioning as a *de facto* price control, and delaying patient access to life-saving medicine. 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, control prices and the health budget, reducing patient access.

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.

In October 2024, the Government of Indonesia enacted Government Regulation No. 42/2024 on the Implementation of Halal Product Assurance. The new regulation reaffirms that all products entering, circulating or traded in Indonesia, including biological products, must be halal-certified unless they contain non-halal materials, in which case they must be labeled “Non-Halal.” The regulation also removes the fixed validity period for Halal certificates (previously four years), making them valid indefinitely unless there is a change in product composition or manufacturing processes. Regulation 42/2024 further mandates physical and process separation between halal and non-halal production lines, storage and distribution. These new requirements are mandated to come into effect no later than October 2026. In early 2026, the Indonesian government published a draft regulation on ingredient origin and halal/non-halal labeling. The draft requires products containing animal- or human-derived ingredients to list the origin of those ingredients on the label, including explicit halal/non-halal labeling.

Indonesia’s innovative pharmaceutical association, International Pharmaceutical Manufacturers Group (IPMG), has raised concerns that the new Halal requirements should be regulated by technical institutions given the complexities, deep knowledge and research required to develop regulations, as well as the impact of the labelling requirement on public health.

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.

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.

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.

SAUDI ARABIA

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

Key Issues of Concern:

- **Government procurement discriminates against foreign manufacturers and requires onerous offsets**: In November 2022, the Local Content and Government Procurement Authority (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, creating significant uncertainty and lack of transparency in the Saudi business environment. Frequent renegotiation of tenders, combined with the lack of clear timelines, have resulted in an unpredictable government procurement system. The creation of the 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 (APIs), serve to discriminate against foreign manufacturers and increase uncertainty in the Saudi market.

- **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.

- **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, and further reduced the basket to 16 countries in 2022, 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.

- **The new health technology assessment system should support 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 2026 Special 301 Report and that the U.S. Government continue to seek prompt and effective resolution of the problems described herein.

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.[362]

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

[362] 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. 27, 2026).

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. We urge SFDA to reconsider its 2020 draft regulation and resolve outstanding concerns ahead of publishing future drafts.

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 Discriminates Against Foreign Manufacturers and Requires Onerous Offsets

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 went into effect in late 2023. Recently, LCGPA committed to amending the policy with provisions specific to the health care sector. 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 went into effect January 1, 2024. These policies remain opaque and confusing, creating uncertainty in the business environment and preventing access to life-saving treatments to patients. PhRMA and its member companies welcome the opportunity to engage with the Saudi Government and provide input to LCGPA to ensure fit-for-purpose policies.

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, and are inconsistent with Saudi Arabia's commitment when it joined the WTO in 2005 that it would accede to the WTO Government Procurement Agreement.

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 36 percent of new medicines launched globally since 2014 have launched in Saudi Arabia, with Saudi patients waiting an average of 33 months from global first launch for new medicines to become available. Only 25 percent of these new medicines are reimbursed in Saudi Arabia's public national health insurance.[363]

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'

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

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.

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 to void creating 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, which aimed to ensure pharmaceutical products were evaluated effectively for their added value to the healthcare system. These new guidelines required manufacturers to submit EES to receive marketing authorization, to keep marketing authorization and for price re-evaluations and renewals. While implementation is still pending, if implemented, the new guidelines would be 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 and deconflict competing systems with overlapping priorities and redundancies.

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.

SWITZERLAND

As the United States and Switzerland work together to build out the recently announced Framework for an Agreement on Fair, Balanced and Reciprocal Trade,[364] we strongly encourage both governments to address the market access barriers identified below and conclude an Agreement on Pharmaceutical Pricing (akin to the agreement in principle concluded with the United Kingdom)[365] to improve the overall operating environment for innovative pharmaceutical companies and ensure that Switzerland bears a more proportionate share of the cost of developing innovative medicines.

