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March 11, 2025

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USTR-2025-0001

The Honorable Jamieson Greer
U.S. Trade Representative
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Re: Request for Comments to Assist in Reviewing and Identifying Unfair Trade Practices and Initiating All Necessary Actions to Investigate Harm From Non-Reciprocal Trade Arrangements, 90 Fed. Reg. 10677 (February 25, 2025)

Dear Ambassador Greer:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to provide the following comments in response to the request by the Office of the U.S. Trade Representative (USTR). PhRMA and its members welcome and support efforts by USTR to eliminate unfair and non-reciprocal foreign trade practices that harm America's innovative biopharmaceutical industry and the 4.9 million jobs it supports across the U.S. economy.[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, manufacture and export life-saving treatments and cures. Whereas the United States has long supported biopharmaceutical innovation through a system of robust intellectual property protections, market-based competition and open trade, trade barriers imposed by foreign governments deny fair and reciprocal treatment to U.S. innovators.

PhRMA welcomes President Trump's commitment to a "robust and reinvigorated trade policy" that seeks to eliminate these unfair and non-reciprocal practices through trade negotiations, agreements and enforcement actions.[2]

PhRMA is also encouraged by USTR's 2025 Trade Policy Agenda, which correctly notes that the 2022 waiver of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) "has not increased access to COVID-19 vaccines but instead may actually negatively impact the development of new treatments and cures for the next

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

[2] Memorandum on America First Trade Policy, Jan. 20, 2025, available at https://www.whitehouse.gov/presidential-actions/2025/01/america-first-trade-policy and Memorandum on Reciprocal Trade and Tariffs, Feb. 13, 2025, available at https://www.whitehouse.gov/articles/2025/02/reciprocal-trade-and-tariffs/.

pandemic by weakening the standard for intellectual property protections and furthering a false narrative about the role of intellectual property and access to medicines."[3] PhRMA members agree that U.S. trade policy must prioritize the protection of U.S. innovation abroad and, consistent with this principle, urge USTR to pursue the elimination of the unfair and non-reciprocal trade practices highlighted in this submission.

The submission below provides the following information in response to USTR's request for comments: (1) information regarding the innovative biopharmaceutical sector's extensive U.S. economic footprint; (2) a brief overview of unfair and non-reciprocal foreign trade practices that inhibit U.S. biopharmaceutical innovation and exports; and (3) PhRMA's views on trade policies and approaches that would be effective in eliminating these unfair and non-reciprocal foreign trade practices. **Appendix I** to this submission outlines the most significant unfair and non-reciprocal trade practices encountered by PhRMA members in key foreign markets and explains the operation of these practices and their impact on the U.S. biopharmaceutical industry.

1. The U.S. Innovative Biopharmaceutical Industry is a Major American Economic Sector and Contributes Significantly to High-Standard U.S. Manufacturing and Employment

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 high-paying, high-standard and diverse jobs in all 50 states. The U.S. biopharmaceutical industry 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.[4]

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.[5] With the right policies and incentives in place at home and abroad, our member companies can continue to bring valuable new medicines to patients around the world. In 2023, U.S. biopharmaceutical goods exports exceeded $101 billion.[6] 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,

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[3] 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.

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

[5] 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-InvestmentReport.Final_.January-2022-1.pdf.

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

semiconductors and other electronic components, medical equipment and supplies, and communications equipment.[7]

The U.S. biopharmaceutical industry is also among the top five employers of U.S. manufacturing jobs, with more Americans directly employed in biopharmaceutical manufacturing than in manufacturing in several other industries, including each of the following: iron and steel products, aerospace products and parts, petroleum and coal products, and electric equipment and appliances.[8] In 2022, 34 percent of U.S. biopharmaceutical industry employees were engaged in manufacturing at over 1,500 manufacturing plants across the country, 39 percent were engaged in biopharmaceutical R&D, 24 percent were engaged in distribution and three percent were engaged in corporate administration.[9]

2. Unfair and Non-Reciprocal Foreign Trade Practices Jeopardize American Innovation and Undermine Exports of Innovative Medicines

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

Appendix I to this submission identifies the most significant unfair and non-reciprocal trade practices encountered by PhRMA members in 11 major markets: **Argentina**, **Australia**, **Brazil**, **Canada**, **China**, **Colombia**, **the European Union**, **India**, **Japan**, **Korea** and **Mexico**. These practices are highlighted because they represent the most commercially significant trade barriers facing the U.S. biopharmaceutical sector in these countries, and because U.S. government engagement to eliminate these practices would therefore yield the greatest benefit in promoting fair and reciprocal trade. PhRMA's annual National Trade Estimate (NTE) and Special 301 submissions to USTR provide a more comprehensive and detailed overview of significant trade barriers facing the U.S. innovative biopharmaceutical industry, including in markets not highlighted in this submission.

The unfair and non-reciprocal trade practices highlighted in this submission fall within the categories listed below. Whereas the United States has long supported biopharmaceutical innovation through a system of robust intellectual property protections, market-based

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

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

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

competition and open trade, the foreign government practices described below deny fair and reciprocal treatment to U.S. innovators.

- **Intellectual property barriers:** Though foreign entities enjoy robust protection of their intellectual property in the U.S. market, many foreign governments deny adequate and effective intellectual property protection to U.S. biopharmaceutical innovators, often in violation of international trade commitments. Intellectual property barriers in the markets listed in this submission prevent biopharmaceutical innovators from securing patents (restrictive patentability criteria and patent backlogs), maintaining and effectively enforcing patents (weak patent enforcement and compulsory licensing), and protecting regulatory test data (regulatory data protection (RDP) failures). For example, despite the high RDP standards in place in the United States, countries such as **Argentina**, **Brazil**, **China** and **India** fail to provide RDP to U.S. innovators, and others provide inadequate RDP. In addition, **Mexico** and **Canada** have yet to implement key intellectual property provisions required by the United States-Mexico-Canada Agreement (USMCA), and **China** has yet to fully implement intellectual property commitments in Phase One of the U.S.-China Economic and Trade Agreement. U.S. biopharmaceutical innovators also face compulsory licensing threats in **Colombia** and other countries.

- **Market access barriers:** Unreasonable regulatory delays prevent U.S. biopharmaceutical innovators from bringing safe and effective medicines to patients who need them. In some markets, including **Canada** and **Mexico**, deadlines for making decisions on whether to approve new medicines are regularly not met. Even after products receive marketing authorization, egregious and discriminatory pricing policies in several markets including **Australia**, **Canada**, **the European Union**, **Japan** and **Korea** undervalue American innovation, threaten billions of dollars in lost sales and undermine American competitiveness, jobs and exports. 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 of new medicines that prevent, treat and cure costly diseases, thereby reducing the need for more costly interventions that drive overall health care costs in the United States and around the world, while supporting U.S. competitiveness and jobs.[10]

- **Non-reciprocal tariff treatment:** Tariffs on biopharmaceuticals and their inputs increase healthcare costs, impede patient access to medicines and divert resources that could instead

[10] *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; 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.

be directed to investments in R&D and manufacturing. For these and other reasons, the United States has not applied tariffs to most imported biopharmaceutical products. Unfortunately, biopharmaceutical manufacturers in the United States do not benefit from the same access to **Argentina**, **Brazil**, **India** and other emerging economies, where biopharmaceutical products from the United States face significant import tariffs. On the other hand, the economies that play significant roles in the *innovative* biopharmaceutical supply chain *do* afford reciprocal, tariff-free treatment to U.S. biopharmaceutical exports, including the European Union, Japan, Singapore, Switzerland and the United Kingdom. PhRMA encourages the Administration to refrain from imposing tariffs on imports of biopharmaceutical products from these important trading partners that, as noted, provide reciprocal, tariff-free access to exports of U.S. biopharmaceutical products.

