

**PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA (PhRMA)
SPECIAL 301 SUBMISSION 2018**

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PhRMA 2018 Special 301 Overview

PhRMA 2018 SPECIAL 301 OVERVIEW

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide this submission for the *2018 Special 301 Report*. Established by the Trade Act of 1974, the Special 301 review gives the Administration a critical tool to address damaging market access and intellectual property barriers abroad that harm America's leading innovative and creative industries and the more than 45 million jobs they support across the country.¹

Urgent action is required to address serious market access and intellectual property barriers in the 19 overseas markets named in this submission. As explained further below, biopharmaceutical innovators in the United States face a wide array of discriminatory pricing policies abroad that threaten billions of dollars in lost sales and put American jobs and exports at risk. 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.

The Office of the U.S. Trade Representative and other federal agencies should prioritize action to reverse compulsory licensing in **Malaysia** and to end discriminatory pricing policies in **Canada, Japan** and **Korea**. Government price controls in Canada, Japan, Korea 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 and undermine the expected benefit of intellectual property protections. Ending discriminatory pricing policies in these markets and others could add billions of dollars to research and development for new medicines and lower overall healthcare costs around the world.²

I. The Innovative Biopharmaceutical Sector

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.³ 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

¹ U.S. Department of Commerce, *Intellectual Property and the U.S. Economy: 2016 Update*, September 2016, available at <https://www.uspto.gov/sites/default/files/documents/IPandtheUSEconomySept2016.pdf> (last visited Feb. 8, 2018).

² U.S. Department of Commerce, International Trade Administration, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation*, December 2004.

³ Battelle Technology Partnership Practice, *The Biopharmaceutical Research and Development Enterprise: Growth Platform for Economies around the World*, Battelle Memorial Institute, May 2012, available at http://www.phrma.org/sites/default/files/pdf/phrma_growthplatformforeconomiesaroundtheworld_20120508.pdf (last visited Feb. 8, 2018).

in place at home and abroad, they can continue to bring valuable new medicines to patients and contribute powerfully to the American economy and jobs.

A. Biopharmaceutical innovation delivers value for patients and economies

PhRMA member companies and the more than 800,000 women and men they employ across the United States are devoted to inventing, manufacturing and distributing valuable medicines that enable people to live longer, healthier, and more productive lives.⁴ They work in partnership with universities, clinical researchers, patient organizations, healthcare providers and others to bring new treatments and cures to patients who need them at home and abroad – introducing nearly 600 new therapies since 2000⁵ and investing in many of the over 7,000 new drugs currently in development worldwide.⁶

Pioneering work by biopharmaceutical innovators in the United States contributes significantly to economic growth and supports good-paying jobs in all 50 states. In 2015, biopharmaceutical research and development activity added more than \$1.3 trillion to the U.S. economy and supported 4.8 million American jobs, including indirect and induced jobs.⁷ For all occupations involved in the biopharmaceutical industry, the average total compensation per direct employee is twice the average compensation in any other U.S. private sector industry.⁸ In 2016, the industry exported more than \$52 billion in biopharmaceuticals,⁹ making the sector one of the top U.S. exporters among intellectual property-intensive industries.¹⁰

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 healthcare costs. Between 1950 and 2014, life

⁴ TEconomy Partners; for PhRMA. *The Economic Impact of the U.S. Biopharmaceutical Industry*, July 2017.

⁵ U.S. Food and Drug Administration, "New Drugs at FDA: CDER's new molecular entities and new therapeutic biological products, available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm20025676.htm> (last visited Feb. 8, 2018); and U.S. Food and Drug Administration, Biological approvals by year, available at <http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicalApprovalsbyYear/default.htm> (last visited Feb. 8, 2018).

⁶ *Adis R&D Insight database*, accessed Mar. 2016.

⁷ TEconomy Partners, *The Economic Impact of the US Biopharmaceutical Industry*, Nov. 2017.

⁸ Id.

⁹ PhRMA analysis of data from U.S. Department of Commerce, International Trade Administration, Web site. <http://tse.export.gov/TSE/TSEhome.aspx>.

¹⁰ Industry R&D data from National Science Board of the National Science Foundation, *Science and Engineering Indicators 2012*, 2012; Industry export data from PhRMA analysis of data from U.S. ITA, *TradeStats Express: National Export Data*; Software publishers data from the International Intellectual Property Alliance.

expectancy for women and men in the United States increased by more than a decade¹¹ – adding trillions of dollars to the U.S. economy.¹² 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 2009.¹³

For example, the AIDS death rate has dropped nearly 87% since the approval of antiretroviral treatments in 1995.¹⁴ Today, a 20-year old diagnosed with HIV can expect to live another 50 years.¹⁵ New medicines have cut heart disease deaths by 38%, according to the Centers for Disease Control and Prevention.¹⁶ More than 80% of the increase in life expectancy of cancer patients since 1980 is attributable to new treatments.¹⁷ New hepatitis C therapies approved since 2013 cure over 90% of patients – a more than two-fold increase from previously available treatment options.¹⁸

PhRMA member companies are building on these achievements and pioneering new treatments and cures for some of the world's most devastating diseases.

¹¹ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Health, United States, 2015*, Table 15, May 2016, available at <https://www.cdc.gov/nchs/data/abus/abus15.pdf> (last visited Feb. 8, 2018).

¹² Between 1970 and 2000, increased longevity added about \$3.2 trillion per year to national wealth in the United States. See Murphy, K.M. and R.H. Topel, "The Value of Health and Longevity," National Bureau of Economic Research, June 2005, available at <http://www.nber.org/papers/w11405> (last visited Feb. 8, 2018).

¹³ Lichtenberg, F.R., "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 Feb. 8, 2018).

¹⁴ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Health, United States, 2014*, Table 29, May 2015, available at <http://www.cdc.gov/nchs/data/abus/abus14.pdf> (last visited Feb. 8, 2018).

¹⁵ *Id.*

¹⁶ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "New CDC Vital Signs: CDC finds 200,000 heart disease deaths could be prevented," Dec. 2013, available at <https://www.cdc.gov/media/releases/2013/p0903-vs-heart-disease.html> (last visited Feb. 8, 2018); and U.S. Department 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," Sep. 2013, available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a4.htm> (last visited Feb. 8, 2018).

¹⁷ Sun, E., D. Lakdawalla et al., "The determinants of recent gains in cancer survival: an analysis of the surveillance, epidemiology and end results [SEER] database," *Journal of Clinical Oncology*, 2008, available at http://ascopubs.org/doi/abs/10.1200/jco.2008.26.15_suppl.6616 (last visited Feb. 8, 2018); A more recent article by the American Cancer Society (dated Jan. 7, 2016) reported that cancer death rates have been reduced nearly 23% since 1991. See <http://www.cancer.org/cancer/news/news/cancer-statistics-report-death-rate-down-23-percent-in-21-years> (last visited Feb. 8, 2018).

¹⁸ See, for example, Tracey Walker, "FDA approves Viekira Pak to treat hepatitis C," Dec. 19, 2014, available at

<http://formularyjournal.modernmedicine.com/formulary-journal/news/fda-approves-viekira-pak-treat-hepatitis-c?page=full> (last visited Feb. 8, 2018)

Researchers are developing more than 1,200 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.¹⁹ 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, which today lack effective treatments.²⁰

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. healthcare system at least \$5 billion.²¹ Every \$24 spent on new medicines for cardiovascular diseases in OECD countries saves \$89 in hospitalization costs.²² Treating high blood pressure according to clinical guidelines would result in annual health system savings of about \$15.6 billion.²³ In addition to lowering overall healthcare costs, appropriate use of medicines can increase worker productivity by reducing rates of absenteeism and short-term disability.²⁴

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 340 initiatives with more than 600 partners to help shape sustainable solutions that improve the health of all people.²⁵ Last year, more than 20 biopharmaceutical companies joined the World Bank and the Union for International Cancer Control to launch Access Accelerated – a first-of-its-kind global

¹⁹ *Adis R&D Insight database*.

²⁰ *Id.*

²¹ Grabowski, D., D. Lakdawalla et al., "The Large Social Value Resulting From Use Of Statins Warrants Steps To Improve Adherence And Broaden Treatment," *Health Affairs*, Oct. 2012, available at <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.1120> (last visited Feb. 8, 2018).

²² Lichtenberg, F., "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 Feb. 8, 2018).

²³ Cutler, D.M., G. Long et al., "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation," *Health Affairs*, Jan. 2007, available at <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.26.1.97> (last visited Feb. 8, 2018).

²⁴ Carls G.S., M.C. Roebuck et al., "Impact of medication adherence on absenteeism and short-term disability for five chronic diseases," *Journal of Occupational and Environmental Medicine*, July 2012, available at http://journals.lww.com/joem/Abstract/2012/07000/Impact_of_Medication_Adherence_on_Absenteeism_and.7.aspx (last visited Feb. 8, 2018).

²⁵ See Global Health Progress, available at <http://www.globalhealthprogress.org>.

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.²⁶

Between 2000 and 2011, biopharmaceutical innovators contributed an estimated \$98.4 billion dollars toward achieving health-related Millennium Development Goals.²⁷ Despite a three percent drop in public funding for neglected disease (excluding Ebola) research and development in 2014, biopharmaceutical industry funding increased by 28% during the same period.²⁸

B. Policies that power prevention, treatments and cures

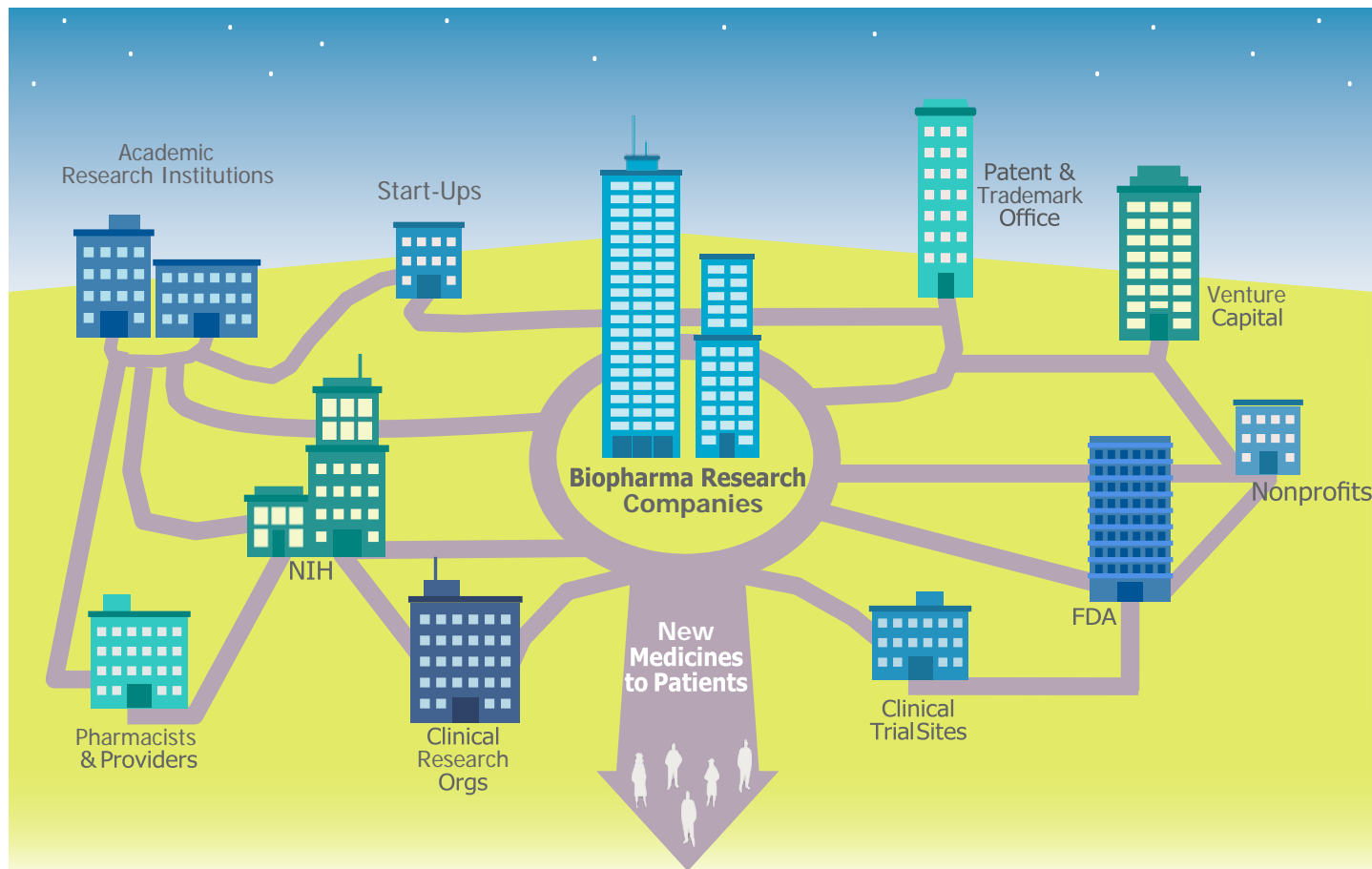
Strong protection and enforcement of patents, regulatory test data and other intellectual property, and fair and transparent market access to overseas markets provide powerful incentives that drive and sustain substantial investments in valuable treatments and cures. Where markets are open and intellectual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

²⁶ Access Accelerated, "Biopharma Companies Partner and Launch First-of-its-Kind Global Initiative to Address Rise of Non-Communicable Diseases," Jan. 2017, available at <https://accessaccelerated.org/22-biopharma-companies-partner-launch-first-kind-global-initiative-address-rise-non-communicable-diseases/> (last visited Feb. 8, 2018).

²⁷ Morris, Jeremiah et al., *The Pharmaceutical Industry's Contributions to the United Nations Millennium Development Goals*, Hudson Institute, May 2013, available at http://www.hudson.org/content/researchattachments/attachment/1260/the_pharmaceutical_industry_s_contributions_to_the_un_millennium_development_goals.pdf (last visited Feb. 8, 2018).

²⁸ Global Funding of Innovation for Neglected Diseases: G-Finder.

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 between multiple partners across borders and around the world. Strong intellectual property protection and enforcement enable innovators to license their patented inventions to others with the certainty that valuable information disclosed is secure. Thanks to the technology transfer framework established by the Bayh-Dole Act, 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 \$518 million to the U.S. economy and supporting more than 3.8 million American jobs between 1996 and 2013, according to one study.²⁹ Such collaboration is delivering similar benefits in other countries. Recent research in the United Kingdom found that public expenditure on biomedical and health research

²⁹ Pressman, L., D. Roessner et al., “The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2013,” Mar. 2015, available at https://www.bio.org/sites/default/files/files/BIO_2015_Update_of_I-O_Eco_Imp.pdf (last visited Feb. 8, 2018).

leveraged even greater private sector investment, delivering a total rate of return to public biomedical and health research of up to 28%.³⁰

Patents and non-discriminatory pricing policies promote competition and greater treatment options. In exchange for the limited period of protection 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.³¹ 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 claims hepatitis C treatment is less expensive in America than in other western countries.³²

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 ten years or more. By the 2000s, that period had declined to about two years.³³ Generic competitors now challenge patents earlier and more frequently – even as early as four years after the launch of an innovative medicine.³⁴ Today, over 94% of innovative medicines experience at least one patent challenge prior to generic entry – compared to 25% in 1995.³⁵

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

³⁰ Sussex, J., Y. Feng 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://bmcmmedicine.biomedcentral.com/articles/10.1186/s12916-016-0564-z> (last visited Feb. 8, 2018).

³¹ International Federation of Pharmaceutical Manufacturers and Associations, *The New Frontiers of Biopharmaceutical Innovation, 2012*, available at http://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_New_Frontiers_Biopharma_Innovation_2012_Web.pdf (last visited Feb. 8, 2018).

³² 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 Feb. 8, 2018).

³³ Tufts Center for the Study of Drug Development, “First-in-class drugs in competitive development races with later entrants,” *Impact Report*, Dec. 2015, available at <http://csdd.tufts.edu/files/uploads/Summary-NovDeclR2015.pdf> (last visited Feb. 8, 2018).

³⁴ Grabowski, H., G. Long et al., “Updated trends in US brand-name and generic drug competition,” *Journal of Medical Economics*, Sep. 2016, available at <https://www.ncbi.nlm.nih.gov/pubmed/27064194> (last visited Feb. 8, 2018).

³⁵ *Id.*

accelerates new product launches in higher and lower income countries alike.³⁶ Launching a medicine in a particular country also has important effects on the whole healthcare system. For instance, when a new medicine is introduced, biopharmaceutical companies invest in educating healthcare providers on the science and appropriate use of that medicine.³⁷ This investment later enables accelerated acceptance of generic versions once relevant patents expire.

Strong intellectual property protection and enforcement has long been a critical goal of America's trade policy agenda. Strong intellectual property protection and enforcement at home and abroad provides essential incentives for investment in the biopharmaceutical sector and in all of the innovative industries that today account for nearly 40% of U.S. gross domestic product.³⁸ 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.³⁹ And even those that succeed often fail to make a profit. Biopharmaceutical firms face similar challenges. Just two of every ten marketed medicines achieve returns that match or exceed average research and development costs.⁴⁰ Of the approximately 1,200 biopharmaceutical companies in the United States, more than 90% do not earn a profit.⁴¹

³⁶ Cockburn, I.M. et al., "Patents and the Global Diffusion of New Drugs," *National Bureau of Economic Research*, Sep. 2014, available at <http://nber.org/papers/w20492> (last visited Feb. 8, 2018).

³⁷ Wilsdon, Tim and Glyn Chambers, "The wider value delivered to patients, healthcare systems and competitors when innovators launch new products," *Charles River Associates*, Apr. 2013.

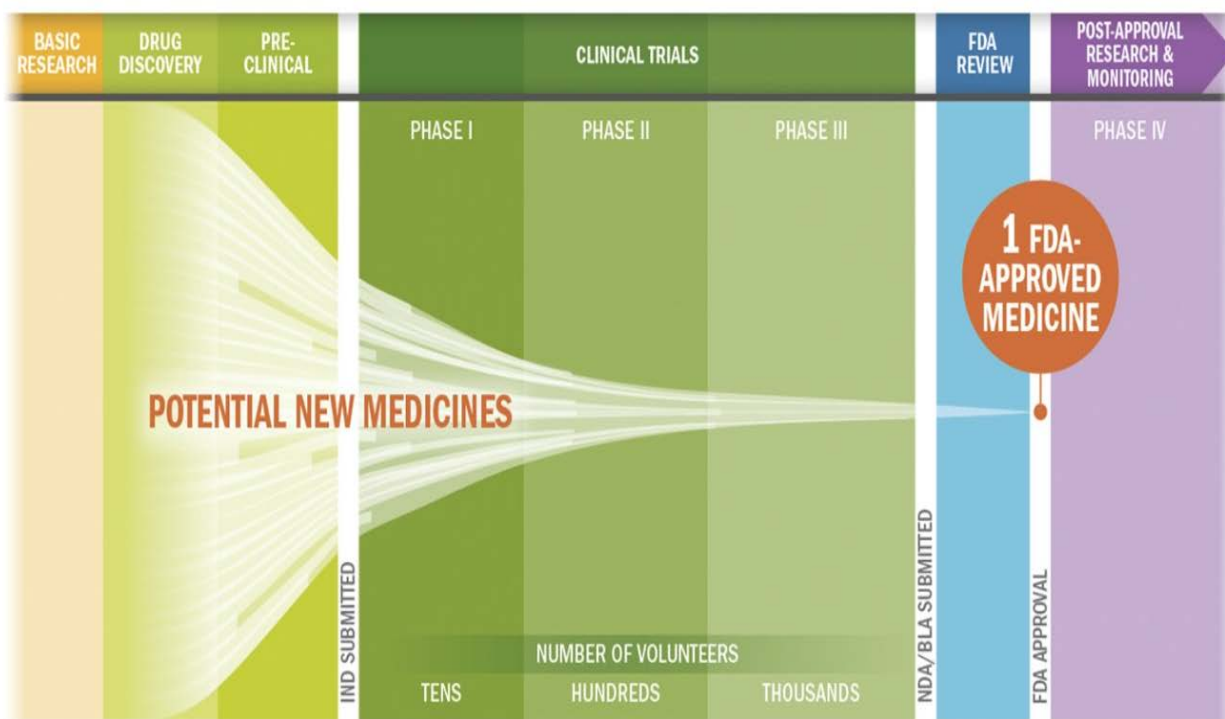
³⁸ U.S. Department of Commerce, *Intellectual Property and the U.S. Economy: 2016 Update*, Sep. 2016, available at <https://www.uspto.gov/sites/default/files/documents/IPandtheUSEconomySept2016.pdf> (last visited Feb. 8, 2018).

³⁹ Gage, D., "The Venture Capital Secret: 3 Out of 4 Start-Ups Fail," *The Wall Street Journal*, Sep. 2012, available at <http://www.wsj.com/articles/SB10000872396390443720204578004980476429190> (last visited Feb. 8, 2018).

⁴⁰ Vernon, J.A., J.H. Golec and J.A. DiMasi, "Drug development costs when financial risk is measured using the fama-french three-factor model," *Health Economics*, Aug. 2010, available at <http://onlinelibrary.wiley.com/doi/10.1002/hec.1538/abstract> (last visited Feb. 8, 2018).

⁴¹ Biotechnology Industry Organization, *Unleashing the Next Generation of Biotechnology Innovation*, available at https://www.bio.org/sites/default/files/files/Whitepaper-Final_0.pdf (last visited Feb. 8, 2018).

Figure 2: The biopharmaceutical research and development process



Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

The lengthy approval process for new products makes the research-based biopharmaceutical sector particularly reliant on the temporary protection intellectual property rights provide.⁴² 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.⁴³ In 2013, the innovative biopharmaceutical industry sponsored nearly 6,200 clinical trials across all 50 states.⁴⁴ Test data generated through those trials is then submitted to national regulatory agencies for marketing approval.

⁴² Without patent protection, an estimated 65% 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 Feb. 8, 2018).

⁴³ PhRMA adaptation based on Dimasi J.A., "Cost of Developing a New Drug," Tufts Center for the Study of Drug Development, *R&D Cost Study Briefing* available at http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf (last visited Feb. 8, 2018); and U.S. Food and Drug Administration, *Development and Approval Process (Drugs)*, available at <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/> (last visited Feb. 8, 2018).

⁴⁴ Battelle Technology Partnership Practice, *Biopharmaceutical Industry-sponsored Clinical Trials: Impact on State Economies*, Battelle Memorial Institute, Feb. 2015, available at <http://www.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-sponsored-clinical-trials-impact-on-state-economies.pdf> (last visited Feb. 8, 2018).

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.⁴⁵ In 2015 alone, American biopharmaceutical companies invested approximately \$75 billion in research and development.⁴⁶ Clinical trials can account for more than 60% 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.⁴⁷ The process of evaluating potential new therapies is so exacting that less than 12% of all potential new drugs entering clinical trials result in an approved medicine.⁴⁸

Advances in the treatment of diseases typically are not driven by large, dramatic developments, but more commonly build on a series of incremental 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 healthcare providers gain real-world experience. Incremental 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.⁴⁹ And more than 60% of therapies on the World Health Organization's (WHO's) Essential Medicines List relate to improvements on older treatments.⁵⁰ This step by step transformation in knowledge has led to increased survival, improved patient outcomes and enhanced quality of life for many patients.⁵¹

⁴⁵ Pham, N., *IP-Intensive Manufacturing Industries: Driving U.S. Economic Growth*, NDP Analytics, Mar. 2015, available at <http://www.ndpanalytics.com/ip-intensive-manufacturing-industries-driving-us-economic-growth-2015/> (last visited Feb. 8, 2018).

⁴⁶ TEconomy Partners, U.S. Biopharmaceutical Industry Investments in Research & Development in 2015, July 2017.

⁴⁷ IFPMA, *New Frontiers of Biopharmaceutical Innovation, 2012*, available at http://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_New_Frontiers_Biopharma_Innovation_2012_Web.pdf (last visited Feb. 8, 2018).

⁴⁸ PhRMA adaptation based on Dimasi JA. Cost of developing a new drug. Tufts Center for the Study of Drug Development (CSDD). R&D Cost Study Briefing (Nov. 18, 2014), available at http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf (last visited Feb. 8, 2018).

⁴⁹ Jin, G. and S. Wong, "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 Feb. 8, 2018).

⁵⁰ See Cohen, J. and K. Kaitin, "Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice," *American Journal 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 Feb. 8, 2018).

⁵¹ Goss, T.F., E.H. Picard, and A. Tarab, *Recognizing the Value in Oncology Innovation*, Boston Healthcare Associates, June 2012, available at http://www.phrma.org/sites/default/files/flash/phrma_innovation_oncology.pdf (last visited Feb. 8, 2018).

II. Practices that Undermine Innovation and Access to New Treatments

To research, develop and deliver new treatments and cures for patients who need them around the world, biopharmaceutical innovators must be able to secure and effectively enforce patents and protect regulatory test data. They must be able to obtain timely marketing approval for new medicines and make those therapies available to patients according to reimbursement rules and procedures that are fair, transparent, reasonable and non-discriminatory, and that appropriately value and reward patented pharmaceuticals.

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% of all countries are members of the Paris Convention and the PCT.

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 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,⁵² 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 not only in fully and effectively implementing, but also in reiterating and enforcing, TRIPS minimum standards.

Critically, the United States and other countries have promoted, given effect to and built on the global minimum standards of protection provided by these international rules 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

⁵² 164 members as of July 29, 2016.

access for innovative medicines. In many cases, they appear to be inconsistent with global, regional and bilateral rules.

Multilateral organizations that once served as custodians of the international rules-based system increasingly are seeking 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, the WHO, the United Nations Development Program (UNDP), the United Nations Conference on Trade and Development (UNCTAD) and other organizations are promoting acts, policies and practices globally and in specific countries that prevent biopharmaceutical innovators from securing and maintaining patents, protecting regulatory test data and from enjoying fair and equitable market access.⁵³

The following sections highlight the most serious challenges facing PhRMA members around the world. The acts, policies and practices of specific countries are described further below. PhRMA members urge USTR and other federal agencies to highlight these challenges, acts, policies and practices in the 2018 Special 301 Report and to use all available tools to address and resolve them.

A. Practices that deny fair and equitable market access

The Special 301 provisions require USTR to identify countries that deny fair and equitable market access to U.S. persons who rely on intellectual property protection. PhRMA members increasingly encounter acts, policies and practices abroad that deny fair and equitable market access. These barriers undermine the ability of biopharmaceutical innovators in the United States to bring new medicines to patients around the world and to invest in future treatments and cures. By contributing to an unpredictable business environment, they threaten U.S. exports and jobs and delay access to or reduce the availability of new medicines in key countries. Some examples of the most serious barriers that prevent access to innovative medicines include:

- *Discriminatory pricing policies.* In many countries, governments are the principal purchaser of medicines and effectively dictate prices. Often, this dominant position is used to benefit domestic drug companies and wholesalers at the expense of innovators in the United States. For example, changes Japan announced to its pricing policies in December use biased criteria to select those companies that will realize the most favorable prices. The criteria – including the number of local clinical trials and whether the product was launched first in **Japan** – favor domestic companies at the expense of American innovators. A new pricing policy **Korea** announced in 2016 would impose similarly discriminatory rules for premium pricing.

⁵³ Hudson Institute, “The Patent Truth about Health, Innovation and Access,” 2016, available at <https://s3.amazonaws.com/media.hudson.org/files/publications/20160706ThePatentTruthAboutHealthInnovationandAccess.pdf> (last visited Feb. 8, 2018).

- *Import barriers.* High tariffs and taxes can limit U.S. biopharmaceutical exports and prevent access to new treatments in overseas markets. Under the WTO Pharmaceutical Agreement, the United States and the 33 other countries do not impose any import duties on a wide range of medicines and other health products.⁵⁴ However, biopharmaceutical innovators in the United States do not benefit from the same access to China, India and other emerging economies that are leading producers and net exporters of drugs⁵⁵ and active pharmaceutical ingredients⁵⁶ but 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%. This means that a larger proportion of medicines distributed around the world are potentially subject to tariffs.⁵⁷ For example, the United States is by far the largest market for Indian generic drug exports,⁵⁸ but **India's** basic import duties on biopharmaceutical products and active ingredients average about ten percent.⁵⁹ Additional duties and assessments can raise the effective import duty to as high as 20% or more.⁶⁰ Federal and state taxes on medicines in **Brazil** can add nearly 34% to the retail price of medicines – among the highest tax burdens on medicines in the world.⁶¹ Other countries that maintain high tariffs and taxes on imported medicines include **Argentina, Russia and Thailand.**

⁵⁴ General Agreement on Tariffs and Trade, “Trade in Pharmaceutical Products” (L/7430), Mar. 1994, available at <https://ustr.gov/sites/default/files/WTO%20Pharmaceutrical%20Agreement%20March%201994.pdf> (last visited Feb. 8, 2018).

⁵⁵ WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade*, 2012, available at https://www.wto.org/english/res_e/booksp_e/pantiwhowipowtoweb13_e.pdf (last visited Feb. 8, 2018).

⁵⁶ China is the world’s leader in active pharmaceutical ingredient manufacturing and exports. See Huang, Y., “Chinese Pharma: A Global Health Game Changer?,” Council on Foreign Relations, Mar. 2015, available at <http://www.cfr.org/china/chinese-pharma-global-health-game-changer/p36365> (last visited Feb. 8, 2018).

⁵⁷ Banik, N. and P. Stevens, “Pharmaceutical tariffs, trade flows and emerging economies,” Geneva Network, Sep. 2015, available at <http://geneva-network.com/wp-content/uploads/2015/09/GN-Tariffs-on-medicines.pdf> (last visited Feb. 8, 2018).

⁵⁸ Pharmaceuticals Export Promotion Council of India, *12th Annual Report 2015-16*, 2016, available at <http://www.pharmexcil.com/annual-report> (last visited Feb. 8, 2018).

⁵⁹ Banik, N. and P. Stevens, “Pharmaceutical tariffs, trade flows and emerging economies,” Geneva Network, September 2015, available at <http://geneva-network.com/wp-content/uploads/2015/09/GN-Tariffs-on-medicines.pdf> (last visited Feb. 8, 2018).

⁶⁰ Olcay, M. and R. Laing, “Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation,” World Health Organization, May 2005, available at <http://www.who.int/intellectualproperty/studies/TariffsOnEssentialMedicines.pdf> (last visited Feb. 8, 2018).

⁶¹ Globally, on average, taxes account for 6.3% of the retail price of medicines. See EMIS, “Pharmaceutical Sector in Brazil,” Dec. 2013, available at <https://www.emis.com/sites/default/files/EMIS%20Insight%20-%20Brazil%20Pharmaceutical%20Sector.pdf> (last visited Feb. 8, 2018).

- *Regulatory approval delays.* **China** is making significant strides in reforming and strengthening its regulatory framework, but remains an outlier in the drug approval process compared to other regulatory authorities, with new medicines typically taking three to five years longer to reach the China market than other major markets. In other words, a "drug lag" remains in China. Other markets with complex and lengthy regulatory approval processes include **Korea, Russia and Turkey**. Accelerating regulatory approval in these countries and others will improve the efficiency of global drug development, facilitate U.S. exports and reduce the time it takes for new medicines to reach patients.
- *Government pricing and reimbursement delays.* Restrictive government pricing and reimbursement policies delay market access for biopharmaceutical innovators in the United States and prevent timely patient access to new treatments and cures. For example, prior to 2017, **China** had only undertaken two substantive updates (2004 and 2009) to the National Reimbursement Drug List. In **Mexico**, delays can stretch as long as 1,500 days or more, on average, compared to 230 days in other countries.⁶² PhRMA is encouraged by efforts China and Mexico have made to accelerate updates to their reimbursement lists. However, patients would be better served by a model that allows new drugs to be reviewed for reimbursement on a regular, or rolling, basis.
- *Lack of transparency and due process.* Lack of transparency, due process, and delayed reimbursement decisions are widespread across the world. For example, as **Japan** developed its detailed plans to overall pricing policies, there were few formal attempts by the decision-making bodies to seek input from stakeholders, including the innovative pharmaceutical industry. In **Mexico**, excessive regulatory approval delays are compounded by consolidated procurement processes that lack transparency and are applied inconsistently. In **Turkey**, 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.

In recent years, America's biopharmaceutical sector has witnessed a surge in the number and severity of discriminatory pricing policies. Such measures threaten serious damage in the countries that propose them and can have significant ripple effects across other markets. For example, price cuts implemented in one country can directly and indirectly impact the price of medicines in many other markets due to international reference pricing, where a government considers the price of a medicine across a set (or "basket") of countries to determine the price of medicine in its own country. This can

⁶² Mexico data provided by the Asociación Mexicana de Industrias de Investigación Farmacéutica. Comparison data from the European Federation of Pharmaceutical Industries and Associations (EFPIA) *Patients' W.A.I.T. Indicator Report*, available at <http://studylib.net/doc/7634123/patients--w.a.i.t.-indicator--report-201> (last visited Feb. 8, 2018). See also Salieri, G. and F. Fuentes, "Biopharmaceutical Innovation in Mexico: At the Crossroads," Fundación IDEA, 2016, available at <http://geneva-network.com/article/biopharmaceutical-innovation-mexico-crossroads/> (last visited Feb. 8, 2018).

artificially depress prices below market value and restrict competition. It may result in product shortages for medicines patients need.

Some governments have proposed or implemented pricing policies without a predictable, transparent, and consultative processes. Such policies typically put short-term government objectives ahead of long-term strategies that would ensure continued R&D into medicines that patients need most. A 2004 Commerce Department study⁶³ found that many countries employ systems, such as reference pricing, that “rely heavily on government fiat to set prices rather than competition in the marketplace.” The report showed that moving to market-based systems would add billions to research and development for new medicines and lower overall healthcare costs around the world by promoting greater efficiencies in off-patent markets.

Other examples of damaging pricing policies include *ad hoc* government price cuts, international reference pricing, therapeutic reference pricing, and mandatory rebates. Such measures can delay or reduce the availability of new medicines and can contribute to an unpredictable business environment in foreign markets for U.S. companies.

- *Ad Hoc and Arbitrary Government Price Cuts.* *Ad hoc* and arbitrary price cuts include measures employed by some countries to meet short-term budgetary demands without considering long-term implications to innovation and other critical policies. **Japan** announced in December that approximately one-third of patented medicines would be subject to biennial price cuts. Other countries, such as **Colombia**, are using *ad hoc* price cuts as an alternative to issuing a compulsory license. In 2017, Colombia issued a declaration of public interest (DPI) – typically a precursor to issuing a compulsory license – to secure a substantial mandatory price reduction on an innovative leukemia medicine, effectively wiping out the expected value of the patent. At no point was it suggested, let alone demonstrated, that the DPI was needed due to a lack of patient access.
- *International Reference Pricing (IRP).* IRP is a cost containment mechanism used by many of the countries identified in these comments whereby a government considers the price of a medicine in other countries to establish the price in its own country. The reference price for a medicine is calculated by considering the price of the same medicine across a set (or “basket”) of countries using one of several possible methodologies. IRP is a suboptimal tool for setting medicine prices because it imports prices from other countries that typically have different disease burdens, indications, willingness (preferences) and ability (income) to pay, and market structures. **Canada** has proposed amending its list of referenced countries to replace the U.S. with countries which are poorer and/or have onerous price control policies.

⁶³ U.S. Department of Commerce, International Trade Administration, Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation, Dec. 2004.

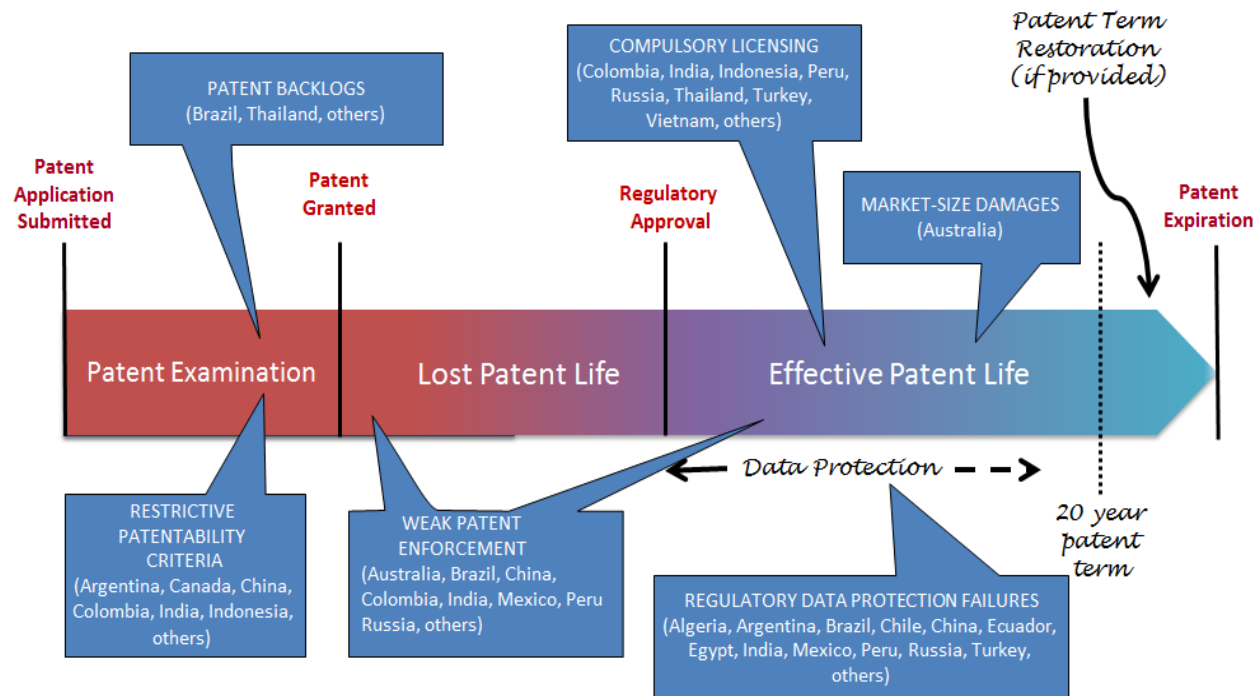
- *Therapeutic Reference Pricing (TRP)*. TRP is a cost containment mechanism whereby a maximum reimbursement limit (or reference price) is set for a group of medicines within a country that is ultimately designated as a unique cluster of “pharmacological-therapeutic equivalents.” TRP fails to account for the therapeutic differences between drugs in the same class because it assumes without evidence that all products used to treat the same condition are interchangeable. Treating medicines as if they are identical can harm patients, erode the benefits of patent protection, impede competition, and chill future innovation. TRP is common in several **European Union** countries, as well as in **Korea**, which bases prices of patented medicines on heavily discounted generic products deemed to be in the same therapeutic class.
- *Mandatory Discounts and Rebates*. Rebates are measures whereby payers achieve a lower real purchase cost than what they would have incurred at list price levels. In rebate systems, a price reduction is negotiated with the payer while maintaining the official price of a product. Mandatory rebates can negatively impact a company’s ability to plan ahead, and contribute to creating a highly unpredictable business environment. For example, for reimbursed products, **Turkey** levies a 41% mandatory discount off the lowest price in a reference basket of six countries, including Greece.