Key Issues of Concern:

- **Longstanding restrictions on the valuation of innovative medicines and patient access**: Switzerland has compulsory private health insurance, but the government regulates which medicines are reimbursed and sets the prices of those products based on the average price in other European countries (all with lower GDP per capita) and the domestic 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 and in purchase power parity. 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 domestic therapeutic reference price. The products chosen for the therapeutic reference price are often unpredictable, arbitrary and lack scientific evidence. Over the past two years, government pricing authorities have begun using additional tools such as capitation, pay for performance, indication-based pricing, budget impact models and rebating for medicines used in combination or for multiple indications. Finally, starting in 2024, the Swiss Government began implementing revisions to the Ordinance on Health Insurance that threaten to reduce patient access to medicines for rare diseases. As a result of these combined policies, Switzerland has experienced more pronounced market access delays for certain innovative medicines in recent years that erode the period of effective IP protections for innovative medicines. Only 34 percent of new medicines launched globally since 2014 are reimbursed in Switzerland's public national health insurance, with patients waiting an average of 29 months after global first launch for medicines to be reimbursed.[366]

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[364] *See* Joint Statement on a Framework for a United States – Switzerland – Liechtenstein Agreement on Fair, Balanced, and Reciprocal Trade, Nov. 14, 2025, available at https://www.whitehouse.gov/briefings-statements/2025/11/joint-statement-on-a-framework-for-a-united-states-switzerland-liechtenstein-agreement-on-fair-balanced-and-reciprocal-trade/ (last visited Jan. 27, 2026).

[365] *See* USTR, U.S. Government Announces Agreement in Principle with the United Kingdom on Pharmaceutical Pricing, Dec. 1, 2025, available at https://ustr.gov/about/policy-offices/press-office/press-releases/2025/december/us-government-announces-agreement-principle-united-kingdom-pharmaceutical-pricing (last visited Jan. 27, 2026).

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

For these reasons, PhRMA requests that Switzerland be placed on the **Watch List** in the 2026 Special 301 Report and that the U.S. Government continue to seek prompt and effective resolution of the problems described herein.

Market Access

Government Restrictions on the Valuation of Innovative Medicines and Patient Access

Switzerland has mandatory health insurance, which is regulated under the Swiss Federal Health Insurance Act (HIA), Ordinance on Health Insurance and the Healthcare Benefits Ordinance (HBO). Under this framework, the Federal Office of Public Health (FOPH) is responsible for determining which medicines are reimbursed under the mandatory health insurance regime. In the vast majority of cases, for a medicine to be reimbursed, it must be listed on the "Specialty List," which is compiled by FOPH and defines the drug's maximum reimbursement price as set by the FOPH. Of the approximately 8,000 medicines that have been approved for marketing by Swiss authorities, less than half, or about 3,000, appear on the Specialty List for reimbursement.[367]

To add a product to the Specialty List, a manufacturer must apply to the FOPH, which evaluates whether the product is effective, appropriate and cost-effective. In assessing cost-effectiveness, FOPH evaluates the product based on (1) an international reference price comparison with the product's price in the basket of reference countries; and (2) a domestic therapeutic reference price comparison with comparator products already on the Specialty List. Both elements of this cost-effectiveness analysis contain serious flaws. For instance, Swiss authorities base the international reference price on prices in other European countries, all of which have a lower GDP per capita than Switzerland. Furthermore, the products chosen for the domestic therapeutic comparison are often unpredictable, arbitrary and lack scientific evidence as to therapeutic equivalence, such that drug prices in Switzerland are often based on the prices of alternative therapies that may represent a lower standard of care.[368]

In addition to these shortcomings, the pricing and reimbursement system lacks predictability and transparency, and fails to appropriately account for changes in currency exchange rates and in purchase power parity. For example, in 2015, Switzerland expanded the basket of countries used for its international reference pricing to include Belgium, Finland and Sweden (in addition to the existing six countries of Austria, Denmark, France, Germany, the Netherlands and United Kingdom). However, given the

[367] FOPH, Reimbursement Procedures for Medicines, (Nov. 26, 2024), available at https://www.swissmedic.ch/dam/swissmedic/en/dokumente/stab/veranstaltung/regulatory-2024/reimbursement-procedures-for-medicines.pdf.download.pdf/13_Reimbursement%20procedures%20for%20medicines_J%C3%B6rg%20Indermitte_BAG.pdf (last visited Jan. 27, 2026).