Appendix I to this submission outlines the most significant unfair and non-reciprocal trade practices in each of the above-listed markets and explains the impact of these practices on the U.S. innovative biopharmaceutical industry. When foreign government regulators undervalue and delay access to new medicines developed and produced by U.S. innovators or fail to protect IP, American workers suffer damages. In particular, U.S. biopharmaceutical exports, R&D and investment activities are substantially reduced by foreign government regulations that artificially lower the demand for innovative medicines. PhRMA appreciates the request for quantification of the economic effects of unfair and non-reciprocal trade practices and looks forward to working with the Administration to provide this information.

3. PhRMA Urges USTR to Secure the Elimination of Unfair and Non-Reciprocal Foreign Trade Practices That Impede U.S. Biopharmaceutical Innovation and Exports

PhRMA members welcome President Trump's commitment to a "robust and reinvigorated trade policy" that benefits American workers and manufacturers, promotes investment and productivity, and enhances the United States' industrial and technological advantages.[11] To further these objectives, PhRMA urges USTR to engage with foreign governments to secure the elimination of the unfair and non-reciprocal trade practices identified in this submission, including through initiatives envisioned in President Trump's Memorandum on an America First Trade Policy. PhRMA members support the following approaches to promote fair and reciprocal treatment of U.S. biopharmaceutical exports and intellectual property abroad:

- **Trade enforcement**: PhRMA members urge USTR to use all available trade enforcement tools to eliminate the unfair and non-reciprocal trade practices identified in this submission. PhRMA welcomes the efforts outlined in the America First Trade Policy Memorandum to review and ensure compliance with U.S. trade agreements, including the USMCA and Phase One of the U.S.-China Economic and Trade Agreement. As described in **Appendix I**, many unfair and non-reciprocal trade practices encountered by PhRMA members are inconsistent with commitments under multilateral, regional and bilateral trade agreements. USTR should pursue multiple enforcement initiatives to secure compliance with those commitments –

[11] Memorandum on America First Trade Policy, Jan. 20, 2025, available at https://www.whitehouse.gov/presidential-actions/2025/01/america-first-trade-policy and Memorandum on Reciprocal Trade and Tariffs, Feb. 13, 2025, available at https://www.whitehouse.gov/articles/2025/02/reciprocal-trade-and-tariffs/.

including the use of WTO and FTA dispute settlement procedures, which unfortunately have not prioritized intellectual property abuses by foreign governments in the past.

USTR also should leverage consultative mechanisms, such as the upcoming Joint Review of the USMCA and the Medicine Working Groups anticipated in several trade agreements, to ensure that trading partners fully implement their obligations to protect U.S. intellectual property and provide fair market access for innovative biopharmaceutical products. In addition, USTR should use all available tools, including the annual Special 301 report and investigations under Section 301 of the Trade Act of 1974, to highlight and remedy the unfair and non-reciprocal trade practices identified in this submission. PhRMA and its members are prepared to assist USTR in developing results-oriented work plans to address these unfair trade practices.

- **Negotiation of bilateral and sectoral trade agreements**: PhRMA encourages USTR to pursue bilateral and sectoral trade agreements, as envisioned in Section 2(g) of the Memorandum, to eliminate the unfair and non-reciprocal trade practices described in this submission. Such agreements should promote fair and reciprocal trade by: (1) including strong intellectual property provisions that reflect a standard of protection similar to that found in U.S. law; (2) ensuring fair and equitable market access through requirements that pricing and reimbursement policies abroad appropriately value patented medicines and are fair, reasonable and non-discriminatory; (3) eliminating foreign tariffs on biopharmaceutical products; and (4) fostering transparency, due process and good regulatory practices. America's innovative biopharmaceutical industry regrets that the previous Administration declined to negotiate commercially meaningful trade agreements that reduce foreign barriers to U.S. exports. PhRMA and its members therefore strongly support the Administration's intention to pursue bilateral and sectoral trade agreements and encourage the Administration to partner with Congress, including through such initiatives as the bipartisan Medical Supply Chain Resiliency Act, to negotiate trade agreements with trusted trading partners that eliminate tariffs and other trade barriers, and promote strong IP, regulatory and other standards.

  In addition to pursuing new trade agreements with the economies identified in this submission, USTR should consider modernizing and building on existing agreements, including through negotiations with China for a second phase of the Economic and Trade Agreement. USTR also should use the upcoming Joint Review of the USMCA to strengthen the Agreement's intellectual property chapter, ensuring that Canada and Mexico afford reciprocal intellectual property protections to the United States consistent with President Trump's original vision for the Agreement. PhRMA also encourages USTR to pursue bilateral or sectoral trade agreements with like-minded partners, such as the European Union, Japan, Switzerland and the United Kingdom, that maintain high intellectual property and regulatory standards. Such agreements can strengthen U.S. biopharmaceutical supply chains by incentivizing trade and investment with reliable allies that have demonstrated a commitment to open and reciprocal trade with the United States.

PhRMA also supports targeted U.S. government engagement to eliminate foreign tariffs on biopharmaceuticals, active pharmaceutical ingredients and other inputs. USTR should engage with trading partners bilaterally and at the WTO to seek reciprocal tariff-free treatment of these products exported from the United States.

Urgent action is required to address the unfair and non-reciprocal trade practices identified in this submission. Unfortunately, the previous Administration demonstrated no 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 protect and support 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 TRIPS Agreement – a deeply unnecessary decision that directly harmed America's biopharmaceutical 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. innovations abroad. PhRMA welcomes the positive steps the Administration has already taken toward a more ambitious and pro-innovation trade agenda, including by acknowledging the harmful effects of the WTO TRIPS waiver and the importance of intellectual property protection and exploring meaningful trade negotiations and enforcement initiatives to address unfair and non-reciprocal trade practices abroad.[12]

4. U.S. Trade Policies Should Prioritize, and Not Undermine, Public Health and the Global Competitiveness of the U.S. Innovative Biopharmaceutical Industry

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, healthcare 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 and equipment used to produce those medicines in the United States, as these actions would be detrimental to U.S competitiveness and increase healthcare costs at home.

The U.S. biopharmaceutical industry is a global leader in manufacturing, producing $351.7 billion of gross output[13] annually and employing nearly 360,000 manufacturing workers across

[12] Office of the U.S. Trade Representative, 2025 Trade Policy Agenda and 2024 Annual Report, 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.

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

the country.[14] While more than half (53 percent) of the $85.6 billion of active pharmaceutical ingredients used in U.S.-consumed medicines is manufactured in the United States, another 33 percent is sourced from reliable European allies through carefully coordinated supply chains (i.e., the European Union, Switzerland and the United Kingdom).[15] Tariffs on API and other inputs would increase production costs for U.S. manufacturers of innovative medicines, undermining their ability to invest in the next generation of treatments and cures and weakening their global competitiveness.

Similarly, while 64 percent of finished medicines consumed in the United States are produced domestically, imports of finished medicines from partners such as the European Union, Switzerland, the United Kingdom and Japan enable U.S. patients to access a broader range of cutting-edge treatments and cures. Tariffs on these innovative medicines would significantly increase their cost and jeopardize investments in biopharmaceutical research and manufacturing, undermining the Administration's efforts to promote affordable healthcare and U.S. industrial competitiveness.