Urgent action is needed to address and resolve these barriers and to ensure that U.S. innovation is appropriately valued and that patients have faster access to new treatments and cures, including through effective enforcement of U.S. trade agreements.

B. Practices that undermine biopharmaceutical innovation

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

Figure 3: Biopharmaceutical intellectual property challenges



Restrictive Patentability Criteria

To bring valuable new medicines to patients, biopharmaceutical innovators must be able to secure patents on all inventions that are new, involve an inventive step and are capable of industrial application.⁶⁴ 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

⁶⁴ See, generally, TRIPS Article 27.1.

treatments that can improve health outcomes⁶⁵ and reduce costs⁶⁶ 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, *per se*, prevent the patenting of a wide range of specific improvements to existing medicines – improvements that are valuable to patients and payers and that require significant investment and research to develop. For example, **Argentina** issued regulations in 2012 that prevent biopharmaceutical innovators from securing patents on certain types of inventions, including new dosage forms and combinations. In the **Philippines**, national law limits patentability of new forms and new uses of existing medicines. **Indonesia** adopted a new patent law in 2016 that similarly prohibits patents for new forms and new uses of existing medicines. **India**'s Patent Law prohibits patents on known substances, unless applicants can demonstrate they meet an additional “enhanced therapeutic efficacy” test. While UNDP does not appear to have specialized expertise on intellectual property matters, it issued patent examination

⁶⁵ 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%, compared to about 50% 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, William H. et al., A Blueprint for Pharmacy Benefit Managers to Increase Value, *American Journal of Managed Care*, Feb. 2009, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2737824/> (last visited Feb. 8, 2018).

⁶⁶ 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 incremental 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 healthcare providers. See Osterberg, Lars and Terrence Blaschke, “Adherence to Medication,” *New England Journal of Medicine*, Aug. 2005, available at <http://www.nejm.org/doi/full/10.1056/NEJMra050100> (last visited Feb. 8, 2018); and DiMatteo, M. Robin, “Variations in Patients’ Adherence to Medical Recommendations: A Quantitative Review of 50 Years of Research,” *Medical Care*, Mar. 2004, available at http://journals.lww.com/lww-medicalcare/Abstract/2004/03000/Variations_in_Patients__Adherence_to_Medical.2.aspx (last visited Feb. 8, 2018); and DiMasi, Joseph A., *Price Trends for Prescription Pharmaceuticals 1995-1999*, background report prepared for the Department of Health and Human Services Conference on Pharmaceutical Pricing Practices, Utilization and Costs, Aug. 2000, available at <https://aspe.hhs.gov/basic-report/price-trends-prescription-pharmaceuticals-1995-1999> (last visited Feb. 8, 2018).

guidelines in 2016 that, if followed, would prevent innovators from securing patents on many kinds of biopharmaceutical inventions.⁶⁷

- *Restrictions on post-filing submissions.* Unlike patent offices in the United States, Europe, Japan, Korea and other major markets, **China's** State Intellectual Property Office (SIPO) does not consistently accept data generated after a patent is filed during patent prosecution to describe inventions or satisfy inventive step requirements. This practice has caused significant uncertainty about the ability to obtain and maintain biopharmaceutical patents in China and caused denials of patents on new medicines in that country that received patents in other jurisdictions. In 2016, SIPO issued draft Patent Examination Guidelines that would require examiners to consider post-filing experimental data and that appear intended to implement its December 2013 U.S.-China Joint Commission on Commerce and Trade (JCCT) commitment to allow patent applicants to submit additional data after filing patent applications. PhRMA and other associations representing the innovative biopharmaceutical sector provided comments on the draft Guidelines. We look forward to final Guidelines that reflect those comments.

Restrictive patentability criteria in many of these countries and others appear to be contrary to 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. 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 appreciate steps USTR and other federal agencies have taken to address restrictive patentability criteria and look forward to continuing to work closely with these agencies to secure concrete progress and real results. Effective enforcement of U.S. trade agreements is needed to resolve these challenges in particular countries and to prevent others from adopting similar practices.

Patent Backlogs

Long patent examination and approval backlogs harm domestic and overseas inventors in every economic sector. Backlogs undermine incentives to innovate, prevent timely patient access to valuable new treatments and cures, and impose huge societal costs.⁶⁸ Because the term of a patent begins on the date an application is filed,

⁶⁷ 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 Feb. 8, 2018).

⁶⁸ Schultz, M. and K. Madigan, "The Long Wait for Innovation: The Global Patent Pendency Problem," George Mason University, Center for the Protection of Intellectual Property, 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 Feb. 8, 2018).

unreasonable delays can directly reduce the value of granted patents and undermine investment in future research. For biopharmaceutical companies, patent backlogs can postpone the introduction of new medicines.⁶⁹ They create legal uncertainty for research-based and generic companies alike, and can increase the time and cost associated with bringing a new treatment to market.

Patent backlogs are a challenge around the world, but a few countries stand out for persistently long delays. In Brazil and Thailand, for example, it can take ten years or more to secure a patent on a new medicine.⁷⁰ Thailand approved a patent application filed by one PhRMA member six weeks before the patent expired. The situation is only somewhat better in markets like India, where it takes an average of six years to secure a patent.⁷¹ In 2015, India granted one patent based on an application filed 19 years earlier.⁷² In Brazil, the patent backlog challenge is compounded by an unnecessary dual examination process for biopharmaceutical patent applications. The Brazilian Health Surveillance Agency (ANVISA) must review all patent applications for new medicines, in addition to the formal patent examination process conducted by the Brazilian Patent Office.⁷³

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.⁷⁴ 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% and its sales growth decreases by 28% on average over the following

⁶⁹ Business Standard, *Delay in Patents Can Slow Down Improvements in Medicines: Experts*, October 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 Feb. 8, 2018).

⁷⁰ Schultz, M. and K. Madigan, "The Long Wait for Innovation: The Global Patent Pendency Problem," George Mason University, Center for the Protection of Intellectual Property, 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 Feb. 8, 2018).

⁷¹ *Id.*

⁷² IndiaSpend, *Patent Delays Threaten 'Make In India'*, Jan. 2016, available at <http://www.indiaspend.com/cover-story/patent-delays-threaten-make-in-india-67033> (last visited Feb. 8, 2018).

⁷³ Cipriano, M., "Biodiversity Law Reform Spurs Innovation, But Patent Backlog Remains," Oct. 2016, available at <https://pink.pharmamedtechbi.com/PS119423/Biodiversity-Law-Reform-Spurs-Innovation-But-Patent-Backlog-Remains> (last visited Feb. 8, 2018).

⁷⁴ London Economics, *Patent Backlogs and Mutual Recognition report to the UK Intellectual Property Office*, Jan. 2010, available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/328678/p-backlog-report.pdf (last visited Feb. 8, 2018).

five years.⁷⁵ Each year a patent application is delayed, the average number of subsequent patents granted decreases by 14%, and the probability that a startup will go public is cut in half.⁷⁶

PhRMA members support patent term restoration provisions in trade agreements and national laws to address unreasonable patent examination delays. They support initiatives to increase the efficiency of patent prosecution and reduce patent backlogs, including the PCT and work sharing arrangements through the IP5 and Patent Prosecution Highway (PPH) programs. Through these and other initiatives, national and regional patent offices in the European Union, Japan, Korea, Mexico and elsewhere are succeeding in reducing patent examination delays. However, a recent review by the **European Union** of Supplementary Protection Certificates and other intellectual property policies threatens to reopen longstanding legislation and potentially weaken patent term restoration mechanisms in Europe. Further work is needed to consolidate gains in patent protections and to extend effective models to other countries.

Compulsory Licensing

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

Some governments, including **India, Indonesia** and **Malaysia**, have issued compulsory licenses (CLs) that allow local companies to make, use, sell or import particular patented medicines without the consent of the patent holder. Other governments, including **Chile, Colombia, Russia, Turkey** and **Vietnam**, have adopted or considered resolutions, laws or regulations that promote or provide broad discretion to issue such licenses. PhRMA believes governments should grant CLs in accordance with international rules and only in exceptional circumstances and as a last resort. Decisions should be made on public health grounds through fair and transparent processes that involve participation by all stakeholders and consider all relevant facts and options.

Experience and recent research demonstrates that compulsory licensing is not an effective way to improve access or achieve other public health objectives. It does not

⁷⁵ Farre-Mensa, J., D. Hegde, and A. Ljungqvist, "The Bright Side of Patents," USPTO Economic Working paper No. 2015-5, Dec. 15, 2015, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2704028 (last visited Feb. 8, 2018).

⁷⁶ *Id.*

necessarily lower prices⁷⁷ or speed access⁷⁸ in the short-term, or provide sustainable or comprehensive solutions to longer-term challenges. It does not address systemic barriers to access – from weak healthcare delivery systems to low national healthcare funding and high taxes and tariffs on medicines. Compulsory licensing is particularly ineffective relative to the many alternatives available. Biopharmaceutical innovators support different tools and programs that make medicines available to patients who could not otherwise afford them, including drug donation and differential pricing programs, voluntary licensing and non-assert declarations.⁷⁹ In sub-Saharan Africa, for example, the majority of antiretrovirals are manufactured under voluntary licenses to local generic drug companies.⁸⁰

Unfortunately, some countries appear to be using CLs to promote the local production of medicines at the expense of manufacturers and jobs in the United States and elsewhere.⁸¹ For example, Malaysia issued a CL in 2017 in a move that appears designed to facilitate the local production of a competing combination product. Indonesia's patent law enables the government to grant CLs on the grounds that an inventor is not manufacturing a patented product in Indonesia within three years after the patent was granted. In 2013, India's Intellectual Property Appellate Board affirmed a CL for a patented oncology medicine, based in part on a finding that the patented medicine was not being manufactured in India.⁸²

PhRMA members urge USTR and other federal agencies to closely monitor the consideration and use of CLs and to encourage decisions on public health grounds and through fair and transparent procedures that involve participation by all stakeholders.

⁷⁷ Beall, R.F. et al., "Compulsory Licensing Often Did Not Produce Lower Prices for Antiretrovirals Compared to International Procurement," *Health Affairs*, Mar. 2015, available at <http://content.healthaffairs.org/content/34/3/493.abstract?etoc> (last visited Feb. 8, 2018).

⁷⁸ When Brazil issued a CL for an antiretroviral treatment in 2007, it took the local manufacturer two years to launch production of a generic version. See Bond, E. and K. Saggi, "Compulsory licensing, price controls, and access to patented foreign products," Vanderbilt University, Apr. 2012, available at http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_4_12/wipo_ip_econ_ge_4_12_ref_saggi.pdf (last visited Feb. 8, 2018).

⁷⁹ IFPMA Policy Position, *Voluntary Licenses and Non-Assert Declarations*, available at <http://www.ifpma.org/wp-content/uploads/2016/03/IFPMA-Position-on-VL-and-Non-Assert-Declarations-18FEB2015.pdf> (last visited Feb. 8, 2018).

⁸⁰ Chien, C., "HIV/AIDS Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare?" *PLoS One*, Mar. 2007, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1805689/> (last visited Feb. 8, 2018).

⁸¹ See, for example, Drugs for Neglected Diseases Initiative, "DNDi welcomes Malaysia's move to secure access to more affordable treatments for hepatitis C," Sep. 2017, available at <https://www.dndi.org/2017/media-centre/press-releases/dndi-welcomes-malaysia-move-access-affordable-treatments-hepc/> (last visited Feb. 8, 2018).

⁸² Chatterjee, P., "India's First Compulsory License Upheld, But Legal Fights Likely to Continue," Intellectual Property Watch, Apr. 2013, available at <http://www.ip-watch.org/2013/03/04/indias-first-compulsory-licence-upheld-but-legal-fights-likely-to-continue/> (last visited Feb. 8, 2018).

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) provide for the timely resolution of patent disputes before marketing approval is granted for a generic or biosimilar.

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, biopharmaceutical innovators in the United States do not receive any notice of a third party's intention to enter the market in **Australia** and are unable to quickly secure effective preliminary injunctions in **Mexico**. **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, the **United Arab Emirates** has recently 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. In 2017, **Kazakhstan** has repeatedly allowed patent-infringing generic copies of innovative and patent protected medicines in state procurement tenders. According to Kazakhstan's regulations, the Ministry of Health can accept a generic product registration during the term of patent protection. However, the generic registration certificate is required to note that the generic cannot be commercialized until the expiration date of the originator's patent. Moreover, the lack of technical expertise and government coordination on intellectual property issues make it difficult to effectively and quickly resolve patent infringement disputes in Kazakhstan. Effective early resolution mechanisms are also needed in **China, India, Russia** and other countries, where innovators are not notified of marketing approval applications filed for potentially infringing products and generally are unable to secure provisional enforcement measures.

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 the JCCT, the U.S.-India Trade Policy Forum and other bilateral dialogues.

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 a patent dispute to collect “market-size damages” 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.

Australia’s Therapeutic Goods Act passed as part of legislation implementing the U.S.-Australia Free Trade Agreement,⁸³ 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 with WTO intellectual property rules, including with respect to provisional measures.

⁸³ 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 Feb. 8, 2018).

In a 2004 letter⁸⁴ to Australia's trade minister, USTR raised concerns about the significant and negative impact that the Therapeutic Goods Act amendments permitting market-size damages could have on patent rights and the consistency of those amendments with Australia's international obligations. The letter stated that the "United States reserves its right to challenge the consistency of these amendments with such obligations." PhRMA members urge USTR and other federal agencies to prioritize actions to address Australia's pursuit of market-size damages.

Regulatory Data Protection Failures

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

RDP is a carefully balanced mechanism that improves access to medicines of all kinds. Prior to 1984, generic drug companies in the United States were required to generate their own test data for marketing approval. The Hatch-Waxman Act introduced abbreviated pathways that enabled generic drug companies to rely on test data developed by innovators.⁸⁵ In exchange, innovators received a period of protection for test data gained through substantial investments in clinical trials over many years. As a result of this and other provisions of Hatch-Waxman, the percentage of prescription drugs filled by generics soared from 19% in 1984 to 74% in 2009. Today, generics account for more than 90% of all prescriptions filled in the United States.⁸⁶

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.⁸⁷

⁸⁴ Letter from U.S. Trade Representative Robert B. Zoellick to Australian Minister of Trade Mark Vaile, Nov. 17, 2004, available at https://ustr.gov/archive/assets/Trade_Agreements/Bilateral/Australia_FTA/Implementation/asset_upload_file393_6951.pdf (last visited Feb. 8, 2018).

⁸⁵ Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §355 and 35 U.S.C. §156, 271 and 282).

⁸⁶ PhRMA analysis based on IMS Health, IMS national prescription audit™, 2016.

⁸⁷ See, for example, Grabowski, H. et al., "Data exclusivity for biologics," *Nature Reviews – Drug Discovery*, Jan. 2011, available at <https://fds.duke.edu/db/attachment/1592> (last visited Feb. 8, 2018).

Unfortunately, many U.S. trading partners do not provide RDP. This is contrary to WTO rules, which require parties to protect regulatory test data submitted as a condition of obtaining marketing approval against both disclosure and unfair commercial use. Examples, some of which are described further in the country profiles below, include **Argentina, Brazil, China, Egypt, India** and **Turkey**. 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** provides RDP for small-molecule treatments, but not for biologics. In **Chile**, RDP is not made available for new uses, formulations, compositions or dosage forms. **Canada** passed legislation in 2014 that gives the Health Minister broad discretion to share undisclosed test data without safeguards to protect against unfair commercial use. Other countries provide RDP in a manner that discriminates against foreign innovators. For example, **Saudi Arabia** and other countries assert that they provide RDP but have allowed local companies to rely on data submitted by U.S. innovators during the period of protection.

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 countries like **China, India, Indonesia, Russia** and **Turkey**, 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 appear to violate 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. They 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 are undermining the ability of PhRMA members to develop and deliver new treatments and cures include:

- *Market participation 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,⁸⁸ an alarming number are seeking to grow their economies by discriminating against innovators in the United States and other countries. For example, **Turkey** is once again pursuing a policy that would remove from the reimbursement list products that are not produced in Turkey. **Algeria** prohibits imports of virtually all biopharmaceutical products that compete with similar products manufactured domestically. **Russia's** Law on the Federal Contract System allows government medicines procurement agencies to ban foreign goods in public procurement tenders. Moreover, Russia is implementing legislation that limits national medicine procurement to manufacturers in the Eurasian Economic Union (EAEU) if there are two or more manufacturers for a particular class of medicine. **Indonesia's** new Patent Law permits the government to compulsory license patented medicines if the patent holder does not begin manufacturing that medicine in Indonesia within three years after the patent is granted.⁸⁹

- *Technology transfer requirements.* 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, **Turkey** does not recognize internationally accepted GMP certifications from other countries unless they have mutual recognition agreements (MRAs) on inspections with Turkey. Given, however, the many steps that would need to be satisfied before an MRA could be pursued between the United States and Turkey, this policy serves as a *de facto* ban on imports from biopharmaceutical innovators in the United States. Turkey has stated publicly that the purpose of this policy is to promote Turkish drug companies.

⁸⁸ 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 Feb. 8, 2018).

⁸⁹ Cory, N., “The Worst Innovation Mercantilist Policies of 2016,” Information Technology and Innovation Foundation, Jan. 2017, available at http://www2.itif.org/2017-worst-innovation-mercantilist-policies.pdf?_ga=1.176855585.581989633.1484510758 (last visited Feb. 8, 2018).

Recent research⁹⁰ is demonstrating the significant and widespread damage localization barriers can inflict on the global economy and on markets that put such barriers in place. 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.⁹¹

PhRMA members appreciate the attention USTR and other federal agencies have given to localization barriers in recent reports and publications. However, action is urgently needed to remove these barriers and to discourage other countries from adopting similar acts, policies and practices. Biopharmaceutical innovators in the United States look forward to concrete progress and real results in 2018.

III. Addressing Challenges and Securing the Benefits of Biopharmaceutical Innovation

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

A. Enforce and defend global, regional and bilateral rules

USTR and other federal agencies should use all available tools and leverage to ensure America's trading partners live up to their obligations in global, regional and bilateral trade and investment agreements. Modernizing existing trade agreements and stepping up enforcement activity in the months ahead will be critical to end discriminatory

⁹⁰ See, for example, Stone, S., J. Messent and D. Flaig, "Emerging Policy Issues: Localisation Barriers to Trade," OECD Trade Policy Papers, No. 180, 2015, available at http://www.oecd-ilibrary.org/trade/emerging-policy-issues_5js1m6v5qd5j-en;jsessionid=ai5pr32hanqoq.x-oecd-live-03 (last visited Feb. 8, 2018); Ezell, S.J., R.D. Atkinson and M.A. Wein, "Localization Barriers to Trade: Threat to the Global Innovation Economy," Information Technology and Innovation Foundation, Sep. 2013, available at http://www2.itif.org/2013-localization-barriers-to-trade.pdf?_ga=1.136058805.581989633.1484510758 (last visited Feb. 8, 2018). Hufbauer, G.C., J.J. Schott et al., *Local Content Requirements: A Global Problem*, Peterson Institute for International Economics, Sep. 2013, available at <http://bookstore.piie.com/book-store/6802.html> (last visited Feb. 8, 2018).

⁹¹ 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 Feb. 8, 2018).

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.

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** 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 take steps necessary to ensure agreed rules are followed.

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.⁹² China has never implemented this obligation, despite agreement to do so during the 2012 U.S.-China Joint Commission on Commerce and Trade meeting.⁹³ In light of these deficiencies, we strongly welcome the CFDA draft Circular 55 (Relevant Policies on Protecting Innovators' Rights to Encourage New Drug and Medical Device Innovation), which proposes ten years of RDP for new 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 China's international obligations and commitments.

The Generalized System of Preferences (GSP) program provides unilateral duty-free access to the U.S. market for more than 3,500 products.⁹⁴ 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.”⁹⁵ However, GSP beneficiaries like **Argentina, Brazil, India, Indonesia**

⁹² World Trade Organization, “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 Feb. 8, 2018).

⁹³ 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 Feb. 8, 2018).

⁹⁴ Office of the United States Trade Representative, *U.S. Generalized System of Preferences Guidebook*, Sep. 2016, available at <https://ustr.gov/sites/default/files/GSP-Guidebook-September-16-2016.pdf> (last visited Feb. 8, 2018).

⁹⁵ See Title V of the Trade Act of 1974 (19 U.S.C. 2461 et seq.), as amended.

and **Turkey** do not provide adequate and effective protection of intellectual property rights or fair and equitable market access.

The Special 301 Report is an important tool to 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 this tool is used effectively. 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.⁹⁶ Out-of-cycle reviews announced in the Special 301 Report should be conducted and should involve the participation of relevant stakeholders.

USTR should prioritize actions to fill key enforcement positions, including the position of Chief Innovation and Intellectual Property Negotiator. Where necessary, USTR should consider bringing dispute settlement cases to secure compliance with trade and investment agreement commitments.

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

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

PhRMA supports 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 open new markets. They help grow our economy and create better, higher-paying jobs. PhRMA members look forward to continuing to work with USTR and other federal agencies to modernize 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.⁹⁷

⁹⁶ See Section 182 of the Trade Act of 1974 (19 U.S.C. 2242), as amended.

⁹⁷ U.S. Department of Commerce, International Trade Administration, "2016 Top Markets Report: Pharmaceuticals," 2016, available at http://trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf (last visited Feb. 8, 2018).

C. End discrimination in pricing and reimbursement

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

The biopharmaceutical industry is unique in that most foreign governments, as sole or primary healthcare providers, impose burdensome and often discriminatory price controls and regulations on the sector. Others have resorted to improperly using national compulsory licensing provisions to threaten or coerce manufacturers to accept pricing agreements on unreasonable commercial terms and conditions. As a result, market access for pharmaceuticals is not only dependent on innovators meeting strict regulatory approval standards and obtaining necessary intellectual property protections, but also on obtaining positive government pricing and reimbursement determinations. It is imperative, therefore, that regulatory procedures and decisions regarding the approval and reimbursement of medicines are governed by fair, transparent and verifiable rules guided by science-based decision making. There should be meaningful opportunities for input from manufacturers and other stakeholders to health authorities and other regulatory agencies and a right to appeal government pricing and reimbursement decisions to an independent, objective court or administrative body.

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

PhRMA members appreciate steps USTR and other federal agencies have taken to ensure fair and equitable market access for innovative medicines in overseas markets, including seeking and securing commitments in trade agreements that ensure pricing and reimbursement policies abroad are fair, reasonable, and non-discriminatory, and appropriately value patented pharmaceuticals. PhRMA urges USTR and other federal agencies to continue to promote the full implementation of these commitments and to build on them in future trade negotiations by ensuring future trade agreements meet the Trade Promotion Authority objective to “ensure that government regulatory

reimbursement regimes are transparent, provide procedural fairness, are non-discriminatory, and provide full market access for United States products.”⁹⁸

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

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

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

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

D. Combat the worldwide proliferation of counterfeit medicines

PhRMA members view counterfeit medicines as a critical public health and safety concern threatening patients around the world. At best, counterfeit medicines have no effect on patients. At worst, they may contribute to drug-resistant forms of tuberculosis and other serious diseases and contain impurities or toxins that can cause harm or even

⁹⁸ Section 102(b)(7)(G) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2016 (P.L. 114-26).

death.⁹⁹ This challenge is exacerbated by the ease with which counterfeiters can offer fake medicines over the Internet¹⁰⁰ and ship them by mail¹⁰¹ to patients and consumers worldwide.¹⁰²

Counterfeit medicines are a potential danger to patients everywhere, including in the United States. During fiscal year 2016, U.S. Customs and Border Protection seized more than 850 shipments of counterfeit pharmaceuticals at America's borders.¹⁰³ Using a broader measure that includes counterfeiting, illegal diversion and theft, the Pharmaceutical Security Institute documented more than 3,100 incidents of pharmaceutical crime in the United States in calendar year 2016 – the highest number ever recorded since the Institute began compiling such data 15 years ago.¹⁰⁴ Across all sectors, the Organization for Economic Cooperation and Development (OECD) found that global counterfeiting and piracy accounts for 2.5% of world trade and disproportionately harms innovators in the United States.¹⁰⁵

⁹⁹ Testing reported in *The Lancet* found one-third of anti-malarial medicines in sub-Saharan Africa and South East Asia lacked active ingredients. See Guarvika, M.L.N. et al., "Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa," *The Lancet*, June 2012, available at <http://www.thelancet.com/journals/laninf/article/PIIS1473-3099%2812%2970064-6/fulltext> (last visited Feb. 8, 2018). 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-113hhr88828/pdf/CHRG-113hhr88828.pdf> (last visited Feb. 8, 2018).

¹⁰⁰ 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% 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 Feb. 8, 2018).

¹⁰¹ An OECD study published last year found that more than 60% of counterfeit goods seized around the world between 2011 and 2013 were shipped by mail or express carrier. See OECD, "Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact," 2016, available at http://www.keepeek.com/Digital-Asset-Management/oecd/governance/trade-in-counterfeit-and-pirated-goods_9789264252653-en#.WHv5mpcraBc#page1 (last visited Feb. 8, 2018).

¹⁰² Institute of Medicine (IOM), *Countering the Problem of Falsified and Substandard Drugs*, February 2013, available at https://iom.nationalacademies.org/~media/Files/Report%20Files/2013/Substandard-and-Falsified-Drugs/CounteringtheProblemofFalsifiedandSubstandardDrugs_RB.pdf (last visited Feb. 8, 2018). The IOM notes that "because the internet facilitates easy international sales, online drug stores have spread the problem of falsified and substandard drugs...."

¹⁰³ U.S. Customs and Border Protection, Office of Trade, "Intellectual Property Rights: Fiscal Year 2016 Seizure Statistics," Jan. 2018, available at https://www.cbp.gov/sites/default/files/assets/documents/2018-Jan/FY2016%20IPR%20Seizure%20Statistics%20Book%20%28PDF%20Formatting%29_OT.pdf (last visited Feb. 8, 2018).

¹⁰⁴ Pharmaceutical Security Institute, "Incident Trends," available at <http://www.psi-inc.org/incidentTrends.cfm> (last visited Feb. 8, 2018).

¹⁰⁵ OECD, "Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact," 2016, available at http://www.keepeek.com/Digital-Asset-Management/oecd/governance/trade-in-counterfeit-and-pirated-goods_9789264252653-en#.WHv5mpcraBc#page1 (last visited Feb. 8, 2018).

China and **India** are leading sources of fake medicines seized at ports of entry in the United States¹⁰⁶ and elsewhere,¹⁰⁷ though many other jurisdictions are involved – particularly in online sales.¹⁰⁸ 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.¹⁰⁹

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

¹⁰⁶ Office of the United States Trade Representative, 2016 Special 301 Report, Apr. 2016, available at <https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf> (last visited Feb. 8, 2018).

¹⁰⁷ See, for example, European Commission, “Report on EU customs enforcement of intellectual property rights: Results at the EU border,” 2015, available at http://ec.europa.eu/taxation_customs/sites/taxation/files/2016_ipr_statistics.pdf (last visited Feb. 8, 2018).

¹⁰⁸ 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 Feb. 8, 2018).

¹⁰⁹ 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 Feb. 8, 2018).

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 USTR and other federal agencies are already taking to strengthen cooperation with other governments. Bilateral forums like the Transatlantic IPR Working Group have helped to build understanding and to identify and advance common priorities. They can be a model for similar engagement with other countries. 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 PPH 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. Fostering and strengthening coalitions that support innovation will be particularly critical in multilateral organizations, such as the WHO, the World Intellectual Property Organization (WIPO), the WTO, UNDP and UNCTAD. At best, work in these forums and others is focused on limitations and exceptions to intellectual property rights. At worst, international organizations are actively seeking to undermine and even eliminate the intellectual property protections that drive America's innovation economy. This is even the case at WIPO – an organization that was created to “encourage creative activity” and to “promote the protection of intellectual property throughout the world.”¹¹⁰

As a leading contributor to multilateral organizations, the United States must remain vigilant in these forums and work with other like-minded countries to advocate for robust intellectual property protection and fair and equitable market access. Federal agencies should ensure intellectual property matters are addressed in organizations with the appropriate mandate and expertise. They should strengthen interagency coordination and ensure officials with intellectual property expertise are part of U.S. delegations to relevant global meetings. They should enable all stakeholders to engage in discussions underway in multilateral organizations.

IV. Country Designation Index

A. Priority Foreign Country

PhRMA urges USTR to designate **Canada**, **Korea** and **Malaysia** as Priority Foreign Countries. Market access and/or intellectual property acts, policies and practices in these three countries are the most onerous and egregious. They are having or could have the greatest adverse impact on medicines developed and manufactured in the United States. USTR and other federal agencies should use all available tools to remedy

¹¹⁰ See, generally, Convention Establishing the World Intellectual Property Organization, July 14, 1967, available at http://www.wipo.int/treaties/en/text.jsp?file_id=283854 (last visited Feb. 8, 2018).

serious concerns in these countries. Ongoing negotiations with Canada and Korea offer opportunities to achieve significant progress.

B. Priority Watch List

PhRMA recommends that **Japan** and **eleven other countries** be included on the Priority Watch List. We further recommend that **China** continue under Section 306 Monitoring. The detailed information presented in the country-specific sections below demonstrates that the acts, policies and practices of these countries are denying adequate and effective intellectual property protection or fair and equitable market access. They are harming biopharmaceutical innovators and their employees in the United States and limiting their ability to bring new treatments to patients around the world. In many cases, they appear to be inconsistent with relevant global, regional and bilateral trade and investment agreement rules. To evaluate progress and secure action and real results, PhRMA recommends that USTR conduct a meaningful Out-of-Cycle Review for **Colombia**.

C. Watch List

PhRMA recommends that **four** markets be included on the Watch List. We urge USTR and other federal agencies to include all these countries in the *2018 Special 301 Report* – particularly Australia and other countries that are U.S. bilateral trade agreement partners. USTR and other federal agencies should monitor developments in these countries and address specific intellectual property and market access concerns through bilateral and multilateral engagement.

Priority Foreign Country

CANADA

PhRMA and its member companies operating in Canada are extremely concerned about Canada's intellectual property (IP), and pricing environment for patented products which continue to be characterized by significant uncertainty and instability for U.S. innovative biopharmaceutical companies. Canada's IP regime lags behind that of other developed nations in several significant respects. Of particular concern are Canada's proposed new pricing policies for patented products that would significantly undermine the practical benefits to U.S. companies of Canada's trade-related intellectual property commitments and which create uncertainty for patients.

Key Issues of Concern:

- **The Patented Medicine Prices Review Board (PMPRB):** In December 2017, Canada proposed regulatory changes to the current mandate of the PMPRB from ensuring "non-excessive" prices to ensuring "affordable" prices, and to change its pricing regulations accordingly. One conservative analysis of the potential impacts of proposed changes to the PMPRB estimates that industry revenues could be reduced by a minimum of \$2.2 billion annually, or 25% of the Canadian market for innovative medicines. Key proposals would amend the basket of reference countries with the intent of setting prices of patented medicines at the OECD median, introduce various new factors to determine whether a price is "excessive," and require manufacturers to report all indirect price reductions. These proposed changes could have a serious negative impact on U.S. biopharmaceutical companies operating in Canada, the availability of new medicines to Canadian patients, and the competitiveness of Canada for research-based pharmaceutical investment. Canada plans to implement these changes in January 2019.
- **Weak patent enforcement:** The Canadian Patented Medicines (Notice of Compliance) Regulations (the PM(NOC) Regulations) include several key deficiencies that weaken Canada's enforcement of patents, including the nature of patent dispute proceedings and rights of appeal for patent owners, excessive and windfall damage awards to generic litigants, and limitations and inequitable eligibility requirements on the listing of patents in the Patent Register. Recent jurisprudence under the regulations has also resulted in a heightened level of liability for patent owners akin to punitive damages. PhRMA and its member companies are also troubled to see that Canada has used implementation of the Canada-EU Comprehensive Economic and Trade Agreement (CETA)¹¹¹ to implement reforms not required by that Agreement, which expose innovators to even greater potential liability under Section 8 of the PM(NOC) Regulations.

¹¹¹ 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 Feb. 7, 2018).

- **Inadequate patent term restoration:** Under CETA, Canada has made a significant step to provide innovators with some compensation for delays in obtaining marketing approval for pharmaceuticals. However, in its implementing regulations, Canada has chosen to implement an “export” exception that is inconsistent with the fundamental purpose of restoring a portion of the patent term lost due to the marketing approval process, and has only adopted the minimum term of patent term restoration (PTR) negotiated under CETA further deviating from global standards. Furthermore, Canada’s adoption of restrictive time limits and eligibility criteria will unduly and unreasonably limit patent term restoration eligibility in Canada in a manner that is contrary to the intent of the negotiation and the CETA text itself. PhRMA’s member companies believe Canada should support innovation by ensuring that its PTR system effectively ameliorates the effects of delays caused by its regulatory processes, which can significantly erode the duration of the IP rights of innovators.
- **Standard for the disclosure of confidential business information (CBI):** In November 2014, Canada enacted legislation to update its Food and Drugs Act (Bill C-17). Provisions in that law granted the Health Minister discretion to disclose a company’s CBI without notice to the owner of the CBI and in accordance with a standard that is both inconsistent with other similar Canadian legislation and Canada’s treaty obligations under NAFTA and TRIPS. In December 2017, Health Canada released a draft regulatory package to facilitate automatic public access to manufacturer submitted clinical information in drug submissions for human use following the issuance of a final Health Canada regulatory decision. The proposal would amend the Food and Drug Regulations and is currently open for a 75-day comment period, ending February 22, 2018.
- **Regulatory barriers to patient access to new medicines:** Bureaucratic barriers exist in Canada that extend the time between submission to the federal government of newly discovered medicines and vaccines for safety approval, and their ultimate availability through public formularies to benefit Canadian patients. This results in significant delays in access to innovative medicines, while also decreasing the time that innovative companies have to recoup their investments.

For these reasons, PhRMA requests that Canada be designated a **Priority Foreign Country** in the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection and Pricing of Patented Products

The Patented Medicine Prices Review Board (PMPRB)

The Patented Medicine Prices Review Board (PMPRB) is a quasi-judicial body, created under the Canadian Patent Act.¹¹² The legislative mandate of the Board is to ensure that patented prices are not “excessive.” Due to its power in shaping the real-world benefits of IP property protections, the PMPRB is an important institution within Canada’s broader IP regime for pharmaceuticals. The PMPRB regulates the maximum allowable price that a manufacturer can charge for all patented medicines in Canada. The Board does not make decisions about the amount of reimbursement for a product, which is appropriately the responsibility of separate federal and provincial government agencies, or private insurers.

On December 2, 2017, Health Canada proposed Regulations Amending the Patented Medicines Regulations in Canada Gazette, Part I.¹¹³ The PMPRB changes were initiated as part of the Board’s professed role as a “counterweight to the patent rights of pharmaceutical manufacturers.”¹¹⁴ The contemplated changes could negatively impact the innovative biopharmaceutical industry, the availability of new medicines to Canadian patients, and the competitiveness of Canada for research-based pharmaceutical investment.

Recent analysis found that patented drugs accounted for only 6.7% of the \$232.9 billion reported by the Canadian Institute for Health Innovation for total health spending in Canada in 2016.¹¹⁵ Moreover, patented drugs have experienced near zero real cost growth for the last decade.¹¹⁶ These data suggest that patented medicines are not the primary cost driver of Canadian health expenditure, so we question whether the reforms will generate benefits to outweigh the potential risks to innovation that will be created. Low prices should not be the *only* goal of pharmaceutical policy and we urge the government to take a more holistic review. It is crucial to carefully consider the impact of pricing policy on access to new medicines, clinical studies, launch of new treatments, investment, jobs, and the research ecosystem as a whole.

¹¹² *Patent Act*, R.S.C. 1985, c.P-4, ss.79-103.

¹¹³ Canada Gazette, Part I, Regulations Amending the Patented Medicines Regulations, Vol. 151, No. 48, December 2, 2017, available at <http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html> (last visited Feb. 7, 2018).

¹¹⁴ PMPRB 2015–16 Report on Plans and Priorities, <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1163> (last visited Feb. 7, 2018).

¹¹⁵ Brett Skinner, Editorial, “How Ottawa's using a fake drug crisis to force through damaging pharmaceutical policy” Vancouver Sun, Jan. 16, 2018, available at <http://business.financialpost.com/opinion/how-ottawas-using-a-fake-drug-crisis-to-force-through-damaging-pharmaceutical-policy> (last visited Feb. 7, 2018).

¹¹⁶ *Id.*

One conservative analysis of the proposed changes to the Patented Medicine Prices Review Board (PMPRB) estimates that industry revenues could be reduced by a minimum of \$2.2 billion annually, or 25% of the Canadian market for innovative medicines.¹¹⁷ This analysis does not account for the full scope of the potential impacts to the innovative industry and the Canadian economy. Depending on how the reforms are implemented, the financial and non-financial impacts could be more severe.¹¹⁸ Moreover, taken as a whole, the proposed PMPRB changes will increase Canada-U.S. regulatory asymmetries, and may also create new border enforcement challenges by incenting inappropriate cross-border trade in innovative medicines.

Canada proposes to amend the PMPRB's basket of reference countries with the goal of setting ceiling prices of patented medicines in Canada at the Organization for Economic Cooperation and Development (OECD) median. Specifically, the PMPRB proposes to remove the U.S. and Switzerland, with the new basket consisting of: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden and the United Kingdom. Despite being at the forefront of OECD economies, Canada would amend its list of referenced countries to replace the U.S. with countries which are poorer and/or have onerous price control policies. The U.S. is Canada's largest trading partner and the pharmaceutical markets in both countries share many common features. Any pricing determinations in Canada based on reference to other countries should include the U.S. and other countries with pro-innovation pharmaceutical policies.

Canada also proposes to introduce new factors to determine whether a price is "excessive." New proposed factors to regulate prices would include pharmacoeconomic evaluation based on an arbitrary monetary threshold of the value of an additional year of life; price ceilings based on projected market size; and the proportion of gross domestic product spent on patented medicines. Such cost-effectiveness thresholds could impact the future viability of many drugs for rare diseases and oncology treatments in Canada. While cost-effectiveness thresholds are used downstream in other nations, their utilization as part of a binding regulatory price ceiling would be unique in the world.

In the thirty years since the PMPRB was established, a variety of mechanisms have emerged in Canada for the government and industry to effectively address the affordability of medicines. These mechanisms include the Canadian Agency for Drugs and Technologies in Health (CADTH), the Common Drug Review, the pan-Canadian Pharmaceutical Alliance, and Product Listing Agreements, among others. Indeed, the specific change to include a cost-effectiveness test as part of PMPRB's new mandate

¹¹⁷ PCDI Market Access, Proposed Amendments to the Patented Medicines Regulations: A Critical Appraisal of the Cost-Benefit Analysis, January 2018, available at: http://www.pdci.ca/wp-content/uploads/2018/01/20180129_PDCI-Critical-Assessment-PM-Regs-Amendments_Report-Final.pdf (last visited Feb. 7, 2018).