[368] Handbook on the Specialty List (SL) and Congenital Defects Specialty List (GGSL), § C.2.2 (Jan. 1, 2025), available in German at https://www.bag.admin.ch/dam/de/sd-web/eWqYyGMBwYb0/handbuch-betreffend-die-spezialitaetenliste-gueltig-ab-1-1-2025.pdf (last visited Jan. 27, 2026).

increasing strength of the Swiss franc relative to the currencies of the other countries in the basket (Euro, UK Pound, Swedish Krona and Danish Krone), this has increasingly exacerbated distortions resulting from the use of international reference pricing, as many of these currencies continue to lose value relative to the Swiss franc.

Every year, one-third of the medications on the Specialty List are subject to price adjustments, such that every medication undergoes a price review by the FOPH at least once every three years. For purposes of these reviews, the FOPH uses the international reference price comparison and the domestic therapeutic comparison as the statutory price-setting criteria. Compounding the inherent distortions and lack of predictability that arise as a result of these price adjustments, the Swiss government amended its drug pricing practices in 2017 to require that prices be set by giving equal weight to the international reference price and the domestic therapeutic reference price.[369] Prior to this change, the international reference price had been weighted higher than the domestic therapeutic reference price in the triennial price review. As a result of these policies, the prices of more than 2,700 medicinal products were reduced by an average of 14 percent between 2017 and 2023.[370] In 2024 alone, nearly 300 innovative medicines saw their prices reduced by an average of 12 percent.[371]

The FOPH has also begun using additional tools such as capitation, pay for performance, indication-based pricing, budget impact models and rebating for medicines used in combination or for multiple indications.[372] As a result of these combined policies, Switzerland has experienced more pronounced market access delays for certain innovative medicines in recent years. Recently, the Swiss Parliament passed budget impact models that will come into effect in 2027, requiring pharmaceutical companies to make paybacks if sales exceed a defined sales threshold.[373] Only 34 percent of new medicines launched globally since 2014 are reimbursed in Switzerland's public national health insurance, with patients waiting an average of 29 months after global first launch for the medicines that are reimbursed.[374] Manufacturers may also be required to pay back

[369] Ordinance of 27 June 1995 on Health Insurance (KVV) and Ordinance of the Federal Department of Home Affairs (EDI) of 29 September 1995 on Benefits in Compulsory Health Insurance (Health Insurance Benefits Ordinance, KLV) (adjustments to the pricing of pharmaceuticals following the Federal Supreme Court ruling of 14 December 2015 and adjustments to the reimbursement of pharmaceuticals in individual cases), planned amendments as of 1 March 2017, full text of the amendments and commentary, § III.1.5 (Feb. 2017).

[370] Interpharma, Health Panorama 2024, at 25, available at https://www.interpharma.ch/wp-content/uploads/2024/08/iph_panorama_2024_3_E_web.pdf (last visited Jan. 27, 2026).

[371] Federal Office of Public Health, Drug Review 2025 – Savings of 65 million, available in German at https://www.bag.admin.ch/de/newnsb/-9iljJR7fRGGf5CKNabqX (last visited Jan. 27, 2026).

[372] Handbook on the Specialty List (SL) and Congenital Defects Specialty List (GGSL), § A.11 (Jan. 1, 2025), available in German at https://www.bag.admin.ch/dam/de/sd-web/eWqYyGMBwYb0/handbuch-betreffend-die-spezialitaetenliste-gueltig-ab-1-1-2025.pdf (last visited Jan. 27, 2026).

[373] Federal Law on Health Insurance (KVG), BBl 2025 1108 (Amendment on Cost-Containment Measures, Package 2) (March 2025), available in German at https://www.fedlex.admin.ch/eli/fga/2025/1108/de (last visited Jan. 27, 2026).

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

revenue after a product's first triennial price review if the price was reduced by more than three percent and the previous price generated more than CHF 20,000 in so-called "excess revenue."