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.

Sincerely,

/s/ Douglas Petersen

Douglas Petersen
Deputy Vice President, International

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

[15] https://avalere.com/insights/majority-of-api-in-us-consumed-medicines-produced-in-the-us.

APPENDIX I

UNFAIR AND NON-RECIPROCAL TRADE PRACTICES IN KEY MARKETS

ARGENTINA

PhRMA members have identified the following as the most significant unfair and non-reciprocal trade practices that inhibit U.S. innovation and exports of biopharmaceutical products to Argentina:

- **Lack of regulatory data protection (RDP)**: International rules, consistent with U.S. law, require regulators to provide RDP for the confidential data that biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval. RDP must protect against both disclosure of test data and, for a limited time, unfair commercial use (e.g., third-party reliance on the data). Further, RDP should be available for both small and biologic molecules.

  Argentina does not comply with its RDP commitments because regulators inappropriately allow domestic companies and other third parties to rely on the confidential data submitted by innovators in other countries to approve marketing requests for competing products in Argentina.

- **Discriminatory patent regime compounded by weak patent enforcement system**: Argentina's restrictive patentability regime and weak patent enforcement practices impose significant barriers for American biopharmaceutical innovators seeking to secure and enforce their intellectual property.

  Restrictive patentability criteria: International rules, consistent with U.S. law, require that patents must be available on all inventions, regardless of the technology, that are new, involve an inventive step and are capable of industrial application. Denying patents for certain types of biopharmaceutical inventions or imposing additional or heightened patentability criteria for biopharmaceutical innovators are contrary to international obligations.

  For over a decade, Argentina has maintained a policy that restricts virtually all patenting of biopharmaceutical inventions. A 2012 joint resolution by the Ministries of Health and Industry and the Argentina Patent Office (INPI) targeted only biopharmaceutical technologies and created guidelines requiring INPI examiners to deny the patenting of important and valuable biopharmaceutical inventions in Argentina. This discriminatory practice creates significant obstacles to introduce new medicines to patients and provides a windfall to non-originators. These guidelines contradict provisions of Argentina's Patent Law and are contrary to Argentina's international obligations, the norms and standards of the Organization for Economic Cooperation and Development which Argentina seeks to join, and the laws, policies and practices of other jurisdictions around the world, including the United States.

  Weak patent enforcement: Effective patent enforcement mechanisms facilitate the timely resolution of patent disputes before potentially infringing follow-on products enter the market. They provide notice to patent holders when third parties apply for marketing approval of follow-on products, give patent holders adequate time and opportunity to seek provisional remedies (e.g., preliminary injunctions) prior to the marketing of the allegedly infringing products, and facilitate timely resolution of patent disputes prior to the expiration of the provisional remedies.

Biopharmaceutical innovators face lengthy and burdensome procedures to obtaining preliminary injunctions in Argentina. Moreover, Argentina does not provide patent holders meaningful notice when third parties apply for marketing approval of follow-on products, therefore denying innovators with real opportunities to anticipate and mitigate potential patent infringements.

- **Discriminatory reimbursement policies**: Argentina maintains reimbursement policies that discriminate against imported biopharmaceutical products in favor of locally manufactured products. Two 2015 joint resolutions by the Ministry of Health and the Secretary of Commerce require public and private health insurers to prioritize coverage for "high cost" medicines manufactured in Argentina when such products contain the same active ingredient as an imported product. This discriminatory policy increases the windfall already provided to non-originators through Argentina's restrictive patentability criteria.

- **Non-reciprocal tariff treatment**: Tariffs on biopharmaceuticals and their inputs inhibit trade, increase health care costs and divert resources that could instead be directed to investments in biopharmaceutical R&D and manufacturing. For these and other reasons, the United States does not apply most-favored nation (MFN) tariffs to most imported biopharmaceutical products. Unfortunately, biopharmaceutical manufacturers in the United States do not benefit from the same access to Argentina, which applies MFN tariffs averaging 7.2 percent on pharmaceutical products classified under HS Chapter 30. The United States' average applied MFN tariff on these products is 0.2 percent.

AUSTRALIA

PhRMA members have identified the following as the most significant unfair and non-reciprocal trade practices that inhibit U.S. innovation and exports of biopharmaceutical products to Australia:

- **Inadequate regulatory data protection**: International rules, including the Australia-United States Free Trade Agreement (AUSFTA), require regulators to provide regulatory data protection (RDP) for the confidential data that biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval. RDP must protect against both disclosure of test data and, for a limited time, unfair commercial use (e.g., third-party reliance on the data). Further, RDP should be available for both small and biologic molecules.
  Australia does not provide RDP terms that are reciprocal with those provided in the United States and other developed economies. Presently, Australia has opted to adopt the minimum RDP term (5 years) required by AUSFTA for both small molecules and biologic products. In contrast, the United States provides 12 years of RDP for biologic products recognizing the complexity of biologics and that it may be 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. In addition, Australia does not extend RDP for new indications, new formulations, new patient populations and new dosage forms. 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.

- **Patent issues**: While Australia has taken steps in terms of implementing AUSFTA, significant issues remain related to effective patent enforcement (Articles 17.10(4) and 17.11(17-18)) and compulsory licensing (Article 17.9.7):

  Ineffective patent enforcement: Pursuant to the AUSFTA, Australia must provide effective patent enforcement mechanisms to facilitate the timely resolution of patent disputes before potentially infringing follow-on products enter the market. Specifically, Australia must (1) provide notice to patent holders when third parties apply for marketing approval of follow-on products; (2) give patent holders adequate time and opportunity to seek provisional remedies (e.g., stays and preliminary injunctions) prior to the marketing of the allegedly infringing products; and (3) facilitate timely resolution of patent disputes prior to the expiration of the provisional remedies.

  Australia has not yet implemented a system by which patent holders, as a matter of practice, receive advance notice of third-party applications for marketing approval of potentially patent-infringing pharmaceutical products. The lack of adequate 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 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).

  In addition, Australia's patent enforcement regime penalizes legitimate efforts by innovators to protect their intellectual property rights. In cases of patent invalidation by the courts, the

Australian Government has joined legal actions against innovators for damages attributed to delays in price reductions for patented medicines due to preliminary injunctions on generic launches while the patent disputes are 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, and are inconsistent with Article 17.11(18) of the AUSFTA.

- **Government pricing and reimbursement systematically devalues U.S. medicines**: The Australian Government employs pricing policies that do not appropriately recognize innovation, such as using the lowest-cost comparator when setting the prices of new medicines as well as statutory price reductions and subsidy caps.

  Pharmaceutical Benefits Advisory Committee (PBAC): PBAC creates significant barriers to listing new medicines on the Pharmaceutical Benefits Scheme (PBS). PBAC conducts biased health technology assessments that compare innovative medicines to the lowest cost comparator, rather than the most appropriate clinical comparator, and then values health and longevity gains based on low monetary values that are designed to demand excessive discounts. In too many cases, comparators are old, off-patent medicines that are subject to generic or biosimilar competition 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 innovation by excluding patented products from the price reductions applied to off-patent products. In addition, statutory price reductions for innovative medicines and subsidy caps further erode product prices during the patent term.

- **Unreasonable patient access delays due to protracted government processes**: Australia creates unnecessary data requirements and other administrative hurdles to secure PBS listing, causing significant delays.