¹¹⁸ Ernst & Young, Innovative Medicines Canada Data Analytics and Members' Economic Footprint and Impact in Canada, September 2017, available at: http://innovativemedicines.ca/wp-content/uploads/2017/10/20171030_EY-REPORT_IMC_FINAL.pdf (last visited Feb. 7, 2018).

overlaps with and duplicates the work of existing federally funded agencies (e.g., CADTH), and its major beneficiary would be for-profit private insurers as opposed to patients. Any expansion of the PMPRB's mandate is therefore unnecessary and would harm U.S. innovative biopharmaceutical companies through additional downward pricing pressures.

In addition, Canada proposes to require manufacturers to report all indirect price reductions given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts, or any other benefit in Canada. Given the lack of information on the purpose and use of this information, potential legal concerns and the risk of significant and negative consequences for public payers and other market participants, PhRMA opposes the mandatory submission of indirect price reduction information to the PMPRB.

It appears that the PMPRB is also considering an unprecedented level of intervention into competitive markets, through "tiered" pricing for similar patented products, forcing some new products to a price lower than previously launched products. While few details are currently available, this would treat many innovative products in a similar manner to non-patented generic drugs and would pose barriers to important innovations and the range of therapeutic alternatives available to Canadians.

The proposed Regulations will go into force on January 1, 2019, with the proposals applying to new and existing medicines for sales that occur after January 1, 2019. In addition to the regulations, the way in which they are to be implemented will flow through a guidance document put forth by the PMPRB that raises many additional points of uncertainty and risk for U.S. IP owners.

PhRMA recommends that the U.S. Government urge the Canada to not move forward with any changes to the PMPRB's mandate that would harm U.S. innovative biopharmaceutical companies and undermine the competitiveness of Canada's innovative medicines sector. Any PMPRB policy changes must ensure that the PMPRB's role is placed in its proper context with the many other price regulating agencies already active in the Canadian pharmaceutical marketplace. Any changes to the PMPRB's basket of comparator countries or other pricing methods, likewise, must be based on evidence, only made after a sound consultative process, and must include reasonable transitional measures to avoid or minimize disruptions to existing business arrangements.

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 included in its governing regulations, PMPRB has consistently and systematically under-reported the R&D levels of innovative pharmaceutical companies operating in Canada for many years, underestimating the industry's contribution to private sector R&D spending and lessening the government's willingness to address the myriad issues described above. To the extent that PMPRB should have a mandate to report on R&D spending in Canada, PhRMA members urge the U.S. Government to encourage the Government of Canada to update the regulatory R&D definition in order that the PMPRB can more accurately calculate the

significant R&D contributions made by pharmaceutical patentees to the Canadian knowledge-based economy.

Weak Patent Enforcement

In 1993, the PM (NOC) Regulations were promulgated for the stated purpose of preventing the infringement of patents by the premature market entry of generic drugs as a result of the “early working” exception. Despite these challenges, PhRMA acknowledges that, in 2015, the Canadian government helped resolve a significant issue related to inappropriate court decisions that prevented the listing of patents relevant to combination inventions, seriously undermining patent enforcement actions relevant to those inventions. However, serious and systemic deficiencies remain with the PM(NOC) Regulations that need to be addressed. There is ample evidence that the PM(NOC) Regulations do not reliably provide “expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements,” as required under the TRIPS Agreement and NAFTA. 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 asymmetry in legal rights that flowed from Canada’s previous restrictive PM(NOC) Regulations regime under which a patent owner did not have an equal ROA as that afforded to a generic drug producer. CETA simply required Canada to correct this imbalance. The changes to the PM(NOC) Regulations,¹¹⁹ however, have proven to be far more extensive than necessary to comply with Canada’s CETA obligations in a manner that prejudices existing innovator rights.

For example, despite adopting significantly more procedural complexity under the new regime, including 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. Given that 90% of patent infringement/invalidity actions in Canada in recent years have taken over two years to be determined, the innovative industry is concerned that patentees will now be forced to choose between the surrender of procedural rights and obtaining any kind of meaningful injunction under the new regime, contrary to Canada’s many other related international obligations to protect intellectual property 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

¹¹⁹ 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 Feb. 7, 2018).

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.

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 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.

PhRMA members are 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% 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.¹²⁰

Recent CETA implementing regulations established new rules that further expose innovators to excessive liability under Section 8. The amended PM(NOC) 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.

¹²⁰ 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 Feb. 7, 2018). 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.

Inadequate Patent Term Restoration

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 has made a potentially 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 new *Certificate of Supplemental Protection Regulations (CSP) Regulations*.¹²¹ 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 an exception for "manufacture for export." While this is permitted by the CETA text, this is not consistent with PTR in other jurisdictions and appears to be inconsistent with the text of U.S. free trade agreements.¹²² Such an implementation of PTR that does not confer full patent rights, e.g., that would provide an exception for "manufacturing for export" or other infringing activities, is not consistent with the fundamental purpose of restoring patent term lost due to marketing approval delays and should be avoided.

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

In particular, the *CSP Regulations* introduce a new and complex CSP application requirement whereby only those Canadian NDSs filed within 1 year of any first international drug submission filed for the same drug (in any of EU, US, 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 patent term restoration regimes of Canada's major trading partners, including the United States. PhRMA is concerned that the 1 year time limit being enforced

¹²¹ Available at <http://www.gazette.gc.ca/rp-pr/p2/2017/2017-09-07-x1/html/sor-dors165-eng.php> (last visited Feb. 7, 2018).

¹²² See Solovy, E., "A Manufacturing-for-Export Exception to Patent Protection: A Proposal for Exporting Violations of the TRIPS Agreement and Beyond," *Journal of IP Law and Practice* (Sep. 2017).

under the Timely Submission Requirement will inappropriately bar otherwise deserving and eligible innovative medicines from benefiting from the period of *sui generis* protection.

Moreover, Canada's new PTR regime requires that CSP-eligible medicinal ingredients be "first" approvals. 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 patent term extension regimes provide enumerated lists of excluded variations ineligible for CSP.

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

Standard for the Disclosure of Confidential Business Information

PhRMA members are concerned with provisions of the recently enacted Bill C-17, An Act to Amend the Food and Drugs Act,¹²³ which could allow for an unprecedented disclosure of CBI contained in clinical trial and other data submitted by pharmaceutical companies to Health Canada in the course of seeking regulatory approval for medicines. The amendments 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 amendments are inconsistent with the standards set out in other Canadian federal health and safety legislation, are inconsistent with Canada's treaty obligations under NAFTA and TRIPS, and are also inconsistent with the standards and practices of other national health regulators, including the FDA.

Both NAFTA and the TRIPS Agreement require that CBI be protected against disclosure except where necessary to protect the public. For disclosure to the public, the amendments 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 amendments merely require that the Minister believes the disclosure to be necessary.

¹²³ See

<http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=6676418&File=4> (last visited Feb. 7, 2018).

The amendments also state 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. NAFTA and TRIPS do not refer to disclosure for the promotion of health, but rather to disclosure needed to protect the health of the public.

Finally, the amendments provide 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.¹²⁴ PhRMA and its member companies are pleased that the document provides some reassurances with respect to the administration of Health Canada’s new powers under Bill-C17. However, the document is a non-binding guidance as opposed to binding law or regulations, and as such Health Canada has the discretion not to follow its requirements, and it is also potentially vulnerable to future legal challenges.

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 *Food and Drugs 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.¹²⁵

More recently, in December 2017, Health Canada released a draft regulatory package to facilitate automatic public access to manufacturer submitted clinical information in drug submissions for human use following the issuance of a final Health

¹²⁴ See 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-droguessedangeuses-amendments-modifications-eng.php> (last visited Feb. 7, 2018).

¹²⁵ See selected media reports on the CBI disclosure: David Bruser and Jesse McLean, “Health Canada Hands Over Documents But Muzzles Doctor” *Toronto Star* (Oct. 14, 2016), available at <https://www.thestar.com/news/canada/2015/10/14/health-canada-hands-over-documents-but-muzzles-doctor.html> (last visited Feb. 7, 2018); Anne Kingston, “Health Canada OKs research into popular morning-sickness drug” *Macleans* (Nov. 23, 2015), available at <http://www.macleans.ca/society/health/health-canada-oks-research-into-popular-morning-sickness-drug/> (last visited Feb. 7, 2018).

Canada regulatory decision.¹²⁶ The proposal would amend the Food and Drug Regulations (Regulations) and is currently open for a 75-day comment period, ending February 22, 2018.

The proposed amendments to the Regulations specify the scope of clinical information in drug submissions that would 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 amendments would 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 proposed amendments would apply to drugs for human use and medical devices, and would apply to clinical information in drug submissions filed with Health Canada both before and after the coming into force of the Regulations. The intention appears to be to include previously submitted information, even from years or decades ago, within the scope of automatic public disclosure.

PhRMA members therefore urge the U.S. Government to press the Government of Canada to ensure that the Bill C-17 implementing regulations are consistent with Canada's international treaty obligations.

Market Access Barriers

Regulatory Barriers to Patient Access to New Medicines

Beyond the Health Canada safety approval process, there are additional time-consuming market access hurdles that significantly delay Canadian patients' ability to access new medicines and vaccines. These include the Patented Medicine Prices Review Board review, health technology assessments, price negotiations through the Pan-Canadian Pharmaceutical Alliance, and, finally, the negotiation of product listing agreements with individual public drug plans.

Most recent (2016) data indicates that it takes an average of 449 days after Health Canada approval before a patient can access a new medicine through a Canadian public drug plan.¹²⁷ This delays access to the benefits of new medicines and vaccines for Canadian citizens, and also erodes the already limited time that innovative companies have to recoup their significant investments in R&D, clinical trials and regulatory approval processes. PhRMA members urge the U.S. Government to engage with the Government of Canada departments and agencies, appealing to them to review their drug evaluation

¹²⁶ Canada Gazette, Part I, Regulations Amending the Food and Drug Regulations (Public Release of Clinical Information), Vol. 151, No. 49, December 9, 2017, available at <http://gazette.gc.ca/rp-pr/p1/2017/2017-12-09/html/reg3-eng.html> (last visited Feb. 7, 2018).

¹²⁷ Canadians Facing Delayed Access to New, Innovative Medicines: Report (May 24, 2016, available at <http://innovativemedicines.ca/canadians-facing-delayed-access-to-new-innovative-medicines-report/> (last visited Feb. 7, 2018).

and approval processes with a view to finding efficiencies and reducing duplication in order to improve patient access to new medicines.

KOREA

PhRMA and its member companies remain concerned with several intellectual property (IP) and market access issues in Korea. Korea's drug pricing policies severely devalue U.S. IP and favor Korea's own pharmaceutical industry at the expense of U.S. companies. As a result, America's cutting-edge R&D and manufacturing sectors are losing out. The upshot is fewer U.S. jobs, fewer U.S. exports, and fewer new medicines for patients worldwide. The United States should make clear that Korea's pricing practices are inconsistent with its commitments under the U.S.-Korea Free Trade Agreement (KORUS).

Key Issues of Concern:

- **Discriminatory government pricing and reimbursement policies:** On multiple levels, Korea's pricing practices flout its KORUS commitments and trample on the rights of U.S. innovators. First, Korea restricts the prices of innovative medicines by valuing them according to the prices of older medicines or prices in poorer countries. Given the vast amount of medical research that occurs in the United States, Korea seeks to benefit from this research without paying its fair share. This incredibly short-sighted approach, however, harms not just the U.S. industry but patients overall. It is also inconsistent with Korea's commitments under KORUS to value U.S. innovation appropriately, to ensure that patent owners can reap economic rewards, and to guarantee market access free from price distortions. In addition, Korea's pricing policies overtly favor the domestic pharmaceutical industry and are formulated without the degree of stakeholder input required by KORUS. The U.S. should seek to enforce KORUS' innovation, IP, and market access provisions immediately, to prevent continued mistreatment of the U.S. pharmaceutical industry, and to demonstrate more broadly that developed countries cannot free-ride on U.S. innovation.
- **Patent term restoration:** As required by KORUS, Korean law provides for patent term restoration to compensate for unreasonable delays in granting marketing approval for new medicines. However, a recent Korean court decision has effectively undermined the purpose and value of patent term restoration by impermissibly narrowing the subject matter eligible for a compensatory period of exclusivity. By limiting the restoration only to the innovative product approved, rather than to the patented invention related to the product, the decision allows competitors to seek marketing approval for variations of the product during the restored period that would otherwise infringe the innovator's patent.
- **Patent enforcement concerns:** While Korea has implemented a patent linkage mechanism pursuant to its KORUS commitment, certain key issues of concern remain. These issues include the discretion afforded to the Ministry of Food and Drug Safety (MFDS) as to whether to list a patent in the Green List or to permit a

change to the patent listing and the limited period of only nine months for a sales stay.

For these reasons, PhRMA requests that Korea be designated a **Priority Foreign Country** in the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection and Pricing of Patented Pharmaceuticals

Discriminatory Pricing and Reimbursement Policies

Korea's current P&R system has its origins in a controversial, sweeping regulatory reform that took effect in December 2006. Under this reform, known as the Drug Expenditure Rationalization Plan (DERP), drug prices are determined in a two-step process based primarily on cost reduction rather than a holistic assessment of a drug's value. *First*, the Health Insurance Review Agency (HIRA), through its Drug Reimbursement Evaluation Committee (DREC), recommends drugs for listing on the basis of a "pharmaco-economic" or PE analysis, which takes into account clinical usefulness and cost-effectiveness. *Second*, the National Health Insurance Corporation (NHIC) makes pricing recommendations following negotiations with pharmaceutical manufacturers, using HIRA's price as a ceiling. The Ministry of Health and Welfare (MOHW) has the ultimate authority for approving all P&R decisions.

This two-step process inappropriately depresses the price of innovative medicines in several significant ways. First, HIRA's PE analysis recommends reimbursement prices for patented drugs by referencing comparator groups based on therapeutic class, which include off-patent and generic drugs. Off-patent and generic drugs are already subject to drastic price reduction measures in Korea. Linking prices of new patented drugs to prices of already heavily-discounted prices of off-patent and generic drugs results in unsustainably low prices for innovative drugs. In 2012 alone, existing off-patent and generic drugs experienced an average price reduction of 14%. During the period from 2011 to 2013, all existing off-patent and generic drugs saw an overall 20% price reduction. Second, after the HIRA process, the NHIC exploits its superior bargaining power as a single payer, which allows it to secure an even lower negotiated price from the manufacturer of the innovative medicine. These problems are exacerbated by Korea's failure to provide an independent mechanism to review these pricing determinations (discussed further below).

Over the last decade, the Korean Government has used other *ad hoc* measures to further reduce prices of patented drugs. Beginning in 2009, Price-Volume (PV) Agreements were negotiated and implemented under the theory that increased volume of drug consumption should improve efficiency and result in lower prices. In 2010, Korea initiated its Actual Transaction Pricing program, which created incentives for larger hospitals to select drugs based on rebates rather than therapeutic needs. Although the ATP program was suspended a year later, it was revived in more recent years and remains in effect today. Because the ATP program was layered onto price cuts made

while the program was suspended, the result is that patented pharmaceuticals are subject to repetitive and excessive price control mechanisms.

The deleterious impact of DERP and other pricing measures on Korea's market for innovative medicines has been striking. One study found that during the 2007–2014 period, new drug prices in Korea were less than half of the average in Organization for Economic Co-operation and Development (OECD) countries.¹²⁸ The impact of price cuts is compounded because existing drug prices are then referenced in setting new drug prices. It is difficult for a new drug to be listed under the Korea's pharmaco-economic (PE) evaluation given the current the comparator selection criteria, which inappropriately reference generics. As a consequence, from 2007 to 2014, only about 69% of new medicines approved in Korea have been successfully listed for reimbursement.¹²⁹ In sum, while these policies have been driven by goals of cost-savings and cost-containment, the end result has been reduced access to innovative medicines by Korean patients and doctors.

Korea is also implementing new pricing policies that discriminate against U.S. innovators. In 2016, MOHW and HIRA issued a revised pricing policy (known as the "7.7 Pricing Policy" or "Plan of Improving Drug Pricing System") that authorized premium pricing based on certain criteria. In its final form, the policy sets forth three cumulative requirements that new drugs must meet in order to qualify for premium pricing. Under the first requirement, the drug must obtain its first approval worldwide in Korea, or alternatively, the drug must meet one of three criteria—certain manufacturing processes must be located in Korea; the drug must be the product of a foreign-domestic joint R&D agreement; or the drug must provide a "social contribution." The second requirement is that the new drug complete clinical trials in Korea. Third, the new drug must be developed either by an innovative pharmaceutical company (IPC) as determined by the DREC,¹³⁰ by a company with an R&D investment level exceeding the IPC average, or through "open innovation," a reference to technology transfer-based collaborations between foreign and domestic companies.¹³¹

Korea's numerous price controls constitute a failure to "appropriately recognize the value of the patented pharmaceutical product," in violation of KORUS Article 5.2(b). Korea's PE system inappropriately links patented drug prices to off-patent and generic drug prices. This unavoidably and automatically devalues patents and undermines incentives for innovation. These effects are amplified by a second round of price reductions following negotiations with NHIC—which, as a single payer, is necessarily driven by budget concerns—as well as *ad hoc* price cuts that further lower reference prices for new drugs. As a result of this two-step price reduction process, and other *ad*

¹²⁸ EK Lee, "Price Comparison Among OECD Countries" (2014).

¹²⁹ QuintilesIMS analysis (2017).

¹³⁰ A company meets the criteria of innovative pharmaceutical companies pursuant to Article 7 of the Special Act on Fostering and Support of Pharmaceutical Industry

¹³¹ *Id.*

hoc price cuts, Korea is failing to recognize the value of the patented drug. In so doing, Korea's P&R system has severely restricted Korean patients' access to patented medicines—as demonstrated, for example, by the exceptionally low rate of cancer drugs listed for reimbursement. This outcome is precisely what KORUS Article 5.2(b) seeks to prevent.

Moreover, Korea's P&R regime goes far beyond a "limited exception" to the patent holder's exclusive rights, thereby violating KORUS Article 18.8(3). "Exclusive rights" are understood as "the acts of: making, using, offering for sale, selling, or importing for these purposes that product."¹³² The *Canada—Pharmaceuticals* 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."¹³³ 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. This TRIPS jurisprudence supports a parallel reading of KORUS Article 18.8(3).¹³⁴

The fact that new drug prices in Korea were *less than half of the OECD average* during the 2007–2014 period is a stark indicator of how far Korea's P&R measures have gone beyond their purported goal of reasonably controlling healthcare costs. As the U.S. Department of Commerce has noted, when countries rely on "government fiat rather than competition to set prices" for new drugs, their price controls "reduce company compensation to levels closer to direct production costs," and leave less revenue for

¹³² AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS ("TRIPS"), Apr. 15, 1994, 1869 U.N.T.S. 299, art. 28.1 (footnote omitted); See also the WTO Panel's interpretation of this Article in *Canada – Pharmaceuticals*, WT/DS/114/R, ¶¶ 7.32-33.

¹³³ *Id.* ¶¶ 7.54-55.

¹³⁴ 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." See Statement by the United States at Meeting of 25 March 1987, MTN.GNG/NG11/W/2 (Apr. 3, 1987), at 3. As the United States expressed at that time, "[s]uch policies interfere with obtaining and maintaining intellectual property rights and thus reinforce the direct distortion of trade that results from such policies." *Id.* Others involved in the TRIPS negotiations made similar statements. At a September 1989 meeting, a participant discussed providing patentees "the right to exclude others from making, using or selling the patent or invention for a specified time" and asserted that "[t]hese rights were necessary to provide patentees with the necessary economic incentive 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.

research and development “that would provide substantial health benefits to all.”¹³⁵ Korea’s onerous and multiple layers of price cuts are depriving U.S. pharmaceutical manufacturers of the right to sell pharmaceutical products at prices that would permit recoupment of investments and are undermining the incentive to develop innovative products.

Further, the 7.7 Pricing Policy is inconsistent with Korea’s national treatment commitments under KORUS Article 5.2(a) and 18.1(6). The 7.7 Pricing Policy favors Korean pharmaceutical patent holders by according price and other preferences to locally-developed new medicines, while withholding such benefits from imported innovative medicines. Until the Korean Government fully and fairly implements the “social contribution” and “open innovation” provisions of the 7.7 Pricing Policy, U.S. pharmaceutical companies are afforded no opportunity to compete on equal footing with domestic competitors for access to premium pricing.

Patent Term Restoration

At the request of the patent owner, KORUS Article 18.8(6)(b) requires Korea to restore the term of a patent on a new medicine to compensate for unreasonable marketing approval delays. That Article specifies that any extension “shall confer all of the exclusive rights ... of the patent claims.” However, recent decisions by the Korean Intellectual Property Trial and Appeal Board¹³⁶ that were later affirmed by the Korean Patent Court¹³⁷ appear to violate Korea’s commitment to the United States by impermissibly limiting the extension only to the product actually approved for marketing, rather than to the patented invention related to the product.

These decisions, which have been appealed to Korea’s Supreme Court, completely undermine the purpose and value of patent term restoration. During the period of any extension, they would allow a competitor to seek marketing authorization for a follow-on product that contains an alternative form of the innovator’s active ingredient, even though it would otherwise infringe the innovator’s patent. For example, the follow-on product might be prepared as a different salt or a different free acid or free base. By permitting the marketing of follow-on products that contain an alternative form of the same active ingredient and are designed to treat the same disease or condition during the restored period, these decisions essentially render meaningless any additional exclusivity provided by the restored patent term.

¹³⁵ U.S. Department of Commerce, International Trade Administration, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development and Innovation* (Dec. 2004), at vii.

¹³⁶ See Intellectual Property Trial Appeal Board decisions in Case No. 2015Dang3931, rendered in September 2016 and Case No. 2016Dang547, rendered in October 2016.

¹³⁷ See Patent Court decision in Case Nos. 2016Heo8636 and 2016Heo8918 (consolidated), and Case No. 2016Na1929, all rendered in June 2017.

PhRMA members urge USTR to engage the Korean Government on this matter through additional special sessions of the U.S.-Korea FTA Joint Committee, with a view to ensuring swift compliance with Korea's trade agreement obligations.

Patent Enforcement

Consistent with its IP obligations under KORUS,¹³⁸ effective March 15, 2015, Korea implemented the framework of an effective patent enforcement system. Key issues that PhRMA continues to monitor include:

- The discretion afforded to MFDS to determine whether to list a patent in the Green List or to permit a change to the patent listing.
- Korean law only provides for a nine-month sales stay. It is unclear whether this will be 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.
- The sales stay system under Korean law is problematic in that the patentee cannot request a sales stay against an infringing generic product unless a sales stay is also sought against non-infringing generic products.

Market Access Barriers

Lack of Transparency and Predictability in Government Policy-making

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.

Also, there are still repetitive and excessive price cut mechanisms working in the market after reimbursement listing, such as biannual ATP investigations, Price-Volume Agreements (PVAs), listing of first generic and expanding reimbursement scope with new indications or change of treatment guidelines.

Separately, the Risk Sharing Agreement (RSA) system should be expanded to provide an alternative pathway for reimbursement listing to enhance patient access to innovative medicines regardless of disease area and alternatives. The RSA is permitted only for rare diseases and anti-cancer products and is dependent on mandatory submission of pharmacoeconomic data not only at the time of initial agreement but for the renewal every three years. In order to provide greater predictability for pharmaceutical companies, companies should be able to negotiate fixed contract terms until all IP protections have expired.

¹³⁸ See U.S.-Korea Free Trade Agreement, Art. 18.9, para. 5.

Independent Review Mechanism (IRM)

Under Article 5.3(5)(e) of the U.S.-Korea Free Trade Agreement 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 IRM because the NHIS does not make “determinations” and merely negotiates the final price at which a company will be reimbursed. However, this interpretation totally negates the original purpose of the IRM, which we believe should apply to the negotiation process for prices of all reimbursed drugs, particularly patented medicines.

Ethical Business Practices (EBP) Reform

The Act on Prohibition of Improper Solicitation and Provision/Receipt of Money and Valuables (the “Anti-Graft Law”) took effect on September 28, 2016. However, insufficient information regarding how the law will be implemented has created ambiguity for the pharmaceutical industry. Industry seeks clarification on how activities such as, among other things, investigator meetings and advisory board meetings will be impacted. In light of the strict penalties for unethical business practices, it is critical that there is a clear understanding of how the EBP standards will be enforced.

MALAYSIA

PhRMA and its member companies operating in Malaysia are alarmed by recent Government of Malaysia actions which undermine a core tenant of intellectual property (IP) protection and, if unaddressed, could inspire other countries to advance similar compulsory license schemes undermining vital IP. We hope to continue our engagement with the Government of Malaysia as it looks to improve the IP and regulatory environment for the research-based pharmaceutical industry, which is necessary to attract biopharmaceutical innovator investment in research and development in Malaysia. Addressing these issues will further narrow the United States' current \$25B trade deficit with Malaysia.

Key Issues of Concern:

- **Compulsory License:** The Malaysian government has approved what it is characterizing as a government use license for a breakthrough innovative medicine. This action could cause serious harm to a U.S. manufacturer that was engaged in ongoing negotiations with the Government of Malaysia on a voluntary license at the time this compulsory license was unilaterally issued. Additionally, if not met with a forceful U.S. Government response, this action carries significant risks of contagion to other markets, which would significantly undermine the current R&D model for innovative medicines on which the U.S. pharmaceutical industry and patients around the world rely.
- **Inadequate IP protection and enforcement:** Malaysia does not have an effective patent enforcement system that provides for the early resolution of patent disputes before marketing approval is granted to infringing follow-on products during the patent term. In addition, its regulatory data protection (RDP) system fails to provide (1) any 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.
- **Listing pharmaceuticals on the national formulary:** Effective 2016, Malaysia adopted a new process for listing products on the Ministry of Health (MOH) Medicines Formulary. While this is a welcome development, PhRMA and its members are concerned that the final guidelines require one year 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 maintain access during this period. In addition, if a product is not approved for listing on the Formulary, the applicant should be provided a rationale 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.
- **Mandatory Price Disclosure:** The MOH is in the process of amending the Control of Drugs and Cosmetics Regulations 1984 to create a new regulation that would mandate the disclosure of prices throughout the pharmaceutical supply

chain. Implementation of such a policy would require companies to provide commercially sensitive information that is confidential and proprietary, which is inconsistent with international practice and also raises competition issues.

- **Halal Pharmaceuticals:** In December 2017, the MOH published a guideline on the use of medicines that contain non-halal ingredients. PhRMA's member companies are strongly supportive of religious and cultural sensitivities, but do not believe that the government should provide preferential treatment to such products in government procurement and are concerned that these guidelines could have unexpected negative implications on patient health.
- **Preferential treatment of local manufacturers:** The Government of Malaysia indirectly discourages an open and competitive marketplace for international pharmaceutical compounds through procurement preferences for locally manufactured products. For example, the Government of Malaysia has recently announced that it will grant three-year procurement contracts to companies who move production of imported products to Malaysia (with the potential for a two-year extension if those locally produced products are exported).

For these reasons, PhRMA requests that Malaysia be designated a **Priority Foreign Country** in the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Compulsory License

Late last year, the Malaysian government utilized a non-transparent process to issue a compulsory license (CL) on a patent-protected innovative U.S. medicine. This unnecessary and unjustified measure was taken in a unilateral and non-transparent fashion, even as the manufacturer was engaged in good faith negotiations with the government on a voluntary licensing regime. The CL has sent a devastating signal to America's biopharmaceutical innovators that their patents are not safe in Malaysia. Additionally, if this action is not met by a strong response, the Government of Malaysia may use compulsory licenses on other innovative medicines, or inspire other countries to unilaterally determine that it is exempt from its obligations with respect to IP protections under well-established and binding international agreements.

While imposing a license is rarely, if ever, an appropriate mechanism to improve patient access, that is particularly true in this instance where the innovative company has already announced plans to voluntarily license the patent. The manufacturer in this instance was in the process of an in-depth negotiation for a mutually beneficial voluntary licensing scheme when the Government of Malaysia issued its decision on a compulsory path. Following the announcement of the CL, Malaysia continued negotiating with the manufacturer for a voluntary license for use throughout the country, and despite coming

to an agreement on price with the manufacturer, appears to be moving forward with a CL for use in state-owned hospitals.

The non-transparent manner in which this decision was made raises serious questions around how such decision was made. The sudden and unexpected announcement of a CL was made immediately following a meeting between President Donald Trump and Prime Minister Najib Razak, without any indication during the visit that such a provocative step would be taken. Furthermore, at no point prior to the announcement did the Ministry of Health or any other government ministry or agency offer to meet with relevant industry stakeholders, consider their concerns, or evaluate their input. This is surprising given the Government of Malaysia's historical support for open, transparent, and fair market practices, and denies U.S. manufacturers any sense of predictability around Malaysia's regulatory decision-making. The lack of industry stakeholder input is also troubling given the immediate significance of such a decision to the market for medicines globally, and the potential long-term ramifications for U.S. producers of innovative medicines and other cutting-edge IP.

Malaysia appears to be seeking to use a CL as a method to coerce price reductions, despite the fact that the Malaysian government invests just 2.3% of GDP on health (compared to a world average of nearly 6%) and yet has a GDP level per capita (based on purchasing power parity) that is higher than in many European countries. If a country of this relative prosperity can disregard U.S. intellectual property, it raises substantially the risk that similarly situated countries will follow. If left unaddressed, this threatens to undermine the R&D funding system upon which the U.S. innovative pharmaceuticals industry is based.

Effective Patent Enforcement

PhRMA members encourage Malaysia to efficiently and effectively enforce its Patent Act. A competent and practical enforcement mechanism provides redress and solutions to infringements of IP rights and deters future infringement. Timely and efficient patent enforcement gives owners an appropriate period over which to recoup the value of their significant efforts and investment. For example, patent protection and enforcement would be enhanced by structured enforcement guidelines and a mechanism to curb unfair promotion and sale of generic drugs either prior to patent expiry of innovator drugs, or, in the event of a patent dispute, prior to a court decision on patent disputes.

PhRMA's member companies strongly encourage the improvement and adoption of mechanisms that strengthen patent enforcement and the ability to resolve outstanding patent concerns prior to marketing approval of follow-on products, such as generics. These mechanisms could greatly enhance Malaysia's business environment by: (1) providing transparency and predictability to the process for both innovative and the generic pharmaceutical companies; (2) creating a more predictable environment for investment decisions; and (3) ensuring timely redress of genuine disputes.

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% of medicines that enter clinical trials ever result in approved treatments.¹³⁹

To support the significant investment of time and resources needed to develop test data showing a potential new medicine is safe and effective, governments around the world protect that data submitted for regulatory approval from unfair commercial use for a period of time. TRIPS Article 39.3 requires WTO members, including Malaysia, to protect proprietary test data submitted to market authorizing bodies, including the MOH, “against unfair commercial use” and against “disclosure.”

The stated objective of Malaysia’s Directive (11) dlm. BPFK/PPP/01/03 Jilid 1 is “to protect the undisclosed, unpublished and non-public domain pharmaceutical test data ... for the purpose of scientific assessment in consideration of the quality, safety, and efficacy of any new drug product....”¹⁴⁰

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....¹⁴¹

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 data protection 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

¹³⁹ DiMasi JA, Grabowski HG, Hansen RW; Tufts Center for the Study of Drug Development. Innovation in the pharmaceutical industry: new estimates of R&D costs. In: Briefing: Cost of Developing a New Drug, available at http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf (last visited Feb. 7, 2018).

¹⁴⁰ See paragraph 1.2 of Directive BPFK/PPP/01/037.

¹⁴¹ Id.

the United States (both are relied upon for the Certificate of Pharmaceutical Product (CPP) application).

In addition to this inappropriate time 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.

This interpretation of RDP 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. Unlike generic versions of traditional chemically-synthesized compounds, biosimilars are not identical to the original innovative medicine and there is greater uncertainty about whether an innovator's patent right will cover a biosimilar version. Without the certainty of a substantial period of exclusivity, innovators will not have the incentives needed to conduct the expensive, risky and time-consuming work to discover and bring new biologics to market.

Patent and Trademark Laws

Proposed amendments to Malaysia's patent and trademark laws that include provisions for disclosure of traditional knowledge and genetic resources, as well as compulsory licensing, raise concerns for the research-based pharmaceutical industry, and PhRMA encourages a continued consultative process with stakeholders before such amendments are implemented in order to avoid policies that deter or discourage innovation across fields of technology. These proposed amendments also include provisions for effective patent enforcement and patent term restoration. PhRMA member companies are eager to engage in meaningful dialogue with Malaysian Regulatory Authorities to build a system that reflects international best practices.

Market Access Barriers

Listing Pharmaceuticals on the National Formulary

Industry commends the Malaysian Government for allowing companies to directly request inclusion on the national formulary through guidelines introduced in January 2016. However, industry is disappointed that the final guidelines require one year of post-marketing surveillance data prior to listing and one year from date of registration. If local clinical trials have been completed for a product, it should be automatically listed on the national formulary to enable patients who were on the treatment to continue receiving the

product after the clinical trial is completed. A policy is needed to bridge the gap for patients from the end of a clinical trial to the listing in the formulary.

Further, as the government pursues reforms aimed at improving access of medicines to its population, member companies hope that sufficient financing is provided to ensure that more patients can receive innovative medicines in as timely a manner as possible to achieve better health outcomes. We hope that short term measures, such as cost containment policies, do not become a barrier to access and the government considers fair mechanisms to value innovations that are proven to raise the standards of care in Malaysia.

Mandatory Price Disclosures

The Malaysian Ministry of Health is in the process of amending the Control of Drugs and Cosmetics Regulations 1984 to empower the Senior Director of Pharmaceutical Services to mandate the disclosure of prices throughout the pharmaceutical supply chain. In particular, the amendment would mandate disclosure of the medicine's landing price, ex-manufacturer price, wholesale price, retail price and any other price from all parties involved in the sale of registered medicines. This amendment is expected to be sent to the Minister for approval soon, with a view of implementing it in January 2018.

This proposed amendment raises serious concerns for the pharmaceutical industry in Malaysia. Implementation of the policy would require companies to provide commercially sensitive information that is confidential and proprietary, which is inconsistent with international practice and also raises competition issues. It is unclear whether the trade and competition authorities have been included in the Ministry of Health's decision-making process. In addition to being contrary to international practice, it appears to contravene Malaysia's Competition Act of 2010, which protects upstream price information as confidential business information. Malaysia already has policies in place (Good Pharmaceutical Trade Practice, Component 2) to empower consumers and their physicians to make informed decisions based on factors such as affordability and a patient's health; thus, such a policy would serve no further purpose.

Halal Pharmaceuticals

In December 2017, the MOH published a guideline on the use of medicines that contain non-halal ingredients. PhRMA's member companies are strongly supportive of religious and cultural sensitivities, but do not believe that the government should provide preferential treatment to such products in government procurement and are concerned that these guidelines could have unexpected negative implications on patient health.

Preferential Treatment of Local Manufacturers

Malaysia's National Medicines Policy (MNMP/DUNas), which prioritizes the medium and long-term goals set by the Government for the pharmaceutical sector,

endorses potential price controls, generic drugs substitution, and preferences for generics and local manufacturers by promoting national self-reliance for drugs listed on the National Essential Medicines List (NEML). PhRMA member companies submit that the Government of Malaysia should eliminate discriminatory preferences for locally manufactured pharmaceuticals. This preferential treatment discourages an open and competitive marketplace in Malaysia.

Additionally, as part of its aspiration to achieve high-income nation status by 2020, Malaysia has in place various initiatives such as the National Key Economic Area program, offering economic incentives to enhance local manufacturing capacity and capability in pharmaceuticals. Under this government scheme if a company locally produces a medicine that was previously imported, it is assured a 3-year tender purchase contract for that product (with the potential to extend that contract for an additional 2 years if the locally produced product is exported). Such measures discriminate against importers including many U.S.-based innovative pharmaceutical companies.

Regulatory Approval Process

PhRMA's member companies continue to advocate for further streamlining of Malaysia's regulatory approval process for innovative pharmaceutical products. In November 2010, MOH gave notice of their intention to streamline the approval process to 210 working days. However, PhRMA's member companies continue to report lengthy delays. Effective reform that streamlines Malaysia's regulatory approval process to 210 working days or less could greatly expand market access and patients' access to medicines. To help achieve this goal, PhRMA's members would encourage Malaysia, as a standard practice, to no longer require an applicant to submit a Certificate of Pharmaceutical Product (CPP) at the time of submitting their regulatory dossier (currently submission of the regulatory dossier without the CPP is allowed only on a case-by-case basis). Instead the CPP could be provided later in the regulatory approval process.

Further, the recent introduction of the QUEST system for dossier submissions has created significant administrative hurdles in the processing of biopharmaceutical industry regulatory submissions and threatens to delay patient access to new medicines in Malaysia.

Section 306 Monitoring

THE PEOPLE'S REPUBLIC OF CHINA

PhRMA and its member companies operating in The People's Republic of China are committed to supporting the government's efforts to build a patient-centered and pro-innovation healthcare system. China is taking very important and positive steps to strengthen its regulatory framework, intellectual property (IP) protection and enforcement system, and government reimbursement for innovative medicines. However, we remain concerned about the lack of effective regulatory data protection (RDP) and patent enforcement, inconsistent patent examination guidelines, the non-transparent and unpredictable government pricing and reimbursement policies, the lack of predictability and transparency in the regulatory approval process, burdensome biological sample exportation policies, rampant counterfeiting of medicines, and under-regulated active pharmaceutical ingredients.

PhRMA is encouraged by China's ongoing work to strengthen its drug regulatory framework and intellectual property protection and enforcement system, including through the draft China Food and Drug Administration (CFDA) amendments to the Drug Administration Law (DAL) and Drug Registration Regulation (DRR) in October 2017; the Central Committee of the Communist Party / State Council Opinion (CCP/State Council Opinion) on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices issued in October 2017; and the draft CFDA Circulars (Nos. 52-55) issued in May 2017. CFDA's May 2017 accession to the International Council on Harmonization (ICH) further exemplifies China's reform efforts. In addition, we are encouraged by the 2017 update to the National Reimbursement Drug List (NRDL). These proposals and reforms provide a critical opportunity to enhance patient access to innovative medicines and to address many of the following issues of concern.

PhRMA is eager to continue supporting China in this reform effort to strengthen RDP, patent term restoration, patent enforcement and patent examination guidelines, accelerate and simplify the regulatory approval process. We are highly concerned, however, that the recent draft DRR amendment undercuts the laudable goals of the CCP/State Council Opinion and China's long-term innovation plans generally by reintroducing the concept of a globally new drug or biologic. This globally new standard is very likely to be counterproductive for China, making it more difficult for both foreign and domestic innovative manufacturers to benefit from the proposed policy reforms and engage in the type of meaningful development and collaboration with partners in China and around the world that promotes innovation. Requiring innovators to wait until they have first obtained approval for development or marketing in China to obtain regulatory data protection is not consistent with China's aspirations to promote local innovation, particularly given that it would require innovators to delay launches in other markets that offer significantly stronger intellectual property protections. As such we urge CFDA to clarify the definition of new as it applies to drug and biologic registration applications and define "new" to mean never marketed in China, as opposed to new to the world.

In addition, PhRMA urges China to establish a comprehensive and sustainable policy framework for government pricing and reimbursement that would include predictable and timely reimbursement decisions for new drugs, systematic and transparent mechanisms for price negotiation linked to reimbursement, and an enhanced role for commercial health insurance.