Inadequate Reimbursement for Treatments for Rare Diseases

In 2024, the Swiss government began implementing revisions to the Ordinance on Health Insurance that threaten to reduce patient access to medicines for rare diseases. Articles 71a through 71d of the Ordinance establish the process by which patients can seek reimbursement from compulsory health insurance for innovative therapies not on the Specialty List, which includes many rare disease drugs. Under this process, health insurers have considerable discretion in deciding whether to grant coverage, leading to a significant lack of predictability. Recent revisions to these provisions of the Ordinance require compulsory health insurers to use a benefit assessment tool (OLU tool) to evaluate patient requests and limit reimbursement amounts for unlisted medicines. The new provisions, combined with the continued ability of insurers to exercise wide discretion in determining the therapeutic benefit of a medicine, threaten patients' access to rare disease treatments.

Intellectual Property Protection

Switzerland recognizes that effective intellectual property (IP) protection and enforcement is essential to develop new medicines for patients who need them. With the European Union moving forward with changes to its IP regime that will reduce IP protection and inappropriately condition restoration of lost protections on localization requirements, it is critical that Switzerland maintain its robust IP regime that serves to distinguish its innovation environment for the life sciences from the European Union. To this end, as the United States seeks to finalize an Agreement on Reciprocal, Fair and Balanced Trade with Switzerland, it should enshrine the provision of strong IP protections in Switzerland and seek to ensure that these protections are required by both countries in their respective bilateral trade agreements with other trading partners.

UNITED KINGDOM

PhRMA members welcome the recently announced Agreement in Principle with the United Kingdom (UK) on Pharmaceutical Pricing (Pricing Agreement) under the auspice of the U.S.-UK Economic Prosperity Deal (EPD).[375] As reflected below, the Pricing Agreement represents an important first step in terms of improving "the overall environment for pharmaceutical companies operating in the UK." However, details on how the UK intends to implement several of the commitments in the Pricing Agreement remain unclear and further reforms will be essential to ensure that the UK shoulders a more proportionate share of the cost of developing innovative medicines. Identified below are the key intellectual property (IP) challenges and market access barriers faced by innovative biopharmaceutical companies in the United Kingdom:

Key Issues of Concern:

- **Longstanding restrictions on the valuation of innovative medicines and patient access**: Rigid health technology assessment (HTA) methods require increasing discounts to meet low monetary thresholds for cost-effectiveness, which have not been updated for inflation since NICE was established in 1999. In the context of implementing the Pricing Agreement, the UK Government has indicated that it will increase these thresholds from £20,000-£30,000 per quality adjusted life year (QALY) to £25,000-£35,000 from April 2026, but this does not account for most of the inflation since these thresholds were established. When combined with overlapping cost containment measures across the health care system designed to limit the pharmaceutical share of health spending below that of most developed markets, the UK remains challenging for biopharmaceutical innovators and inhibit the ability of UK patients to access the full range of licensed indications for the latest innovative medicines. NHS patients often cannot access new treatments with proven added clinical benefit. Despite multiple initiatives, progress on improving uptake has been limited and full patient access to some of the newest medicines remains slow and variable across the health system compared to peer countries.

- **Delivering on ambitions for the life sciences sector**: In July 2025, the UK Government published a new *Life Sciences Sector Plan* (LSSP) as part of its broader industrial strategy. The Plan replaced and enhanced the previous *Life Sciences Vision,* which outlined industrial policy for the life sciences sector. The new Plan contains a suite of new recommendations that if implemented could transform the life sciences sector in the UK. While ambitious, the success and execution of the Plan hinges on key improvements needed, including an increase in net spending on medicines, improvements in NICE HTA methods and cost-

[375] *See* USTR, U.S. Government Announces Agreement in Principle with the United Kingdom on Pharmaceutical Pricing, Dec. 1, 2025, available at https://ustr.gov/about/policy-offices/press-office/press-releases/2025/december/us-government-announces-agreement-principle-united-kingdom-pharmaceutical-pricing (last visited Jan. 27, 2026).

effectiveness analysis and a reduction in revenue clawbacks. Promisingly, the Pricing Agreement includes commitments to increase net prices in the UK by 25 percent and increase spending on innovative medicines from 0.3 to 0.6 percent of GDP by 2035. As the UK develops plans to achieve these commitments and thereby deliver on the ambitious vision set out in the LSSP, PhRMA and its members continue to view revenue clawbacks and cost-effectiveness thresholds as inappropriate policies that devalue innovation and undermine patient access.