  The purpose of the PBS is to provide timely, reliable and affordable access to medicines for Australians. Prescription medicines accessed via the PBS constitute the vast majority of prescription medicines dispensed in Australia. Unnecessary supplemental data requests, infrequent PBAC meetings and other administration motions cause significant delays between regulatory approval and reimbursement listing, contrary to Article 2(a) of Annex 2-C in the AUSFTA. Australian patients wait an average of 33 months from global first launch for new medicines to become available. New medicines listed on the PBS experience delays of over a year, on average, between receiving Therapeutic Goods Administration marketing authorization and PBS listing.

- **Preferential treatment of locally produced vaccines**: The Australian government revealed in October 2024 a range of new and advantageous procurement processes for a local vaccine manufacturer not available to other competitors. These include alternative methods of HTA approval and exemption from standard procurement rules, independent of merits review and decision-making transparency. This creates an uneven playing field for U.S. companies that manufacture competing products. These preferences are inconsistent with Australia's national treatment obligations and AUSFTA commitments.

BRAZIL

PhRMA members have identified the following as the most significant unfair and non-reciprocal trade practices that inhibit U.S. innovation and exports of biopharmaceutical products to Brazil:

- **Lack of regulatory data protection (RDP)**: International rules, consistent with U.S. law, require regulators to provide RDP for the confidential data that biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval. RDP must protect against both disclosure of test data and, for a limited time, unfair commercial use (e.g., third-party reliance on the data). Further, RDP should be available for both small and biologic molecules.

  Brazil maintains a discriminatory RDP policy by not providing protection for biopharmaceutical products, despite extending RDP to veterinary, fertilizer and agrochemical products.

- **Extreme patent backlogs**: Patent backlogs directly reduce the value of granted patents and should be mitigated with patent term adjustment (PTA) mechanisms that compensate for unreasonable delays in the patent examination process.

  Brazil's patent examination backlog is particularly egregious. According to a recent study, the average patent examination timeline for biopharmaceutical patents granted from January 2020 through November 2024 was 9.5 years. Patent offices in OECD countries (e.g., United States and Korea), China, Europe and other economies have an average patent pendency period of two to four years. The need for PTA in Brazil is even more acute following the Brazilian Supreme Court's 2021 decision eliminating provisions of law providing a minimum patent term to offset Brazil's egregious patent office examination delays. Even worse for pharmaceutical and other health-sector innovators, the Supreme Court held that the decision should be applied retroactively to their patents – eliminating overnight thousands of patents and raising discrimination concerns under Brazil's international commitments.

- **Restrictive government pricing and reimbursement policies**: Brazil sets prices for both the public and private health insurance markets. Pricing and public reimbursement decisions for new medicines are exceptionally slow, causing patients to wait over four years for new medicines to be covered by the public health insurance program.

  Brazil's Drug Market Regulation Chamber (CMED) regulates the pricing and reimbursement of medicines in Brazil, which often creates market access barriers and unreasonable delays. Challenges include lengthy 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 requirements by the National Committee for Technology Incorporation (CONITEC) that prevent value-based approaches to evaluating and paying for innovative medicines.

- **Non-reciprocal tariff treatment**: Tariffs on biopharmaceuticals and their inputs inhibit trade, increase health care costs and divert resources that could instead be directed to investments in

biopharmaceutical R&D and manufacturing. For these and other reasons, the United States does not apply most-favored nation (MFN) tariffs to most imported biopharmaceutical products. Unfortunately, biopharmaceutical manufacturers in the United States do not benefit from the same access to Brazil, which applies MFN tariffs averaging 6.8 percent on pharmaceutical products classified under HS Chapter 30. The United States' average applied MFN tariff on these products is 0.2 percent.

CANADA

PhRMA members have identified the following as the most significant unfair and non-reciprocal trade practices that inhibit U.S. innovation and exports of biopharmaceutical products to Canada:

- **Inadequate regulatory data protection**: International rules, including the U.S.-Mexico-Canada Agreement (USMCA), require regulators to provide regulatory data protection (RDP) for the confidential data that biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval. RDP must protect against both disclosure of test data and, for a limited time, unfair commercial use (e.g., third-party reliance on the data). Further, RDP should be available for both small and biologic molecules.

  Canada does not provide RDP terms that are reciprocal to those provided in the United States. and other developed economies. Despite agreeing to provide ten years of RDP for biologic medicines in the USMCA text signed in 2018, Canada maintains an eight-year RDP term for biologics. The 2018 USMCA text would have been a major advance to incentivize American innovation and rectified the failure of Canada to afford reciprocal IP protections to U.S. innovators. Regrettably, this provision was removed during congressional debate over the USMCA in 2019, along with other pro-innovation provisions designed to ensure reciprocal protection of U.S. IP in Canada and Mexico.

- **Patent issues**: While Canada has made progress in terms of implementing the USMCA, significant issues remain related to ensuring effective patent enforcement (Article 20.50 and Annex 20-A), patent backlogs (Article 20.44) and patent term extension (Article 20.46):

  Ineffective patent enforcement: Pursuant to the USMCA, Canada must provide effective patent enforcement mechanisms that (1) provide notice to patent holders when third parties apply for marketing approval of follow-on products; (2) give patent holders adequate time and opportunity to seek provisional remedies (e.g., stays and preliminary injunctions) prior to the marketing of the allegedly infringing products; and (3) facilitate timely resolution of patent disputes prior to the expiration of the provisional remedies.

  The Canadian Patented Medicines (Notice of Compliance) Regulations (the "PM(NOC) Regulations") include several key deficiencies that weaken Canada's enforcement of biopharmaceutical 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.

  Further, Canada used implementation of the Canada-EU Comprehensive Economic and Trade Agreement to implement reforms to the system that are not required by that Agreement. These revisions have resulted in a system that has more procedural complexity (but with no change to the 24-month statutory stay to account for these complexities) and new rules that further expose innovators to even greater potential liability under Section 8 of the PM(NOC) Regulations.

New patent term adjustment mechanism inconsistent with USMCA commitments: Patent backlogs directly reduce the value of granted patents and should be mitigated with patent term adjustment (PTA) mechanisms that compensate for unreasonable delays in the patent examination process.

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. By taking this approach, Canada fails to fulfill two independent trade obligations, which each serve important purposes and compensate for distinct delays.

In addition, Canada's PTA system imposes significant and inequitable barriers that will prevent innovators from receiving the intended meaningful remedy for patent office delays. These include ill-defined timelines for granting PTA, high application and maintenance fees, and arbitrary standards for determining what days may be subtracted in the determination of the PTA term. Further, there is no mechanism available (other than through judicial intervention) to challenge the PTA calculation to secure a longer adjustment (can only challenge to reduce the PTA term).

PTR mechanism inconsistent with USMCA commitments: PTR seeks to restore a portion of the patent term lost due to the lengthy development and regulatory approval process for new medicines. Canada's PTR system (certificates of supplementary protection or CSP) suffers from several deficiencies (separate from the concerns noted above regarding the concurrent application of PTA and PTR):

- The maximum CSP term that may be granted in Canada is only two years, compared to five years of PTR in the United States;
- The protections afforded during the CSP term are not the same as those afforded during the regular patent term (includes an exception for manufacturing for export);
- An applicant is only eligible for a CSP if marketing authorization is sought in Canada within one year of seeking approval in Australia, the European Union, Japan, Switzerland, the United Kingdom or the United States; and
- "Variations" of medicinal ingredients and other prior drug approvals are not eligible for a CSP.