A fair and transparent regulatory and legal process is another priority element for a sound and sustainable drug regulatory regime in China. PhRMA is concerned about China's inconsistency in meeting its domestic legal requirements and bilateral U.S.-China commitments in this regard. In particular, China frequently does not provide reasonable periods for public comment on draft laws, rules, regulations and other binding measures, despite these obligations.¹⁴² As China moves forward in its next phase of reform, PhRMA urges China to publish draft measures and provide ample time for stakeholders to provide meaningful comments.

Key Issues of Concern:

- **Restrictive patentability criteria:** In late 2016, the State Intellectual Property Office (SIPO) issued an amendment to its Patent Examination Guidelines that would require examiners to take into account post-filing experimental data submitted by an applicant. This amendment appears to be intended to implement China's commitment, made during the 2013 Joint Commission on Commerce and Trade (JCCT), to permit patent applicants to file additional data after the application filing date. PhRMA recognizes and welcomes this positive step, but concerns remain regarding SIPO implementation and interpretation of the proposed amendment. In addition, certain therapeutic methods, referred to as "specific therapeutic methods," essentially 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). Inventions in such methods very often bring important patient benefits, and the inability to obtain patents on these inventions undermines the incentives to invest in them, particularly to the extent they are targeted at particular medical and health problems in China.
- **Weak patent enforcement:** Transparent mechanisms are needed in China to ensure parties are afforded the opportunity to resolve patent disputes before potentially infringing pharmaceutical products are launched on the market. Neither China's DAL nor the DRR provide an effective mechanism for enforcing an innovator's patent rights vis-à-vis regulatory approval of follow-on products and the proposed DRR revisions would eliminate the existing weak mechanism. In this

¹⁴² See, e.g., Fact Sheet: 25th U.S.-China Joint Commission on Commerce and Trade (Dec. 2014), available at <https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2014/december/us-fact-sheet-25th-us-china-joint> (last visited Feb. 7, 2018) (stating that "China and the United States agree that for all draft pharmaceutical and medical device rules and regulations where notifications are required under the relevant WTO rules, a comment period will be provided that will be no less than 60 days.").

light, we are greatly encouraged by CFDA's draft Circular 55 (Relevant Policies on Protecting Innovators' Rights to Encourage New Drug and Medical Device Innovation), which proposes a patent enforcement system with the critical components of: a) notice to innovators of potentially infringing subsequent applications referencing the original application prior to approval of such subsequent applications; and b) a stay of marketing approval pending the resolution of disputes concerning those patents.

- **Regulatory data protection failures:** China committed as part of its accession to the World Trade Organization (WTO) to provide a 6-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. In practice, however, China's RDP system is not effective. In this regard, we strongly welcome the CFDA draft Circular 55, which proposes ten years of RDP for new 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.
- **Loss of Patent Term Due to Regulatory Delay:** Lengthy regulatory approval processes for pharmaceutical products results in a significant loss of effective patent term for such products. Though China has indicated it will address this problem by implementing patent term restoration to account for the lengthy regulatory approval process, this continues to be a problem that undermines the incentives intended to be created by the patent system.
- **Delays and lack of transparency in government pricing and reimbursement:** PhRMA welcomes the 2017 update to the NRDL – the first update since 2009 – which will improve the access and affordability of innovative medicines for Chinese patients. We encourage the Chinese government to shift towards a more timely, transparent and predictable reimbursement system, in which manufacturers may apply for reimbursement at any time, drug clinical assessment is completed within a pre-defined period following the application (e.g., within 90 days), and negotiations between manufacturers and the responsible government agency take place periodically (e.g., semi-annually). While the manner in which the first national reimbursement negotiation was conducted by MOHRSS in July 2017 diverges from a sound pricing and reimbursement system, PhRMA is pleased to see MOHRSS moving forward with a negotiation process and requesting input on establishing a regular reimbursement mechanism.
- **Lengthy regulatory approval process:** The process for approving a medicine in China still takes much longer than international practice and is particularly lengthy and cumbersome for vaccines. This lengthy regulatory approval process results in a significant loss of effective patent term for biopharmaceutical products. However, CFDA is undertaking significant reform efforts to accelerate the drug review and approval process and align its regulatory framework with international standards. PhRMA is encouraged by many recent proposals, including in the draft CFDA amendments to the DAL and DRR, the CCP/State Council Opinion, and the draft

CFDA Circulars (Nos. 52-54), to improve the efficiency of global drug development and reduce the time it takes for all innovative new medicines to reach Chinese patients.

- **Counterfeit medicines:** China has been implementing national plans to improve drug safety and severely 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 remain rampant in China and continue to pose a threat to China and its trading partners. PhRMA looks forward to meaningful implementation of China's commitment made during the sixth meeting of the U.S.-China Strategic and Economic Dialogue (S&ED) in July 2014 related to effective regulatory control of APIs and anti-counterfeiting.

For these reasons, PhRMA requests that China remain on the **Priority Watch List** and be subject to **Section 306 Monitoring** for the 2018 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Over the past year, China has released a series of proposed policies that could strengthen its regulatory framework for innovative medicines in a way that may address long-standing industry concerns about the lack of RDP, loss of patent term due to lengthy regulatory approval processes, ineffective patent enforcement, and inconsistent patent examination guidelines. For example, the CCP/State Council Opinion, which was issued in October 2017, is the first time that this level of the Chinese government has openly endorsed RDP and patent linkage in a meaningful way. In addition, the CFDA draft Circulars, which were issued in May 2017, propose the establishment of a patent linkage system and specific RDP terms. We also see progress on these issues in the October 2017 CFDA draft DRR amendment, which is a significant improvement over the draft DRR issued in 2016. At the same time, we urge CFDA to tighten the patent linkage and RDP provisions in the draft DRR amendment to ensure that they serve their intended purpose of encouraging stakeholder innovation.

PhRMA looks forward to working with the Chinese and U.S. governments through all available pathways to see these proposed reforms finalized, fully grounded in best practices. The input U.S. stakeholders have already submitted offers important guidance in this regard. It is equally critical to ensure that these reforms are implemented fully in a manner that advances innovation and patient access, is consistent with China's bilateral commitments and international obligations, and ensures that U.S. biopharmaceutical companies can compete on a level playing field with China's domestic industry.

Restrictive Patentability Criteria

Reforms need to continue in China to provide clear and coherent standards, consistent with other major drug markets, for obtaining biopharmaceutical patents. It is critical that such standards reflect the realities of the drug development lifecycle. For example, unlike patent offices in the United States, Europe, Japan, Korea and other major markets, SIPO does not consistently accept data generated after a patent is filed to describe inventions or satisfy inventive step requirements, pursuant to Articles 26.3 and 22.3 of China's Patent Law, respectively. 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 late 2016, SIPO issued an amendment to its Patent Examination Guidelines that would require examiners to examine the post-filing experimental data submitted by the applicant. This amendment appears to be intended to implement China's commitment, made during the 2013 JCCT, to permit patent applicants to file additional data after the application filing date. PhRMA recognizes and welcomes this positive step, and is committed to working collaboratively with the appropriate government authorities to facilitate practical implementation of the proposed amendment in a manner that provides greater certainty and protection for U.S. biopharmaceutical innovators.

PhRMA views the 2016 SIPO revision to Section 3.5 of the Patent Examination Guidelines as an important step toward implementing a clear and consistent standard that permits pharmaceutical manufacturers to submit additional data to confirm that the invention is novel, useful and contains an inventive step. The submission of supplemental data will also support and confirm statements that have already been disclosed in the patent application. We assume that by requiring the examiner to examine supplemental experimental data, this new provision will be implemented in such a way that the supplemental data can be relied upon to successfully respond to an examiner's rejection for lack of inventive step or insufficient disclosure provided in the patent application.

While PhRMA recognizes and welcomes this positive step, we have two concerns with the data supplementation amendment. First, the amendment to Section 3.5 would make the data supplementation approach applicable only to "Sufficiency of Disclosure of Chemical Inventions." We believe the same approach should be taken to the examination of other patentability issues, such as inventive step, and therefore should be incorporated into Section 6, Chapter 10 of Part II as well. Second, we are concerned that certain language in the proposed amendment may be interpreted too narrowly by SIPO examiners, resulting in less patent incentives for new medicines in China and thereby harming Chinese patients. Specifically, the amendment permits data supplementation only where "the technical effect to be proved by the supplemented experimental data shall be one which can be derived by a person skilled in the art from the disclosure of the patent application." If this is interpreted so as to require the application to already disclose or demonstrate the precise technical effect to be proven by the offered supplemental data, the result would be that supplemental data is rarely accepted. This result can be avoided by incorporating more detailed guidance in the Guidelines to make it explicit that the

requirements are in line with those commonly used in other countries. For example, the European Patentability Examination Guidelines (Section 11) provide that supplemental data will be accepted if it proves effects that “are implied by or at least related to the technical problem initially suggested in the originally filed application.”¹⁴³ In implementing this provision, we urge SIPO to keep these considerations, goals and benefits in mind and provide additional guidance consistent with them.

Specific therapeutic methods essentially 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 that, in effect, can provide patent protection for such inventions). Incentives to develop such new specific therapeutic methods should be provided by the patent system because such new uses of existing medicines can bring important patient benefits, including methods of treatment specific to the Chinese population that may not be developed in the absence of a local incentive to do so. However, Article 25(3) of China’s Patent Law does not allow for direct patenting of methods of treatment. The courts, including the Supreme Court (see, e.g., in the decision on *Genentech v. PRB* against validity of patent No. ZL 00814590.3) and SIPO (as stipulated in the Guidelines for Patent Examination), do not permit alternative claim formats that could protect specific therapeutic methods, including either Swiss-type claims where the point of novelty is a specific therapeutic method or other alternative formats that are accepted by patent offices in other countries, including the European Patent Office). We urge SIPO to revisit this gap in China’s patent system and conform China’s practice to that of many other countries.

Weak Patent Enforcement

Transparent mechanisms are needed in China to ensure parties are afforded the opportunity to resolve patent disputes before potentially infringing pharmaceutical products are launched on the market. If a follow-on company actually 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 fact, CFDA has approved infringing follow-on products, and research-based pharmaceutical companies have not been able to consistently resolve patent disputes prior to the marketing of those infringing drugs. Further, although China’s laws and regulations provide for injunctive relief, in practice

¹⁴³ Available at [http://documents.epo.org/projects/babylon/eponet.nsf/0/0791474853510FFFC125805A004C9571/\\$File/guidelines_for_examination_part_g_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/0791474853510FFFC125805A004C9571/$File/guidelines_for_examination_part_g_en.pdf) (last visited Feb. 7, 2018).

injunctions are rarely, if ever, granted in the context of preventing premature follow-on product market entry, due to high procedural barriers.

In this light, we are greatly encouraged by CFDA's draft Circular 55, which proposes a patent enforcement system with the critical components of: a) notice to innovators of potentially infringing subsequent applications referencing the original application prior to approval of such subsequent applications; and b) a stay of marketing approval pending the resolution of disputes concerning those patents. We also welcome the October 2017 draft DRR amendment, which is a significant improvement over the 2016 DRR amendment. At the same time, this draft does not include the level of detail and specificity required to establish an effective patent enforcement system. For example, we strongly suggest that CFDA make it clear in the DRR that it will not approve potentially infringing follow-on application during the pendency of timely filed patent litigation or for a designated period of time, whichever is shorter. CFDA should also apply linkage to "relevant" patents, *i.e.*, formulation, composition, and method of use patents, as well as process patents for biologics.

Further, PhRMA and its member companies are encouraged by recent, preliminary proposals by the Center for Drug Evaluation to establish an Approved Drug List, akin to the Orange Book maintained by the U.S. Food and Drug Administration, that would provide greater certainty to innovators and generic manufacturers alike regarding the patent status of approved medicines and facilitate effective patent enforcement and implementation of regulatory data protection. We are hopeful that CFDA and SIPO will provide more guidance on the listing process and mechanics of the stay described in Circular 55, and we look forward to working with the Chinese and U.S. governments to ensure that China implements an effective patent enforcement system.

In addition, parallel patent enforcement proceedings through China's judiciary and SIPO's Patent Review Board (PRB) 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 SIPO's PRB during an ongoing judicial proceeding are grounds for automatic dismissal of relevant infringement litigations. In that situation, patent owners are required to appeal the PRB decision through the judiciary, and if successful, seek a court to compel PRB to confirm the judgment. Due to PRB's extremely strict inventive step and supplemental data requirements, and fast docket times, patent infringement defendants can use the PRB proceedings as a tactic to circumvent the judicial process.

Regulatory Data Protection Failures

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).¹⁴⁴ Indeed, China's DAL and DRR, administered by the CFDA, establish a six-year period of protection for test data of products containing a new chemical ingredient against unfair commercial use.¹⁴⁵ In practice, however, China's regulatory environment allows for unfair commercial use of safety and efficacy data generated by PhRMA member companies.

China's current RDP system in practice is inconsistent with TRIPS Article 39.3 in several ways. First, certain key concepts such as "new chemical ingredient" (sometimes referred to as "new chemical entity") and "unfair commercial use" are undefined or are not in line with international standards. This leads to the inconsistent and arbitrary application of the law by CFDA, in addition to confusion and uncertainty for sponsors of marketing approval applications. The term "new chemical ingredient" should be clearly defined in the DAL, DRR, and other relevant laws and regulations in line with international standards and include biologic and chemically synthesized drugs, recognizing the considerable investment by innovative pharmaceutical companies in developing and proving safety and efficacy of a new product.

Second, RDP should be granted to any product that is "new" to China, *i.e.*, has not been approved by CFDA. In practice, however, China grants RDP only to pharmaceutical products that are "new" to the world – in other words, products that make their international debut in China. That is at odds with the approach of other regulatory systems and even at odds with the approach taken in China for RDP for agricultural chemicals.

During the December 2012 JCCT, China "agreed to define new chemical entity in a manner consistent with international research and development practices in order to ensure regulatory data of pharmaceutical products are protected against unfair commercial use and unauthorized disclosure."¹⁴⁶ Following many years of discussion in the JCCT and other venues, this commitment was a positive development. Unfortunately, this commitment remains unfulfilled. Effective implementation of this commitment is necessary. Although the U.S. Government has actively engaged CFDA to revise the definition of new chemical entity, little progress has been made.

The February 2016 CFDA "Chemical Drug Registration Category Work Plan," defines a "new drug" as a chemical entity that is "new to the world." PhRMA is concerned that this revised definition of "new drug" may signal a similar narrowing of thinking with respect to the definition of new chemical ingredient, and therefore, creates a risk that a

¹⁴⁴ 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.

¹⁴⁵ See Regulations for Implementation of the Drug Administration Law of the People's Republic of China, Art. 35; Provisions for Drug Registration (SFDA Order No. 28), Art. 20.

¹⁴⁶ See Fact Sheet: 23rd U.S.-China Joint Commission on Commerce and Trade (Dec. 19, 2012, available at <https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2012/december/23rd-JCCT> (last visited Feb. 7, 2018)).

drug approved or marketed first outside of China may receive weaker or no exclusivity in China. In addition, this revised definition of “new drug” could potentially impact China’s JCCT RDP commitment.

Third, China’s regulatory procedures permit non-originator, or follow-on, applicants to rely on the data submitted to CFDA or a foreign regulatory agency’s approval of the originator product in another market during the RDP term in China. 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 CFDA. CFDA should not approve follow-on drugs during the RDP period unless the follow-on applicant submits full clinical trial data that it has independently developed or received a license to cross-reference from the innovative drug manufacturer. This approach would be consistent with the goals of encouraging innovation in China by protecting innovators’ investment in clinical trials. To meet these goals, China will need to ensure that it has regulatory and legal systems that are compatible with other major markets. While the systems need not be identical, implementation of a meaningful RDP mechanism can promote harmonization and enable companies to function more easily in multiple markets. PhRMA notes that it has been 14 years since China’s WTO commitment to provide RDP. Thus, prompt and meaningful RDP reform should be a high priority.

In light of these deficiencies, we strongly welcome the October 2017 CCP / State Council Opinion, which endorses stronger RDP and the May 2017 CFDA draft Circular 55 (Relevant Policies on Protecting Innovators’ Rights to Encourage New Drug and Medical Device Innovation), which proposes ten years of RDP for new 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.

We are also encouraged by the October 2017 draft DRR amendment, which provides a designated time and mechanism for applying for RDP, as well as a public list of marketed drugs that will give notice of that protection to follow-on manufacturers. However, we are concerned that RDP may not apply to certain categories of drugs and urge CFDA to clarify that drugs supported by full safety and effectiveness data, whether new to China or new to the world, may receive data protection. Furthermore, it is critical that improved or modified drugs and all innovative biologics, including vaccines, also receive RDP.

Lack of Patent Term Restoration

Pharmaceutical companies must adhere to a drug registration process before marketing drugs in China, as they must in other countries, which causes delays in marketing that reduce the effective term of patent protection for products once they reach the market. Many other countries respond to this problem by restoring the term of patents to compensate for regulatory delay. Currently, such patent term restoration is not available under China’s Patent Law (and not proposed in a pending proposed draft 4th

Amendment to the Patent Law), even though regulatory delays in China are longer than in most other countries.

In early 2017, CFDA indicated informally that it intends to introduce patent term extensions, and both CFDA and SIPO appear to be discussing this possibility. Per the CCP/State Council Opinion issued in October 2017, patent term extensions will be piloted on selected drugs, but further details have not yet been forthcoming. We encourage China to include this reform in the steps it is now taking to strengthen pharmaceutical patent protection.

Mandatory intellectual property sharing related to certain biological material

The Ministry of Science and Technology (“MOST”) originally issued the Interim Measures for the Administration of Human Genetic Resources in 1998 to restrict the exploitation and exportation of human biological samples accessed in China. In relevant part, that interim measure required that any research conducted by foreign companies using Chinese human biological samples must be undertaken in collaboration with Chinese partners. These measures remain in effect. Practical guidelines had made unclear for some time what use of human biological samples triggered the requirement for prior approval under these measures.

In 2015, MOST published the Guidelines on Administrative Approvals of Collection, Trade and Exportation of Human Genetic Resources (“2015 Guidelines”), which requires unique clinical trial procedures for research and development that utilizes Chinese human biological samples. According to the 2015 Guidelines, collection and/or exportation of human biological samples from all Sino-foreign collaborations (including clinical studies) are subject to strict review and approval of China Human Genetic Resources Administration Office (HGRAO). Specifically, HGRAO requires that the intellectual property rights arising from the utilization of such samples in exploratory research must be shared with the Chinese and foreign parties, in proportion with the contributions of each party.

In 2017, MOST further released the Guidelines on Optimizing the Approval Process of Human Genetic Resources to streamline the approval process. Under the new process, foreign sponsors and vendors are required to sign an “undertaking letter,” which certifies that they will comply with Chinese regulations that govern clinical studies and the Chinese Administrative Permit Law. They are also accountable for the validity and accuracy of the application in its entirety, based on the official instructions on the application form. The intellectual property sharing requirement and the undertaking letter together form a significant hurdle for foreign companies conducting clinical research in China.

Sample collection during a clinical trial should be left out of the approval process. More clarity with respect to the intellectual property sharing requirement is also needed. We look forward to working with the Chinese and U.S. governments to ensure 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 China's international obligations and commitments.

Market Access Barriers

Government Pricing and Reimbursement

To appropriately address the Chinese patient access and affordability challenges, PhRMA urges China to establish a comprehensive and sustainable policy framework for government pricing and reimbursement that would include predictable and timely reimbursement decisions for new drugs, systematic and transparent mechanisms for price negotiation linked to reimbursement, adoption of fact-based methodologies for drug value assessment, and an enhanced role for commercial health insurance. PhRMA and its members are committed to working with the appropriate government authorities in China to assist in the timely and transparent development of this policy framework.

Government Reimbursement List

PhRMA welcomes the 2017 update to the NRDL—the first update since 2009—which will improve the access and affordability of innovative medicines for patients in China. In many developed markets, new medicines are reimbursed shortly after receiving regulatory approval. However, once drug approval is achieved in China, patients must often wait an additional six years or more¹⁴⁷ before they receive access through national reimbursement. Prior to 2017, China has only undertaken two substantive updates (2004 and 2009) to the NRDL. The lengthy periods of time between each NRDL update delay market access to innovative pharmaceuticals and prevent their timely availability to patients.

In April of 2017, the Ministry of Human Resources and Social Security (MOHRSS) requested input on the establishment of a regular adjustment mechanism for the NRDL. We appreciated the opportunity to provide our comments and urge MOHRSS to press forward with implementation as quickly as possible.

In July 2017, MOHRSS announced that 36 medicines (23 MNC products and 13 Chinese products) were successfully added to List B of the NRDL, and that there was an average price reduction of 44% as compared to average 2016 public prices. According to the MOHRSS statement, all provinces are required to add these 36 products to their provincial reimbursement drug list (PRDL). For the 36 negotiated medicines, the MOHRSS set the amount reimbursed by the government's basic medical insurance (BMI). Each provincial government will determine the reimbursed amount that will be paid by the BMI and the patient co-payment amount to the hospital. The MOHRSS reimbursed amounts for the negotiated medicines are valid through December 31, 2019. However, if a generic medicine receives marketing approval during this period, the MOHRSS will

¹⁴⁷ IMS Consulting Group, *China Drug Lag and the Impact of Reimbursement Delays* (July 2014).

revise the reimbursed amount of the innovative medicine based on the price of the corresponding generic medicine.

While any additions to the NRDL are a positive development, it appears that the negotiation process for these new medicines lacked transparency and diverges from a sound government pricing and reimbursement system. PhRMA is closely monitoring implementation of the first national reimbursement negotiation, including the availability of these new medicines at the provincial and hospital levels via the PRDLs.

PhRMA recommends that the Chinese government shift towards a more timely, transparent and predictable reimbursement system, in which manufacturers may apply for reimbursement at any time, drug clinical assessment is completed within a pre-defined period following the application (e.g., within 90 days), and negotiations between manufacturers and the responsible government agency take place periodically (e.g., semi-annually). The drug clinical assessment should be transparent, evidence-based, focused on clinical benefits and independent from economic considerations. Following the clinical assessment, a fair negotiation based on clear conditions and open communication should be conducted between the national reimbursement authority and the manufacturer. These reimbursement system reforms would provide U.S. companies increased market access and improve patient access to innovative medicines.

Government Pricing Policies

China, as part of its WTO accession, committed to apply price controls in a WTO-consistent fashion, taking into account the interests of exporting WTO members, and without having the effect of limiting or impairing China's market access commitments on goods and services.¹⁴⁸ Notwithstanding that commitment, PhRMA is concerned that reforms to China's government pricing mechanisms could exacerbate the already uncertain business environment and further reduce reward for innovation, restrict patient access to high-quality medicines and undermine China's healthcare reform and innovation policy objectives.

PhRMA is committed to working collaboratively and expeditiously with the appropriate government authorities to implement a transparent and appropriate government pricing policy that recognizes quality-systems, innovation, and the value that our member companies' products bring to patients and China.

Regulatory Approval Process

China is making significant strides in reforming and strengthening its regulatory framework, but remains an outlier in the drug approval process compared to other regulatory authorities, with new medicines typically taking three to five years longer to reach the China market than other major markets. Furthermore, there is a particularly

¹⁴⁸ Report of the Working Party on the Accession of China to the World Trade Organization, WT/MIN(01)/3 (Nov. 10, 2001), at para. 64.

lengthy and cumbersome registration and approval process for vaccines. In other words, a “drug lag” remains in China.

PhRMA is greatly encouraged by China's recent regulatory proposals included in the draft CFDA amendments to the DAL and DRR, the CCP/State Council Opinion and the CFDA draft Circulars (Nos. 52-54), which are intended to accelerate the drug review and approval process and facilitate China's participation in simultaneous global drug development. Regarding the recent draft of the DRR, PhRMA is encouraged to see greater flexibility in the drug development process, including a considerably shortened timeline for the approval of small molecule drug and biologic clinical trials, new channels for stakeholder-CFDA communications, procedures for amending clinical trial applications and conditional approval of drugs that fill unmet medical needs and treat orphan diseases. Furthermore, we support CFDA's December 2017 draft guidance on Conditional Marketing Approval of Drugs for Urgent Clinical Use, which provides some direction to sponsors, but still lacks full clarity on the application of a conditional registration pathway in China. Additionally, CFDA's May 2017 accession to the ICH further exemplifies China's reform efforts. Being an ICH Member will further encourage CFDA's harmonization with international regulatory standards, including but not limited to the China Pharmacopeia 2020, enforcement of GXP as well as CTD, 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 CFDA to implement all of ICH's technical guidelines in the coming years.

Clinical Trials Applications (CTAs)

Approval of clinical trial applications in China takes much longer than in other countries, thus it remains one of the primary causes to China's lengthy drug approval timeline and a significant barrier to multinational companies being able to include China in global drug development.

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 shorten the CTA review and approval time. Although CFDA draft Circular 53 indicates a 60-day review period, an underlying misalignment between CFDA human resource capacity and capability represent challenges for CFDA to successfully implement a shorter review process. A 60-day CTA approval would significantly reduce the drug lag as China's CTA review time – currently estimated to be nine to 18 months – has represented the largest regulatory barrier for multinational companies in China. Therefore, PhRMA recognizes and applauds the important steps CFDA is taking to enhance agency capacity and capability by encouraging investment in additional resources and trained evaluators.

Based on PhRMA member company experience in other major markets, it is critically important for CFDA to maintain consistent and specific timelines for reviewing and approving applications. In addition, applications should be evaluated based on a clear set of standardized criteria that applies equally to both local and foreign manufacturers.

Specifically, we are encouraged that the draft amendment to the DRR indicates an intent to abolish unnecessary distinctions between foreign and domestic applicants and the use of MRCT versus a purely local trial in China to support marketing applications. Furthermore, the State Council Opinion on drug and device reform (October 2017) stipulates that clinical trial data obtained from overseas multi-center trials may be used for registration in China. However, there is a degree of ambiguity because the Opinion also states that the applicant “shall provide clinical trial data regarding whether there is any ethnic difference,” which could be interpreted to mean that additional clinical studies in China are required independent of the global clinical drug profile. Without greater clarity on the acceptance of global clinical data in lieu of clinical data from China to satisfy marketing authorization in China, realizing simultaneous drug development in China with global drug development is uncertain.

Drug Approvals Process

PhRMA welcomes a number of other key regulatory proposals in draft Circulars 52-54, because they would represent positive movement in China's regulatory reform toward supporting a simultaneous global development / registration framework in China. The proposed changes are consistent with industry's primary recommendations, including streamlined processes for multi-regional clinical trial (MRCT) registrations, expedited pathway for drugs that treat serious and life threatening illnesses, acceptance of foreign clinical data to satisfy registration in China, structured agency consultation, and establishing an orphan drug system.

To ensure Chinese patients receive timely access to new therapies and Chinese companies have the ability to compete globally, PhRMA recommends that the CFDA bring its regulatory framework into compliance with accepted international standards and adopt science-based, transparent, consistent and predictable policies for evaluating and approving drugs and biologics. PhRMA recommends revisions to the DAL and DRR consistent with the proposals stated in CFDA draft Circulars in order to accelerate and simplify the drug regulatory approval process, provide the same requirements for locally manufactured and imported products and clearly outline 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.

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 active pharmaceutical ingredients (API) used to manufacture counterfeit products. China has been stepping up enforcement efforts against counterfeited drugs in recent years, both through legislative reforms and increased police activity. However, online distribution of counterfeit medicines and unregulated API remain the most serious challenges in China.

Under current pharmaceutical regulations, there is no effective regulatory control over the manufacture and distribution of API, which creates a major regulatory loop-hole that impacts negatively on the security of China's upstream drug supply chain. During the Sixth Meeting of the U.S.-China S&ED in July 2014, China committed to develop and seriously consider amendments to the DAL requiring regulatory control of API. To effectively reduce the risks caused by unregulated API to patient health, a multi-prong approach or "road map" is needed. Targeted measures may include:

- amending the Criminal Code to ease the burden of proof to prosecute brokers or API suppliers who knowingly deal with illegal APIs;
- empowering CFDA or another authority to regulate any party that manufactures API even if that party has not declared an intent to do so;
- empowering CFDA 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;
- amending the DAL to require adherence to ICH Q7A (*Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients*) with meaningful penalties for failure to do so; and
- deepening cooperation with major Internet Service Providers, portal sites, and search engines for earlier identification and tracking of illegitimate API suppliers through B2B websites.

While CFDA 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 current campaign against counterfeit drugs in order to enhance the effectiveness of China's national drug safety plan objectives.

China has continued to coordinate joint special enforcement campaigns targeting counterfeit drug crimes.¹⁴⁹ It also appears that China is beginning to spend more efforts tackling the sale of counterfeits on the Internet. In 2013, CFDA and the State Information Office jointly led a 5-month crackdown campaign with collaboration of several ministries and offices against illegal online sales of drugs. Reportedly, the government also demands major search engines to filter out fake drug posts, which is a significant

¹⁴⁹ See, e.g., "2,000 Arrested in China in Counterfeit Drug Crackdown," Aug. 5, 2012, available at: http://www.nytimes.com/2012/08/06/world/asia/2000-arrested-in-china-in-crackdown-on-counterfeit-drugs.html?_r=0 (last visited Feb. 7, 2018); "China Detains 1,300 People Suspected of Making and Selling Counterfeit Drugs," Dec. 15, 2013, available at http://www.huffingtonpost.com/2013/12/16/counterfeit-drugs-china-medicine_n_4447483.html (last visited Feb. 7, 2018).

partnership with the private sector aimed at protecting Chinese patients.¹⁵⁰ PhRMA hopes that the U.S. Government will work with China to increase transparency of such campaigns, 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 China and the U.S. Government to continue and increase further their cooperation related to counterfeit medicines sold on the Internet, given the role of the Internet in the global counterfeit drug trade.

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 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 could consider working with the World Customs Organization to exchange information and potentially align activities.

¹⁵⁰ Reportedly, search engines have been required to ensure that qualified websites are listed earlier in the search results, to conduct active searches for illegal online drug sales, to delete false and illegal medical advertising, and to report unqualified websites to the National Internet Information Office and the CFDA. In response, several Internet companies have stepped in to support the fight against counterfeit drugs. One of the most prominent companies, 360, introduced several products to provide users with accurate information on medicines and block false medical information websites, claiming that such sites accounted for 7.9% of all blocked websites or approximately 40,606 websites.

Priority Watch List

Asia-Pacific

INDIA

We support the Indian Government's efforts to create a stronger business, innovation, and healthcare environment through the "Make in India" initiative, the National Intellectual Property Rights (IPR) Policy, and the new National Health Policy. These efforts can advance improved access to healthcare for Indian patients, while driving economic growth by enhancing India's global competitiveness and improving ease of doing business. However, despite some positive signs, PhRMA's members remain concerned about the challenging policy environment in India.

Market access challenges persist and despite important announcements to expand healthcare programs, the Indian Government has not increased investment in this critical area, leaving public healthcare spending at a very low level of approximately 1.5 % of GDP during the year 2016-17. There are delays and cumbersome procedures which prevent India from becoming a part of a global clinical trial programs and thereby limit patient access to innovative medicines in India. Data from the Indian drug regulator shows that since 2011, when a total of 41 new medicines were approved, the number has remained significantly low, with only 22 approved in 2016.¹⁵¹

Pharmaceutical innovators again saw positive signs from the Indian Government in 2017; however, these signals have not yet been translated into real policy and practical change. To research, develop, and deliver new treatments and cures to patients, biopharmaceutical innovators must be able to secure and effectively enforce intellectual property (IP) rights. With the right policies put in place, India could become a globally-competitive leader in life sciences and biomedical development. The new National IPR Policy puts forward an important framework for strengthening India's innovation ecosystem; still, greater predictability and reliability is needed and implementation of the policy offers an opportunity to advance concrete policy improvements and could serve as a basis for revisiting India's designation in the future.

The innovative biopharmaceutical industry greatly appreciates the efforts to address these concerns at the highest levels of the U.S. and Indian Governments. We welcome the opportunity to continue working with both Governments to improve access to medicines for patients and advancing a "Healthy India" by removing market access barriers and fostering legal and regulatory certainty for the protection of IP in India.

Key Issues of Concern:

- **Unpredictable Patent environment:** India's legal and regulatory systems pose procedural and substantive barriers at every step of the patent process, ranging from impermissible hurdles to patentability posed by Section 3(d) of India's Patents

¹⁵¹ See <http://www.cdsc0.nic.in/forms/list.aspx?lid=2034&ld=11> (last visited Feb. 7, 2018); and Indian Express, "New drug launches take a hit in India amid tight USFDA scrutiny," October 26, 2015, available at <http://indianexpress.com/article/business/business-others/new-drug-launches-take-a-hit-in-india-amid-tight-usfda-scrutiny/> (last visited Feb. 7, 2018).

Act, narrow patentability standards applied in pre-grant and post-grant opposition proceedings, to onerous patent application disclosure requirements that disproportionately affect foreign patent applicants. Not only is this a concern in the Indian market, but also in other emerging markets that may see India as a model to be emulated. Between May and December 2017, at least 149 patent applications faced rejections under Section 3(d), infringement due to state-level marketing authorization for generic versions of on-patented drugs, and the threat of compulsory licenses (CLs), all of which demonstrate that much work needs to be done to improve the patent environment in India.

- **Regulatory data protection failures:** The Indian Regulatory Authority relies on test data submitted by originators to seek approval in India and/or another country when granting marketing approval to follow-on pharmaceutical products. This reliance results in unfair commercial use prohibited by the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and discourages the development and introduction into India of new medicines for unmet medical needs.
- **High tariffs and taxes on medicines:** Medicines in India face high effective import duties for active ingredients and finished products. The basic import duties for pharmaceutical products average about ten percent, and when combined with the Integrated Goods and Service Tax the effective import duty can exceed 20%. This is in addition to the recently initiated 5-12% General Sales Tax (GST) on medicines.¹⁵²
- **Discriminatory and non-transparent market access policies:** The recent price control orders on coronary stents and knee implants, and the threat of an existing recommendation to implement price controls on patented medicines, represent an effort to significantly reduce the benefits of patent protection and create an unviable government pricing framework and business environment for medicines in India. In addition, the National Pharmaceutical Pricing Authority (NPPA) recently revised price controls on medicines for which prices were already fixed under the Drug Price Control Order (DPCO) 2013. The DPCO 2013 discriminates against foreign pharmaceutical companies by exempting new medicines developed through indigenous research from price controls. These pricing decisions, as well as the broad authority granted to NPPA, do not adhere to the need for transparency, predictability, and trust in the decision-making process, which hinders industry's ability to further invest in India.
- **Unpredictable environment for clinical research:** While the Government is keen to reinvigorate clinical research in India, ambiguities in the Indian regulatory space prevail. In particular, the definition of "trial related injury" is not well defined, and the determination of local clinical trials requirements is highly subjective and

¹⁵² See, e.g., Ernst & Young, GST Implementation in India, <http://www.ey.com/in/en/services/ey-goods-and-services-tax-gst> (last visited Feb. 7, 2018).

perpetuates a burdensome environment for clinical research that undermines the availability of new treatments and vaccines for Indian patients.

For these reasons, PhRMA requests that India remain on the **Priority Watch List** in the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

India announced the new National IPR Policy in May 2016.¹⁵³ India's National IPR 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 should be strengthened to accelerate the reforms needed to foster medical innovation and enhance India's global competitiveness. For example, while the policy focuses on government, open source R&D, Corporate Social Responsibility credits, tax breaks, loan guarantees for start-ups, support systems for Micro-, Small- and Medium-sized Enterprises and other mechanisms to encourage innovation in India, it is also important to incentivize the private sector and scientific institutions by providing effective and meaningful IP protection and enforcement mechanisms. Implementation of the National IPR Policy should include a consultative process with relevant stakeholders and meaningful reforms to India's IP policies that lead to improvements in IP protection and enforcement for medicines.

Restrictive Patentability Criteria

TRIPS requires that an invention that is new, involves an inventive step, and is capable of industrial application, be entitled to patent protection. Section 3(d) of the Indian Patents Act 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, 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 efficacy. Further, indiscriminate and routine use of Section 3(d) in patent applications by the Indian Patent Office even for a novel compound or a derivative with onus of proof on the applicant to prove otherwise poses unnecessary burden on the 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

¹⁵³ Department of Industrial Policy and Promotion, "National Intellectual Property Rights Policy," May 12, 2016, available at http://dipp.nic.in/sites/default/files/National_IPR_Policy_English.pdf (last visited Feb. 7, 2018).

that can be precluded from patent coverage, and this list does not include “new forms of known substances lacking enhanced efficacy,” as excluded by Section 3(d) of the Indian law. Therefore, Section 3(d) is inconsistent with the framework provided by the TRIPS Agreement. Moreover, Section 3(d) represents an additional hurdle for patents on inventions specifically relating to chemical compounds and, therefore, the Indian law is in conflict with the non-discrimination principles provided by TRIPS Article 27 and WTO rules.¹⁵⁴ In 2016, two anti-cancer products and a schizophrenia product were denied patent protection, as India claimed they showed no enhanced efficacy and thus were not patentable under Section 3(d). All three products successfully obtained U.S. patent protection. Between May and December 2017, at least 149 patent applications faced rejections under Section 3(d). 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 of a product. Further, Section 3(i) of the Indian Patents Act excludes method of treatment claims preventing U.S. biotechnology companies with needed treatment methods from entering the Indian market and providing life-saving products.

India’s pre- and post-grant patent opposition system is another source of 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 have created significant uncertainty and delayed the introduction of new inventions by undermining patent office efficiency and delaying patent prosecution – exacerbating India’s already significant patent examination backlog of approximately 6 years.

Weak Patent Enforcement

Indian law permits state drug regulatory authorities to grant manufacturing approval for a generic version of a medicine four years after the original product was first approved.¹⁵⁵ State regulatory authorities are not required to verify or consider the

¹⁵⁴ The additional patentability hurdle imposed by section 3(d) was recently reinforced by the Pharmaceutical Patent Examination Guidelines issued in October 2014.

¹⁵⁵ Rule 122E of the Drugs and Cosmetics Rules states that a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier. The Drugs and Cosmetics Act goes on to specify that “Where an application under this Rule is for the manufacture of drug formulations falling under the purview of new drug as defined in rule 122-E, such application shall also be accompanied with approval, in writing in favor of the applicant, from the licensing authority.” Thus, to obtain a manufacturing license for a new drug, the Central Drug Regulatory must provide written approval. In the case of drugs which do not meet the definition of a new drug, an “Application for grant and renewal of license to manufacture for sale or distribution of drugs shall be made to the licensing authority appointed by the State Government.” See Ministry of Health and Family Welfare, “The Drugs and Cosmetics Rules, 1955 (As amended up to the 30th June, 2005),” available at <http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf> (last visited Feb. 7, 2018).

remaining term of the patent protection on the original product. Therefore, an infringer can obtain marketing authorization from the state government 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 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.¹⁵⁶ India should amend the definition of a new drug, as well as ensure innovators have timely notice of marketing approval applications and are able to seek injunctive relief before potentially infringing products enter the market.