- **Evolution of the UK's intellectual property framework post-Brexit**: The UK's exit from the European Union (EU) provides an opportunity to maintain strong IP protections and further drive robust innovation policies, including effective periods of regulatory data protection and supplementary protection to restore a portion of the time lost during the marketing approval process. U.S.-UK trade negotiations provide an opportunity for the United Kingdom to affirm high IP standards. Through its independent trade negotiations, the United Kingdom should continue to push for strengthening IP frameworks and look to set precedent where possible. This will support the global pharmaceutical industry, at a time when IP frameworks look to be weakened globally.

- **Maintenance of the Medicines and Healthcare products Regulatory Agency (MHRA) as a world-leading health regulatory body**: The United Kingdom should ensure the MHRA is sufficiently funded and resourced to enable it to operate effectively. To this end, it is critical that MHRA partner with industry to develop its five-year strategy. Furthermore, MHRA should continue to explore collaborations with regulators around the world to shape policy, boost UK trade and influence emerging areas of technology.

For these reasons, PhRMA requests that the United Kingdom be placed on the **Watch List** in the 2026 Special 301 Report and that the U.S. Government seek to address these challenges as part of implementation of the EPD and Pricing Agreement.

Market Access

Government Restrictions on the Valuation of Innovative Medicines and Patient Access

PhRMA member companies recognize the UK Government's interest in controlling health care spending, but spending on medicines has not been a driver of growing health care costs. On the contrary, the United Kingdom invests less than other developed economies on medicines, with just nine percent of its health care budget spent on medicines compared to an average of 15 percent among peer countries.[376] There are a range of measures used by the NHS to manage expenditure on branded medicines, including cost-effectiveness thresholds set by NICE, requirements to lower prices for

[376] IQVIA, "Drug Expenditure Dynamics 2000-2022," Oct. 21, 2025, available at https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-expenditure-dynamics-2000-2022 (last visited Jan. 27, 2026).

flexible commercial arrangements like indication-specific pricing, a budget impact test managing affordability at the product level, and then further price cuts through revenue clawback (VPAG) capping growth in the market. The contribution required from industry to cap market growth through clawbacks soared to as high as 35.6 percent of revenue from sales on branded medicines to the NHS, making the UK uncompetitive and unattractive for innovative medicine launches. The commitments made in the Pricing Agreement, including the changes to the NICE cost-effectiveness threshold and the 15 percent cap on the VPAG clawback rate over the next three years, represent important first steps to address these deficiencies in the UK system. However, as outlined below, further reforms are needed to ensure that the UK more appropriately values innovative medicines and achieves its commitment to increase spending on innovative medicines to 0.6 percent of the UK's GDP by 2035.

New medicines in the United Kingdom can be launched upon regulatory approval, potentially making it one of the world's fastest countries for market access. However, in practice, despite the introduction of the International Recognition Procedure (IRP), Project Orbis and the Innovative Licensing and Access Pathway (ILAP), UK patients experience delays in being treated with new medicines due to barriers in the market access pathway, including slow adoption after marketing authorization and reimbursement is granted. Only 42 percent of new medicines launched globally since 2014 are publicly funded for patients in the NHS in England, compared to 87 percent in the United States, and patients in NHS England experience far more restrictions when attempting to access the new medicines that are funded.[377] Only 34 percent of the new medicines that NICE recommends are funded for their full market authorization and all approved indications.[378] In addition, patients in the NHS in England wait an average of 31 months from global first launch to public funding.[379]