- **Government pricing and reimbursement systematically devalues U.S. medicines**: Canada sets a ceiling price at launch for all patented medicines sold to public or private payers by referencing prices from a broad basket of countries, followed by health technology assessments that demand excessive discounts.

Patented Medicine Prices Review Board (PMPRB): The stated purpose of Canada's PMPRB is to ensure that prices of patented medicines are not "excessive" (i.e., the prices do not violate Canada's antitrust laws). Instead, the PMPRB employs a combination of international reference pricing to define as "excessive" any price of a patented medicine that exceeds the price in a basket of 11 countries and ambiguous therapeutic class comparisons. To compound this deeply flawed approach, in 2022 Canada removed the United States and Switzerland from its reference basket and added six countries with lower drug prices and more onerous price

controls, all with the purpose of further lowering the ceiling price on patented medicines sold in Canada.

Canadian Drug Agency (CDA): In 2023, Canada established the CDA, which conducts health technology assessment (HTA) to determine whether an innovative medicine should be recommended for coverage on a public health insurance plan. In particular, the HTA methods value health and longevity gains from innovative medicines based on low monetary values that are not indexed to inflation and that are designed to demand excessive discounts below the PMPRB ceiling price, including 70 percent for many cancer medicines and over 90 percent for some rare disease medicines.

Canada should reform the roles and policies of the PMPRB and CDA to reflect the spirit of the USMCA commitments (Article 29.6) to appropriately value innovative medicines.

- **Unreasonable patient access delays due to protracted government processes**: Canada's many bureaucratic barriers unreasonably prolong the time between a company's submission to the federal government to approve a new medicine and patient access through public health insurance plans. Provincial governments impose additional barriers through lengthy interprovincial price negotiations and administrative delays to provincial listings for reimbursement.

  The average time between regulatory approval of a new medicine and listing on public provincial formularies was 736 days (over two years) in 2022, which is twice as long as reported in other OECD countries. These barriers significantly delay patient access to new medicines and erode the amount of time in which companies may commercialize their innovations in Canada.

  Canada should substantially reduce the current delays in government reimbursement processes consistent with USMCA commitments to provide procedural fairness in the pricing and reimbursement of new pharmaceuticals (Article 29.7).

THE PEOPLE'S REPUBLIC OF CHINA

PhRMA members have identified the following as the most significant unfair and non-reciprocal trade practices that inhibit U.S. innovation and exports of biopharmaceutical products to China:

- **Lack of regulatory data protection (RDP)**: International rules, consistent with U.S. law, require regulators to provide RDP for the confidential data that biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval. RDP must protect against both disclosure of test data and, for a limited time, unfair commercial use (e.g., third-party reliance on the data). Further, RDP should be available for both small and biologic molecules.

  China committed as part of its accession to the World Trade Organization (WTO) in 2001 to provide at least 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). To this day, China has yet to honor this commitment, issuing draft after draft of proposals to implement RDP without taking final action to provide this critical protection to American innovative biopharmaceutical companies. China must provide RDP without further delay and ensure that it is granted in full to any product that is "new" to China (see discussion of new drug definition issue below).

- **Patent issues**: While China has made progress in terms of implementing the Economic and Trade Agreement between the United States and China (Phase One Agreement), significant issues remain related to effective patent enforcement (Article 1.11), patent term extensions (Article 1.12) and restrictive patentability criteria (Article 1.10).

  Ineffective patent linkage: Pursuant to the Phase One Agreement, China must provide effective patent enforcement mechanisms to facilitate the timely resolution of patent disputes before potentially infringing follow-on products enter the market. Specifically, China must provide notice to patent holders when third parties apply for marketing approval of follow-on products; give patent holders adequate time and opportunity to seek provisional remedies prior to the marketing of the allegedly infringing products; and facilitate timely resolution of patent disputes prior to the expiration of the provisional remedies.

  China's patent linkage mechanism suffers from several deficiencies including: (1) the scope of patents for which notice is provided is severely limited, particularly for biologics; (2) the stay period of nine months (with no stay provided for biologics) is inadequate; (3) the availability of injunctive relief to allow for the resolution of patent disputes outside of or beyond the proposed patent linkage mechanism is unclear; (4) unclear remedies if a generic or biosimilar manufacturer submits an erroneous declaration; (5) lack of a mechanism for a generic or biosimilar company to change or correct an erroneous declaration (other than refiling the entire application); and (6) 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., where the follow-on company promises not to launch its product before the expiry of the listed patents).

In addition, while China has created a cause of action (Article 76), the scope of that action is limited to listed patents. This, combined with the fact that 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. These challenges enforcing patents in China are compounded by high invalidation rates and inconsistent consideration of supplemental data (discussed below).

Discriminatory patent term extension (PTE): China has committed, pursuant to the Phase One Agreement, to restore a portion of the patent term lost due to the lengthy development and regulatory approval process for new medicines.

China's recently implemented PTE mechanism appears to be 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. This approach denies PTE to those innovative medicines first approved outside of China, contrary to the way any other economy – including the United States – provides PTE. It is critical that China revise its PTE mechanism so that the compensation is available to all "new drugs," "innovative drugs" and "improved new drugs" that are new to China.

Restrictive patentability criteria: International rules, consistent with U.S. law, require that patents must be available on all inventions, regardless of the technology, that are new, involve an inventive step and are capable of industrial application. Denying patents for certain types of biopharmaceutical inventions or imposing additional or heightened patentability criteria for biopharmaceutical innovators are contrary to international obligations.

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.

- **New drug definition 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. This new-to-the-world definition is inconsistent with international standards, under which new drugs are those that are new to a specific country, and has paved the way for China to treat drugs manufactured and approved abroad differently in various policies. For example, only new-to-the-world drugs qualify for the expedited approval pathway for breakthrough drugs and certain determinations of innovativeness in the National Reimbursement Drug List (NRDL) price negotiations, as well as the NRDL price renegotiation pathway. Proposals for RDP in China have similarly limited full benefits to new-to-the-world drugs. As discussed above, it has also been applied in the recently established PTE mechanism, contrary to Article 1.12 of the Phase One 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. Consistent with U.S. practice, it is critical that China define new drugs to mean newly approved for marketing in China, as opposed to new to the world.

COLOMBIA

PhRMA members have identified the following as the most significant unfair and non-reciprocal trade practices that inhibit U.S. innovation and exports of biopharmaceutical products to Colombia:

- **Compulsory licenses**: Compulsory licensing, through which a government permits the use of patented pharmaceuticals without the patent holder's permission, is increasingly being used in a manner not compatible with international norms and legal requirements either to implement industrial policies or as undue leverage in pricing negotiations between governments and rights holders. U.S. administrations have specifically called out such practices and made clear that compulsory licensing should not be used as undue leverage in pricing negotiations.

  In 2024, Colombia issued its first ever compulsory license on an innovative medicine and is publicly threatening to consider the same action on more than a dozen other products. Colombia issued the compulsory license to secure lower prices than those already set by the Colombian Government.

- **Inadequate regulatory data protection (RDP)**: International rules, consistent with U.S. law, require regulators to provide RDP for the confidential data that biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval. RDP must protect against both disclosure of test data and, for a limited time, unfair commercial use (e.g., third-party reliance on the data). Further, RDP should be available for both small and biologic molecules.

  While Colombia has legislation in place to provide five-years of RDP for new chemical entities as required by Article 16.10.2 of the U.S.-Colombia Trade Promotion Agreement (TPA), the National Food and Drug Surveillance Institute (INVIMA) does not grant RDP to products that share any portion of their chemical structure with previously approved products.