Moreover, India does not provide mechanisms for notification or resolution of patent disputes prior to marketing approval of third party products. Such mechanisms are needed to prevent the marketing of patent infringing products and resolve disputes in a timely manner. Even, the Sugam initiative launched in November 2015 to implement e-Governance with respect to licensing system within India's Central Drugs Standard Control Organization (CDSCO) lacks transparency and does not facilitate timely notification to a patentee of a possible infringement. In April 2017, India amended Form 44 of the Drugs and Cosmetics Rules¹⁵⁷ to omit Item 8 which previously required new drug applicants to disclose the "patent status of the drug."¹⁵⁸ This action further eroded the ability of patent owners to put generic manufacturers and state drug regulatory authorities on notice of existing patents related to medicines approved by CDSCO.

In one case, the patent holder waited 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.¹⁵⁹ The Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015 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. While this is a promising development, these courts are now overburdened with cases and will require a significant amount of technical expertise and commitment of resources to be properly implemented. While the draft National IPR Policy proposed to establish specialized patent benches at the High Court level and designate an IP court at the district level, the final National IPR Policy did not include this provision.¹⁶⁰

¹⁵⁶ See Secs. 3.8 and 3.8.3 of the National IPR Policy.

¹⁵⁷ Form 44, Schedule A, Drugs and Cosmetics Rules, 1945.

¹⁵⁸ *Id.*

¹⁵⁹ Times of India, "Cipla infringing Roche's cancer drug patent: HC" Nov. 28, 2015, available at <http://timesofindia.indiatimes.com/business/india-business/Cipla-infringing-Roches-cancer-drug-patent-HC/articleshow/49956000.cms> (last visited Feb. 7, 2018).

¹⁶⁰ Department of Industrial Policy and Promotion, Press Release, Oct. 22, 2014, available at http://dipp.nic.in/sites/default/files/ipr_PressRelease_24October2014_0.pdf (last visited Feb. 7, 2018); "National Intellectual Property Rights Policy," May 12, 2016, available at http://dipp.nic.in/sites/default/files/National_IPR_Policy_English.pdf (last visited Feb. 7, 2018).

Compulsory Licensing

The grounds for issuing a CL in India 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 Ministry of Health (MOH) continues to entertain potential recommendations to impose CLs on certain anti-cancer medicines under the special provisions of Section 92 of India's Patents Act, which would make it even more difficult for patent owners to defend their patents. Moreover, Indian pharmaceutical companies continue to make requests for voluntary licenses under Section 84(6)(iv) of the Patent Act as a strategy and subsequently seek a CL by using it as a commercial tool under the guise of better access to medicines, rather than a measure of last resort. Internationally, in various multilateral forums, India has advocated for the broad adoption and implementation of legislation that facilitates the 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, Section 146 of the India Patents Act further exacerbates the uncertainty and scope of India's CL provisions. Rules promulgated under that section require all patent holders to file an annual statement summarizing "the extent to which the patented invention has been worked on a commercial scale in India."¹⁶¹ Notwithstanding the commercially sensitive nature of information required to satisfy Section 146, it also provides an impermissible basis for local companies to seek compulsory licenses, as occurred in 2012.

We believe that resort to CLs is not a sustainable or effective way to address healthcare 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.¹⁶² These are misunderstandings and do not justify widespread use of compulsory licensing.

At a minimum, India should ensure that CLs are exercised with extreme caution and as a measure of last resort. India should also clarify that importation satisfies the "working" requirement, pursuant to TRIPS Article 27.1.

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 six years to 18 months. Currently, the applications that are being examined

¹⁶¹ India Patents Act, Section 146(2).

¹⁶² See, e.g., <http://thehill.com/blogs/congress-blog/campaign/316883-india-honors--not-dishonors--patent-laws> (last visited Feb. 7, 2018). These allegations 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.

were filed in 2013. 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 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 postpone clinical trial activity and ultimately the introduction of new medicines. 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 Patents Act sets forth requirements that have been interpreted in a manner that creates heightened and unduly burdensome procedures that mainly impact foreign patent applicants – those most likely to have patent applications pending in other jurisdictions. Section 8(1) requires patent applicants to notify the Controller and “keep the Controller informed in writing” of the “detailed particulars” of patent applications for the “same or substantially the same invention” filed outside of India. Section 8(2) requires a patent applicant in India to furnish details to the Indian Controller about the processing of those corresponding foreign patent applications if that information is requested. These additional patent application processing requirements have been interpreted in a manner that creates heightened and unduly burdensome patent application procedures that mainly impact foreign patent applicants – those most likely to have patent applications pending in other jurisdictions. Further, Section 8 was enacted in 1970 when the information was only available from the applicant; much of the information sought is now publicly available on patent office websites in most major jurisdictions. For example, through the Global Dossier Initiative of five major patent offices (the U.S. Patent and Trademark Office, the European Patent Office, the State Intellectual Property Office of China, the Japanese Patent Office, and the Korean Intellectual Property Office), the current file histories from each of these offices are accessible at one website. Thus, accurate information about counterpart foreign applications is easily available to the India Patent Office examiners. Recent court decisions provide greater clarity on the applicability and scope of Section 8. In particular, current jurisprudence limits Section 8 to information that is material to patentability and to deliberate failures to disclose this information.¹⁶³

In June 2017, India became a receiving office of information accessible via the World Intellectual Property Organization Centralized Access to Search and Examination (WIPO CASE) system. However, the practical effect of India’s participation as a WIPO CASE receiving country remains unclear. Despite signaling the need for clarification, the

¹⁶³ See, *Telefonaktiebolaget Lm Ericsson v. Intex Technologies (India) Ltd.*, Delhi High Court Judgment dated Mar. 13, 2015 in CS (OS) No. 1045 of 2014, available at http://lobis.nic.in/d_dir/dhc/MAN/judgement/16-03-2015/MAN13032015S10452014.pdf (last visited Feb. 7, 2018); *Sukesh Behl & Anr. v. Koninklijke Phillips Electronics*, Delhi High Court, 2015(61) PTC183(Del); *Merck Sharp & Dohme Corp. v. Glenmark Pharms*, Delhi High Court, 2015 (64) PTC417(Del).

Indian Patent Office has yet to issue guidance on the scope of Section 8 or how information accessible on the WIPO CASE system affects disclosure under that section.

In view of the expressed goals to ensure consistency at the Indian Patent Office, the IP5 Patent Prosecution Highway program may also be of interest to India. India's inclusion in this initiative will help facilitate removing anomalies in Indian patent examination process, as well as advancing India's goals of enhancing quality and consistency in Indian-issued patents. Such participation would also help to alleviate further administrative burdens on patent applicants, while also providing the relevant information to facilitate more efficient examination in the Indian Patent Office.

Additionally, recent requests pursuant to Section 8(2) for the translation of foreign search and/or examination reports are not only unduly burdensome but costly as well. In practice, attorneys routinely receive informal translations of foreign search and/or examination reports intermingled with local attorney advice and counsel (information subject to attorney-client privilege). Moreover, translations of the search and/or examination reports may not yet be available at the time of the Section 8(2) request.

Moreover, the remedy for failure to comply with Sections 8(1) and 8(2) is extreme compared to other countries with similar (but less onerous) administrative requirements. In India, the failure to disclose under Section 8 can be treated as a strict liability offense that by itself can invalidate a patent (although a recent court decision indicates some flexibility for mere clerical errors). This is in contrast to a requirement that the failure to disclose be material and/or intentional as in the U.S. or Israel. Thus, India's disclosure requirement and remedy are each more burdensome as compared to other jurisdictions, thereby creating a barrier to patentability that has an unfairly greater effect on foreign patent applicants, and, in some instances resulted in India revoking patents on the grounds of non-compliance with this particular provision.¹⁶⁴

Regulatory Data Protection Failures

Contrary to its TRIPS Article 39.3 obligation, India fails to ensure that there is no unfair commercial use of the regulatory data submitted by another party 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 some cases involving as few as 16 Indian patients). This is *in lieu* of requiring submission of the entire dossier for review by India's Regulatory Authority. Moreover, in some instances when an applicant seeks approval for a drug that has already been approved abroad, Indian authorities waive the requirement to submit even this data.¹⁶⁵ In those circumstances, any subsequent approval of the drug in India is based entirely on the prior approval of the drug in a third country.

¹⁶⁴ See, e.g., *Ajantha Pharma Ltd. v. Allergan*, Intellectual Property Appellate Board (2013).

¹⁶⁵ See Rules 122A and B of the Ministry of Health and Family Welfare, "The Drugs and Cosmetics Rules, 1945 (As amended up to the 30th June, 2005)," available at <http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf> (last visited Feb. 7, 2018).

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 based on third-country approvals amounts to indirect reliance on the clinical trial and other test data that underlie the third-country approvals. This indirect reliance results in unfair commercial use prohibited by TRIPS Article 39.3.

Market Access Barriers

High Tariffs and Taxes on Medicines

PhRMA member companies operating in India face high effective import duties for active ingredients and finished products. Though the basic import duties for pharmaceutical products average about ten percent, due to the Integrated Goods and Service Tax imposed on imports, the effective import duty can exceed 20%. Moreover, excessive duties on the reagents and equipment imported for use in research and development and manufacture of biotech products make biotech operations difficult to sustain. Compared to other Asian countries in similar stages of development, import duties in India are very high. And while certain essential and life-saving medicines may be granted exemptions from some of the taxes, the eligibility criteria are vague and subject to constant revision and debate.¹⁶⁶

The Goods and Services Tax (GST) was implemented in July 2017. While GST is expected to significantly reduce layers and complexity in the indirect tax system, it levies an additional 5-12% tax on medicines.¹⁶⁷ Proposals to exempt certain life-saving drugs from Goods & Service Tax (GST) and customs duties should be expanded to all medicines.¹⁶⁸

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, which calls for greater access to healthcare for low-income patients. The policy denotes expanding comprehensive primary health care through "Health and Wellness Centres," 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% of GDP by 2025.

¹⁶⁶ See, e.g., Business Standard, "Puzzle in Wednesday order on duty exemption," Feb. 19, 2016, available at http://www.business-standard.com/article/companies/puzzle-in-wednesday-order-on-duty-exemption-116021800993_1.html (last visited Feb. 7, 2018).

¹⁶⁷ See, Ernst & Young, GST Implementation in India, <http://www.ey.com/in/en/services/ey-goods-and-services-tax-gst> (last visited Feb. 7, 2018).

¹⁶⁸ Hindu Business Line, "GST: The right prescription," Aug. 5, 2016, available at <http://www.thehindubusinessline.com/specials/pulse/gst-the-right-prescription/article8949378.ece> (last visited Feb. 7, 2018).

India has insufficient numbers of qualified healthcare personnel, inadequate and poorly equipped healthcare facilities, and most importantly lacks a comprehensive system of healthcare financing that would pool financial risk through insurance and help to share the cost burdens.¹⁶⁹ Despite the encouraging and ambitious goals in the new National Health Policy, government spending on healthcare remains at about 1.5% of GDP, one of the lowest levels of expenditure in the world.¹⁷⁰ Without increased resources and a full implementation of the reform, high out-of-pocket spending on healthcare and pressure on the cost of medicines will persist.

Discriminatory and Non-Transparent Pharmaceutical Pricing Policies

Despite decades of government price controls in India, the objective of which has been to improve access to medicines, essential medicines are still not easily accessible. Still, India has thousands of manufacturers of pharmaceuticals who operate in a very competitive environment, and as a result, India has some of the lowest prices of medicines in the world.¹⁷¹ Focusing on the key barriers to access in India – insufficient financing, infrastructure, and quality – would significantly improve access to medicines for patients.

In 2014, an Inter-Ministerial Committee was constituted to suggest a methodology to be applied to pricing of patented medicines before their marketing in India.¹⁷² A Department of Pharmaceuticals (DoP) Committee on Price Negotiation for Patented Drugs report in 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 more recent draft of the methodology is currently under discussion internally; however a decision by the Committee has yet to be taken. PhRMA members are highly concerned that the threat of the 2013 or follow-on recommendations represent a potential effort to significantly reduce the benefits of patent protection, which will *de facto* discriminate against importers, and will create an unviable government pricing framework and business environment for innovative pharmaceutical companies.

DPCO 2013 sought to establish price stability by setting ceiling prices for medicines listed on Schedule I every five years. Despite doing so in 2013, the NPPA announced in June 2016, per Paragraph 18 of the DPCO, that it was going to set new ceiling prices for all medicines, including those for which a ceiling price had already been set only three years prior. Transparency and predictability are paramount to a robust environment for business investment. These pricing decisions, as well as the broad

¹⁶⁹ “Health Systems Financing: The Path to Universal Coverage,” *The World Health Report*, World Health Organization, 2010.

¹⁷⁰ “National Health Policy 2015 Draft.” Ministry of Health & Family Welfare. Dec. 2014.

¹⁷¹ Analysis based on IMS MIDAS Data.

¹⁷² Government of India Speed Post No. 31011/5/2009/PI-II(pt), Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, Subject: Inter-Ministerial Committee on Prices of Patented Drugs. New Delhi, Feb. 17, 2014.

authority granted to NPPA under this provision, do not respect the need for transparency, predictability, and trust in the decision-making process, and ultimately impact patient access to medicines. Furthermore, frequent repricing imposes an unnecessary administrative burden, due to the need to recall and re-label medicines to reflect the new price, and in turn can result in product shortages.

Finally, Paragraph 32 of the DPCO 2013 exempts from the pricing formula, for a period of five years, new medicines developed through indigenous research and development that obtain a product patent, are produced through a new process, or involve a new delivery system. This section creates an un-level playing field that favors local Indian companies and discriminates against foreign pharmaceutical companies, contrary to India's National Treatment obligations. In addition, pursuant to the draft national pharmaceutical policy proposal currently under consideration, the Government of India has proposed that formulations made from indigenously produced API in India and its intermediates be given preference in government procurement processes.

Expansion of price controls to a larger range of medicines will not substantially improve access to medicines in India because lack of access is more a function of insufficient healthcare financing, poor access to physicians, and inadequate healthcare facilities.¹⁷³ For example, even medicines and vaccines that are offered free of charge often do not reach the patients who need these medicines.¹⁷⁴ A 2015 study by IMS – “Analyzing the Impact of Price Controls on Access to Medicines” – found that price controls are neither an effective nor a sustainable strategy for improving access to medicines. The study further found that the primary beneficiaries of price controls have been high-income patients, rather than the intended low-income population.¹⁷⁵ A considerable body of evidence demonstrates that price controls contribute to lower investment in pharmaceutical research and development, ultimately harming patients who are in need of improved therapies.¹⁷⁶

PhRMA members believe that competitive market conditions are the most efficient way of allocating resources and rewarding innovation; however, the research-based pharmaceutical industry recognizes the unique circumstances in India and is committed to engaging with the Government to discuss pragmatic public policy approaches that will enable the development of simple and transparent government pricing and

¹⁷³ “A Study of Healthcare Accessibility,” Dr. DY Patil Medical College, Pune, India, prepared for India Health Progress, Mar. 2011. Wagstaff, Adam, “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 Feb. 7, 2018).

¹⁷⁴ “India Turns to Mobile Phones in Bid to Improve Vaccination Rate,” *India Real Time/Wall Street Journal*, Aug. 4, 2011. Patra, Nilanjan, “When Will They Ever Learn?: The Great Indian Experience of Universal Immunisation Programme,” Dec. 2009, available at http://www.isid.ac.in/~pu/conference/dec_09_conf/Papers/NilanjanPatra.pdf (last visited Feb. 7, 2018).

¹⁷⁵ IMS, “Assessing the Impact of Price Control Measures on Access to Medicines in India.” June 2015.

¹⁷⁶ “Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation,” U.S. Dept. of Commerce, Int'l Trade Administration, Dec. 2004. Vernon, John, “Drug Research and Price Controls,” *Regulation*, Winter 2002-2003.

reimbursement mechanisms that provide access to medicines, reward innovation, include the patient perspective, and encourage continued investment into unmet medical needs.

Unpredictable Environment for Clinical Research & 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. Still, India faces the consequences of an unpredictable regulatory environment as clinical trials falter¹⁷⁷ and new medicines face significant launch delays.¹⁷⁸

We welcome the fact that the MOH and the Central CDSCO have undertaken regulatory reform efforts with the goal of strengthening the regulatory regime and reinvigorating clinical research. Strong, transparent and predictable regulatory frameworks are essential to protecting patients as well as to promoting globally-competitive innovative and generic pharmaceutical industries. In 2016 the Indian Government announced its intention to revise the Drugs & Cosmetics Act and Rules “to make it easier for companies to do business while ensuring the safety and efficacy of medicines.”¹⁷⁹ However, MOH has yet to issue the New Drugs & Clinical Trials Rules. In the meantime, inconsistencies and ambiguities continue to prevail in the Indian regulatory space resulting in lack of clarity and a cumbersome approval process for trial sponsors. In particular, the Indian regulatory system exhibits slow approval times, ambiguities in the interpretation of compensation rules, and a lack of an appeals mechanism in decisions about causation. The piecemeal approach to reform continues to reinforce the unpredictability of the clinical trials regime and the slow resurgence of trials, especially in the presence of global multiregional trials. As a result, clinical trial investment in India has decreased significantly since 2010.¹⁸⁰ Such uncertainty in the regulatory process for clinical trials threatens the overall clinical research environment in India, as well as the availability of new treatments and vaccines for Indian patients.

The Indian Government, as per the notice issued on August 4, 2016, has taken several measures to improve the clinical trial environment, such as removal of restrictions

¹⁷⁷ Scrip, “Industry Sponsored Trials Fall Sharply In Challenging Indian Environment,” Sept. 8, 2016, available at <https://scrip.pharmamedtechbi.com/SC097232/Industry-Sponsored-Trials-Fall-Sharply-In-Challenging-Indian-Environment> (last visited Feb. 7, 2018); Asia Sentinel “Southeast Asia Steals Indian Pharma,” July 14, 2014, available at <http://www.asiasentinel.com/econ-business/southeast-asia-steals-indian-pharma/> (last visited Feb. 7, 2018).

¹⁷⁸ Ernst R. Berndt and Iain M. Cockburn. The Hidden Cost of Low Prices: Limited Access to New Drugs in India. *Health Affairs*, 33, no.9 (2014): 1567-1575.

¹⁷⁹ Reuters, “India to revise drugs law, draft new rules for medical devices,” June 22, 2016, available at <http://in.reuters.com/article/us-india-drug-lawmaking-idINKCN0Z819O> (last visited Feb. 7, 2018).

¹⁸⁰ Scrip, “Industry Sponsored Trials Fall Sharply in Challenging Indian Environment,” Sept. 8, 2016, available at <https://scrip.pharmamedtechbi.com/SC097232/Industry-Sponsored-Trials-Fall-Sharply-In-Challenging-Indian-Environment> (last visited Feb. 7, 2018).

on the number of trials that may be conducted by an investigator at a given point of time, the minimum number of beds at the clinical trial site, and the need to obtain an objection certificate from the DCGI in case of addition or deletion of new clinical trial site or investigator.¹⁸¹

Still, challenges remain. Rule 122 DAB of the Drugs & Cosmetics Rules (1945) originally dated January 30, 2013, and subsequently amended on December 12, 2014, is overly broad and lacks a legally or scientifically sound process for determining causality of injury. Definitions for “trial related injury,” “standard of care,” and “medical management” remain uncertain. Further, clinical trial waiver decisions related to cases of national emergency, extreme urgency, epidemics and for orphan drugs for rare diseases can be considered, but are often highly subjective. The shared recommendation of the Drug Technical Advisory Board (DTAB) on February 16, 2015, and the Apex Committee on July 26, 2016, to amend the Drugs and Cosmetics Rules, 1945 permitting waiver of local clinical trial for approval of new drugs if already approved and marketed in a well-regulated country, has not been acted upon.

As a result, there is great uncertainty relating to future costs and liabilities associated with conducting trials in India, resulting in many sponsors not launching trials in India until these uncertainties have been resolved. Research shows that if India were to address outstanding concerns with clinical trials regulations, India could see an increase in the number of new clinical trials per year to above 800, adding over \$600 million in economic gains.¹⁸² Greater clarity and predictability are needed for administrative procedures of drug registration applications and drug review standards and procedures in order to make the latest research products available in India.

¹⁸¹ CDSCO Notice, Aug. 4, 2016, available at <http://www.cdsc.nic.in/writereaddata/NOTICE%20DATED%204th%20August%202016.pdf> (last visited Feb. 7, 2018).

¹⁸² 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 Feb. 7, 2018).

INDONESIA

PhRMA and its member companies operating in Indonesia remain concerned with the country's discriminatory intellectual property (IP) and market access barriers, and as well as limited anti-counterfeiting enforcement efforts. These barriers stem from the lack of legislative and regulatory transparency and advance consultation. As a result, PhRMA's member companies continue to face significant market access constraints.

Key Issues of Concern:

- **Restrictive patentability criteria:** Recent amendments to the Patent Law preclude patents on new uses (indications) and establish an additional patentability criterion of "increased meaningful benefit" for certain forms of innovation, such as new salts or new dosage forms. These restrictions are overly broad and will undermine support for important innovations and appear to conflict with existing international obligations by imposing additional or heightened patentability criteria that discriminate against particular classes of technology. We are also concerned by amendments to the Patent Law that would impose new patent disclosure requirements regarding the source and origin of genetic resources. Such requirements introduce uncertainties into the patent system that inhibit innovation in relevant technologies and undermine the potential of benefit-sharing.
- **Compulsory licensing:** In recent years (2004, 2007, and 2012), Indonesia has issued compulsory licenses (CLs) on nine patented pharmaceutical products, despite concerns raised by the affected PhRMA member companies. PhRMA is troubled by Indonesia's decision to issue these licenses, which were promulgated without attempts to engage with the affected PhRMA member companies to find more sustainable and long-term solutions and in a manner that appears inconsistent with Indonesia's international obligations. PhRMA is also concerned by the recent passage of the Patent Law, which includes provisions that discourage voluntary licensing between private parties and promote compulsory licensing on grounds that are vague or appear to be inconsistent with Indonesia's international obligations, including under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). PhRMA member companies are prepared to work collaboratively with Indonesian authorities to find solutions that benefit patients in Indonesia while maintaining adequate and effective IP protection.
- **Registration delays:** PhRMA member companies continue to face burdensome regulatory delays in the registration process of new products, in contravention of Indonesia's own regulations. We understand that efforts to achieve stronger conformance with international best practices are being made with respect to regulatory timelines and processes as part of the ASEAN Pharmaceutical Regulatory Harmonization. We encourage the Indonesian Government to also

make efforts to achieve stronger conformance with international best practices with respect to regulatory data protection and bioequivalence requirements.

- **Forced localization requirements:** Government policies driving forced localization requirements have been increasing. The local manufacturing and technology transfer requirements of Decree 1010, and the apparent requirement in the recent Patent Law that patented products be made and processed in Indonesia, are discriminatory, difficult to implement, or implemented inconsistently. Indonesia's positions contravene its obligations under the TRIPS Agreement (as well as the General Agreement on Tariffs and Trade and the WTO Agreement on Trade-related Investment Measures), which prohibit WTO members from discriminating based on whether products are imported or locally produced. TRIPS Article 27.1 states that patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." These regulations will have lasting implications for market access and patient health in Indonesia. To prevent import restrictions on innovative medicines, it is imperative that a solution is reached to allow all legitimate high quality pharmaceuticals to be traded, sold and distributed in Indonesia, regardless of origin.
- **Cost-Focused Formulary Decisions:** While Indonesia is to be commended for developing guidelines and an online portal (eFORNAS) for listing new molecules on the Indonesian National Formulary, actual listing decisions appear to be primarily based on price and the overall Social Insurance Administration Organization (BPJS) budget. Consistent with the guidelines, listing decisions should better reflect all of the evidence submitted, including scientific data demonstrating the drug's safety and efficacy.
- **Mandatory Halal certification:** On September 25, 2014, the Indonesian Parliament passed the Halal Products Law. The Law, as passed, has broad application to all consumables, including pharmaceuticals, and requires that producers label their products as "halal" or as "non halal," based on whether the products are halal certified. PhRMA's member companies are strongly supportive of religious and cultural sensitivities, but are concerned that this mandatory labeling requirement could have unexpected negative implications on patient health.

For these reasons, PhRMA requests that Indonesia remain on the **Priority Watch List** in the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Restrictive Patentability Criteria

The recently revised Patent Law would preclude patents on new uses (indications) and establish an additional patentability criterion of “increased meaningful benefit” for certain forms of innovation, such as new salts or new dosage forms. These restrictions are bad policy because they undermine support for important innovations and appear to conflict with existing international obligations by imposing additional or heightened patentability criteria in a manner that discriminates against particular classes of technology.

TRIPS requires that an invention which is new, involves an inventive step, and is capable of industrial application, be entitled to patent protection. The revised Patent law appears to add an impermissible hurdle to patentability by adding a fourth substantive criterion of “increased meaningful benefit” to the TRIPS requirements. Moreover, this additional hurdle appears to be applied only to chemicals.

Additional substantive requirements for patentability beyond that the invention be new, involve an inventive step and capable of industrial application, are inconsistent with the TRIPS Agreement. Article 27 of the TRIPS Agreement provides a non-extendable list of the types of subject matter that can be excluded from patent coverage, and this list does not include new uses of existing compounds. Therefore, the new Patent Law appears to be inconsistent with the framework provided by the TRIPS Agreement. Moreover, the new Patent Law imposes an additional hurdle for patents on inventions specifically relating to chemical compounds and, therefore, is in conflict with the non-discrimination principle provided by TRIPS Article 27.

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 reduce costs by making it easier for patients to take medicines and improving patient adherence to prescribed therapies.

Burdensome and Vague Disclosure Obligations

The amended Patent Law also requires disclosure of the origin of genetic resources or traditional knowledge “related” to inventions. We support the objectives of the Convention on Biological Diversity (“CBD”) and recognize the national sovereignty of States over biological resources. However, such requirements introduce uncertainties into the patent system that inhibit innovation in relevant technologies and undermine the potential of benefit-sharing. We therefore recommend eliminating this vague requirement, which is likely to cause uncertainty for innovators and undermine the sustainable use of technology related to biological resources.

Compulsory Licensing

In recent years, Indonesia issued CLs on nine patented pharmaceutical products. PhRMA is troubled by Indonesia's decision to issue government use permits without attempts to engage the affected PhRMA member companies in discussions to find more sustainable and long-term solutions. We are further concerned that a number of patents on different products were aggregated together and dealt with as a group rather than considering each on its merits as required by Article 31(a) of TRIPS. In addition, other than the stipulated remuneration, there is no ability to appeal the CL or otherwise obtain judicial or other independent body review, as required by TRIPS Article 31(i).

The recently amended Patent Law creates further uncertainty in this area by discouraging voluntary licensing agreements between private parties and by promoting compulsory licensing on grounds that are vague or appear to be inconsistent with Indonesia's international obligations. In particular, the Patent Law unnecessarily requires disclosure of private licensing agreements and allows compulsory licensing if a patented product is not being manufactured in Indonesia. Requiring disclosure of private agreement terms would discourage entry into such agreements to the detriment of Indonesia. The local manufacturing requirement would also appear to contravene Indonesia's national treatment obligations pursuant to which manufacturers should be able to meet the "local working" requirements through importation.

Indonesia should make clear in its law that any compulsory licensing action needs to be taken on a patent-by-patent basis with full consideration of 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 healthcare needs. Voluntary arrangements independently undertaken by member companies better ensure that current and future patients have access to innovative medicines. PhRMA member companies are willing to work with Indonesian authorities to find solutions that benefit patients in Indonesia, while maintaining adequate and effective IP protections that are essential to sustain research toward the next generation of treatments.

Market Access Barriers

Registration Delays

PhRMA's member companies continue to face burdensome regulatory delays in the registration process of new products. There are a variety of causes for the unpredictable delays, which ultimately result in new products being temporarily or permanently blocked from entering the market. It is uncertain whether the lack of attention to new product applications is due to insufficient personnel capacity or other regulatory reasons. In addition to regulatory delays, PhRMA's member companies would like to see Indonesia take steps to bring the National Agency for Food and Drug Control (BPOM) further in line with international best practices, namely in regards to regulatory data protection and bioequivalence requirements.

PhRMA's Members are encouraged to note that BPOM hired 20 additional registration staff in 2015. Both BPOM and the industry have agreed to improve the know-how and skills of their registration staff in order to improve the timeliness of the regulatory review process.

Forced Localization Requirements

Ministry of Health (MOH) Decree 1010/MENKES/PER/XI/2008 ("Decree 1010"), formally implemented in November 2010, prevents multinational research-based pharmaceutical companies from obtaining marketing authorization for their products. Under Decree 1010, only companies registered as "local pharmaceutical industry" are granted marketing approval. As several of PhRMA's member companies do not manufacture products in Indonesia, they are instead classified as distributors, or "PBF" enterprises. They are so classified despite following globally recognized good manufacturing practices in the same manner as other high quality pharmaceutical firms manufacturing in Indonesia. Product of multinational research-based pharmaceutical companies and other foreign companies are barred from the Indonesian market unless (1) a local manufacturing facility is established; or (2) sensitive IP is transferred to another pharmaceutical firm with local manufacturing facilities in Indonesia. 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.

Another key concern of PhRMA member companies with Decree 1010 is the requirement to locally manufacture imported products within five years after the first importation with some exceptions, e.g., products under patent protection. Even for companies with local manufacturing facilities in Indonesia, this is not always possible for several reasons, including the structure of their global pharmaceutical supply chains and lack of required technology within their local facilities to produce innovative products.

Rather than amend Decree 1010 to mitigate damaging provisions, the MOH created Decree 1799 on December 16, 2010, altering the definition of local manufacturing and introducing the concept of partial manufacture. PhRMA's member companies have sought clarification on several vague and conflicting provisions of Decree 1799 since its release. Furthermore, in July 2011, BPOM released a draft of the Brown Book containing implementation guidelines for several Decree 1010 and 1799 provisions. Final revisions to the Brown Book were released on September 14, 2011, following BPOM's review of stakeholder comments; some of the provisions in the revised Brown Book provided leeway for PhRMA's member companies to comply with the requirement to locally manufacture imported products within five years of patent expiration. However, under the new Patent Law, the requirements have been made more restrictive and appear to require a patent holder to manufacture or use the relevant patented product or process in Indonesia. While PhRMA's member companies acknowledge the initial steps taken by BPOM to engage in consultations, key concerns remain unresolved and several provisions of Decree 1010, 1799, and the new Patent Law still require further clarification.

As a result of the Presidential Instruction No. 6/2016 to accelerate the development of the pharmaceutical and medical device industry in Indonesia, the Minister of Industry is planning to impose a local content requirement as one of the criteria for government procurement for biopharmaceutical and medical device products. The method to calculate the threshold lacks clarity such that it may be impossible to implement or to monitor, and might create another barrier to access to medicines and healthcare for patients.

In short, PhRMA's member companies are concerned about the localization requirements as well as the lasting implications to market access, IP protection, and patient health if unresolved.

Cost-Focused Formulary Decisions

While Indonesia is to be commended for developing guidelines and an online portal (eFORNAS) for listing new molecules on the Indonesian National Formulary, actual listing decisions appear to be primarily based on price and the overall BPJS budget. Consistent with the guidelines, listing decisions should better reflect all of the evidence submitted, including scientific data demonstrating the drug's safety and efficacy.

Mandatory Halal Certification

Indonesia's Mandatory Halal Certification Bill, enacted in September 2014, mandates Halal certification and Halal labeling for food and beverages, medicines, cosmetics, chemical products, biological products, and genetically-engineered products. The legislation establishes a new Halal certification authority, and requires pharmaceutical firms to hire a Halal specialist and disclose sensitive product formulas to the new Halal authority.

Despite public opposition to the Law, including the objection of the Ministry of Health, the most recent draft of the government regulation on the implementation of the Halal Law unfortunately still includes drugs and cosmetics in the regulation. PhRMA's member companies recognize and support the religious and cultural sensitivities of all Indonesians, but are concerned that this Act may have negative implications for patient health. In particular, significant questions remain regarding the process for securing halal certification and how the government will ensure that the new requirements do not impact 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. Although new leadership at BPOM have focused their efforts on combatting counterfeit food and medicine products, the budget and resources for this effort remain inadequate. Increasing and especially 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.

Research conducted by Masyarakat Indonesia Anti-Pemalsuan (MIAP), Indonesia's anti-counterfeiting society, suggests that losses incurred by the state as a result of counterfeiting practices continue to rise each year. 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 the Indonesian people.

JAPAN

Over the past decade, Japan has made important reforms in the areas of drug pricing, drug evaluation and approval, and vaccine policy that have made the system more transparent, more supportive of innovation, and more conducive to innovative biomedical research and development. These changes have increased patient access to life-saving medicines and reduced regulatory delays in the introduction of new drugs, making Japan the second largest market in the world for innovative medicines.¹⁸³ However, on December 20, 2017, the Central Social Insurance Medical Council (Chuikyo) approved a drug pricing reform package that contains a number of new pricing efforts that significantly undermine Japan's pro-innovation environment and its efforts to carry its fair share of the costs of global R&D efforts. In particular, the eligibility criteria for the new Price Maintenance Premium (PMP) program will mean that some of American's most innovative pharmaceutical products will be significantly undervalued. In addition, specific elements of the PMP call into question Japan's commitment to fair and non-discriminatory policies, including that of national treatment. The final reform package was developed with limited opportunities for stakeholders to provide timely input that was then meaningfully considered, which has raised serious questions about the fairness, transparency and predictability of the reform process.

Key Issues of Concern:

- **Inappropriate and Discriminatory Revisions to the Price Maintenance Premium System:** The new drug pricing package announced last December contains a number of new pricing policies that run counter to the government's pledge to fuel innovation in Japan and efforts to appropriately value innovation. In particular, PhRMA member companies are concerned that the number of innovative products to qualify for the Price Maintenance Premium (PMP) will be reduced dramatically and fewer companies will qualify for the full benefit of the PMP under the new company requirements for the PMP. Recent estimates indicate that approximately one-third of patented medicines would no longer qualify, resulting in \$1.7 billion in lost revenues annually.¹⁸⁴ This move threatens to severely and inappropriately undervalue U.S. intellectual property. Further, the PMP eligibility criteria appear to be inherently biased towards local companies and seriously call into question Japan's commitment to fair and non-discriminatory policies.
- **Other Concerning Government Pricing Reforms:** Other changes to the pricing rules such as "huge seller repricing" and "optimal use guidelines" that have been imposed suddenly and without meaningful stakeholder involvement by the Japanese government reduce the predictability and transparency of the drug pricing system in Japan and threaten to undervalue U.S. products.

¹⁸³ IQVIA MIDAS™, 2017.

¹⁸⁴ IQVIA Japan analysis, 2018.

- **Reform Initiative Continues to Lack Transparency:** As the Japanese government developed its detailed plans to carry out the drug pricing reform initiative, there were few formal attempts by the decision-making bodies to seek input from stakeholders, including the innovative pharmaceutical industry. For example, details on the topics for discussion at meetings of the Chuikyo, were not shared in advance. Further, except for four formal hearings at which industry was invited to testify, industry representatives were only able to attend Chuikyo meetings as observers. Related to the new PMP system:
 - No pre-notice was made or discussions held with companies before MHLW sent the request to submit product information for the new PMP eligibility assessment.
 - MHLW requested detailed information on a product-by-product basis and allowed very little time to prepare submissions.
 - MHLW notified, at the end of last year, only the result of their analysis as to whether individual products were eligible under the new PMP system. MHLW did not provide any reasoning or explanation on how the products were evaluated.
 - Companies were given very little time to file appeals, and what time was given was over a major Japanese holiday (Note: PhRMA requested a longer period for companies to prepare their appeals, but MHLW only agreed to move the deadline by three hours).
 - Appeals were not allowed for all products.

Moving forward, PhRMA's member companies request more regular and meaningful opportunities to provide input regarding the development of further reforms to Japan's government pricing and reimbursement systems.

- **Lack of Predictability in the Japanese Marketplace:** Another issue of serious concern is the stated intention by the Japanese government to move from the current biennial price revision system into an annual revision system. Furthermore, the Japanese government has indicated that it plans to develop and implement a new Health Technology Assessment (HTA) in Japan by early 2019. These lingering elements of the reform that remain undecided continue to make the Japanese market highly unpredictable and make planning for the future for companies extremely difficult.

For these reasons, PhRMA requests that Japan be placed on the **Priority Watch List** in the 2018 Special 301 Report, and that the U.S. Government work with the Japanese government to ensure that the problems described herein are quickly and effectively resolved.

Market Access Barriers

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 the innovative drugs, and ensuring that U.S. and other innovative products were appropriately valued. 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% ceiling on the innovation premium under certain circumstances and the continued use of the market expansion and other re-pricing rules.

Investment in drug innovation is a long-term endeavor, such that any unpredictability in the PMP could lead to slower development of new drugs. Therefore, the top public policy priority of PhRMA's member companies over the years has been to push for the PMP to be made a permanent part of the government's pricing and reimbursement system without reducing the scope of products eligible for the premium.

However, under the government pricing reforms announced in December, products eligible to receive the PMP are those that either: (1) received a price premium at launch or post-launch; (2) meet certain criteria for new mechanisms of action; (3) are second- or third-in-class and launched within three years of a comparator product in the above groups; (4) received an orphan designation or; (5) were developed in response to an open request from MHLW. In essence, this new system equates "innovativeness" with the order in which products launch. PhRMA is opposed to such a non-science-based evaluation of innovation, and notes that several U.S. global best-selling products would have been deemed "non-innovative" under the new criteria and stripped of their PMP eligibility. This clearly demonstrates that the new system fails to adequately reward U.S. innovation.

Companies with products eligible to receive the PMP will be ranked and sorted into three tiers based on: (1) the number of phase 2+ clinical trials conducted in Japan; (2) the number of new products launched in Japan within the past five years; (3) the number of new products developed in response to open requests from MHLW; and (4) the number of products with a Sakigake designation. The number of companies eligible for Tier 1 status will be limited to "25% but not exceeding 30%, even if there are many companies with the same score." All of the eligible products from these companies will be awarded the full premium. Eligible products marketed by the middle tier or bottom tier of companies will be awarded 90% or 80% of the premium, respectively. PhRMA believes that limiting the number of companies eligible for the full PMP cannot be seen as a true test of innovativeness. Further, these criteria inappropriately favor larger companies.

In addition, specific elements of the PMP company eligibility criteria appear to be inherently biased towards local companies and seriously call into question Japan's commitment to fair and non-discriminatory policies. For example:

1. *The company criteria appear to be inconsistent with Japan's national treatment obligations*

A key tenet and obligation of the international trading system, as indicated in several of the World Trade Organization (WTO) Agreements, is the national treatment principle. More specifically, imported products should be accorded no less favorable treatment than that accorded to like products of national origin¹⁸⁵ and that WTO members shall not "establish or maintain any internal quantitative regulation relating to the mixture, processing or use of products in specified amounts or proportions which requires, directly or indirectly, that any specified amount or proportion of any product which is the subject of the regulation must be supplied from domestic sources."¹⁸⁶

The criteria proposed for selecting those companies who will benefit from full price stability during the patent term (*i.e.*, a full premium) under the price maintenance system (PMP) are inherently biased towards local companies:

- The first criterion ranks companies based on the number of clinical trials that they conduct in Japan. By definition, therefore, it conditions receipt of the premium on local research and development. If international manufacturers do not engage in this local activity and thus do not qualify for the full premium, their pharmaceutical products, which are more likely to be imported, would be accorded less favorable treatment than locally developed and produced pharmaceuticals.
- The second criterion similarly favors companies who are launching more medicines in Japan.
- The third criterion takes into account the number of products manufactured by the company that have qualified under the Sakigake program for faster marketing approval and preferential reimbursement rates. In turn, one of the criteria that must be met in order for a product to qualify for Sakigake status is whether the product has been developed and planned for approval in Japan ahead of other markets. Whether the product was produced for launch first in Japan or elsewhere should not be the basis for granting preferential reimbursement rates, nor, in turn, for determining eligibility for full price premiums under the PMP system.