A key reason why UK patients experience reduced access to new medicines is the high rate of "positive" recommendations by NICE that restrict the patient populations who can access those medicines compared to their market authorizations; 66 percent of new medicines with "positive" NICE recommendations have such restrictions.[380] When making recommendations, NICE assesses medicines using a baseline cost-effectiveness threshold per QALY, which can be adjusted by a severity weighting for medicines treating very severe diseases (the bar for which is set very high). This baseline threshold has not been revised – even in line with inflation – since NICE's inception in 1999, which means

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

[378] PhRMA, "Analysis of Access Restrictions to New Medicines in the UK," Nov. 21, 2023, available at https://phrma.org/resource-center/Topics/Intellectual-Property/Analysis-of-Access-Restrictions-to-New-Medicines-in-the-United-Kingdom (last visited Jan. 27, 2026).

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

[380] PhRMA, "Analysis of Access Restrictions to New Medicines in the UK," Nov. 21, 2023, available at https://phrma.org/resource-center/Topics/Intellectual-Property/Analysis-of-Access-Restrictions-to-New-Medicines-in-the-United-Kingdom (last visited Jan. 27, 2026).

that the threshold has declined in real terms by 48 percent over the past 26 years.[381] While the recently announced increase of the QALY threshold from £20,000-£30,000 to £25,000-£35,000 from April 2026 is welcome, it accounts for only a portion of the inflation since the NICE was established in 1999 and does not assume future adjustments and increases to account for inflation. Innovative medicines exceeding this cost per QALY threshold are generally viewed as not cost-effective, which can leave patients without access, or with restricted access, to clinically superior products. In addition, as companies develop new therapeutic advances, often in areas where there are many older off-patent medicines that are much lower in cost or where a combination of medicines forms the treatment regimen, demonstration of cost-effectiveness becomes exceedingly difficult.

Moreover, NICE has often been criticized for being inflexible in evaluating new medicines for which there is greater uncertainty about data (e.g., due to the immaturity of data or single-arm trials), which disproportionately impacts patient access to treatments for small patient populations (e.g., rare conditions) or for subsets of populations (e.g., targeted therapies). Uncertainty in the evidence base can be used to demand a price that is set at the lower end of the cost-effectiveness threshold range.

These challenges result in a high percentage (approximately 20 percent between 2019 and 2024) of NICE terminations where either NICE determines that a company has not submitted sufficient evidence or companies withdraw their applications from consideration given NICE's inflexible review standards. A recent survey of ten companies with the highest rates of terminations found that 55 percent of these medicines are available in Germany, France, Italy and Spain – but not to NHS patients in the UK. The survey, jointly conducted with NICE, also found that 70 percent of medicines were terminated because they were unlikely to be found cost-effective, with terminations being the most prevalent in medicines with multiple indications and combination therapies.[382] These challenges were compounded by the 2022 introduction of the previously mentioned "severity modifier" which further reduced the willingness to pay threshold for metastatic, end-of-life cancers, and led to the termination or rejection of several cancer medicines otherwise widely available in other European countries.

PhRMA and its member companies remain concerned that the UK commercial operating environment and government pressure to contain spending on medicines reduces UK patient access to new treatments and cures. While the Pricing Agreement represents an important first step in terms of improving the UK operating environment, it is critical that the UK Government work with industry to develop a plan and milestones for achieving the UK's commitment to double its spend on innovative medicines from 0.3 to 0.6 percent of the UK's GDP by 2035. The UK Government should adjust for inflation the

[381] Bank of England Inflation Calculator, available at https://www.bankofengland.co.uk/monetary-policy/inflation/inflation-calculator (last visited Jan. 27, 2026).

[382] NICE, "Medicines data: NICE approvals and availability in England," Sept. 18, 2025, available at https://a.storyblok.com/f/243782/x/c00c9f9c9f/september-25-pbm-medicines-approvals-and-availability-in-england-report.pdf (last visited Jan. 27, 2026).

QALY threshold used by NICE and reduce the revenue clawback (VPAG) to single-digit percentages.