- **Patent issues**: While Colombia has made progress in terms of implementing the TPA, significant issues remain related to effective patent enforcement (Article 16.10.3-4) and restrictive patentability criteria (Article 16.9.1):

  Ineffective patent enforcement: Effective patent enforcement mechanisms facilitate the timely resolution of patent disputes before potentially infringing follow-on products enter the market. They provide notice to patent holders when third parties apply for marketing approval of follow-on products, give patent holders adequate time and opportunity to seek provisional remedies prior to the marketing of the allegedly infringing products, and facilitate timely resolution of patent disputes prior to the expiration of the provisional remedies.

  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.

Restrictive patentability criteria: International rules, consistent with U.S. law, require that patents must be available on all inventions, regardless of the technology, that are new, involve an inventive step and are capable of industrial application. Denying patents for certain types of biopharmaceutical inventions or imposing additional or heightened patentability criteria for biopharmaceutical innovators are contrary to international obligations.

Colombia does not recognize patents for second uses. The Andean Court of Justice has issued several legal opinions holding that Andean Community members (including Colombia) should not recognize patents for second uses. These decisions are contrary to long-standing precedents and inconsistent with both Colombia's commitments under the TPA, as well as Article 27.1 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights.

EUROPEAN UNION

PhRMA members have identified the following as the most significant unfair and non-reciprocal trade practices that inhibit U.S. innovation and exports of biopharmaceutical products to the European Union:

- **The EU's pending "General Pharmaceutical Legislation" exploits regulatory data protection (RDP) and other incentives to achieve localization objectives**: While the European Union currently provides strong RDP, it is finalizing legislation ("General Pharmaceutical Legislation") that could significantly erode and exploit RDP to inappropriately achieve localization objectives. The European Commission's proposal for this legislation seeks to reduce RDP and creates illusory opportunities to restore the lost term if the biopharmaceutical product is "released and continuously supplied" to all EU Member States within twenty-four months from obtaining an EU marketing authorization. That condition is wholly outside the control of the innovator because market launch depends on timely pricing and reimbursement determinations by each Member State. Meanwhile, other proposals include provisions that would condition RDP terms on domestic manufacturing and clinical development.

  In addition, the General Pharmaceutical Legislation 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 European Commission (EC) seeks to expand the exemption to include the conduct of third-party studies and trials needed not only for follow-on marketing authorizations but also for applications for health technology assessment (HTA) and reimbursement – activities that are commercial and not considered by the Bolar exemption in the United States or any other jurisdiction with similar policies.

- **Patent issues**: In parallel to the General Pharmaceutical Legislation, the European Union is finalizing a legislative "Patent Package" that would create sweeping compulsory licensing authorities and further weaken patent term extension mechanisms (referred to as supplementary protection certificates (SPCs) in the European Union) by establishing new opposition SPC mechanisms.

  Compulsory licensing: The European Union is finalizing legislation to establish a pan-European compulsory licensing mechanism for "crisis" management. Separate from the question of the European Commission's jurisdictional authority to implement a pan-EU CL that would override patents granted at the Member State level, the proposed legislation is inconsistent with international rules. Specifically, the proposal seems to target exclusively the biopharmaceutical sector, fails to consider CLs on their individual merits, disregards voluntary negotiations prior to granting a CL and lacks appropriate judicial review. Further, the CL proposal implicates IP beyond granted patents, including patent applications, trade secrets and know-how – measures that would be inconsistent with the EU's international obligations to protect trade secrets and RDP.

Supplementary Protection Certificates: In 2019, the EU adopted an export and stockpiling waiver to SPCs that enables non-innovators to manufacture for export or domestic stockpiling of a patent protected biopharmaceutical product during the SPC term. The SPC manufacturing waiver reduces the scope of the exclusive patent rights conferred by an SPC and furthers the unlevel playing field relative to similar protections (i.e., patent term extension) provided under U.S. law. In 2023, the European Commission introduced draft legislation that would further erode SPC rights by establishing a new pre-grant mechanism for third parties to oppose SPCs before they are even granted. The proposed opposition procedure is redundant and unnecessary because existing procedures are already available to third parties to submit observations, appeal or otherwise contest the validity of patents subject to SPCs.

- **Government pricing and reimbursement systematically devalues U.S. medicines**: Pricing and reimbursement policies across EU member countries restrict patient access to innovative medicines and fail to acknowledge the value of state-of-the-art technologies that prevent, treat and cure disease. Collectively, these policies substantially reduce the value of U.S. exports of innovative biopharmaceutical products.

  International reference pricing: Nearly all European countries use IRP to set or "negotiate" drug prices based on those in countries with lower incomes. This widespread financial mechanism in effect compels the biopharmaceutical industry to subsidize public health care expenditures, even in high-income countries, often leading to downward pricing pressure.

  Biased health technology assessment: Rigid HTA frameworks in countries like Germany impose narrow interpretations of value, limiting the recognition of the broader benefits of novel therapies and benchmarking new medicines to the prices of older generic products. Other countries value health and longevity gains from innovative medicines based on low monetary values that are not indexed to inflation and that are designed to demand excessive price cuts.

  Mandatory price cuts and clawbacks: European governments shift the burden of underfunded health budgets by mandating price cuts or employing clawback mechanisms to recover "excess" biopharmaceutical spending to keep public expenditures within budget limits. In Greece, an extensive range of clawback policies have been enforced, keeping public biopharmaceutical spending on medicines stagnant since 2015 despite rising health care demands and the volume of biopharmaceutical products sold.

  Discriminatory pricing policies to localize industry: Recent pricing and reimbursement policies, such as those in France and Germany, increasingly favor locally developed or manufactured medicines through preferential pricing. These policies create an uneven playing field for U.S. biopharmaceutical companies and violate national treatment obligations.

INDIA

PhRMA members have identified the following as the most significant unfair and non-reciprocal trade practices that inhibit U.S. innovation and exports of biopharmaceutical products to India:

- **No regulatory data protection (RDP)**: International rules, consistent with U.S. law, require regulators to provide RDP for the confidential data that biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval. RDP must protect against both disclosure of test data and, for a limited time, unfair commercial use (e.g., third-party reliance on the data). Further, RDP should be available for both small and biologic molecules.

  When a pharmaceutical product has been previously approved by India's state or union regulatory authority in India or even in another country, India's Central Drug Authority requires only limited clinical data (sometimes as few as 16 Indian patients) to approve follow-on (non-innovative) products. When an applicant seeks approval for a drug already approved abroad, Indian authorities waive the requirement for test data. Providing approvals to third parties in this manner amounts to indirect and unfair reliance on the data generated and submitted by innovators for marketing approvals.

- **Patent issues**: India severely restricts the types of inventions that are patent eligible in other jurisdictions, including the United States. In addition, India's system undercuts American biopharmaceutical innovators by enabling others to file frivolous oppositions to patent applications. Even when American innovators secure a patent, India does not have mechanisms in place to prevent the approval, manufacture or sale of patent infringing products.

  Restrictive patentability criteria: International rules, consistent with U.S. law, require that patents must be available on all inventions, regardless of the technology, that are new, involve an inventive step and are capable of industrial application. Denying patents for certain types of biopharmaceutical inventions or imposing additional or heightened patentability criteria for biopharmaceutical innovators are contrary to international obligations.