¹⁸⁵ See, e.g., Article III:4 of the General Agreement on Tariffs and Trade (GATT), Article 3 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and Article 2.1 of the WTO Technical Barriers to Trade (TBT) Agreement.

¹⁸⁶ GATT Article III:5.

- Finally, depending on how the Ministry of Health, Labour and Welfare selects companies to develop certain medicines, including this as a criterion for full PMP eligibility could, *de facto*, discriminate against U.S. companies.
2. *The proposed company criteria appear to impose unreasonable restrictions on the exclusive rights conferred by a patent*

Providing premiums to certain innovative products over others based solely on local development (clinical trials) and the number of products launched in that country is also inconsistent with Japan's obligations not to create impermissibly broad exceptions to the exclusive rights of patent holders. TRIPS Article 30 permits members to grant only "limited" exceptions to patent rights, and only so long as such exceptions do not "unreasonably conflict with a normal exploitation of the patent" or "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."¹⁸⁷ In *Canada – Pharmaceuticals*, a WTO panel construed TRIPS Article 30 as setting forth three cumulative requirements for exceptions: (1) they must be limited, (2) they must not unreasonably conflict with normal exploitation of the patent, *and* (3) they must not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.¹⁸⁸

Among the "exclusive rights conferred by a patent," TRIPS Article 28.1 states that a patent "shall confer" on its owner the "exclusive rights" to "prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product."¹⁸⁹ A WTO panel has interpreted the TRIPS Agreement as providing five rights to patent owners—making, using, offering for sale, selling, and importing—each of which is "considered a meaningful and independent part of the patent owner's rights."¹⁹⁰ That 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."¹⁹¹

The proposed company criteria, above and beyond those already used to determine that the product is innovative, unreasonably limit a company's ability to realize the expected economic returns during the patent term of that product. As such, they appear to be inconsistent with TRIPS Articles 28 and 30.

3. *The proposed company criteria appear to create unnecessary obstacles to trade*

¹⁸⁷ As this provision states, "[m]embers may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." TRIPS, Art. 30.

¹⁸⁸ Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS/114/R (Mar. 17, 2000), ¶ 7.20 [hereinafter "Panel Report, *Canada – Pharmaceuticals*"].

¹⁸⁹ TRIPS, Art. 28.1 (footnote omitted).

¹⁹⁰ Panel Report, *Canada – Pharmaceuticals*, WT/DS/114/R, ¶¶ 7.32-33.

¹⁹¹ Id. ¶¶ 7.54-55.

Finally, WTO Members are required under Article 2.2 of the TBT Agreement to ensure that:

technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment.

While it is legitimate for the Government of Japan to require local clinical trials for the purpose of ensuring the safety and efficacy of medicines for Japanese patients, it is not legitimate to condition the receipt of the full PMP on the quantum of clinical trials and product launches in Japan. As noted above, the proposed criteria on their face or *de facto* appear to impose restrictions on imported medicines as compared to locally produced medicines. The Government of Japan has identified no legitimate objective that will be achieved by imposing these additional company criteria.

Other Government Pricing Policies of Concern

Other changes to the pricing rules such as “huge seller repricing” and “optimal use guidelines” that have been imposed suddenly and without meaningful stakeholder involvement by the Japanese government reduce the predictability and transparency of the drug pricing system in Japan and threaten to undervalue U.S. products. Reform of the pricing system should be done via a fully fair and transparent system and should avoid reactive short-term, *ad hoc* re-pricing mechanisms that fail to appropriately value innovation. The huge seller repricing program should be revisited and the effect of optimal use guidelines on the health insurance system should be strictly limited so that patients’ early access to innovative drugs is ensured.

Lack of Predictability in the Japanese Marketplace

Another issue of serious concern is the stated intention by the Japanese government to move from the current biennial price revision system to an annual revision system. In December 2017, the government postponed a decision on the criteria to be used to determine those products subject to annual price revisions. Given that there will be regular biennial price revisions in 2018 and 2020, and the planned increase of the consumption tax in 2019 will also involve price revisions for all products, the first annual repricing under the new system will take place in 2021. PhRMA and its members believe that the current system should be maintained, and that if annual price revisions need to be conducted, products subject to revisions in off-years should be limited to those with a significant price discrepancy rate between the NHI price and the current market price.

The Japanese government also has indicated that it plans to implement a new Health Technology Assessment (HTA) system in Japan. Beginning in April 2018, the Japanese government will revise the prices of those products that have been subject to an ongoing cost-effectiveness assessment pilot program. For these products, the price premium granted at launch will be adjusted based on a cost-effectiveness threshold of 5 million yen per a quality-adjusted life year and additional factors. Given challenges experienced during the pilot program, the Japanese government decided that if the company assessment and the review commitment assessment produce divergent results, then any adjustment to the price premium will be based on whichever assessment results in a smaller adjustment. In such cases, the review will continue in 2018. In addition, the Japanese government postponed a decision on the full-scale introduction of a new HTA system and now plans implementation for early 2019.

PhRMA agrees that appropriate HTA has the potential to assist governments in making informed decisions about allocating resources. However, deficient HTA processes like the ones currently proposed 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 pure cost containment methods.

THAILAND

PhRMA's member companies continue to have concerns over market access barriers and the intellectual property (IP) environment in Thailand.

Key Issues of Concern:

- **Generally weak IP environment:** PhRMA's member companies recognize and commend the Department of Intellectual Property's (DIP's) inclusion of industry in the discussion and construction of the Patent Examination Guidelines. However, additional improvement in the IP environment in Thailand remains necessary to avert negative impact on market access. Concerns include delays in obtaining pharmaceutical patents, inadequate regulatory data protection (RDP), and weak patent protection and enforcement regimes.
- **Discriminatory government procurement:** The Thai Government continues to implement policies aimed at growing the domestic Thai industry at the expense of medicines imported from the United States. These policies have created discriminatory procurement practices that drastically and arbitrarily cut prices of U.S. products and harm the ability of U.S. companies to conduct business in Thailand.

For these reasons, PhRMA requests that Thailand remain on the **Priority Watch List** in the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Patent Backlogs

In 2013, DIP finalized the Patent Examination Guidelines to complement the Thai Patent Act. The innovative biopharmaceutical industry was invited to provide its input during the drafting, which was appreciated. The Patent Examination Guidelines were intended to set clear benchmarking and examination rationale which would enhance transparency in patent registration as well as help ensure balance and fairness with respect to innovative products.

However, unresolved issues remain, including how to clear the patent backlog and ensure that there are sufficient resources to maintain the patent registration process. The waiting-period for a patent review and grant in Thailand is unpredictable and averages ten years after application submission. Further, these long patent grant delays create uncertainty regarding investment protection and increase the risk that a third party will use a patentable invention that is the subject of a pending patent application during the pending/review periods. Indeed, at least one PhRMA member has experienced a third-party launch of a product that was the subject of a pending patent application. In that

instance it took over 18 years for the patent to be granted, and even then the member was unable to obtain meaningful enforcement of the patent. Patent term adjustments are not available in Thailand to compensate for unreasonable patent office delays, thereby reducing the effective patent term and further exacerbating the uncertainty caused by its patent grant delays.

Restrictive Patentability Criteria

Thailand's patentability criteria restrict patent protection for new uses of biopharmaceutical products. PhRMA's member companies strongly encourage the Royal Thai Government to recognize the significant health, scientific, and commercial benefits of new uses for existing pharmaceuticals. Patent applications for new improvements, advances, and next generation products should be reviewed in accordance with internationally recognized patentability criteria as well as applied consistently among all technology dependent sectors. Although industry representatives have been asked to sit on the Patent Amendment Committee and Patent Examination Guideline committee, PhRMA's member companies encourage the Royal Thai Government to work with all technology-based industries to improve the patent system for the benefit of all innovators in all fields of technology. This approach will ensure that the incentive for innovation is preserved as well as that all technologies are granted equal treatment with respect to patent grant criteria and patent prosecutions.

Weak Patent Enforcement

PhRMA's member companies strongly encourage the Thai Food and Drug Administration (TFDA) to implement effective mechanisms to allow for sufficient time to resolve patent disputes before follow-on products are approved. Effective patent enforcement could greatly enhance the business environment in Thailand by: (1) providing transparency and predictability to the process for both innovative and generic firms; (2) creating a more predictable environment for investment decisions; and (3) ensuring timely redress of genuine disputes.

Regulatory Data Protection Failures

Ministerial regulations issued by the TFDA regarding the Trade Secrets Act of 2002 do not provide RDP that would prevent generic or biosimilar drug applicants, for a fixed period of time, from relying on the innovator's regulatory data to gain approval for generic versions of the innovator's product. The Act aims only to protect against the "physical disclosure" of confidential information.

PhRMA's member companies strongly encourage the Royal Thai Government to institute meaningful RDP. Specifically, Thailand should: (1) implement new regulations that do not permit generic or biosimilars producers to rely directly or indirectly on the originators' data, unless consent has been provided by the originator, for the approval of generic or biosimilar pharmaceutical products during the designated period of protection; (2) bring the country's regulations in line with international standards by making clear that

data protection is provided to test or other data submitted by an innovator to obtain marketing approval; (3) provide protection to new indications; and (4) require TFDA officials to protect information provided by the originator by ensuring it is not improperly made public or relied upon by a subsequent producer of a generic or biosimilar pharmaceutical product.

Compulsory Licensing

Despite assurances that Thailand would be judicious in its use of compulsory licenses (CLs) and consult with affected parties as required by the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights, Thailand continues to threaten the use of CLs. Further, royalty payments have not been made on products for which CLs have been issued. Thailand's compulsory licensing regime lacks sufficient due process and dialogue with affected companies, and suffers from a lack of transparency in the reasoning behind CL decisions.

Market Access Barriers

Discriminatory and Non-Transparent Government Procurement Policies

The Thai Ministry of Public Health currently sets the "median price or maximum procurement price" (MPP) for each medicine. This policy has been used as a cost containment measure especially for innovative medicines. The current methodology and implementation of the MPP policy lacks transparency, predictability, and fairness. For example, companies are required to "negotiate" a price, but in reality there is very little negotiation. Products are subject to price cuts announced with little notice, disrupting the business plans of U.S. companies, and there is no independent appeals process. In addition, the MPP can be set by reference to prices in other countries, even though there is no defined basket of reference countries and even when such countries are not comparable in terms of their patient populations and healthcare systems. In some cases, the Thai Government selectively sets prices of patented medicines based on prices of generic medicines, which undermines intellectual property rights and the value of innovation. Overall, these actions have resulted in price cuts of 50-90% for U.S. products, contributing to an increase in the trade deficit.

In addition, the Thai Government established the Thai Innovation List, a new program to develop domestic industrial capacity in several innovation sectors, including pharmaceuticals. Only Thai majority-owned companies qualify, and they receive special government procurement privileges including an earmark for up to 30% of orders by Thai agencies.

The MPP policy is inconsistent with Thai Government efforts to foster a positive business environment based on good governance, ease of doing business, and rule of law. The MPP process combined with Thailand's poor record of protecting U.S. patents and its recent preference for domestic companies harms U.S. innovators and could delay or prevent the introduction of new medicines.

The government of Thailand should revise the current process for setting the MPP to ensure that pharmaceutical companies have an opportunity to provide timely input about innovative products for Thai patients. Greater stakeholder engagement between the pharmaceutical industry and the government regarding pricing decisions that affect the availability of innovative medicines for Thai patients would also be mutually beneficial. The innovative biopharmaceutical industry stands ready to work with the Thai Government to develop policy solutions that will bring stability and predictability to U.S. innovators and investors, and thereby better ensure that Thai patients and physicians have increased access to life-saving innovative medicines.

Regulatory Reform

PhRMA's member companies are encouraged by recent developments to reform regulatory processes for innovative drug registrations. The Licensing Facilitation Act, effective as of July 21, 2015, requires the TFDA to publish operating manuals which outline all regulatory processes related to drug and medical registration. In addition, a new registration fee scheme was implemented in August 2017 to better resource TFDA to review drug registrations applications. Industry is hopeful that this reform will improve TFDA accountability and transparency and, in the process, ensure a more secure business environment for innovative biopharmaceutical companies. PhRMA also encourages the implementation of processes like e-submissions and abridged reviews during TFDA registration applications in order to improve lengthy Thai processing times.

Europe

RUSSIA

PhRMA and its member companies operating in Russia are concerned with numerous market access barriers, especially those linked to intellectual property protection and import substitution efforts, all of which decrease the value awarded to innovation in Russia and the benefits it brings to Russian patients.

Key Issues of Concern:

- **Regulatory data protection failures:** As part of its accession to the WTO, Russia agreed to provide six years of regulatory data protection (RDP). While the Law on Circulation of Medicines provides RDP, a 2014 amendment to that law undermines the term of protection available to innovators. In 2016, the Supreme Court of Russia further eroded RDP by allowing local generic companies to rely on partial clinical data sets published in scientific journals abroad to seek marketing approval in Russia. Russia's Ministry of Health is seeking to codify that ruling. PhRMA and its member companies are concerned that these combined developments substantially weaken RDP protection for innovative medicines in Russia.
- **Compulsory licensing and restrictive patentability criteria:** Notwithstanding the Russian Government's goal to stimulate the development of an innovative pharmaceutical industry in Russia (as described in the *Pharma 2020 Strategy*),¹⁹² Russia's Federal Anti-monopoly Service (FAS) continues to express strong support for expanded use of compulsory licenses (CLs) and expressed its intent to adopt restrictive patentability criteria for pharmaceuticals. Since 2016, FAS released for public review several draft amendments to the Anticompetitive regulation and Civil Code in order to exclude "intellectual property immunities" in relevant competition regulations. FAS is also seeking to broaden the authority and discretion available to the Government to issue compulsory licenses.
- **Weak patent enforcement:** Currently, there is no mechanism in place to provide patent holders with the opportunity to resolve patent disputes prior to the launch of a follow-on product. Russian courts were not only reluctant to issue court injunctions in patent infringement cases related to pharmaceuticals but had previously decided that marketing authorization of generics is not an infringement of the patent before the infringing product is sold to a customer. This has led to the approval and marketing of follow-on products, despite the fact that a patent for the original drug is still in force. The Russian regulation is then compounding this injury by permitting prematurely launched generics to participate in state procurement tenders.

¹⁹² Strategy for Developing the Russian Pharmaceutical Industry until 2020, approved by the Order of the Ministry of Industry and Trade, dated October 23, 2009, No. 956.

- **Parallel imports initiatives:** Regulations are under development to allow for the parallel import of pharmaceuticals from outside the Eurasian Economic Union (EAEU). The Intergovernmental Council of the EAEU has approved the regulations underpinning the single EAEU market for pharmaceuticals and allowing free trade in the EAEU; however the market will not operate as planned until the approved procedures are technically implemented at the national levels.
- **Localization and restrictions for state procurement:** Despite support for accession to the World Trade Organization (WTO) Agreement on Government Procurement (GPA), Russia continues to impose pressure to locally produce through its government procurement system (e.g., restrictions on public procurement of imported drugs where there are at least two locally produced pharmaceuticals, and a 15% price preference for locally produced pharmaceuticals in government procurement tenders). In addition, in October 2017 the Ministry of Industry and Trade (MIT) preliminarily approved a 25% pricing preference for locally produced products.
- **Uncertainty of the pricing environment:** Russia recently issued draft policies that propose crucial changes to the methodology for calculating maximum prices for medicines. Over the last seven years the Essential Drug List (EDL) pricing methodology has changed several times, including significant revision in 2015. New major revisions aimed at re-registration of all maximum selling prices for EDL medicines were officially released in May 2017 with discussion still ongoing. In addition, in December 2017, the MoH Order, which sets forth the procedure for determining the initial auction prices for medicines (based, *inter alia*, on average-weighted historical prices of state tenders) entered into force. These frequent revisions to the pricing methodology destabilize the market, discourage local investment and hinder the launch of new medicines all while promoting a downward spiral for pharmaceutical prices in Russia.

For these reasons, PhRMA requests that Russia remain on the **Priority Watch List** in the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Regulatory Data Protection Failures

As part of its accession to the WTO, Russia agreed to provide six years of regulatory data protection (RDP). While the Law on Circulation of Medicines provides for this protection, weaknesses in Russia's judicial system are particularly concerning to PhRMA members in light of amendments to Russia's Law on the Circulation of Medicines passed in 2014. Specifically, beginning in 2016, a registration application is allowed for follow-on medicines as early as four years after the granting of marketing authorization for a reference small molecule drug and three years after marketing authorization of a reference biologic medicine. While, on paper, marketing is restricted until after the six-

year RDP term has expired, the inability of PhRMA members to seek effective and efficient court rulings may lead to the launch of infringing follow-on products during the regulatory data protection term.¹⁹³

These weaknesses were further compounded in 2016 when the Supreme Court of Russia held that follow-on generic manufacturers can rely on the partial clinical data sets reported in scientific journals following approval of the innovative product in seeking marketing approval for its own follow-on product during the regulatory data protection (RDP) term.¹⁹⁴ The Ministry of Health has proposed amendments to Article 18 of Russia's Law on the Circulation of Medicines that would codify the ruling (the Draft Law).¹⁹⁵ However, as found by the Russian Ministry of Economic Development (MED) last year during their regulatory assessment of the relevant proposals, the Draft Law could negatively affect Russia's innovation and investment climate. At the same time, PhRMA and its member companies strongly believe that the Russian RDP regulations require further improvement and transparent enforcement mechanisms to be consistent with the requirements of TRIPS Article 39.3.

Compulsory Licensing

PhRMA and its member companies are concerned about continuous FAS proposals to expand the use of CLs in Russia. On December 21, 2017, the Russian President signed Order No. 618 "On Key Areas for the Development of Competition Policy," which approved the National Plan for the Development of Competition in the Russian Federation in 2018-2020 (the Competition Development Plan). According to the Competition Development Plan, by January 1, 2019, the Russian Government is proposing the submission of a draft law to the State Duma allowing the Russian Government to authorize the usage of an invention without the consent of a patent owner where determined to be in the interests of national security and health protection. While the Order does provide that due notification and reasonable compensation must be provided to the affected patent holder, the breadth of the proposal does not appear to be consistent with the TRIPS Agreement. As such the proposed law would weaken Russia's intellectual property framework and undermine the incentive system that underpins the ability of our members to undertake essential R&D. It would also discourage investment in Russia and is contrary to positive statements made by others in the Government, including the Deputy Prime Minister Arcady Dvorkovich, who sent a letter to the Russian President in April 2016 rejecting the greater use of CLs.

On July 26, 2017, the Russian President signed Federal Law No. 184-FZ "On Approval of the Protocol Amending the TRIPS." That law was a response to codify

¹⁹³ At the same time, the Law on the Circulation of Medicines states that the Federal Register of Medicines must identify the earliest date on which a follow-on product may enter the market. However, it is still not clear if the implementation of this rule will be effective.

¹⁹⁴ Supreme Court of the Russian Federation, Resolution No. 305-ES16-2399, May 26, 2016.

¹⁹⁵ On Amendments to Article 18 of the Federal Law "On the Circulation of Medicines," available in Russian at <http://regulation.gov.ru/projects#npa=56342> (last visited Feb. 7, 2018).

amendments to the WTO TRIPS Agreement (Article 31bis), which allows generic copies made under compulsory licenses to be exported to WTO member states that lack production capacity, provided certain conditions and procedures are followed. The legislative note to Federal Law No. 184-FZ posits that Russia would be able to import medicines under a compulsory license. It appears that the governmental stakeholders have improperly interpreted the scope of Article 31bis – namely that it is reserved for WTO Members with insufficient or no manufacturing capacity.

Weak Patent Enforcement

Russia does not maintain an effective mechanism that provides for the early resolution of patent disputes before potentially infringing products enter the market. Follow-on drug manufacturers can apply for and receive marketing approval for a generic product, despite the fact that a patent for the original drug is still in force. The Law on the Circulation of Medicines does not include provisions for patent status review, when a company applies for marketing authorization.

Further, pharmaceutical innovators face significant legal challenges that limit their ability to effectively protect their innovative products against infringement. For example, the Russian courts do not, in practice, grant preliminary injunctions to patentees in pharmaceutical patent infringement cases, thereby facilitating premature market entry by patent-infringing follow-on products, including participation in government tenders. As a result, PhRMA member companies have not been able to resolve patent disputes, prior to marketing approval being granted to infringing follow-on products, leading to injury that is rarely compensable via damages.

Russia's court practices appear contrary to Russia's obligations under the TRIPS Agreement and assurances Russia made to the Working Party on the Accession of the Russian Federation of the WTO. In particular, they appear to violate TRIPS Article 41, which requires Members to provide "expeditious remedies to *prevent* infringements" (emphasis added) and provisions of Article 50 with respect to provisional measures. Russia assured the Working Party that it would "counteract ... infringements of intellectual property through improvements in enforcement."

To avoid unnecessary costs and time in patent litigation, and to increase market predictability, Russia should ensure its Courts are granting preliminary injunctions when sought by patent holders, enable patent holders to seek and receive preliminary injunctions before marketing authorization is granted for follow-on products, and afford sufficient time for such disputes to be resolved before marketing occurs. This might include a form of automatic postponement of drug registration approval pending resolution of the patent dispute or for a set period of time.

Predictable and effective patent enforcement procedures are especially important in connection with the transition to the common EAEU market for medicines. PhRMA and its member companies are concerned that the current EAEU regulatory frameworks

creating the common pharmaceutical market do not provide robust patent protection for innovative medicines.

Restrictive Patentability Criteria

On May 27, 2016, FAS published on its official web-site, the draft Roadmap for Development of Competition in the Healthcare Sector. This document, inter alia, proposed amendments to patentability criteria, for any new property or new application of a known active ingredient of a medicinal product (including new indications, new treatment methods, new combinations, new dosage forms and manufacturing methods). PhRMA and its members are concerned that the FAS may renew discussion of these amendments in 2018, which may inappropriately restrict the availability of patents for innovative medicines in Russia, and thus undermine incentives to innovate.

Parallel Imports

Currently, parallel imports are prohibited from countries outside the EAEU, based on the regional principle of exhaustion of trademark rights.

In April 2017 the Board of the Eurasian Economic Commission (EEC) approved the draft Protocol on Amendments to the Treaty on the Eurasian Economic Union of May 29, 2014. The document grants the Eurasian Intergovernmental Council the authority to use the international principle of exhaustion of trademark rights in respect to certain products, including pharmaceuticals. PhRMA and its member companies remain concerned that such exemptions may exacerbate medicine shortages in exporting countries and compromise the security of medicine supply chains, thereby inadvertently introducing counterfeit medicines into the Russian market.

Although parallel importation was not authorized in 2017, PhRMA and its member companies remain concerned that proposals to implement PI in the pharmaceutical sector may at some point be renewed.

Market Access Barriers

Localization Barriers

In 2016, Russia officially began the process of joining the GPA. Notwithstanding this process however, Russia continues to impose pressure to locally produce through its government procurement system.

On November 30, 2015, the Russian Government adopted Resolution No. 1289 “On Restrictions and Conditions of Access of Foreign Essential Medicines to State and Municipal Tenders,” which codifies the so-called “three’s a crowd” approach in relation to medicines included on the Essential Drugs List (EDL). According to Resolution No. 1289, if two or more EAEU pharmaceutical manufacturers bid on a tender for an EDL product, any foreign bid for that same tender must be rejected. Medicines not falling within

Resolution No. 1289, remain subject to the tender preferences established by the Ministry of Economic Development (MoED), where local companies receive a 15% price preference.

In early November 2016, the Russian Government proposed additional discriminatory measures aimed at further restricting the ability of foreign manufacturers to win tenders for products included in the EDL.¹⁹⁶ According to the proposed amendments, the order of prioritization for evaluating tenders will be: 1) products with full cycle production in Russia, 2) products manufactured in Russia or other Member States of the EAEU using foreign-sourced content, and 3) foreign produced products. The proposed amendments were further modified by MIT in 2017 to provide a 25% price preference for products containing local content. PhRMA and its members are concerned that not only will these provisions, if enacted, discriminate against foreign products, they may also impact patient access to quality innovative medicines.

The Russian Government has also taken a number of steps to isolate certain segments of the pharmaceutical market for sole-supply contracts given to Russian companies. For example, in August 2017 the Russian Government signed Decree No. 1721-r and appointed the National Immunobiological Company (NIB) as the sole supplier of certain medicines and medical devices for the Federal Service for the Execution of Sentences in 2017-2018. Earlier in 2016-2017, NIB acted as sole supplier of certain blood products (for a number of state purchasers) and certain locally produced vaccines (within the national immunization schedule) based on other Decrees of the Russian Government.

A number of other measures aimed at supporting local manufacturers are being implemented in Russia. For instance, in October 2017 the Russian Government modified a number of regulatory acts governing the provision of subsidies to local manufacturers for development costs (e.g., clinical trials and organization of local pharmaceutical manufacturing processes, etc.) under the framework of State Program for “Development of Pharmaceutical and Medical Devices Industry in 2013-2020.”¹⁹⁷ Some of these measures (e.g., the practice of appointing a sole supplier for government tenders) may discriminate against U.S. companies and limit patient access to certain medicines.

Deteriorating Pricing Environment

Over the last seven years, the EDL pricing methodology has changed five times, including significant revision in 2015. In May 2017, the Russian government issued yet further draft amendments to the Pricing Registration Rules and Pricing Methodology. These draft amendments propose changing the methodology for calculating ceiling prices for EDL medicines, and skews the reference basket used to set prices towards the lowest-price in lower-income countries. If implemented, this approach could result in a downward price spiral.

¹⁹⁶ The Ministry of Industry and Trade, “On Amending the Regulation of the Government of the Russian Federation No. 1289 dated November 30, 2015.”

¹⁹⁷ Approved by the Decree of the Russian Government dated April 15, 2014, No. 305.

Good Manufacturing Practice

Since January 2016, Russia requires local GMP certificates for foreign producers as part of the drug registration application. Due to the timelines for GMP inspections and capacity constraints, this effectively hinders access to the market for U.S. producers. PhRMA's members welcome and seek quick passage and implementation of amendments currently pending in the Duma which it is hoped will mitigate these concerns. PhRMA's members are also concerned with the existing discriminatory approaches exercised by the MIT related to GMP inspections of foreign sites. However, PhRMA's members hope that these constraints may be addressed through constructive dialogue between the inspectorate, MIT and the industry.

Eurasian Economic Union

The EAEU, comprised of Russia, Belarus, Kazakhstan, Armenia, and Kyrgyzstan entered into force on January 1, 2015. The treaties establishing the Eurasian Customs Union and the Single Economic Space were terminated by the agreement establishing the EAEU, which incorporated both into its legal framework. The EAEU envisages the gradual integration of the former Soviet countries' economies, establishing free trade, unbarred financial interaction and unhindered labor migration. One of the first sectors to be integrated is the pharmaceutical sector through creation of a single pharmaceutical market. To this end, the EAEU Agreement on Common Principles and Rules of Drug Circulation in the EAEU was executed in the city of Minsk on December 23, 2014, and the EAEU Intergovernmental Council approved the necessary regulations to establish a common pharmaceutical market in the EAEU entered into force on May 6, 2017.

Although the innovative pharmaceutical industry has some concerns regarding how the single pharmaceutical market is being implemented (discussed further below), we stand ready to work with the Government to ensure that there is a robust regulatory review system and continued patient access throughout the EAEU.

Orphan Drugs Legislation

The Law on the Circulation of Medicines includes a definition and an accelerated registration procedure for orphan drugs that eliminates the need for otherwise obligatory local trials. Although the industry, as a general matter, supports accelerated pathways for orphan drugs, the procedure lacks sufficient detail to fully evaluate its effectiveness. PhRMA's members are hopeful that these issues may be resolved under the EAEU regulatory framework.

Biologic and Biosimilar products in Russia

The Law on the Circulation of Medicines sets forth the basic regulations for biologics and biosimilars. Although PhRMA's members welcome Russia's actions to better regulate biologics and biosimilars, there remain some concerns regarding implementation of the relevant regulations (including assessment guidelines for biosimilar

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drugs, determining the interchangeability of biologic drugs, *etc.*). PhRMA's members are hopeful that these issues may be resolved under the EAEU regulatory framework.

TURKEY

PhRMA and its member companies face significant market access barriers in Turkey due to the deficiencies in Turkey's intellectual property (IP) framework, slow and unpredictable product registration and reimbursement processes, severe forced localization policies, and strict government pricing systems.

During the last decade, Turkey has undertaken reforms to modernize its economy and expand its health care system in many positive ways for Turkish patients. However, a general lack of transparency and inconsistency in decision-making has contributed to unclear policies that undermine Turkey's investment climate and damage market access for PhRMA member companies.

While PhRMA and its member companies appreciate the increased dialogue that exists between the Turkish Government and the innovative pharmaceutical industry in Turkey, and welcomes the recently passed Industrial Property Law that better aligned Turkey with the European Patent Convention, still more attention needs to be paid to the link between the short-term impact of Turkish government policies and the innovative pharmaceutical industries' research and development process, including the potential of PhRMA member companies to invest in Turkey.

Key Issues of Concern:

- **Weak patent enforcement and regulatory data protection failures:** While patents and regulatory test data have received IP protection in Turkey since 1995 and 2005, respectively, significant improvements are still needed. For instance, while Turkey's new Industrial Property Law, which was passed by the Turkish Parliament on December 22, 2016, better aligns Turkey with the European Patent Convention, certain provisions in the new law expand the possibility of granting compulsory licenses (CLs) in Turkey. In addition, Turkey does not provide an effective mechanism for resolving patent disputes before the marketing of follow-on products. Further, Turkey inappropriately ties the regulatory data protection period (RDP) to the patent term and the lack of RDP for combination products is still an unresolved issue. Finally, the RDP term begins with first marketing authorization in the European Union and thus, as a result of significant regulatory approval delays in Turkey, the effective RDP term is reduced significantly. Consistent with Turkey's international obligations, the RDP term should begin when a product receives marketing authorization in Turkey.
- **Localization policies:** Following the implementation of provisions in Article 46 of the 64th Government Action Plan (released on December 10, 2015), which call for the delisting of imported products from the reimbursement list and provide preferential reimbursement arrangements for healthcare products produced domestically. PhRMA member companies began receiving notices in February 2017 that their products would be delisted within 12 months unless sufficient

localization plans are put in place. These measures are inconsistent with Turkey's national treatment obligations under the World Trade Organization (WTO) Agreements and contradict Turkey's goal of attracting investment from the world's leading pharmaceutical companies.

- **Regulatory approval delays:** While PhRMA and its member companies appreciate the Turkish Drug and Medical Device Agency's (TITCK's) efforts to improve the period required to complete the regulatory approval procedures for medicinal products, this period exceeds on average 446 days,¹⁹⁸ significantly more than the 210 days targeted in Turkish regulations. Regulatory approval delays have a negative impact on access to medicines in Turkey.
- **Local inspection requirements:** PhRMA and its member companies also welcome TITCK's efforts to improve the regulatory approval procedures of highly innovative and/or life-saving products with no or limited therapeutic alternatives in Turkey. Specifically, prioritizing the Good Manufacturing Practices (GMP) audit procedures and allowing a parallel marketing application process for those products has decreased the delays in approving those products. However, while products deemed highly innovative are receiving preferential reviews, products without this designation face increased delays due to the lack of resources and the absence of efficient procedures for conducting GMP inspections. While, PhRMA and its member companies welcome Turkey's efforts to join the PIC/S (Pharmaceutical Inspection Convention and Co-operation Scheme) and better align its GMP inspections practices with the other members of the Scheme, GMP inspection delays continue to add to registration delays, delaying patient access to innovative medicines and negating the benefits of the patent and data protection periods for many products.
- **Other market access barriers:** The Turkish Government continues to set sub-optimal levels for the overall pharmaceutical budget and specific innovative medicines allocations. The government's budgeting disregards parameters such as economic growth, inflation and exchange rate fluctuations, and result in government price discounts that may compromise access to innovative medicines.

For these reasons, PhRMA requests that Turkey be placed on the **Priority Watch List** in for the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Weak Patent Enforcement

In January 2017, Turkey enacted a new Industrial Property Law (No:6769) to support and strengthen IP rights, including patent rights. However, the IP Court judges

¹⁹⁸ Based on AIFD Survey 2015.

lack relevant training and capacity to effectively resolve disputes. Consequently, the quality of IP trials has substantively decreased and the IP Court judges refer and defer cases to expert panels. Despite the new law on court appointed experts, the expert examination system also lacks appropriate procedural safeguards.

In addition, PhRMA and our member companies are concerned about the new compulsory license provisions of the Industrial Property Law, which provide that a compulsory license can be granted not only in cases of non-use of the patent, but also in cases where a third party claims that market demands are not being met.

Regulatory Data Protection Failures

In 2005, the Turkish Government took positive steps toward establishing protection for the commercially valuable regulatory data generated by innovative pharmaceutical companies, and now provides RDP for a period of six years for products starting from first MA registration in the European Customs Union (ECU), limited by the patent protection period of the product. RDP is an independent and separate form of IP protection that should not be limited to the period of patent protection.

A significant concern for the innovative industry is that the period of RDP currently begins on the first date of marketing authorization in any country of the ECU. Considering the extended regulatory approval times and delays stemming from the GMP certification approval period, current estimates are that it could take 2-3 years (approximately 500 days for registration, and 235 days for reimbursement approval) to register and reimburse a new medicine in Turkey. Under these adverse circumstances, new products will receive, in practice, no more than one to two years of RDP, undermining incentives needed for innovators to undertake risky and expensive research and testing.

Another concern of the innovative pharmaceutical industry is that the legislation governing RDP has been changed by the Regulation to Amend the Registration Regulation of Medicinal Products for Human Use.¹⁹⁹ The change that has been introduced is incompatible with EU standards in that it eliminates RDP for combination products, unless the combination product introduces a new indication. Innovative companies invest considerable amounts of time and effort to develop products that provide increased efficacy and safety, as well as new indications, from new combinations of separate molecules.

In addition, Turkey does not provide RDP for biologic medicines. RDP is essential for all medicines, and particularly critical for biologic therapies. Made using living organisms, biologics are complex and challenging to manufacture and may not be protected adequately by patents alone. Unlike generic versions of traditional chemical compounds, biosimilars are not identical to the original innovative medicine and there is greater uncertainty about whether an innovator's patent right will cover a biosimilar version. Without the certainty of some substantial period of market exclusivity, innovators

¹⁹⁹ Official Gazette No. 27208 (Apr. 22, 2009).

will not have the incentives needed to conduct the expensive, risky and time-consuming work to discover and bring new biologics to market.

Market Access Barriers

Localization Policies

In December 2015, the Turkish government released Article 46 of the 64th Government Immediate Action Plan, which calls for the delisting of products manufactured outside of Turkey from the reimbursement list. In February 2017, the Social Security Institute released a list of 50 products to be delisted from the reimbursement list within one year. The second wave of product delisting notifications concluded in May 2017, with 176 products impacted. Three additional waves of product delistings are expected, and notifications to submit localization plans for the third and fourth wave have already been sent out.

PhRMA and our members believe that these measures are inconsistent with the WTO's national treatment requirements. The vast majority of medicines sold in Turkey are distributed through the SSI reimbursement list, and thus exclusion from this list effectively bars market access for these products. This development is a significant acceleration of forced localization in Turkey, and could have significant long - term consequences for the industry's operating environment and for patient access to certain medicines in the country.

These measures would also contradict Turkey's goal of attracting investment from the world's leading pharmaceutical companies. The Turkish Government has also suggested it will accelerate regulatory approvals for products manufactured locally and, on January 26, 2016, the Minister of Health announced a program to provide a seven - year contract for a foreign firm that agrees to establish a Hepatitis A vaccine manufacturing facility in Turkey.

Pharmaceutical Product Registration

Marketing of new drugs in Turkey is governed by the regulatory procedures prescribed by TITCK and MOH for the approval of medicinal products. The data and documents required to register medicinal products are listed in the MOH's Registration Regulation of Medicinal Products for Human Use.²⁰⁰ Although the legislation requires the Turkish MOH to assess and authorize the registration of medicinal products within 210 days of the dossier being submitted and efforts have been taken to improve the regulatory process, surveys by AIFD indicate that the average regulatory approval period is 446 days.²⁰¹

²⁰⁰ Official Gazette No. 25705 (Jan. 19, 2005) (Registration Regulation).

²⁰¹ Based on AIFD Survey 2015.

In May 2016, TITCK published a “Guideline for the Operating Procedures and Principles of the Priority Evaluation Committee of Medicinal Products for Human Use.” Although PhRMA’s member companies appreciate TITCK’s efforts to create an expedited pathway for product registration, a number of the factors used to determine those products to receive prioritized attention by the health regulator are not related to the safety and efficacy of the product. And, while not included in the May 2016 TITCK document, the agency is requiring companies to commit to a specific retail and public sale price and to estimate the number of SKUs that will be sold at the time the company submits its prioritization application.

Furthermore, without additional resources to complete product registrations, expediting certain applications over others only further delays the review time for those applications not receiving prioritized attention.

Local Inspection Requirements

The MOH’s revisions to the Registration Regulation have compounded the country’s registration delays.²⁰² Effective March 1, 2010, a GMP certificate that is issued by the Turkish MOH must be submitted with each application to register a medicinal product for each of the facilities at which the product is manufactured. The GMP certificate can only be issued by MOH following an on-site inspection by Ministry staff, or by the competent authority of a country that recognizes the GMP certificates issued by the Turkish MOH. However, for the reasons explained further below, neither option can be completed in a timely manner.

Despite increasing the number of inspectors at the end of 2013, the MOH still does not have adequate resources to complete these GMP inspections in a timely manner. However, the period required to complete the regulatory approval procedures of highly innovative and/or life-saving products with no or limited therapeutic alternatives in the country is improved by prioritizing their GMP audit procedures and allowing a marketing application process that runs parallel to the GMP determination (rather than occurring only after the GMP process is complete). Nevertheless, PhRMA and our members remain concerned that the process for determining the innovativeness of the products lacks transparency and is often inconsistent. In addition, the focus of regulatory resources on those products which have been determined, through non-transparent means, to be highly innovative, has reduced the speed at which other products are approved. Furthermore, although the Amended Registration Regulation permits applicants to submit GMP certificates issued by competent authorities in other countries, it does so only to the extent that the pertinent country recognizes the GMP certificates issued by Turkey. While PhRMA’s members welcome Turkey’s recent admission to the Pharmaceutical Inspection Co-operation Scheme (PIC/S), this is but the first of many steps that will be required

²⁰² Regulation to Amend the Registration Regulation of Medicinal Products for Human Use, Official Gazette No. 27208 (Apr. 22, 2009) (Amended Registration Regulation); MOH, *Important Announcement Regarding GMP Certificates*, (Dec. 31, 2009) (establishing an implementation date for the GMP certification requirement).

before Turkey could enter into mutual recognition agreements with the United States and other trading partners. Until then, and to avoid unnecessary obstacles to trade, PhRMA urges Turkey to revert to recognizing GMP certificates issued by institutions like the U.S. Food and Drug Administration, the European Medicines Agency or other PIC/S members for medicinal products.