Reinvigorating the MHRA's Position as a World-leading Health Regulatory Body

The United Kingdom should ensure the MHRA is sufficiently funded and resourced for developing and maintaining a regulatory system for medicines that is innovative, predictable and globally relevant. The operational and leadership strength of the MHRA underpins many of the commitments across the LSSP, and PhRMA members support fully resourcing the MHRA to deliver on an ambitious and sustainable agenda. It is critical that MHRA meaningfully partners with industry to develop the agency's five-year strategy and thereby enhance the UK's regulatory environment.

For the MHRA to be successful, there must be a clearer strategic narrative that focuses on maintaining public trust, enabling healthcare access to safe and effective medical products, and scientific/regulatory excellence. Enhancing these key issues, as laid out in the Corporate Plan, will better address timely and predictable regulatory processes, timelines and resource allocation so that innovative and lifesaving treatments can reach patients in a timely manner. Beyond the MHRA, optimizing the broader regulatory environment is key to boosting UK competitiveness and speeding up patient access to new medicines. Fast MHRA approvals must also be accompanied with fast HTAs – a disconnect between the two will undermine the other. There is, therefore, strong interest in seeing the Innovative Licensing and Access Pathway (ILAP) and the proposals for enhanced interactions between the MHRA and NICE (for example a refreshed joint scientific procedure, sharing of procedural timetabling information and an aligned pathway) deliver on their goals. This requires dedicated resources and a collective mandate to collaborate with industry on the agency's performance metrics and ensure the ambition for earlier patient access is truly realized.

Intellectual Property Protection

Effective IP protection and enforcement is essential to develop new medicines for patients who need them. Subsequent to the United Kingdom exiting the European Union, it is important that the United Kingdom maintain robust IP protections. In addition, the United Kingdom should seek to distinguish its innovation environment for the life sciences from the European Union by enhancing incentives where the European Union has unfortunately weakened its innovation framework. For example, the United Kingdom should eliminate the EU "SPC waiver" that undermines life sciences innovation by exempting from infringement manufacturing of inventions during the SPC term.

Following the end of the post-Brexit transition period, it is critical that the United Kingdom revise its legislation to calculate the duration of SPCs from the date of UK marketing authorization (rather than the earliest date of authorization in the European Union/European Economic Area or United Kingdom, as now). Continuing to make the duration of IP protection offered in the United Kingdom potentially still dependent on the acts of EU authorities is illogical, now that the UK and EU medicines regulatory systems

are operating independently of each other, and consequently may erode the effective protection period in the United Kingdom. Despite industry having raised these specific concerns strongly with the UK Government, these issues remain unresolved.

In addition, PhRMA and its members are concerned about a worrying trend in UK courts of invalidating biopharmaceutical patents that have been upheld in other jurisdictions on so-called "plausibility" grounds.[383] Whereas the European Patent Office (the UK remained a member of the European Patent Convention after Brexit) has held that the plausibility doctrine is not a statutory patentability requirement (instead appropriately focusing on what the skilled person would have understood from the application at the time of filing, rather than what they might have considered credible),[384] UK courts are separately assessing whether the invention was plausible at the time that the application was filed (and have discounted post-filing evidence regarding the credibility of the claimed invention). Such a doctrine does not exist in the United States. This unnecessary divergence by UK courts fundamentally erodes the competitiveness of the UK for launching innovative medicines and broader biopharmaceutical investment.

As the UK Government considers future free trade agreements post-Brexit, including with the United States in implementing the EPD, USTR should ensure that the United Kingdom affirms its commitment to the highest standards of IP protection for innovative medicines.

[383] *See*, *e.g.*, *Generics (UK) Ltd. & Ors v AstraZeneca AB* [2025] EWCA Civ 903, available at https://caselaw.nationalarchives.gov.uk/ewca/civ/2025/903?from_date=2025-07-16&court=ewca%2Fciv (last visited Jan. 27, 2026).

[384] *See*, *e.g.*, European Patent Office (EPO) decision in G2/21 (March 23, 2023), available at https://www.epo.org/boards-of-appeal/decisions/pdf/g210002ex1.pdf (last visited Jan. 27, 2026).