  Section 3(d) of India's Patents Act inappropriately requires American innovators to demonstrate that variations of known substances have "enhanced efficacy" in order to be patentable, even when the product is new, involves an inventive step and is capable of industrial application. This results in weaker IP protection for American innovators in India than provided to Indian innovators in the United States.

  Pre-grant opposition system: India's pre-grant opposition system encourages anybody at any time to oppose a patent application between publication of the application and patent grant. This weakens the IP rights of biopharmaceutical innovators because the system exposes patent applicants to significant delays and unpredictable legal challenges that can last upwards of 10 years. The recently finalized Patent (Amendment) Rules, 2024, seeks to address some of the abuses, but a clear solution would be to eliminate the pre-grant opposition system. No such system exists in the United States.

Lack of patent enforcement mechanisms: Effective patent enforcement mechanisms facilitate the timely resolution of patent disputes before potentially infringing follow-on products enter the market. They provide notice to patent holders when third parties apply for marketing approval of follow-on products, give patent holders adequate time and opportunity to seek provisional remedies prior to the marketing of the allegedly infringing products, and facilitate timely resolution of patent disputes prior to the expiration of the provisional remedies.

Indian law allows state drug regulatory authorities to grant marketing approvals for generic versions of medicines four years after the original products are first approved. The state regulatory authorities are not required to verify or consider the remaining patent terms of the original products. Therefore, an infringer can obtain marketing authorization from the government for a generic version of an on-patent drug.

- **Trade margin rationalization**: The innovative biopharmaceutical industry provides medicines to certain patients at free or discounted prices to increase access and affordability for uninsured and out-of-pocket patients in India. India's Trade Margin Rationalization (TMR) system, which ostensibly seeks to regulate excessive retail trade margins by other actors in the supply chain, counts these non-market charitable programs as retail transactions and mandates price reductions for U.S. innovative biopharmaceutical products based on these charitable programs. As a result, India's application of TMR is less about regulating excessive retail trade margins and more about imposing arbitrary price controls on innovative medicines.

- **Non-reciprocal tariff treatment**: Tariffs on biopharmaceuticals and their inputs inhibit trade, increase health care costs and divert resources that could instead be directed to investments in biopharmaceutical R&D and manufacturing. For these and other reasons, the United States does not apply most-favored nation (MFN) tariffs to most imported biopharmaceutical products. Unfortunately, biopharmaceutical manufacturers in the United States do not benefit from the same access to India, which applies MFN tariffs averaging 9.8 percent on pharmaceutical products classified under HS Chapter 30. The United States' average applied MFN tariff on these products is 0.2 percent.

JAPAN

PhRMA members have identified the following as the most significant unfair and non-reciprocal trade practices that inhibit U.S. innovation and exports of biopharmaceutical products to Japan:

- **Government pricing and reimbursement systematically devalues U.S. medicines**: Japan employs a complex and draconian system of price controls on innovative medicines that sets prices at launch and re-prices products throughout the patent period. Both the increased frequency of price cuts to patented medicines and the negative impacts from the other pricing rules noted below severely devalues U.S. innovation and makes Japan an outlier among leading economies.

  Annual price cuts to patented medicines: In 2021, Japan moved from the prevailing system of biennial price revisions to an annual system in which prices of innovative medicines are cut to meet undisclosed budget targets. On April 1, 2025, Japan will apply price cuts to 43 percent of patented medicines and break precedent by implementing draconian rules that have never been applied before. The reduction in biopharmaceutical revenues from these upcoming prices cuts is estimated to be 247 billion yen. Moreover, under the current budget plan, drug price cuts account for 46 percent of the funds raised to curb the growth of overall social security spending and to support polices outside of health care.

  Excessive application of re-pricing rules: Over the past several years, Japan has introduced or strengthened re-pricing rules that penalize clinically successful products. In 2016, the "huge seller" re-pricing rule was introduced; since 2018, certain re-pricing rules have been applied on a quarterly basis instead of a biennial basis; and in 2020, a special rule for indication change re-pricing was introduced. Such frequent application and strengthening of re-pricing rules significantly undervalues U.S. innovation, reduces the predictability of drug prices and disincentivizes investment in R&D for additional indications.

  Biased health technology assessment (HTA): Japan implemented an HTA system in April 2019 that focuses solely on valuing health and longevity gains from innovative medicines based on low monetary values that are not indexed to inflation and that are designed to demand excessive price cuts after a product has been launched. By August 2024, 27 of 36 innovative medicines that completed mandatory assessments had their prices cut. Current HTA system reform proposals would apply a unique, intentionally biased formula that would re-price a new, innovative medicine paradoxically lower than the price of an older, clinically inferior comparator.

- **Lack of transparency and due process**: As Japan developed detailed plans to substantially change pricing rules over the past decade, there have been few formal attempts by decision-making bodies to seek input from the U.S. biopharmaceutical industry. For example, despite the major policy issues debated, Japan has not once released the proposed new rules for public comment. In addition, the industry is invited to testify before the Central Social Insurance Medical Council (Chuikyo) on limited occasions with the time allotted for testimony typically limited to a matter of minutes. Frequently, no government proposal is put forward in advance of the Chuikyo meeting on which industry can comment. Except for 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 opportunities for input into the development of these policies, Japan has also failed to publish clear guidelines on how policies will be interpreted and implemented. Even after rules are announced, PhRMA members 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. Moreover, once a biopharmaceutical product is marketed in Japan, government regulations make it exceedingly difficult for the marketing authorization holder to withdraw the product. This lack of transparency and frequent changes to the government rules that set prices at launch and re-price the product throughout the patent term with no ability to withdraw the product have made the Japanese market highly unpredictable and lacking in procedural fairness.

KOREA

PhRMA members have identified the following as the most significant unfair and non-reciprocal trade practices that inhibit U.S. innovation and exports of biopharmaceutical products to Korea:

- **Government pricing and reimbursement systematically devalues U.S. medicines**: Korea's system breaches KORUS because it fails to "appropriately recognize the value of the patented pharmaceutical product or medical device in the amount of reimbursement it provides" under Article 5.2(b)(i). Korea's pricing and reimbursement system is designed to delay market entry and to apply multiple non-market, opaque mechanisms that result in prices for innovative biopharmaceutical products that are among the lowest in the OECD, even though Korea is per capita the 12th wealthiest economy in the world.

  Unfair cost basis: Korea's Drug Reimbursement Evaluation Committee (DREC) 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 threshold was set based on Korean GDP per capita in 2007 and does not reflect that Korean GDP per capita is now more than 90 percent higher. For medicines not subject to the cost-effectiveness threshold, Korea diluted its international reference pricing basket in order to achieve the lowest price.

  Excessive, repeated price cuts: Korea uses multiple rounds of lengthy price "negotiation" to leverage biopharmaceutical innovators to non-market prices, running the clock down to devalue U.S. innovation. First, biopharmaceutical companies must contend with the DREC process described above. Then another agency, the National Health Insurance Service (NHIS), requires additional concessions (e.g., risk-sharing agreements) as a condition of NHIS reimbursement and imposes excessive and repeated price cuts even if the DREC found the medicine to be cost-effective. As a result of this system, eighty-four percent of new medicines launched globally since 2014 are available in the United States compared to just 19 percent in Korea. Innovative medicines launch in Korea an average of 40 months after first launch, typically in the United States. Korea also spends much less on innovative medicines as a share of biopharmaceutical expenditure than other comparable countries.