Pricing and Non-Transparent Reimbursement

In Turkey, pharmaceutical pricing is regulated by the TITCK under MOH. The reimbursement system is based on a positive list and reimbursement decisions are carried out by the inter-ministerial Reimbursement Commission, led by the Social Security Institution (SSI) under MoLSS. The reimbursement decision process is relatively slow, lacks transparency and is not subject to clearly defined decision criteria.

Pharmaceutical companies are still burdened with obligatory price discounts from the lowest price in a basket of five European countries (namely France, Portugal, Spain, Italy and Greece). TITCK has begun to annually adjust the fixed Euro/Turkish Lira exchange rate used to set prices under the Pricing Decree, and according to the regulation the exchange rate was expected to increase to 2.87 TL/EUR for 2018 (*i.e.*, 70% of the 2017 exchange rate average). However, citing inflation and budget concerns, the Government has indicated that it will only increase the exchange rate to 2.69 TL/EUR. This is significantly lower than the actual exchange rate (4.68 TL/EUR as of February 7, 2018), and it is particularly troubling that TITCK is not even adjusting the exchange rate to reflect the 70% standard required by the regulation. While the Turkish Government is suggesting that this is a temporary measure, valid only for 2018, overriding the regulation exacerbates the business environment and hinders sustainability and predictability for pharmaceutical companies.

By definition, Turkey's fixed exchange rate discriminates not only against pharmaceuticals – the only sector subject to this fixed exchange rate – but also against imported pharmaceuticals contrary to Turkey's national treatment obligations. Whereas prices for imported products are determined based on the fixed exchange rate, domestic manufacturers of innovative products that are only available in Turkey may negotiate prices directly with the MOH based on cost and pharmaco-economic data. It also appears to be inconsistent with Article II:3 of the Bilateral Investment Treaty (BIT) between U.S. and Turkey, which requires that investments "shall at all times be accorded fair and equitable treatment and shall enjoy full protection and security in a manner consistent with international law." Failure to update the exchange rate to reflect the actual exchange rate has undermined the U.S. pharmaceutical industry's "legitimate expectations" as to the manner in which prices would be calculated. It is also "tantamount to expropriation," in that it substantially deprives the U.S. pharmaceutical industry of the reasonably-to-be-expected economic benefits of its investments in Turkey to the obvious benefit of the Turkish Government, contrary to Article III:1 of the U.S.-Turkey BIT.

Orphan Drug Guidelines

In August 2015, the Ministry of Science, Industry and Technology (MoSIT) published an in-depth analysis of the impact of rare diseases on Turkey's population within its "Pharmaceutical Sector Strategy and Action Plan of 2015." This study called for the creation of a national orphan drug policy, which is due to be fully implemented by January 1, 2019. The innovative pharmaceutical industry looks forward to working with key stakeholders, including the MOH, SSI, MoSIT, Ministry of Economy, Ministry of Development, Ministry of Finance, Treasury and other civil society organizations, to establish a market access pathway and appropriate incentives to facilitate the development and commercialization of medicines to treat rare diseases. As part of this process, it will be critical for Turkey to define orphan drugs based on international best practices, including EU prevalence standards, and thereby better ensure that Turkish citizens have access to the medicines they need and to further the Turkish Government's ambitions of being a globally-competitive hub for medical innovation.

Latin America

ARGENTINA

PhRMA and its member companies operating in Argentina recognize the important economic reforms the Government of Argentina has implemented over the last couple of years. We welcomed the resumption of bilateral dialogue through the Trade and Investment Framework Agreement concluded in March 2016. Recent reforms have the potential to drive future economic growth in Argentina, and constructive dialogue that delivers real results could transform an important bilateral trade and investment relationship. Regulatory reforms by the sanitary authority that brought Argentina closer to international standards and reduced clinical trials approval times are already attracting investment in early phase trials. Nevertheless, registration and evaluation regulations for biopharmaceutical products have not yet been released, thus generating legal uncertainty for companies.

Biopharmaceutical innovators in the United States continue to face serious intellectual property (IP) issues and longstanding market access barriers put in place by the previous Argentine Government. IP issues include patentability restrictions, a lengthy patent application backlog, and the lack of regulatory data protection (RDP).

Key Issues of Concern:

- **Restrictive patentability criteria:** The Argentine Government amended its criteria for granting pharmaceutical patents in 2012. A joint regulation issued by the Ministries of Health and Industry and the Argentina Patent Office (Instituto Nacional de la Propiedad Industrial or INPI) established guidelines that significantly limit the type of pharmaceutical inventions that can be patented. These guidelines appear contrary to Argentina's obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and have led to the rejection of many pharmaceutical patent applications. In addition, there have been reported instances of courts invalidating patents granted under the previous rules by applying the new guidelines retroactively.²⁰³
- **Regulatory data protection failures:** Argentina does not provide protection for regulatory test data, as required under TRIPS. Specifically, Law 24,766 permits Argentine officials to rely on data submitted by originators to approve requests by competitors to market similar products.

For these reasons, PhRMA requests that Argentina remain on the **Priority Watch List** in the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

²⁰³ See, e.g., Argentina: Polymorph patents under fire, available at <http://aippi.org/no-show/argentina-polymorph-patents-under-fire/> (last visited Feb. 7, 2018).

Intellectual Property Protection

Restrictive Patentability Criteria

In 2012, the Argentine Government published a regulation that significantly narrowed the scope of chemical compounds and compositions that can be patented, leading to the rejection of many pharmaceutical patent applications. The regulation contemplates that similar limitations could be added in the future for “pharmaceutical biological inventions.”

The regulation (N^{os} 118/2012, 546/2012 and 107/2012), issued jointly by the Ministries of Health and Industry and INPI sets out Guidelines for Patentability Examination of Patent Applications on Chemical and Pharmaceutical Inventions. It expressly states that pharmaceutical patents are not available for compositions, dosages, salts, esters and ethers, polymorphs, analogous processes, active metabolites and pro-drugs, enantiomers, and selection patents. Also the ability to describe and claim an invention using Markush-type claims is severely limited.

The imposition of additional patentability criteria for pharmaceutical patents beyond those of demonstrating novelty, inventive step and industrial application is inconsistent with Articles 1 and 27.1 of TRIPS, as well as Argentina’s obligations under its bilateral investment treaty with the United States.

On June 6, 2012, Argentina’s innovative biopharmaceutical industry trade association, La Cámara Argentina de Especialidades Medicinales (CAEMe), joined by over 40 innovative biopharmaceutical companies, filed an administrative petition seeking to invalidate the Joint Resolution. That administrative review petition was dismissed on April 5, 2013. On August 30, 2013, CAEMe filed a civil complaint in federal court challenging the Joint Resolution, the administrative review dismissal, and application of the Guidelines to pharmaceutical patent applications. That complaint is currently pending.

On October 5, 2015, INPI issued Resolution No. 283/2015 that further burdens biopharmaceutical innovation. This Resolution provides that plants, animals and essentially biological procedures for reproduction or production shall not be deemed inventions. In addition to imposing additional burdens on the patentability process for biologics, it may contradict Law 24,481, on Patents, which only excludes patentability of living matter and substances pre-existing in nature.

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% of medicines that enter clinical trials ever result in approved treatments.²⁰⁴

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 of time 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 allows 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 “dishonest” use.

Weak Patent Enforcement

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

Articles 83 and 87 of Law No. 24,481 on Patents and Utility Models provide 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.

Patent Backlogs

The ability to secure a patent in a reasonable period of time is critical to attracting investment in the research and development needed to create new medicines and bring

²⁰⁴ DiMasi JA, Grabowski HG, Hansen RW; Tufts Center for the Study of Drug Development. Innovation in the pharmaceutical industry: new estimates of R&D costs. In: Briefing: Cost of Developing a New Drug, available at http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf (last visited Feb. 7, 2018).

them to patients who need them. Patent backlogs hinder innovation by creating uncertainty and significantly raising investment risk.

Patent application delays are particularly acute in Argentina, where pharmaceutical, chemical and biotech innovators must wait eight to nine years, on average, for patents to be granted. 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.

To address this challenge, Argentina should hire additional qualified examiners and consider participating in work sharing arrangements, such as Patent Prosecution Highway programs, with other major patent offices. Argentina should also 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 more than 140 Contracting Parties. Accession to the PCT could allow Argentina to reduce its current patent application backlog and use the PCT system to reduce the review period for future patent applications.

The Argentine Senate approved accession to the PCT in 1998. However, it was never discussed in the Lower House. In 2011, the Lower House resumed consideration at committee level, but with no results.

BRAZIL

PhRMA and its member companies operating in Brazil remain concerned regarding government pricing policies, restrictive patentability criteria and procedures, weak patent enforcement, and the lack of regulatory data protection (RDP).

Key Issues of Concern:

- **Restrictive patentability criteria and procedures:** Amendments to the Brazilian Patent Law in 1999 added Article 229-C have been interpreted inappropriately to permit the health regulatory agency, the Brazilian National Health Surveillance Agency (ANVISA), to review all patent applications for pharmaceutical products and/or processes, resulting in both: i) application of patentability requirements contradictory and/or additive to those established by Brazilian Patent Law and adopted by the Brazilian Patent Authority (INPI); and ii) duplicative, prolonged patent review processes that contribute to the already existing patent backlog. Under the terms of regulatory changes adopted in 2017, ANVISA's opinion on the patentability of new biopharmaceutical inventions will no longer be binding on INPI. This is a welcome step, but does not end Brazil's "dual examination" system. ANVISA remains able to reject patents based on vague and undefined public health grounds.
- **Patent backlogs:** With more than 230,000 patent applications pending at INPI, Brazil's patent backlog now exceeds 11 years (and is even longer for pharmaceuticals), hindering innovation and significantly raising investment risk. Government proposals to address the patent backlog specifically exclude pharmaceutical patents, citing the need to secure ANVISA's opinion prior to proceeding with such patent applications.
- **Patent term adjustment for mailbox patents:** Under Patent Law 9,279/96, Brazil provides 20 years of patent protection from the date of filing or a minimum of ten years from the date of patent grant. However, in September 2013, INPI issued a binding opinion followed by the filing of related lawsuits to entirely invalidate or limit the term of approximately 240 so-called "mailbox patents," *i.e.*, patents related to biopharmaceutical products or agrochemical compounds that were filed after Brazil acceded to the World Trade Organization (WTO) on January 1, 1995, but before the Patent Law went into effect on May 14, 1997. These lawsuits, primarily affecting pharmaceutical patents, are currently proceeding through the legal system including the Court of Appeals, but most decisions have upheld INPI's retrospective decision to no longer provide a minimum ten years of post-grant patent protection.
- **Regulatory data protection failures:** Although Brazil applies RDP for veterinary, fertilizer, and agrochemical products, the same protection is not given to biopharmaceutical products.

- **Regressive taxes on medicines:** Combined federal and state taxes add up to 34% to the cost of medicines in Brazil – one of the highest tax burden on medicines in the world.²⁰⁵ The innovative pharmaceutical industry supports a proposal under consideration by the Special Committee in the House (PEC 491/11) to eliminate taxes on certain products including medicines.
- **Product Development Partnerships (PDPs) and government purchasing:** Brazil has developed a regulatory framework for the establishment of PDPs. While this framework provides improved transparency around PDPs, Brazil still lacks clear rules regarding the purchasing preferences offered to PDPs.

For these reasons, PhRMA requests that Brazil be placed on the **Priority Watch List** in the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Restrictive Patentability Criteria and Procedures

One of the most serious problems facing the pharmaceutical industry today in Brazil was created by Article 229-C, the 1999 amendment to the Brazilian Patent Law that authorizes the health regulatory agency (ANVISA) to review patent applications claiming pharmaceutical products and/or processes that may present a “health risk.” This review has been an additional procedure to, and been given equal weight as, the examination conducted by the Brazilian Patent Office (INPI).

This “dual examination” is incompatible with Brazil’s obligations under the “anti-discrimination” provisions of Article 27.1 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Until recently, ANVISA did not limit its role to the review of the potential sanitary risk aspects of the subject matter of the patent application but also reviewed the patentability requirements. ANVISA lacks sufficient technical expertise on patentability and its role in reviewing patentability has generated uncertainty for patent applicants and undermined incentives for innovation.

Under the terms of a Joint Ordinance signed in April 2017 and new rules published by INPI in May and by ANVISA in August, ANVISA will continue to issue opinions on the patentability of new biopharmaceutical inventions, although those opinions will no longer be binding on INPI. However, ANVISA opinions are binding for patent applications for biopharmaceutical products and processes it believes present a “health risk.” The grounds for determining what constitutes a “health risk” are vague and ill-defined, and it remains to be seen whether the new rules will result in improvements in practice. PhRMA

²⁰⁵ Globally, on average, taxes account for 6.3% of the retail price of medicines. See EMIS, “Pharmaceutical Sector in Brazil,” December 2013, available at <https://www.emis.com/sites/default/files/EMIS%20Insight%20-%20Brazil%20Pharmaceutical%20Sector.pdf> (last visited Feb. 7, 2018).

continues to believe that Brazil must end its “dual examination” system and bring its patent system in line with global rules and norms.

Patent Backlogs

While PhRMA recognizes efforts underway at INPI to reduce the patent backlog, delays in patent grants have continued to worsen, undermining otherwise valid patent rights and incentives for companies to bring innovative products to Brazil. Brazil has not shown a clear commitment to reduce the backlog by completing the examination process for long-pending patent applications that relate to pharmaceutical products.

As of 2017, more than 230,000 patent applications were pending with INPI and the average review time exceeded 11 years. For pharmaceuticals the delays are even longer – more than 13 years for traditional medicines and 12 years for biologics.²⁰⁶ Unfortunately, this is a significant increase from the average time for all patent applications of 5.4 years in 2011. Although former President Dilma Rouseff authorized funding and filled new examiner positions (including in the pharmaceutical and biotech fields) to reduce the backlog, the addition of these new examiners has not mitigated the backlog.

In 2017, INPI announced plans to automatically grant certain patent applications under simplified procedures. However, the proposal expressly states that pharmaceutical patents will not benefit from these procedures, citing the need for ANVISA’s involvement in the “dual examination” process discussed above.

Patent Term Adjustment for Mailbox Patents

In September 2013, INPI issued a binding opinion regarding the term for patents relating to biopharmaceutical or agrochemical compounds that were filed between January 1, 1995 and May 14, 1997 (known as “mailbox patents”). Brazilian Patent Law 9,279/96 Article 40 provides that “Patents will be given a 20-year protection from the date of filing” (caput) and “A minimum of ten-year protection will be given from the date of grant” (paragraph one).²⁰⁷ Per the binding opinion, however, in the event that a company’s patent was filed in Brazil after the country acceded to the WTO on January 1, 1995, but before the Patent Law came into force on May 14, 1997, the application should not have received the minimum ten years of protection from the date that the patent was granted.

²⁰⁶ R. Nunes and R. Salomão Romano, “Brazilian PTO Considers Automatically Granting 231,000 Patents to Get Rid of Backlog” IP Watchdog (Jan. 11, 2018), available at www.ipwatchdog.com/2018/01/11/brazilian-pto-considers-automatically-granting-patents/id=91787/ (last visited Feb. 7, 2018).

²⁰⁷ It should be noted that there are two constitutional challenges pending before the Brazilian Supreme Court requesting that article 40, sole paragraph, of the Brazilian IP Law be declared unconstitutional. The first constitutional challenge was filed by ABIFINA, a Brazilian association representing national companies with chemical interests including many generics companies. The second one was filed by the Brazilian Federal Public Prosecutor Office. Interfarma, among others, has successfully petitioned to participate in these cases as *amicus curiae*.

Under Brazil's Patent Law, approximately 250 mailbox patent applications (the majority on pharmaceuticals) were granted a minimum of ten years patent protection under Paragraph One of Article 40. INPI's September 2013 opinion has the effect of revoking the granted ten-year minimum terms for those mailbox patents. The opinion, however, is not self-executing. As a result, INPI has filed multiple lawsuits in Federal District Courts against the impacted mailbox patent holders seeking to invalidate their patents. Many of those cases are now before the Court of Appeals, which has upheld INPI's retrospective decision to no longer provide a minimum ten years of post-grant patent protection.

INPI is seeking to invalidate the patents entirely or, in the alternative, to adjust the patent term expiration dates for the impacted patents to 20 years from the date of filing. In either case, pharmaceutical patents are being targeted and the patent terms which were originally granted by the Brazilian Government and upon which innovators have relied are now being challenged *ex post facto* by the same Government. The elimination of the ten-year minimum term for these mailbox patents is particularly unfair when the only reason for this minimum level of protection is that it took INPI more than ten years to review the patent application. This is another example of Brazil's deteriorating and unpredictable IP environment for pharmaceutical innovators.

Regulatory Data Protection Failures

Brazilian law (Law 10.603/02) provides data protection for veterinary, fertilizer, and agrochemical products, but still does not provide similar protection for pharmaceutical products for human use, resulting in discriminatory treatment. Contrary to TRIPS Article 39, Brazil continues to allow Government officials to grant marketing approval for pharmaceuticals to competitors relying on test and other data submitted by innovators to prove the safety and efficacy of their products. Additional efforts are needed to provide certainty that test and other data will be fully protected against unauthorized use to secure marketing approval for a fixed period of time.

PhRMA members continue to seek protection for their data through the judicial system. Although there have been lawsuits seeking to secure a period of data protection for specific products, so far the cases are still pending in the Brazilian courts, leaving innovators without reliable RDP.

Market Access Barriers

Regressive Taxes on Medicines

Combined federal and state taxes add up to 34% to the price of medicines in Brazil (one of the highest tax burdens on medicines in the world). As such, the innovative pharmaceutical industry supports a proposal under consideration by the Special Committee in the House (PEC 491/11) to eliminate taxes on certain products including medicines.

Government Purchasing and PDPs

The Brazilian Government issued federal Law 12.349/10 granting preferences for locally manufactured products and services in public tenders. Locally produced medicines automatically have on average a 25% price preference in government tenders. More recently, an amendment to Portaria MDIC 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 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.

More recently, in July 2017, Brazil's Ministry of Health (MoH) announced it was investigating the introduction of new price criteria for public purchases of certain types of drugs in order to further cut spending. The MoH plans to begin with drugs for the treatment of rheumatoid arthritis, and has already contacted the industry to discuss the new measure. According to the MoH, six of the eight drugs currently included in the treatment protocol for the disease would be dropped as a consequence of the new price criterion. No official statements about a new cost-cutting mechanism have been published by the MoH as of yet, and it is unknown which and how many other therapeutic areas are being considered for cost-cutting.

Meanwhile, a new PDP regulation (Portaria 2531/14) was issued in 2014 with participation of the private sector, which on its face appears to provide greater transparency and predictability. Recently, the Brazilian Government announced several PDPs under the new regulation. Even still, 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.

Regulatory Burden

All participants in the pharmaceutical industry, innovative and generic alike, face numerous challenges stemming from the deadlines currently enforced by ANVISA. While Brazilian legislation adequately addresses ethics, safety and efficacy standards, it does not provide a mechanism to ensure that ANVISA has adequate capacity to execute its assigned responsibilities. PhRMA and its members commend ANVISA for hiring new technicians in recent years and hopes that this will help the agency to reduce review timelines. Other improvements ANVISA should consider include:

- More predictable processes, allowing companies to be prepared in advance, resulting in shorter “clock stops” and faster approvals; and

Introduction of an expedited process for line extensions (at least similar to the deadline for new products) providing faster access to post-approval innovations.

CHILE

PhRMA members remain concerned about the absence of effective regulatory data protection and patent enforcement, stemming from shortfalls in implementation of Chile's obligations under its free trade agreement with the United States. In addition, the National Congress is in the process of finalizing draft legislation that would expand considerably the scope of compulsory licensing provisions in Chile. PhRMA also continues to be concerned about unreasonable delays in granting pharmaceutical patents.

Key Issues of Concern:

- **Weak Patent Enforcement:** PhRMA's 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. Unfortunately, this legislation, introduced in 2012, is unlikely to move forward in the near term. Any change in Chile's current Special 301 status must await final congressional approval and full implementation of the government's proposed legislative and regulatory modifications.
- **Regulatory Data Protection:** The Chilean Government's enactment in December 2010 of Supreme Decree 107 corrected several deficiencies in Chile's existing system for protecting proprietary pharmaceutical test data against unfair commercial use and disclosure. The correction of remaining weaknesses, however, will depend upon whether the government makes certain necessary changes to Chile's Industrial Property Law.
- **Compulsory Licensing:** In January 2017, the Chile's Chamber of Deputies of the National Congress passed a Resolution No. 798 to expand the scope and discretion available to the Chilean government to issue compulsory licenses. That resolution calls on the Ministry of Health (MOH) to "incorporate and use the compulsory licensing mechanism provided in Article 51 of Chile's Industrial Property Law ... to facilitate [medicines] acquisition at competitive prices." The scope of Resolution No. 798 does not seem to correspond to legitimate health emergencies and Chile's international and bilateral obligations. Citing Resolution No. 798 and the recent "Medicines II" Bill, the Chamber of Deputies passed Resolution No. 1014 in January 2018 requesting compulsory licenses be considered for certain Hepatitis C medicines.

For these reasons, PhRMA requests that Chile remain on the **Priority Watch List** in the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

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 indicated to USTR and the innovative pharmaceutical industry its recognition of the need to enact new legislation aimed at establishing an effective patent enforcement mechanism that would bring Chile closer to compliance with its FTA obligations. PhRMA would support a final proposal that:

- Provides sufficient time prior to the grant of sanitary registration of a follow-on product to obtain a final decision regarding the validity or non-infringement of the relevant patents;
- Ensures that the patent holder will have access to the courts to assert its patent rights prior to the grant of sanitary registration for a potentially patent-infringing medicine; and
- 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 the impact of a lack of effective patent enforcement continues to worsen.

Regulatory Data Protection

Final enactment in December 2010 of Supreme Decree 107 resolved several longstanding concerns of the U.S. Government and PhRMA regarding deficiencies in Chile’s regulatory data protection (RDP) system. Nevertheless, Chile’s RDP system still contains the following weaknesses, correction of which will likely require amendment of the Industrial Property Law. Specifically:

- RDP is unavailable for certain pharmaceutical innovations (e.g., new uses, formulations, compositions, dosage forms, etc.) that require the presentation of

additional clinical test data as a condition of sanitary registration, but that do not involve a new chemical entity not previously registered in Chile;

- Prior voluntary disclosures by the data owner made in the interest of transparency can still justify incomplete recognition or denial of RDP;
- An applicant for sanitary registration must explicitly request RDP and provide a copy of the data for which protection is sought (Art. 4);
- RDP applicants are required to submit sworn statements and other formalities that could conceivably justify denial of RDP if judged to contain technical or procedural errors (Art. 4);
- RDP is only provided to data specifically identified (by title or name) in the sanitary registration application (Art. 6);
- It is not clearly stated that the ISP's obligation not to disclose protected data does not expire after 5 years; and
- S.D. 107 (Art. 10) repeats the IP Law's enumeration of various grounds for revocation or denial of the right to exclusive use that are not stated in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) or Chile's bilateral trade agreements with the United States and the EU; these conditions significantly weaken the applicability and usefulness of the available data protection.

PhRMA understands that the Chilean Government is working on a reform of Chile's Industrial Property Law. In response to a public call for comments by Chile's Patent Office, the Chamber of the Pharmaceutical Industry of Chile (CIF) submitted a number of specific suggestions aimed at correcting the above-mentioned deficiencies in the context of this reform project. The Industrial Property Law project sent to Congress in April 2013 as a result of this process did not include any amendments to the current RDP scheme; nor does there appear to be appetite for the Chilean Government to address RDP deficiencies at the present time.

Although PhRMA recognizes that enactment of S.D. 107 constitutes an advance toward implementation of Chile's obligations regarding data protection under the U.S.-Chile FTA, TRIPS, and other multilateral agreements, it believes that full compliance with these obligations will require additional action by Chile to correct the aforementioned legislative deficiencies.

Compulsory Licensing

On January 11, 2017, the Chilean Chamber of Deputies of the National Congress passed Resolution No. 798.²⁰⁸ That resolution calls on the Minister of Health “to incorporate and use the compulsory licensing mechanism provided for in Article 51(2) of the Industrial Property Law...to facilitate [medicines] acquisition at *competitive prices*.”²⁰⁹ It also calls for the prioritization of certain classes of medicines to be considered for compulsory licensing and highlights the price reductions realized by certain countries after issuing compulsory licenses on biopharmaceutical products. In addition, in January 2018, the Chilean Senate approved the “Medicines II Bill,” which is now pending final approval from the Lower House. That bill seeks to amend Article 99 of the Sanitary Code to establish that access to medicines is not adequate “when there are economic, financial, geographic or opportunity barriers that prevent access to a medication.”

In January 2018, the Chamber of Deputies approved Resolution No. 1014 seeking to establish that access to certain Hepatitis C medicines is not consistent with the constitutional right to health, thus warranting a compulsory license. Chile’s MOH has denied requests to trigger compulsory licensing mechanisms related to that resolution because the requests lacked fundamental information necessary to inform that process.

The research-based pharmaceutical industry is concerned that actions such as Resolution No. 798, the pending Medicines II Bill, and Resolution No. 1014 inappropriately expand, or seek to expand, the scope of compulsory licensing provisions to pursue cost-containment efforts that are not clearly related to legitimate health emergencies. At a minimum, PhRMA and its member companies believe that compulsory licensing decisions should be exercised with extreme caution and as a measure of last resort. In addition, the Resolution does not appear to comport with international and bilateral agreements.

Delays in Granting Pharmaceutical Patents

For many years, applicants for pharmaceutical patents in Chile have had to wait a significant amount of time to obtain final action on their applications by the Chilean patent office. In 2009, the Chilean Government established the Intellectual Property Institute (INAPI) as the successor agency to the DPI, in part, to remedy these unacceptably long delays. One of INAPI’s stated objectives is to streamline the patent application review process by limiting the number of substantive office actions and facilitating rapid communication between applicants and examiners, thereby enabling it to rule more expeditiously on patent applications.

The administrative and procedural reforms implemented by INAPI to date have decreased waiting times, with most patent applications filed after 2007 receiving a

²⁰⁸ Resolution No. 798, Chamber of Deputies, available in Spanish at <https://www.camara.cl/pdf.aspx?prmid=6893&prmtipo=SOBRETABLA> (last visited Feb. 7, 2018).

²⁰⁹ Id. (emphasis added) (unofficial translation).

definitive decision within 5 years. However, many patents filed prior to 2007 still do not have a final decision. Therefore, while PhRMA supports the Chilean Government's work to improve patent application processing times, it believes that further work must be done to expedite patent application reviews in Chile.

Trademarks

In January 2018, Chile's Senate approved the "Medicines II Bill," which is now pending final approval from the Lower House. That Bill, if enacted, would significantly limit the use of trademarks or other "fanciful" designations for any prescribed medicine. This measure appears to deny another important IP protection that is critical to ensure that innovator companies can distinguish their products from others. 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 that manufacturers strive to build over time.

The Bill proposes a considerable departure from the current trademark protection guaranteed in Article 19 of Chile's Constitution and its international (e.g., WTO TRIPS) and bilateral (e.g., U.S.–Chile FTA) obligations.

COLOMBIA

PhRMA member companies face several intellectual property (IP) issues and market access barriers in Colombia, including the issuance of a declaration of public interest (DPI) to force a price discount, Decree 1782 of 2014 which establishes an unprecedented “third pathway” for approval of non-comparable biologics contrary to World Health Organization (WHO) guidelines and accepted standards of the United States and other countries to ensure the safety and efficacy of biosimilar products. This is in addition to *ad hoc* and non-transparent market access policies that are often paired with initiatives that undermine innovation.

Key Issues of Concern:

- **Issuance of a DPI to force a price discount:** On June 14, 2016, the Ministry of Health and Social Protection (MOH), citing new compulsory licensing provisions of the National Development Plan, issued a DPI for the patented medicine Glivec®. In Colombia, a DPI must be made by the MOH before a CL can be granted. In this case, the MOH preserved the option of imposing a CL, while recommending a mandatory price reduction to bring the price down to levels as if the patent on Glivec did not exist. PhRMA has strong concerns that the DPI is inconsistent with Colombia’s market access commitments under the U.S.-Colombia Trade Promotion Agreement (TPA), which incorporates relevant provisions of the General Agreement on Tariffs and Trade (GATT). On November 22, 2016, the National Pricing Commission issued Circular 03 of 2016, which sets out a *general* pricing methodology that will apply to all medicines subjected to a DPI. This methodology is the same as the price reduction imposed on Glivec and likewise, unduly targets patented products by effectively expropriating relevant patents.

Moreover, while Colombia suggested that the issuance of a DPI in 2016 was an aberration, the MOH announced on December 20, 2017, that it was assessing whether to issue a DPI on a whole class of antiviral medicines to treat Hepatitis C, despite the legal and procedural deficiencies in the third party petition.

- **Weak patent enforcement:** There is no mechanism in place to provide patent holders with the opportunity to resolve patent disputes prior to the launch of a follow-on product. This has led to the approval and marketing of follow-on products, despite the fact that a patent for the original drug is still in force.
- **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.
- **Regulatory data protection failures:** Colombia fails to respect existing legislation that would otherwise provide regulatory data protection upon approval of novel pharmaceutical products.

- **Increased regulatory barriers under the National Development Plan (NDP):** Colombia's NDP, which passed into law on May 7, 2015, undermines recent gains Colombia has made to encourage innovation, delays access for Colombians to cutting edge technologies, and is inconsistent with Colombia's international commitments on IP and trade. Particular concerns include Article 72, which makes price and health technology assessment (HTA) criteria in the regulatory approval process). As yet, implementing regulations (Decreets) have not been released (albeit that a draft was issued in September 2017), but PhRMA's members are working to ensure that implementation of these Articles does not impede patient access to innovative medicines. PhRMA supports the creation of sustainable health care systems, and believes this can be achieved without creating delays to new medicines and in a manner consistent with Colombia's international obligations.
- **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 has established an unprecedented "abbreviated" pathway for the registration of non-comparable products, which is inconsistent with sanitary and WHO standards and practices 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, to no avail. Over the course of the year, MOH has issued relevant guidelines for implementing the Decree, but that process has lacked transparency and due process and not served to resolve the fundamental deficiencies of the third pathway.
- **Arbitrary and non-transparent market access policies:** Colombia's international reference pricing methodology and other cost containment measures are being used to set the same price for both the public and private segments of the market. Such a practice does not account for different supply chain costs in the reference countries, and does not reflect the realities of the Colombian market *vis-à-vis* other jurisdictions.

For these reasons, PhRMA requests that Colombia be placed on the **Priority Watch List** in the 2018 Special 301 Report. Further, we urge USTR to provide an opportunity for an assessment of Colombia's IP regime through an **Out-of-Cycle Review**, so that the U.S. Government can evaluate progress on these important issues and dedicate the required bilateral attention necessary to make progress on the IP and market access barriers confronted by U.S. businesses in Colombia.

Intellectual Property Protection

Issuance of a DPI to force a price discount

On June 14, 2016, the MOH, citing new compulsory licensing provisions of the NDP, issued the DPI. A DPI is typically a first step toward issuance of a compulsory

license (CL) in Colombia, but in this case it was framed as a precursor to a substantial mandatory price reduction designed to render Glivec prices commensurate with prices for generic imatinib. The text of the DPI refers to such a price reduction as an “alternative” to issuing a CL (while still leaving open the possibility of issuing a CL).

The DPI was issued following the recommendation of a technical committee. In its recommendation, the committee stated that the objective of the price reduction would be to return Glivec prices to “the point of . . . simulated competition,” with “a price comparable to that of the competitors before the patent was granted.” However, the DPI was not based on any justifiable concerns about patient access to Glivec or generic imatinib and appears to be inconsistent with Colombia’s obligations under the CTPA, as discussed further below. The lack of apparent patient access concerns and the process by which the DPI was issued have serious implications for all patented medicines in Colombia.

On November 22, 2016, the National Pricing Commission issued Circular No. 3 of 2016, which sets out a general pricing methodology that will apply to all medicines subjected to a DPI. This methodology is the same as the price reduction imposed on Glivec and likewise, unduly targets patented products rendering their patents worthless. Subsequently, on December 2016, the National Pricing Commission issued Circular No. 4 of 2016 which lowers the price of Glivec by 44% of its original price.²¹⁰

While Decree 670 (April 2017) appears to be positive in that it now requires that DPIs must be recommended by an interinstitutional committee, formed by the relevant Minister, the Minister of Trade and the Director of National Planning (versus just a single Minister), the practical impact of this Decree is that, going forward, a DPI may only be used as a precursor to a CL but not to adopt or design any new measures. However, Circular No. 3 of 2016 is still in effect and could be applied at any time, should another DPI be issued.

Limiting the price of patented medicines to levels equivalent to those of generics fails to appropriately value innovation and appears to be inconsistent with Colombia’s market access commitments under the CTPA, which incorporates relevant provisions of the General Agreement on Tariffs and Trade (GATT). Specifically, Article 16.9(3) of the CTPA permits the Parties to “provide limited exceptions to the exclusive rights conferred by a patent, provided such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.”

The DPI and pricing measures contained in Circular No. 03 of 2106 blatantly contravene this obligation. Biopharmaceutical patent holders in Colombia have a legitimate right to expect economic returns on their investments at the levels set by the Colombian government under its existing price control systems. Imposing additional price

²¹⁰ *Colombia Cuts Price of Novartis Cancer Drug by 44 Percent*, REUTERS, Dec. 21, 2016, available at <https://www.reuters.com/article/us-novartis-colombia/colombia-cuts-price-of-novartis-cancer-drug-by-44-percent-idUSKBN14A1FD> (last visited Feb. 7, 2018).

measures that reduce prices to levels equivalent to “that of the competitors before the patent was granted” – as if the patent did not exist – “unreasonably conflict[s] with a normal exploitation of the patent.” The extraordinary measures Colombia is taking through the pricing measure in Circular No. 3 (2016), for products subjected to a DPI, will, by design, destroy the value of the patent. In addition, the DPI and pricing measure also appear to be inconsistent with Colombia’s market access commitments under the CTPA, which incorporates relevant provisions of the GATT. In particular, Colombia’s actions would potentially constitute:

- An impermissible import price requirement under Article 2.8(2)(a) of the CTPA and Article XI:1 of the GATT; and
- An internal maximum price giving rise to prejudicial effects on exporting parties that have not been taken sufficiently into account under GATT Article III:9, and Article 2.2(1) of the CPTA, which incorporates the obligations under GATT Article III.²¹¹

The local association has repeatedly requested that the Government revoke Circular No. 03 of 2016 for these very reasons, however, the Government has denied all legal recourses and publicly doubled down on their position on this matter.

Furthermore, having claimed that the issuance of a DPI in 2016 was an exceptional measure, on December 20, 2017, the MOH issued Resolution 5246, in response to a petition filed by Fundación IFARMA. That resolution initiates the procedure for declaring public interest over “direct action antivirals for the treatment of Hepatitis C, for the patents granted in the country up to the publication of this administrative act.”

Resolution 5246 is both legally and procedurally deficient, and also appears inconsistent with Colombia’s international obligations and aspirations. First, Resolution 5246 is based on a petition that failed to identify the patents for which the DPI is being requested, clearly falling short of the standard set forth in Decree 1074 of 2015 (“Decree”). There is no provision in the Decree that allows for the MOH to unilaterally correct omissions in the petition. On the contrary, Article 2.2.2.24.4 of the Decree expressly places the burden of proof on the petitioner to identify the patented technologies that are supposedly affecting the public interest.

Second, a DPI on a broad category of medicines, namely “antivirals for treatment of Hepatitis C” would be baseless for a number of reasons, including that: a) the petition itself identifies an entire class of medicines, which demonstrates that competition already exists in this market segment; b) Hepatitis C drugs were just recently the subject of significant price reductions in Colombia, and the Ministry itself has asserted in the media, over the course of months, that the price reduction was between 80 and 90%; and c)

²¹¹ Given that the concerns raised by Colombia in imposing the DPI have all been budgetary versus health-related, it is difficult to see how Colombia could legitimately claim that the DPI and pricing measure are “necessary to protect human . . . life or health” within the meaning of GATT Article XX.

there is no indication that a health-related emergency regarding Hepatitis C exists in Colombia; to the contrary, as discussed more fully below, the incidence of Hepatitis C, a disease that has affected people for centuries, is quite low in Colombia.

Third, the DPI, if issued, would be inconsistent not only with Colombia's international obligations and its interest in acceding to the rules-based Organization for Economic Co-operation and Development ("OECD"), but its own domestic laws, namely the Decree. Mere enjoyment of a patent cannot be the basis for issuing a DPI.

Weak Patent Enforcement

There is no mechanism in place to provide patent holders with the opportunity to resolve patent disputes prior to the launch of a follow-on product. This has led to the approval and marketing of follow-on products, despite the fact that a patent for the original drug is still in force.

Second Use Patents

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.

Regulatory Data Protection Failures

Existing Colombian legislation Decree 2085 of 2002 requires that new chemical entities receive a 5-year period of regulatory data protection upon approval. Nevertheless, the Colombian regulatory authority INVIMA has denied regulatory data protection upon approval of some new chemical entities, simply because they share a minor portion of their chemical structure with previously approved products.

This 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 pharmaceutical products.

Market Access Barriers

Substandard Biologics Regulation

On September 18, 2014, Colombia issued Decree 1782, which establishes the marketing approval evaluation requirements for all biologic medicines. As part of the Decree, Colombia has established an unprecedented abbreviated pathway for registration of non-comparable products, which is inconsistent with both WHO and FDA standards and could result in the approval of medicines that are not safe and/or not effective.

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.

PhRMA members urged the Colombian government to remove this third pathway from the Decree, to no avail. This route has been justified by the MOH, and ratified by the President, as a necessary tool to lower prices of medicines by promoting the swift entry into the market of competitors. However, shaping competition policy is not the appropriate role for a sanitary regulation, which should be strictly focused on ensuring the safety and efficacy of products.

Furthermore, per the Decree, a product approved via the “Abbreviated Comparability Pathway” will use the same non-proprietary name as the innovator, despite the fact that 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, and would make it difficult to quickly trace and attribute adverse events to the correct product.

Arbitrary and Non-Transparent Market Access Policies

Colombia sets a maximum price for both the private and institutional markets by setting the price at the level of the distributor. These markets are dissimilar in most characteristics, in that they service different patient populations via different business models.

The pricing system is highly subjective. For example, it provides that certain price control exceptions may be made for products providing a significant technical benefit over medicines containing the same active ingredient (*i.e.*, regular versus modified release

tablets), yet it does not clearly establish the criteria required to grant such exceptions. Furthermore, in June 2017, the National Medicines and Medical Devices Pricing Commission published a list of 148 medicines that will be subject to direct price controls, expected to reduce the average cost of these medicines by 36%. Price cuts for additional medicines are expected in the near future.