- **Lack of transparency and due process**: Applicants are often not provided with a satisfactorily informative written basis for evaluations and decisions, as well as reasonable opportunities for appeal. In Article 5.3(5)(e) of KORUS and the side letter, 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." That does not exist in the NHIS process. Since 2010, the Ministry of Health and Welfare (MoHW) has repeatedly changed its pharmaceutical pricing and reimbursement policies without adequate stakeholder consultation, which is inconsistent with KORUS transparency and due process commitments under Article 5.3. KORUS established a Medicines and Medical Devices Committee under Article 5.7, which has never met.

- **Discriminatory system to localize industry**: MoHW designates certain companies as Innovative Pharmaceutical Companies (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 investments in Korea to

prove "innovativeness." As of January 2025, only four of 49 designated IPCs are non-Korean biopharmaceutical companies. This policy violates national treatment obligations and the spirit of KORUS Article 5.1.

- **Patent issues**: While Korea has made progress in terms of implementing the Korea-U.S. Trade Agreement (KORUS), significant issues remain related to ensuring effective patent term extension (Article 18.8(6)(b)) and patent enforcement (Article 18.9)):

  Inadequate patent term extension (PTE): Korea has committed, pursuant to KORUS, to restore a portion of the patent term lost due to the lengthy development and regulatory approval process for new medicines. However, Korea's system is inconsistent with that commitment in that it (1) excludes foreign clinical trials in PTE calculations; (2) lacks due process in PTE procedures; and (3) has an excessively narrow scope of PTE protections. Revisions to the mechanism at the end of 2024 were rammed through without consultation with U.S. stakeholders or U.S. Government. Korea's revised system cherry-picks elements from PTE mechanisms in other markets that in combination further tip the balance against innovators.

  Ineffective patent enforcement: Under KORUS, Korea committed to provide effective patent enforcement mechanisms to facilitate the timely resolution of patent disputes before potentially infringing follow-on generic products enter the market. Korea must give notice to patent holders when others apply for marketing approval of follow-on products; give patent holders adequate time and opportunity to seek provisional remedies prior to the marketing of the allegedly infringing products; and facilitate timely resolution of patent disputes prior to the expiration of the provisional remedies.

  In Korea, delays in preliminary injunctions frustrate the ability of innovators to prevent irreparable damages when potentially infringing products enter the market. The Ministry of Food and Drug Safety has too much discretion 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 canceled.

MEXICO

PhRMA members have identified the following as the most significant unfair and non-reciprocal trade practices that inhibit U.S. innovation and exports of biopharmaceutical products to Mexico:

- **Regulatory data protection (RDP) failures**: International rules, including the U.S.-Mexico-Canada Agreement (USMCA), require regulators to provide regulatory data protection (RDP) for the confidential data that biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval. RDP must protect against both disclosure of test data and, for a limited time, unfair commercial use (e.g., third-party reliance on the data). Further, RDP should be available for both small and biologic molecules.

  Mexico does not provide appropriate RDP for biologic or chemical medicines, contrary to Mexico's USMCA commitments, which must be implemented by July 2025. In June 2012, COFEPRIS issued guidelines to implement RDP for a period not less than five years. As guidelines, however, their validity may be questioned when applied to a specific case. Further, they are not automatically conferred upon marketing approval and routinely require litigation to secure protection and a term of protection commensurate with the time, expense and risk incurred to obtain the subject data. Further, RDP is hard to enforce in Mexico and may be revoked at any time. Mexico must pass binding federal regulations on RDP, including an appropriate duration of protection for biologics.
  In this regard it should be recalled that Mexico agreed to provide ten years of RDP for biologic medicines in the USMCA text signed in 2018. The 2018 USMCA text would have been a major advance to incentivize American innovation and rectified the failure of Mexico to afford reciprocal IP protections to U.S. innovators. Regrettably, this provision was removed during congressional debate over the USMCA in 2019, along with other pro-innovation provisions designed to ensure reciprocal protection of U.S. IP in Canada and Mexico.

- **Patent issues**: While Mexico has made progress in terms of implementing USMCA, significant issues remain related to effective patent enforcement (Article 20.50 and Annex 20-A), patent backlogs (Article 20.44), patent term extensions (Article 20.46) and the regulatory review exception (Article 20.47):

  Ineffective patent enforcement: Pursuant to the USMCA, Mexico must provide effective patent enforcement mechanisms to facilitate the timely resolution of patent disputes before potentially infringing follow-on products enter the market. Specifically, Mexico must (1) provide notice to patent holders when third parties apply for marketing approval of follow-on products; (2) give patent holders adequate time and opportunity to seek provisional remedies (e.g., stays and preliminary injunctions) prior to the marketing of the allegedly infringing products; and (3) facilitate timely resolution of patent disputes prior to the expiration of the provisional remedies.

  Although Mexico adopted a Linkage Resolution in 2003, to date no secondary regulations have been issued and the resolution has not been implemented in a comprehensive and consistent manner. A key deficiency is the limited scope of patents that can be listed in the Linkage Gazette – use patents still require lengthy and costly litigation to achieve inclusion in the

Gazette, and the matter is further exacerbated by a January 2025 court decision holding that use patents should not be published in the Gazette. In addition, Mexico applies linkage in an inconsistent, non-transparent and possibly discriminatory manner. In several cases, marketing authorizations have been issued despite patents being listed in the Gazette.

Inadequate patent term adjustment (PTA) and patent term extension (PTE): Patent backlogs directly reduce the value of granted patents and should be mitigated with PTA mechanisms that compensate for unreasonable delays in the patent examination process. 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, PTE provisions restore a portion of the patent term lost due to the lengthy development and regulatory approval process for new medicines. Mexico remains one of the few members of the OECD that does not provide a PTE mechanism. This situation is exacerbated by the current regulatory delays (discussed below) in approving medicines, resulting in significant patent term lost due to no fault of the inventor or patent owner. Mexico agreed to implement PTE subject to a 4.5-year transition (i.e., before December 2024). Nonetheless, Mexico has yet to promulgate the necessary regulations.

Potential abuse of the regulatory review exception: Regulatory review exceptions (also known as the "Bolar exception,") allow a third party to use a patented invention without the patent holder's permission for the sole purpose of conducting tests and obtaining regulatory approval to market a generic version of the product before the patent expires.

Mexico allows generic manufacturers to import active pharmaceutical ingredients and other raw materials contained in a patented pharmaceutical for purposes of preparing marketing authorizations during the medicine's patent term, per the regulatory review exception in USMCA. However, Mexico fails to impose any limits on the volume of raw materials that can be imported under this exception. Given some of the import volumes reported, importers may be abusing the Bolar exemption by stockpiling and/or selling patent-infringing and potentially substandard medicines in Mexico or elsewhere.

- **Market access delays**: Mexico's regulator (COFEPRIS) has failed to address the significant backlog in reviewing marketing authorizations for new molecules and new indications. This failure is inconsistent with Article 12.F.6.4 of USMCA. In addition, once COFEPRIS grants a marketing authorization, Mexican patients face further delays in accessing innovative medicines due to Mexico's lengthy, non-transparent and uncertain public procurement system, which adds, on average, two years to patient access timelines. In addition, inclusion into the basic formulary or catalog of a public health institution does not automatically result in the purchase and subsequent availability of those medicines to patients. Overall, Mexico's pricing and reimbursement system is not consistent with the USMCA principles on the need to recognize and appropriately value pharmaceuticals (Article 29.6) or Mexico's commitments to provide procedural fairness in the pricing and reimbursement of new pharmaceuticals (Article 29.7).