Middle East/ Africa

SAUDI ARABIA

Over the last several years, PhRMA and its member companies operating in the Kingdom of Saudi Arabia have observed many improvements in the policy environment. These reforms are consistent with Saudi Arabia's effort to encourage biopharmaceutical innovation, employment, and investment. However, recent actions by the Saudi Food and Drug Administration (SFDA) are undermining these positive developments and the investment climate in Saudi Arabia. We look forward to a constructive dialogue with the relevant Saudi authorities to resolve these concerns.

Key Issues of Concern:

- **Ineffective Patent Enforcement and Regulatory Data Protection (RDP):** The SFDA recently granted marketing approval to a generic version of an innovative medicine during the patent term of that product. Since 2013, Saudi Arabia has operated an effective patent linkage system, so it is highly concerning that at least one generic has been approved and assigned a price despite being under patent protection. PhRMA member companies are also concerned by Saudi Arabia's failure to provide a sufficient period of RDP from the date of marketing authorization of innovator products in Saudi Arabia, contradicting the country's own regulations and World Trade Organization (WTO) commitments.

For these reasons, PhRMA requests that Saudi Arabia be placed on the **Priority Watch List** in the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Ineffective Patent Enforcement and Regulatory Data Protection

Despite creating a mechanism to provide for effective patent enforcement in 2013, last year the SFDA granted marketing authorization to a local company to produce a generic version of a U.S. innovative product prior to the expiration of the patent term on that product. Furthermore, the Ministry of Health proceeded to procure the infringing product despite multiple appeals from the relevant innovator company. The local company is now distributing these copies to the Ministry of Health and selected hospitals.

This action appears to be part of a broader pattern of abuse of American innovation, following SFDA's earlier decision to grant marketing approval to copies of another innovative medicine during the period of RDP provided by Saudi law. Indeed, while Saudi Arabian law provides for RDP, in practice it is not applied effectively.

Specifically, 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.²¹²

Member companies have approached Saudi authorities concerning the need to enforce their regulations on RDP; yet authorities insist they are not sharing the content of the drug registration file of the innovator product – deflecting from the substance of the complaint.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), however, imposes more than a non-disclosure obligation. Rather, TRIPS Article 39.3 additionally requires WTO member states to implement an effective system of pharmaceutical drug registration, which prevents “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, the 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.

In short, these actions appear designed to benefit Saudi Arabia’s local industry at the expense of U.S. innovators. These actions harm U.S. manufacturing workers, infringe proprietary technology and damage U.S. exports. Contrary to the country’s aspirations to promote local investment, intellectual property (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.

We stand ready to work with the Saudi and U.S. governments to ensure that U.S. innovators can rightfully protect and enforce their IP rights in Saudi Arabia, consistent with Saudi Arabia’s international obligations.

²¹² 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.

Watch List

Asia-Pacific

AUSTRALIA

PhRMA and its member companies support the U.S.-Australia Free Trade Agreement (AUSFTA). It has helped expand patient access to new medicines in Australia, a key priority for PhRMA. However, we believe there is much more that could be done to protect and strengthen Australia's intellectual property (IP) regime and further improve market access with new and innovative medicines in Australia.

In the Pharmaceuticals Annex to the AUSFTA, the United States and Australia agreed on provisions for increased transparency and accountability, and enhanced consultation on the operation of Australia's Pharmaceutical Benefits Scheme (PBS). Annex 2-C of the AUSFTA establishes four basic obligations pertaining to the operation of the PBS, including agreed principles on the role of innovation, transparency, an independent review process, and establishment of a bilateral Medicines Working Group.

Progress to date in implementing these obligations has been significant. We look forward to constructive outcomes from the locally-established, recently re-invigorated, bilateral (Government-Industry) Access to Medicines Working Group (AMWG), first established in 2006 as a result of the reforms to the PBS. Industry has also welcomed recent announcements to implement a tranche of reforms to the regulations for the registration and market approval of medicines and medical devices in Australia. These reforms are expected to streamline processes and regulations and bring life-saving medicines and medical devices to Australian patients faster.

PhRMA would also like to see the Medicines Working Group (MWG) resume regular meetings. It has been about ten years since the MWG last met under AUSFTA auspices. The MWG is one of just four working groups that was envisaged under AUSFTA, no doubt in recognition of the fact that the divergent Australian and U.S. approaches to health and medicines fully justify a standing forum in which officials of both countries can discuss and seek to resolve various issues as they arise. During the past decade without a MWG in place, it seems that the frequency of contact between U.S. and Australian officials during other negotiations provided sufficient opportunity for our officials to remain in contact on these and other issues. However, in recent months, it has become clear that the purpose for which the MWG was envisaged during AUSFTA negotiations is no longer being met through other regular contacts. PhRMA therefore believes that the MWG should resume regular meetings.

Key Issues of Concern:

- **Uncompetitive intellectual property environment:** There are a number of weaknesses in Australia's IP regime:
 - The Australian Government has persisted with a policy of seeking to recover damages from innovators in cases where challenges to patents on PBS-listed medicines have ultimately been upheld following an initial granting of a preliminary injunction. This policy creates significant uncertainty for

pharmaceutical patent owners in Australia and undermines the rights of patent holders by introducing a strong disincentive to defend their IP.

- This uncertainty is exacerbated by the difficulty in resolving patent challenges prior to market entry, due to lack of adequate patent holder notification. Contrary to its obligations under the AUSFTA, Australia has not implemented a system by which the patent holder receives advance notice of potentially patent-infringing products applying for marketing approval to enter the market before patent expiry.
- In 2016, the Australian Government commissioned a Productivity Commission (Commission) inquiry into Australia's "Intellectual Property Arrangements."²¹³ The Commission's report was publicly released on December 20, 2016, and contains a number of findings that the industry does not consider appropriate or reasonable. In its August 2017 response to the report, the Australian Government indicated that the most damaging recommendations are not currently accepted. However, industry is still concerned by the decision to further raise the inventiveness threshold for patents, which was only recently raised in alignment with the standards of Australia's major trading partners under the 2012 Intellectual Property Law Amendment (Raising the Bar) Act.
- Australia should strengthen its regulatory data protection (RDP) to improve the country's attractiveness as a destination for foreign investment by global pharmaceutical companies and encourage companies to bring new medicines to Australia sooner.
- **Difficulties in listing new medicines on the PBS:** Companies continue to face uncertainty in the listing of new medicines on the PBS. For new medicines, navigating the regulatory framework of market authorization and reimbursement remains complex and, particularly for reimbursement, reiterative. This is compounded by the existing policy that every dollar spent on new medicines must be counterbalanced by an equivalent offset, determined in advance, from within the health budget. This policy cannot be sustainable alongside a policy of investment in innovation.
- **Disincentives to improve products:** The current interpretations of sections 99ACB and 99ACD of Australia's National Health Act by the Australian Government are inconsistent with the original intent of these provisions, and have led to instances of Australian patients being unable to access improvements in medicines. We welcome the proposed changes to the National Health Act, agreed through the Strategic Agreement with Medicines Australia (Agreement), that have navigated a solution to this issue and look forward to implementation of these changes.

²¹³ See <http://www.pc.gov.au/inquiries/completed/intellectual-property#report> (last visited Oct. 24, 2017).

- **Biosimilars:** There have been significant recent developments regarding the introduction of biosimilar medicines into the Australian market. However, coordinated policy and processes to support the evolving market appear to be lagging behind. Australia needs to develop a considered, consistent and comprehensive biosimilars policy that supports their safe introduction, balanced uptake and appropriate use, and that builds public and global confidence in a sustainable market. We welcome the commitment of the Australian Government, through the Strategic Agreement with Medicines Australia to ensure appropriate and broad consultation with the sector to help deliver this.
- **Government-initiated post-market reviews of PBS listed medicines:** While important steps have been taken by the Australian industry and Government to implement an improved process for post-market reviews, the focus of post-market reviews on cost containment continues to be a concern for industry.

For these reasons, PhRMA requests that Australia be placed on the **Watch List** in the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Market Size Damages

After the Australian Government announced its market size damages policy in 2012, innovative pharmaceutical companies that were engaged in proceedings to enforce their patents began receiving notices from the Australian Government of its intent to seek damages caused by delayed PBS price reductions. A significant number of those companies received such notices *after* the relevant injunctions were sought *and granted* to enjoin generic companies from launching their products. In a number of cases, they received notice after the litigation had progressed through trial, through appeal to the intermediate appeal court and through appeal to Australia's highest court. In addition, these companies could not have foreseen that the Australian Government would take such action because the Australian Government was not a party to those proceedings and had not previously claimed damages in these circumstances.

More fundamentally, the Australian Government's market size damages policy effectively circumvents the due process afforded to inventors through the patent and court systems. It penalizes inventors who have sought to defend their legitimate patent rights in court if they are initially successful in obtaining preliminary injunctive relief from the court, but then ultimately unsuccessful in the litigation. The precedent set by this policy jeopardizes well-accepted principles of due process and severely discourages innovators from exercising their IP rights. Moreover, this policy contravenes Australia's obligations under TRIPS Article 50.

The purpose of applying for a patent from the Australian Patent Office and going through a substantive patent examination is to provide the patent holder with the exclusive

right to make, use, or sell the relevant technology during the patent term. The ability to enjoin others from infringing relevant IP rights provides the legal and practical certainty required by inventors to carry out costly R&D activities. The ability to quickly and efficiently enforce IP is especially critical for pharmaceutical innovators. For this reason, courts often employ provisional enforcement measures, e.g., preliminary injunctions, to ensure that patentees do not suffer irreparable harm.

Biopharmaceutical innovators are severely disadvantaged if they do not seek preliminary injunctive relief in Australia, often suffering irreparable harm. Unlike under United States law, the Australian Government has not provided a mechanism for a biopharmaceutical innovator to prevent the marketing approval of a generic product on the basis of the innovator's patent rights. If a generic product is approved and launches, PBS price reduction mechanisms are triggered, thus significantly lowering the PBS price. However, if the patentee does not seek a preliminary injunction and the generic company launches its product, even if a court later determines that the generic company infringed the originator's patent, restoring PBS prices to levels prior to generic market entry is at the discretion of the Australian Government. In other words, there is no legal mechanism or policy that automatically readjusts the PBS price after a generic product is introduced and subsequently removed from the market.

The Australian Government should immediately and publicly abandon this policy of seeking market size damages, or any damages, merely because a patentee is legitimately seeking to enforce their patent rights.

Weak Patent Law Enforcement

Mechanisms that provide for the early resolution of patent disputes before an infringing product is allowed to enter the market are critical to ensuring adequate and effective protection of IP rights for the research-based biopharmaceutical sector. Such mechanisms prevent marketing of a product known by regulatory entities to be covered by a patent until expiration of the patent. An effective early resolution mechanism provides a procedural gate or safeguard. It ensures drug regulatory entities do not inadvertently contribute to infringement of patent rights granted by another entity of the same government, by providing marketing authorization to a product, or granting PBS listing which must be accompanied by an assurance by the generic company that it will supply its product, where the manufacture and sale of the product would infringe a patent in Australia.

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 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 notification to the patent owner of such request and the identity of any such other

person.”²¹⁴ This should include a database or other mechanism by which a third party may determine whether there are patents that may be infringed by the product or use for which the third party is seeking approval.

However, originator pharmaceutical companies in Australia generally do not receive any notice of a third party’s intention to enter the market with a product that may infringe a valid and enforceable patent prior to its listing on the Australian Register of Therapeutic Goods (ARTG). Originator companies are only able to access this information once the generic has already been registered on the ARTG, and even then, the originator company itself has to actively go and find that information on the ARTG website – originators are not notified by the generic company or the TGA. As a result, originator pharmaceutical companies in Australia are routinely unaware of a potential infringement until after the generic product has received marketing approval (and has been listed on the ARTG). While in recent years the Australian Government has been quicker to identify and publish newly approved generics on the ARTG website, this is not what was envisaged in the AUSFTA. Publishing information on the ARTG that a generic has already been granted marketing approval for its product is not sufficient notification of the *request* by a third party for marketing approval under the AUSFTA.

As discussed above, 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 is to obtain preliminary injunctive relief (or equivalent relief), in the few months between the time marketing approval of the generic product is published on the ARTG and the next possible PBS listing date, to prevent the generic company from launching and PBS listing its product.

This 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 damages as discussed in detail above) significantly weakens an otherwise equitable IP system in Australia. The Australian Government should implement a means for an innovator patentee to publicly identify each patent that covers its innovator product and the approved uses for that product and an effective notification system making it mandatory for generic companies seeking marketing approval to notify a patentee, at the time of filing their application, that they have applied for approval to market a generic product during the life of a patent that the patentee has identified as covering that product or its approved use, so that patent holders are able to defend their IP in a timely manner and without causing unnecessary delays to generic market entry.

²¹⁴ See Article 17.10(4) of AUSFTA.

Productivity Commission

In 2016, the Australian Government commissioned a Productivity Commission (Commission) inquiry into Australia's "Intellectual Property Arrangements."²¹⁵ The Commission's report was publicly released on December 20, 2016, and contains a number of findings that the industry does not consider appropriate or reasonable, such as calls to restrict patent term restoration in Australia, to allow manufacture for export during the restored patent term, and to raise the threshold for inventive step.²¹⁶ The Australian Government has indicated in its response to the report that the most damaging recommendations are not currently accepted. However, industry is still concerned by the decision to further raise the "inventiveness" threshold, which was only recently raised to align with the standard of Australia's major trading partners under the 2012 Intellectual Property Law Amendment (Raising the Bar) Act reforms.

Regulatory Data Protection Failures

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% of medicines that enter clinical trials ever result in approved treatments.²¹⁷

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 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 and there is greater uncertainty about whether an innovator's patent right will cover a biosimilar version. Without the certainty of some substantial period of market exclusivity, innovators will not have the incentives needed to conduct the expensive, risky and time-consuming work to discover and bring new biologics to market.

²¹⁵ See <http://www.pc.gov.au/inquiries/completed/intellectual-property#report> (last visited Feb. 7, 2018).

²¹⁶ In June 2016, PhRMA and a number of its international sister associations submitted comments to the Productivity Commission on these and other concerns with the Commission's draft findings, available at http://www.pc.gov.au/__data/assets/pdf_file/0010/194770/sub087-intellectual-property.pdf (last visited Feb. 7, 2018).

²¹⁷ DiMasi JA, Grabowski HG, Hansen RW; Tufts Center for the Study of Drug Development. Innovation in the pharmaceutical industry: new estimates of R&D costs. In: Briefing: Cost of Developing a New Drug, available at http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf (last visited Feb 7, 2018).

Strengthening RDP protections in Australia so they are aligned with global best practice would further enhance Australia's ability to compete for foreign investments in the knowledge- and innovation-intensive biomedical sector that can drive future economic growth. Australia should also extend the term of RDP for new formulations, new combinations, new indications, new populations (e.g., pediatrics) and new dosage forms.

Market Access

Difficulties in Listing New Medicines on the PBS

Prescription medicines accessed via the PBS constitute the vast majority of prescription medicines dispensed in Australia.²¹⁸ Accordingly, the reimbursement process to obtain PBS-listing, as well as Pharmaceutical Benefits Advisory Committee (PBAC) guidelines and decision making, effectively dictate access to the Australian innovator pharmaceutical market. The outcomes and processes in PBS listings are therefore critical to securing market access to ensure Australian patients have access to innovative medicines. The purpose of the PBS is to provide timely, reliable and affordable access to medicines for all Australians.

In 2017, Medicines Australia signed a Strategic Agreement with the Australian Government to secure predictability and stability in the PBS and policy environment and to support business planning. This Agreement was not without significant cost to the industry by cementing the application of structured, predictable price reductions for on-patent medicines during their term in the single brand (F1) formulary at 5, 10 and 15 years post listing. Additionally, the Agreement resolves issues with the interpretation of section 99ACB of the National Health Act, and commits to no new determination of any Therapeutic Groups during the term of the Agreement.

It is now particularly important that the PBS remains fit for purpose as new and more advanced health technologies become available. To this end, we look forward to the delivery of the Australian Government's commitment in the Agreement to improve and streamline PBS processes to achieve faster access to new medicines.

The PBAC's approach of comparing new products to the "lowest cost" comparator creates an increasingly difficult barrier to patient access, due to these comparisons being made to cheaper, off-patent medicines that have undergone several rounds of competitive price reductions through price disclosure. As the price-disclosure measure has expanded and matured, creating downward pressure on prices in the multi-brand, competitive market for off-patent medicines, comparators are increasingly being drawn from very low cost drugs. This is an additional disincentive to bringing innovative medicines to Australia. As such, we welcome the Australian Government's commitment to consider the issue of comparator selection as part of the AMWG discussions.

²¹⁸ See *Australian Statistics on Medicines 2014*, available at <http://www.pbs.gov.au/statistics/asm/2014/australian-statistics-on-medicines-2014.pdf> (last visited Feb. 7, 2018).

Biosimilars

The continued inclusion of Medicines Australia as a key stakeholder in the development and monitoring of the implementation of biosimilars policy through the Agreement remains a positive element. The implementation and application of stakeholder agreed biosimilar uptake drivers is in its early stages, but offers the potential to encourage competition. It remains critical that measures be taken to improve prescriber and patient understanding in order to build confidence in the appropriate use of biologics and biosimilars medicines. The impact of the Government's policy of allowing decisions regarding substitution between biologic and biosimilar products being allowed at the pharmacy level has not yet been assessed. It will be important to ensure 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.

Industry is very concerned that the Government has declined to implement a unique naming convention for biologics and biosimilars that draws on international experience and decisions that require unique naming conventions to apply to all biologic and biosimilar medicines. This refusal has the potential to weaken pharmacovigilance, post market monitoring, and confidence in the introduction of biosimilar medicines.

Australia needs to develop a considered, consistent and comprehensive biosimilars policy in consultation with Medicines Australia that supports safe introduction and balanced uptake of biosimilars.

Government-initiated Post-market Reviews of PBS Listed Medicines

Recently completed and ongoing post-market reviews include Chronic Obstructive Pulmonary Disease (COPD) Medicines and Ezetimibe in 2015; Post-market Review of Pulmonary Arterial Hypertension (PAH) Medicine in 2016; and Post-market Review of Biological Disease Modifying Anti-Rheumatic Drugs (bDMARDs) to treat Severe Chronic Plaque Psoriasis in 2016.²¹⁹

PhRMA has previously expressed strong concerns about the cost-focus of post-market reviews of medicines listed on the PBS. While the stated objective of the reviews has been to improve Quality Use of Medicine (QUM), in reality, most reviews have narrowly focused on cost. Industry hopes that in light of the statutory price reductions included in the Agreement, the focus of future post-market reviews will be to improve QUM.

²¹⁹ See <http://www.pbs.gov.au/info/browse/reviews> (last visited Feb. 7, 2018).

Europe

THE EUROPEAN UNION

While the European Union (EU) generally maintains intellectual property protections that enable the research and development of innovative biopharmaceuticals, PhRMA and its member companies are very troubled by the potential future direction of an ongoing European Commission review of protections and incentives for innovative biopharmaceuticals that could result in actions to weaken intellectual property in the world's largest market.

For this reason, PhRMA and its members strongly support and encourage a focused effort by the U.S. Government to promote strong intellectual property protection and enforcement policies throughout the European Union and its Member States. We request that the European Union be placed on the **Watch List** in the 2018 Special 301 Report, and that the U.S. Government seek assurances that ongoing reviews will not result in measures to weaken intellectual property protections.

Intellectual Property Protection

EU Incentives Review

In June 2016, European Union Health Ministers asked the European Commission, with assistance from Member States, to undertake a review of existing intellectual property-related incentives for the biopharmaceutical industry to gauge their effectiveness and impact on innovation and the availability and access to medicines. The review involves a number of studies that are likely to be completed later this year.

While the review is still underway, PhRMA and its member companies are very concerned that it could result in proposals to reopen critical parts of Europe's intellectual property framework and potentially weaken existing incentive mechanisms that support biopharmaceutical innovation. Failure to effectively safeguard these incentives in one of the world's largest markets for innovative medicines would harm American exports and jobs and reduce investment in new treatments and cures for patients in Europe and around the world.

Supplementary Protection Certificates

As part of the broader incentives review, PhRMA is also very concerned about proposals to "recalibrate the existing EU Supplementary Protection Certificate (SPC) rules"²²⁰ in a manner that may weaken the scope of the exclusive rights conferred under an SPC. This concern has been exacerbated by the Public Consultation launched in October 2017, which includes a number of questions related to a proposed "SPC manufacturing waiver" that would eliminate the right to exclude others from manufacturing

²²⁰ See "Call for tenders: Study on the legal aspects of the supplementary protection certificates in the EU" (June 9, 2016), available at http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8847 (last visited Feb. 7, 2018)

the invention during the exclusivity period granted by an SPC for purposes of export and/or stockpiling.²²¹ The Commission believes such a waiver would “level the playing field” for EU-based generic manufacturers on global markets. This belief appears to be based on a single study that has been debunked by subsequent analysis showing that, far from creating additional jobs and exports for the EU, the implementation of such an SPC manufacturing waiver would have significant detrimental economic impact on research-based companies both in Europe and around the globe.²²²

SPC’s are a critical part of the European intellectual property system. They partially restore the effective patent term and thereby help to compensate for a portion of the time incurred during the testing and regulatory review period that may “make the period of effective protection under the patent insufficient to cover the investment put into that research.”²²³ The SPC Regulation itself declares that: “[p]harmaceutical research plays a decisive role in the continuing improvement in public health.”²²⁴ It states that “[m]edicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.”²²⁵ Further, as a result of “the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market,” the Regulation explains that “the period of effective protection under the patent [is] insufficient to cover the investment put into the research,” concluding that “[t]his situation leads to a lack of protection which penalises pharmaceutical research.”²²⁶

The role SPCs play in biopharmaceutical innovation is even more important today than when Europe adopted these protections in the early 1990s. Over the years, the science of new medicines development has become more difficult, and the scope,

²²¹ See https://ec.europa.eu/info/consultations/public-consultation-supplementary-protection-certificates-spcs-and-patent-research-exemptions_en (last visited Feb. 7, 2018).

²²² See Pugatch Consilium, “Unintended Consequences,” Oct. 2017, available at http://www.pugatch-consilium.com/reports/Unintended_Consequences_October_%202017.pdf (last visited Feb. 7, 2018); QuintilesIMS, “Assessing the impact of proposals for a Supplementary Protection Certificate Manufacturing Exemption in the EU,” 2017, available at https://www.politico.eu/wp-content/uploads/2017/09/EFPIA-SPC-report_120917_v3.pdf (last visited Feb. 7, 2018); Europe Economics, “Impacts of Reducing Patent and Extended Protections against Manufacturing for Stockpiling and Export,” Jan. 2018, available at <http://www.europabio.org/sites/default/files/Europe%20Economics%20report%20-%20Review%20CRA%20study%20SPC%20waiver.pdf> (last visited Feb. 7, 2018); Office of Health Economics, “Review of the CRA’s Report ‘Assessing the Economic Impacts of Changing Exemption Provisions During Patent and SPC Protection in Europe’,” Jan. 2018, available at <https://www.ohe.org/publications/review-cra%E2%80%99s-report-%E2%80%9CAssessing-economic-impacts-changing-exemption-provisions-during> (last visited Feb. 7, 2018).

²²³ See EC Regulation No. 469/2009 concerning the supplementary protection certificate for medicinal products (May 6, 2009) at Recital 4.

²²⁴ Regulation No. 469/2009; see also Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (no longer in force).

²²⁵ Regulation No. 469/2009.

²²⁶ Id.

complexity and cost of conducting clinical trials has increased dramatically. In large part to meet growing regulatory demands, the number of individual data points that must be collected through such trials has nearly doubled to just under 930,000 between 2001-2005 and 2011-2015.²²⁷ A typical Phase III clinical trial protocol now entails an average of 167 procedures – 60% more than at the start of the last decade.²²⁸ All of this has contributed to an upward trend in the average period for clinical testing required to secure marketing approval for new treatments and to a shorter effective patent term. Indeed, it now takes an average of 15 years to develop and win approval for a new drug.²²⁹ Without the ability to at least partially restore patent life lost to clinical testing in Europe, innovators would find it increasingly difficult to continue to invest in new research and development for the benefit of patients worldwide.

Further, we note that preventing potential abuses of a “manufacturing for export” exemption would be very difficult. Such abuses could consist of illegal diversion of medicines produced pursuant to the exception within Europe, or in foreign markets where the relevant patent term has not expired. Safeguards that would be necessary include inspecting, regulating, and tracking every lot to ensure it is exported as intended. In the end, it may well be impossible to limit the exemption to its intended purpose, further reducing the protections SPCs are intended to provide.

In addition, any “manufacturing for export” waiver will almost certainly be copied by other economies – possibly in an exaggerated form that is even more damaging to biopharmaceutical innovators in the United States, Europe and elsewhere around the world. Already, lawmakers in one Asian country have proposed to permit “manufacturing for export” during the 20-year patent term, which would be inconsistent with World Trade Organization rules.²³⁰ If a leading developed economy like Europe bends the rules, others are sure to break them.

²²⁷ Getz, K.A. and R.A. Campo, “New Benchmarks Characterizing Growth in Protocol Design Complexity,” *SAGE Journals*, June 2017, available at <http://journals.sagepub.com/doi/10.1177/2168479017713039> (last visited Feb. 7, 2018).

²²⁸ Tufts Center for the Study of Drug Development, *Outlook 2016*, Tufts University, January 2016, available at <http://csdd.tufts.edu/files/uploads/Outlook-2016.pdf> (last visited Feb. 7, 2018).

²²⁹ *Id.*

²³⁰ E. Solovy and D. Raju, “A Manufacturing-for-Export Exception to Patent Protection: A Proposal for Exporting Violations of the TRIPS Agreement and Beyond,” *Journal of Intellectual Property Law & Practice*, September 2017, available at <https://doi.org/10.1093/jiplp/jpx161> (last visited Feb. 7, 2018).

Latin America

MEXICO

PhRMA and its member companies operating in Mexico remain concerned over significant intellectual property (IP) and market access barriers including challenges in accessing Mexico's different formularies and weak patent enforcement.

Key Issues of Concern:

- **Weak patent enforcement and regulatory data protection failures:** Mexico's health regulatory agency (COFEPRIS) and the Mexican Patent Office (IMPI) have committed to improve the application of Mexico's 2003 Linkage Decree and to provide protection for data generated to obtain marketing approval for pharmaceutical products. Despite these commitments, PhRMA member companies are unable to obtain accurate and timely information from COFEPRIS prior to marketing authorization being granted on a generic or biosimilar drug where the innovator product is used as a reference. As a result, PhRMA members have little to no notice that a potentially patent infringing product is entering the market. 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 rare exception rather than the norm. Further, implementation of substantive regulatory data protection (RDP), including provision of RDP for biologics, is still pending.
- **Market access delays:** Despite recent improvements to the marketing approval process for pharmaceutical products by the Federal National Commission for Protection against Health Risks (COFEPRIS), significant barriers to the public market for medicines remain due to the lengthy, non-transparent, and unpredictable reimbursement process.

For these reasons, PhRMA requests that Mexico remain on the **Watch List** in the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protections

Weak Patent Enforcement

To ensure adequate and effective protection of IP rights for the research-based biopharmaceutical sector, mechanisms that provide for the early resolution of patent disputes before an infringing product is allowed to enter the market are critical. Mexico has taken some positive steps to improve patent enforcement, including adopting the Linkage Decree of 2003. However, the continued lack of regulatory guidance requires innovators to redirect significant resources to seek judicial orders compelling Mexico's relevant agencies to follow their own rules and regulations.

Mexico's Linkage Decree (2003) constituted important progress toward an early resolution mechanism and the full recognition of pharmaceutical patent rights in Mexico. However, the decree is not being implemented in a comprehensive and consistent manner. For example, the publication in the Official Gazette of medicine-related patents is a positive step toward the goal of eliminating unnecessary, costly and time-consuming court actions to obtain appropriate legal protection for biopharmaceutical patents. However, COFEPRIS appears to apply linkage inconsistently and possibly in a discriminatory manner. In some cases, marketing authorizations have been issued despite patents listed in the Official Gazette. As a result, there have been concerning instances (at least three in April 2017) where COFEPRIS has granted marketing authorization for entry of products for which a valid patent exists. This undermines company confidence in the IP system in Mexico and impedes companies' ability to do business in Mexico.

Both of Mexico's NAFTA partners provide patent enforcement systems for product, formulation and method of use patents. It is therefore inappropriate for Mexico to not provide effective patent enforcement for method of use patents. Furthermore, effective patent enforcement mechanisms are necessary to protect innovator products from patent infringement by premature commercialization of follow-on products.

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

In Mexico, PhRMA member companies are unable to obtain accurate and timely information from COFEPRIS prior to marketing authorization being granted on a generic or biosimilar drug where the innovator product is used as a reference. As a result, PhRMA members have little to no notice that a potentially patent infringing product is entering the market. 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 rare exception rather than the norm. Although injunctions may be initially granted subject to the payment of a bond, counter-bonds, or in some proceedings mere applications, may be submitted by the alleged infringer to lift the injunction.

In the rare event that an innovator enforces successfully its intellectual property rights in Mexico, seeking monetary damages is extremely burdensome. In order to claim damages from patent infringers in Mexico, litigants are required to first obtain a final administrative action and then seek damages through a civil action. It is not uncommon for this process to last longer than ten years because these actions must be adjudicated in two separate legal venues.

The failure to provide effective patent enforcement mechanisms is inconsistent with Mexico's commitments under NAFTA and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

PhRMA's members encourage Mexican authorities to establish uniform criteria consistent with court precedents ordering the listing of use patents in the Official Gazette. In addition, PhRMA and its member companies encourage the Mexican Government to hasten patent infringement proceedings; use all available legal mechanisms to enforce Mexican Supreme Court decisions and implement procedures necessary to provide timely and effective preliminary injunctions.

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% of medicines that enter clinical trials ever result in approved treatments.²³¹

To support the significant investment of time and resources needed to develop test data to prove that a new medicine is safe and effective, the international community has developed a mechanism recognized as essential to biopharmaceutical innovation whereby the data submitted for regulatory approval is protected from unfair commercial use for a period of time. The mechanism is enshrined in TRIPS Article 39.3 which requires WTO members to protect undisclosed test and other data submitted for marketing approval in that country against disclosure and unfair commercial use.

RDP is essential for all medicines, and particularly critical for biologic therapies. Produced using living organisms, biologics are complex and challenging to manufacture and may not be protected adequately by patents alone. Unlike generic versions of traditional chemical compounds, biosimilars are not identical to the original innovative medicine and there is greater uncertainty about whether an innovator's patent right will cover a biosimilar version. Without the certainty of some substantial period of market exclusivity, innovators will not have the incentives needed to conduct the expensive, risky and time-consuming work to discover and bring new biologics to market.

The leaders of COFEPRIS and the IMPI have committed to provide protection for data generated to obtain marketing approval for all pharmaceutical products, including biologics. However, PhRMA and its members remain concerned with the apparent distinction made by the regulatory authorities between the provision of RDP to chemically synthesized (small molecule) and biologic drugs. Consistent with TRIPS, RDP should be provided regardless of the manner in which the medicine is synthesized. Implementation of substantive RDP reform is still pending.

In June 2012, COFEPRIS issued guidelines to implement RDP for a maximum period of five years – an important step toward fulfilling Mexico's obligations under TRIPS

²³¹ DiMasi JA, Grabowski HG, Hansen RW; Tufts Center for the Study of Drug Development. Innovation in the pharmaceutical industry: new estimates of R&D costs. In: Briefing: Cost of Developing a New Drug, available at http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf (last visited Feb. 7, 2018).

and NAFTA. PhRMA members initially welcomed this decision as an important confirmation of Mexico's obligations and its intention to fully implement the NAFTA provisions.

As guidelines, however, their validity may be questioned when applied to a concrete case. Further, they could be hard to enforce or revoked at any time. Therefore, PhRMA members strongly urge the passage of regulations on RDP to provide greater certainty regarding the extent and durability of Mexico's commitment to strong IP protection.

Potential Abuse of the "Bolar" Exemption

Mexico allows generic manufacturers to import active pharmaceutical ingredients and other raw materials contained in a patented pharmaceutical for "experimental use" during the last three years of the patent term, per the *Bolar* exemption. Mexico fails, however, to impose any limits on the amount of raw materials that can be imported under this exception.

Given some of the import volumes reported, PhRMA's members are very concerned that some importers may be abusing the *Bolar* exemption by stockpiling and/or selling patent-infringing and potentially substandard medicines in Mexico or elsewhere. PhRMA members encourage Mexican authorities to establish clear criteria for the issuance of import permits that respect patent rights and appropriately limit imports to quantities required for testing bioequivalence.

Market Access Barriers

Market Access Delays

PhRMA's local sister association (AMIIF) estimates that on average it takes 1,500 days for Mexican patients to access innovative medicines. Key market access issues in Mexico concern the excessive times taken for formulary inclusion and the 5-year registration renewal process. Both significantly exceed stated time frames. COFEPRIS, under the leadership of Julio Sanchez y Tepoz, has made important improvements in the approval process despite limited resources and cost-containment pressures. Industry applauds Commissioner Sanchez y Tepoz's efforts to improve the efficiency and technical capability of COFEPRIS. However, the New Molecules Committee could undermine the positive improvements COFEPRIS has made.

Following COFEPRIS approval, there remain significant barriers for patients, primarily those covered by public institutions, in accessing life-saving and enhancing interventions. This additional delay is caused by the lengthy, non-transparent, and uncertain reimbursement system used in Mexico, which adds on average two years to the access process (if made available at all in the public sector).

After COFEPRIS grants marketing authorization to a new medicine, the national Committee of Health decides which drugs should be included on the national formulary. Recommended prices for patented and unique drugs (or those with exclusive distributors) for all public institutions are negotiated with the Coordinating Commission for the Negotiation of Prices of Medicines and Other Medical Supplies. Following this recommendation, the public health institutions at federal and local levels, such as the Mexican Institute for Social Security (IMSS) and Institute of Security and Social Services for State Workers (ISSSTE), *etc.*, procure the medicine at the negotiated price. At each step, clinical and pharmaco-economic dossiers, which take manufacturers significant time and expense to create, are required. Further, the institutional approval process is an inefficient process, whereby products with regulatory approval and wide reimbursement throughout the world are often denied listing in Mexico based on alleged inadequate efficacy or safety defined through non-transparent criteria. As a result, there has been a dramatic reduction in public formulary listings for innovative medicines that have been approved by COFEPRIS for inclusion in the national formulary. The two largest public formularies, IMSS and ISSSTE, currently include only 25% of innovative medicines that have received regulatory approval. Decisions denying institutional approval are not subject to any effective method of appeal.

Middle East/ Africa

EGYPT

Despite some progress at the beginning of 2017, PhRMA and its member companies remain concerned about the intellectual property (IP) environment and market access in Egypt.

Egypt is one of the most populous countries in the Middle East-Africa region. There is tremendous unmet medical need in the country. Conditions prevailing in the regulatory and IP areas today make it increasingly difficult for PhRMA member companies to operate and invest, though there are encouraging signs that the government may be willing to implement key reforms.

During the past several very challenging years, PhRMA and its member companies have tried to work in good faith with Egyptian officials to address health and industrial issues. Specifically, in 2017, PhRMA and its member companies faced major challenges in meeting the Health Minister to address the government pricing challenges facing the industry. These challenges were a consequence of the Egyptian Government's decision in November 2016 to liberate the foreign exchange rate. That decision triggered a precipitous decline in the value of the Egyptian Pound, jeopardizing the largest, most established pharmaceutical sector in the Middle East region.

Despite the Health Ministry's pledge to implement the second phase of price adjustments in August 2017, to date the Egyptian Government has failed to implement this pledge resulting in significant financial losses for member companies and widely-reported shortages of medicines.

PhRMA notes, however, that other Egyptian officials, particularly the Minister of Investment and International Cooperation have shown a willingness to meet and discuss issues of concern. Those officials recognize the threat to the industry, and have expressed interest in supporting the innovative biopharmaceutical industry and encouraging investment in the country. They understand that the industry faces stagnation and contraction if immediate steps are not taken to redress the combined impact of fixed prices and a devaluing Egyptian Pound.

PhRMA and its member companies continue to appreciate the government's announcement at the end of 2016 that the country would implement a new medicines licensing system that is expected to significantly reduce review times by 90%. If implemented fully, this new system could accelerate patient access to promising new medicines, and greatly enhance Egypt's regional competitiveness in the sector.

Key Issues of Concern:

- **Weak patent enforcement:** Egypt lacks effective patent enforcement, enabling manufacturers to obtain marketing licenses for follow-on products prior to the expiration of the patent on the original product.

- **Market access policies:** The innovative pharmaceutical industry remains concerned that Egypt has not implemented its pledge to adjust prices of medicines, in the wake of the Egyptian pound devaluation by more than 100% in November 2016. Industry is also concerned about the lack of a pricing system that is transparent and equitable, a new system that would systematically address such currency devaluations.

For these reasons, PhRMA requests that Egypt remain on the **Watch List** in the 2018 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Weak Patent Enforcement

Egypt does not provide an effective mechanism to ensure that marketing licenses are not granted to companies making products that infringe an originator's patent. Some officials have opposed putting in place an effective patent enforcement system similar to the process used by the United States or in other neighboring countries.

In those countries, health officials receiving applications from generics companies are required to check for the existence of a valid patent. If the originator can demonstrate a valid patent, there should be a procedure in place whereby the MOH can either defer the file to a date for examination period closer to the date of the patent expiration and/or specify that the license is valid only after the expiration of the innovator's patent, or after a sufficient period to resolve the patent dispute.

As Egypt is a WTO member, has enacted patent laws, and issues patents through the Patent Bureau, it follows that the MOH should have in place an effective system whereby it can defer market entry of newly licensed medicines until after the expiration of any applicable patents or at least until after a sufficient period for resolving patent disputes.

Development on Regulatory Approval Delays

We continue to be encouraged by the announcement by the Minister of Health that as of January 2017, Egypt will provide an expedited 30-day registration process for products approved by the U.S. Food and Drug Administration and the European Medicines Agency, or a 60-day registration process if approved by one of the two entities.

This announcement mirrors other policy advances in the region, notably Saudi Arabia's announcement of an expedited review process and Jordan's announcement and implementation in 2017, followed by the United Arab Emirate's announcement in early 2018.

PhRMA believes that this new policy, if fully implemented, could constitute a major step forward for Egyptian patients and strengthen the competitiveness of the innovative biopharmaceutical sector in Egypt.

Market Access Barriers

Market Access Policies

In November 2016, the government of Egypt liberated the foreign exchange rate, resulting in a devaluation (approximately 100%) of the Egyptian Pound. Because the prices of medicines are fixed, biopharmaceutical companies suffered significant financial losses. After engagement by PhRMA and its member companies, the Egyptian government granted a first phase of price adjustments in January 2017 with the commitment to grant a second phase in August 2017. To date, the Egyptian government has failed to implement this pledged second phase of price increases. Implementing this second phase will be of critical importance to the operations of member companies, and will demonstrate the Egyptian government's commitment to build an ecosystem that fosters innovation and investment.